

PRESSURE BIOSCIENCES INC  
Form S-1/A  
April 11, 2017

**As filed with the Securities and Exchange Commission on April 11 , 2017**

**Registration No. 333-215277**

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

**AMENDMENT NO. 1**

**TO**

**FORM S-1**

**REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

**PRESSURE BIOSCIENCES, INC.**

**(Exact name of registrant as specified in its charter)**

**Massachusetts**

**3826**

**04-2652826**

(State or Other Jurisdiction of (Primary Standard Industrial (I.R.S. Employer  
Incorporation or Organization) Classification Code Number) Identification Number)

**14 Norfolk Avenue**

**South Easton, Massachusetts 02375**

**(508) 230-1828**

(Address, including zip code, and telephone number including area code, of Registrant's principal executive offices)

**Richard T. Schumacher**

**President and Chief Executive Officer**

**Pressure BioSciences, Inc.**

**14 Norfolk Avenue**

**South Easton, Massachusetts 02375**

**(508) 230-1828**

(Name, address, including zip code, and telephone number including area code, of agent for service)

With copies to:

**Joseph M. Lucosky, Esq.  
Steven Lipstein, Esq.  
Lawrence Metelitsa, Esq.**

**Mitchell Nussbaum, Esq.  
Giovanni Caruso, Esq.  
Lili Taheri, Esq.**

**John O'Leary, Esq.  
Lucosky Brookman LLP  
101 Wood Avenue South, 5<sup>th</sup> Floor  
Woodbridge, NJ 08830  
Tel. No.: (732) 395-4400**

**Loeb & Loeb LLP  
345 Park Avenue  
New York, NY 10154  
Tel. No.: (212) 407-4000  
Fax No.: (212) 407-4990**

**Fax No.: (732) 395-4401**

**Approximate date of commencement of proposed sale to the public:** As soon as practicable after this Registration Statement is declared effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. [X]

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. [ ]

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 definitions of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer [ ]    Accelerated Filer [ ]    Non-Accelerated Filer [ ]    Smaller Reporting Company [X]

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price <sup>(1)</sup>	Amount of Registration Fee <sup>(1)</sup>
Common Stock, par value \$0.001 per share <sup>(2) (3)</sup>	\$ 12,000,000	\$ 1,390.80
Warrants to Purchase Common Stock <sup>(4)</sup>	—	—
Representatives' Warrant to Purchase Common Stock <sup>(4)</sup>	\$ N/A	\$ —
Shares of Common Stock issuable upon exercise of the Warrants <sup>(2) (3) (5)</sup>	\$ 7,500,000	\$ 869.25
Shares of Common Stock issuable upon exercise of Representatives' Warrant <sup>(2) (6)</sup>	\$ 750,000	\$ 86.93
Total	\$ 20,250,000	\$ 2,346.98 <sup>(7)</sup>

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act of 1933, as amended (the "Securities Act").

(2) Pursuant to Rule 416, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

(3) Includes shares of common stock which may be issued upon exercise of a 45-day option granted to the underwriters to cover over-allotments, if any.

A warrant to purchase one share of common stock will be issued for every two shares offered. No further consideration will be paid for the warrant. The maximum number of the Warrants and Representative's warrants and the shares of the Registrant's common stock underlying the Warrants and Representative's warrants are being

(4) simultaneously registered hereunder. Consistent with the response to Question 240.06 of the Securities Act Rules Compliance and Disclosure Interpretations, the registration fee with respect to the Warrants and Representative's warrants has been allocated to the shares of the Registrant's common stock underlying the Warrants and Representative's warrants and those shares are included in the registration fee.

(5) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The warrants are exercisable at a per share price of 125% of the common stock public offering price.

Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(g) under the Securities Act. The warrants are exercisable at a per share exercise price equal to 125% of the public offering price

(6) excluding the over-allotment option. The proposed maximum aggregate offering price of the Representative's warrants is \$750,000 which is equal to 125% of \$600,000 (5% of \$12,000,000).

(7) The registrant previously paid \$3,357.49.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act or until the registration statement shall become effective on such date as the Commission, acting pursuant to said section 8(a), may determine.**



The information in this prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting offers to buy these securities in any jurisdiction where the offer or sale is not permitted.

**PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED APRIL 11, 2017**

**Shares of Common Stock**

**Warrants to Purchase up to                      Shares of Common Stock**

**Pressure BioSciences, Inc.**

We are offering an aggregate of                      shares of our common stock, \$0.01 par value per share, and warrants to purchase                      shares of our common stock at a public offering price of \$                      per share and \$                      per warrant. The warrants have an exercise price of \$                      per share and expire five years from the date of issuance. A warrant to purchase one share of common stock will accompany every two shares of common stock purchased. The shares and warrants will trade separately.

Our common stock is presently quoted on the OTCQB under the symbol "PBIO". We intend to apply to have our common stock and warrants listed on The NASDAQ Capital Market under the symbols "PBIO" and "PBIOW," respectively. No assurance can be given that our application will be approved. On April 7, 2017 the last reported sale price for our common stock on the OTCQB was \$0.31 per share. There is no established public trading market for the warrants. No assurance can be given that a trading market will develop for the warrants.

**Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 16 of this prospectus for a discussion of information that should be considered in connection with an investment in our securities.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.**

	<b>Per Share</b>	<b>Per Warrant</b>	<b>Total</b>
Public offering price	\$	\$	\$
Underwriting discounts and commissions <sup>(1)</sup>	\$	\$	\$
Proceeds to us, before expenses	\$	\$	\$

(1) We refer you to “Underwriting” beginning on page 74 of this prospectus for additional information regarding total underwriting compensation.

We have granted a 45-day option to the representative of the underwriters to purchase up to \_\_\_\_\_ additional shares of our common stock at a public offering price of \$ \_\_\_\_\_ per share and/or warrants to purchase \_\_\_\_\_ shares of our common stock at a public offering price of \$ \_\_\_\_\_ per warrant, solely to cover over-allotments, if any.

The underwriters expect to deliver our shares and warrants to purchasers in the offering on or about \_\_\_\_\_, 2017.

**Joseph Gunnar & Co.**

The date of this prospectus is \_\_\_\_\_, 2017.

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**You should rely only on information contained in this prospectus. We have not, and the underwriters have not, authorized anyone to provide you with additional information or information different from that contained in this prospectus. We are not making an offer of these securities in any state or other jurisdiction where the offer is not permitted. The information in this prospectus may only be accurate as of the date on the front of this prospectus regardless of time of delivery of this prospectus or any sale of our securities.**

**No person is authorized in connection with this prospectus to give any information or to make any representations about us, the common stock hereby or any matter discussed in this prospectus, other than the information and representations contained in this prospectus. If any other information or representation is given or made, such information or representation may not be relied upon as having been authorized by us. This prospectus does not constitute an offer to sell, or a solicitation of an offer to buy our common stock in any circumstance under which the offer or solicitation is unlawful. Neither the delivery of this prospectus nor any distribution of our common stock in accordance with this prospectus shall, under any circumstances, imply that there has been no change in our affairs since the date of this prospectus.**



Neither we nor any of the underwriters have done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than the United States. You are required to inform yourself about, and to observe any restrictions relating to, this offering and the distribution of this prospectus.

We have registered certain of our trademarks with the United States Patent and Trademark Office, including Barocycler® and PULSE®. XSTREAMPCT™ is registered in Europe and published in the USA. We also use certain trademarks, trade names, and logos that have not been registered including ProteoSolve™, ProteoSolve<sub>LRS</sub>™, the Power of PCT™, the PCT Shredder™, HUB440™, HUB880™, MicroPestle™, PCT-HD™, Barozyme™, BaroFlex™ Strip, and Discovery Starts with Sample Preparation™.

## PROSPECTUS SUMMARY

*This summary highlights selected information appearing elsewhere in this prospectus. While this summary highlights what we consider to be important information about us, you should carefully read this entire prospectus before investing in our common stock and warrants, especially the risks and other information we discuss under the headings “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operation” and our consolidated financial statements and related notes beginning on page F-1. Our fiscal year end is December 31 and our fiscal years ended December 31, 2015 and 2016 are sometimes referred to herein as fiscal years 2015 and 2016, respectively. Some of the statements made in this prospectus discuss future events and developments, including our future strategy and our ability to generate revenue, income and cash flow. These forward-looking statements involve risks and uncertainties which could cause actual results to differ materially from those contemplated in these forward-looking statements. See “Cautionary Note Regarding Forward-Looking Statements”. Unless otherwise indicated or the context requires otherwise, the words “we,” “us,” “our”, the “Company” or “our Company” and “Pressure Biosciences” refer to Pressure Sciences, Inc., a Massachusetts corporation.*

*This prospectus assumes the over-allotment option of the underwriters has not been exercised, unless otherwise indicated.*

### Overview

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

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

Sample Preparation System (“PCT SPS”).

In 2015, together with an investment bank, we formed a subsidiary called Pressure BioSciences Europe (“PBI Europe”) in Poland. We have 49% ownership interest with the investment bank retaining 51%. Throughout 2016, PBI Europe did not have any operating activities in 2016 and we cannot reasonably predict when operations will commence. Because we don’t have control of the subsidiary, we did not consolidate them in our financial statements.

## Patents

PBI has 14 United States granted patents and one foreign granted patent (Japan: 5587770, EXTRACTION AND PARTITIONING OF MOLECULES) covering multiple applications of PCT in the life sciences field. PBI also has 19 pending patents in the USA, Canada, Europe, Australia, China, Japan, and Taiwan. PCT employs a unique approach that we believe has the potential for broad use in a number of established and emerging life sciences areas, which include, but are not limited to:

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

pathogen inactivation;

protein purification;

control of chemical reactions, particularly enzymatic; and

immunodiagnosics.

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

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

## Primary Fields of Use and Applications for PCT

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

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

*Biomarker Discovery - Mass Spectrometry*

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

A mass spectrometer is a laboratory instrument used in the analysis of biological samples, often focused on proteins, in life sciences research. It is frequently used to help discover biomarkers. According to a recently published market report by Transparency Market Research, 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 next by Europe. We believe PCT and CP-based products offer significant advantages in speed and quality compared with current techniques used in the preparation of samples for mass spectrometry analysis.

*Forensics*

The detection of DNA has become a part of the analysis of forensic samples by laboratories and criminal justice agencies worldwide in their efforts to identify the perpetrators of violent crimes and missing persons. Scientists from the University of North Texas (UNT) and Florida International University (FIU) have published a paper regarding DNA yield from forensic samples (e.g., bone and hair) when using the PCT platform in the sample preparation process. A copy of the paper may be accessed through our website .

**Pressure cycling technology (PCT) reduces effects of inhibitors of the PCR**

Pamela L. Marshall & Jonathan L. King & Nathan P. Lawrence & Alexander Lazarev & Vera S. Gross & Bruce Budowle

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.

We believe that PCT may be capable of differentially extracting DNA from sperm cells and female epithelial cells captured in swabs collected from rape victims and subsequently stored in rape kits. Data from the laboratory of Dr. Bruce McCord (FIU) was published in a paper that may be accessed through our website .

### *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.

### **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.

#### *Barocyler® Instrumentation*

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

Our instruments (the Barocyler® 2320EXTREME (the “2320EXT”), the Barozyme-HT48, the Barocyler® NEP3229, the HUB440 and the HUB880) use cycles of high, hydrostatic pressure to quickly and efficiently break up the cellular structures of a specimen to release proteins, nucleic acids, lipids and small molecules from the specimen into our consumable processing tubes, referred to as our PULSE® Tubes and MicroTubes. Our instruments have temperature control options (on-board heating or chilling and heating via external circulating water-bath), 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 Barocyler® instruments and our consumable products make up our PCT Sample Preparation System.

Barocyler® 2320EXT - The Barocyler® 2320EXT weighs approximately 80lbs, has a maximum pressure of 45,000 psi, and can process either up to 16 MicroTubes simultaneously or 1 PULSE® Tube. The working temperature range is 4 – 95°C and is controlled via an on-board electric heating jacket or external circulating water bath. All tests are entered and recorded on a touch screen interface. Information from each test runs (pressure profile, cycle number, and temperature) is recorded and can be stored on the instrument, on a USB drive, or networked into the user’s lab. Pressure profiles can be manipulated in a number of ways, including static high pressure holds and pressure ramp



programs. The Barocyler® 2320EXT is pneumatic, and requires an input air source of 100psi to reach and cycle at high pressure.

The Barocyler® 2320EXT was developed to support the PCT-HD/PCT-SWATH application. PCT-HD enables faster, less cumbersome and higher quality processing of biopsy tissues. With homogenization, extraction, and digestion of proteins occurring in a single PCT MicroTube under high pressure. This protocol can yield analytical results in under 4 hours from the start of processing tissues. PCT-HD was developed by our scientists and engineers in collaboration with Professor Ruedi Aebersold and Dr. Tiannan Guo of the Institute of Molecular Systems Biology, ETH Zurich, and the University of Zurich, both in Zurich, Switzerland. Drs. Aebersold and Guo combined PCT-HD with SCIEX's SWATH-Mass Spectrometry – calling the resulting method “*PCT-SWATH*”.

Barocyler® NEP3229 – The Barocyler® 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 Barocyler® NEP3229 is capable of processing up to three samples simultaneously using our specially designed, single-use PULSE® Tubes and up to 48 samples simultaneously using our specially-designed MicroTubes.

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

Barocyler® HUB440 –We believe the Barocyler® HUB440 is the first portable, ready to use, “plug-and-play” high pressure generator for the laboratory bench. The Barocyler® HUB440 is capable of creating and controlling hydrostatic pressure from 500 psi to 58,000 psi. It is computer controlled and runs on software that was specially-written by us in LabVIEW (software from National Instruments Corporation). We own the rights and have a license to use the specialty LabVIEW software. We believe that over the coming years, the Barocyler® HUB440 may become the main instrument in our pressure-based instrument line.

Barocyler® HUB880 - The Barocyler® HUB880 is one of our new instruments; it is expected to be available for sale during the first six months of 2017. 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 safety and vaccine industries.

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

#### *Barocyler® Consumable Products*

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

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

PCT-Micro-Pestle (“ $\mu$ Pestles”) - PCT  $\mu$ Pestles are made from Polytetrafluoroethylene (PTFE), a synthetic fluoropolymer of tetrafluoroethylene, also known as Teflon (by DuPont Co). PTFE is practically inert; the only chemicals known to affect it are certain alkali metals and most highly-reactive fluorinating agents. PCT  $\mu$ Pestles, in conjunction with PCT MicroTubes, are designed to enhance the extraction of 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  $\mu$ L. PCT MicroTubes and PCT  $\mu$ Pestles 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  $\mu$ Pestles tip is crushed on every pressure cycle. This mechanical action, combined with the extraction ability of the buffer under high pressure, results in highly effective tissue homogenization and extraction.

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

BaroFlex 8-well Processing Strips - BaroFlex 8-well Strips are used in the Barozyme HT48 (for pressure-enhanced enzymatic digestion at 20,000 psi). BaroFlex 8-well Strips are made of special high density polyethylene (HDPE) and hold up to 140 $\mu$ l 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.

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

## **Customers**

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

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

## **Growth Strategy**

*Our growth strategy includes:*

Expanding our United States salesforce.

Aggressively promoting the PCT-HD System, which includes the Barocycler® 2320EXT, MicroTube System, and MicroPestles.

Expanding our number of International Distributers.

Actively promoting our other Barocycler® products, accessories, and consumables, including but not limited to, the Barozyme, the HUB440, and HUB880.

Development of new applications for the Barocycler® 2320EXT, such as, but not limited to, clinical applications.

Development of new high-pressure applications for industries outside of biotechnology, such as, but not limited to, food science.

Development of new high-pressure instruments, devices, and consumables to meet the growing demand for pressure-based technology.

### **Competitive Advantages/Operational Strengths**

Our platforms are based on our patented and proprietary Pressure Cycling Technology (PCT). We believe the PCT platform provides distinct and important competitive advantages over other sample preparation methods, as it:

is proprietary to PBI

has been shown to extract more classes of proteins from tissues and cells than many other current sample preparation methods. We believe this claim is supported by several publications and presentations available on our website most notably by Dr. R. Aebersold, Professor at the Institute of Molecular Systems Biology, ETH-Zurich. Dr. Aebersold's publications include:

can accelerate enzymatic digestion of proteins for analysis by mass spectrometry from overnight to under an hour. We believe this claim is supported by several experiments. For example, Dr. A. Ivanov published a paper available on our website.

enables efficient sample prep workflows for processing minute amounts of tissue with excellent yields and reproducibility for researchers in the growing precision and translational medicine fields.

## **Our Risks and Challenges**

An investment in our securities involves a high degree of risk including risks related to the following:

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

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

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

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.

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.

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.

We expect that we will be subject to regulation in the United States, such as the Food and Drug Administration (the "FDA"), 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.

## **Recent Developments**

We reported a number of accomplishments in 2016:

On January 12, 2016 SCIEX, a global leader in life science analytical technologies (Framingham, MA) and a wholly-owned subsidiary of Danaher Corporation (NYSE: DHR), announced an exclusive co-marketing agreement with us to improve protein quantification in complex samples.

On February 3, 2016 SCIEX and Children's 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 our PCT platform for increased protein quantitation and reproducibility.

On March 31, 2016, in connection with the seventh and final closing (the “*Final Closing*”) of a private placement debt financing pursuant to the Subscription Agreements, dated as of January, 11, 2016, January 20, 2016, January 29, 2016, February 26, 2016, March 10, 2016, March 17, 2016, March 24, 2016 and March 31, 2016 by and among us and various individuals (each, a “*Purchaser*” and together “*Purchasers*”), including all five members of our Board of Directors, we sold and issued to the Purchasers Senior Secured Convertible Debentures (the “*Debentures*”) and warrants to purchase shares of common stock equal to 50% of the number of shares issuable pursuant to the subscription amount (the “*Warrants*”) for an aggregate purchase price of \$1,419,549 (the “*Purchase Price*”) for the Final Closing, bringing the total raised in the Offering to \$6,329,549. For the Final Closing, we netted \$1,304,049 in cash after taking into account fees related to the offering. Of this amount, an aggregate of \$164,549 was invested by the five members of our Board of Directors. For the entire private placement offering, we netted an aggregate of \$5,101,049 in cash in the aggregate after subtracting \$568,000 in fees and \$660,000 in debt conversions into this private placement.

On July 13, 2016, we announced the unveiling of the newest addition to our product line based on our powerful PCT platform, the 2320EXT. The product unveiling took place during the recent annual conference of the American Society for Mass Spectrometry (“*ASMS*”) in San Antonio, Texas.

On July 21, 2016, we announced the initial shipment of our 2320EXT instrument to an Australian cancer research group (ProCan) named by the White House as a collaborator in the U.S.’s “Cancer Moonshot” initiative.



On October 28, 2016, an accredited investor (the “*Investor*”) purchased from us a promissory note in the aggregate principal amount of up to \$2,000,000 (the “*Revolving Note*”) due and payable on the earlier of October 28, 2017 (the “*Maturity Date*”) or on the seventh business day after the closing of a Qualified Offering (as defined in the Revolving Note). Although the Revolving Note is dated October 26, 2016, the transaction did not close until October 28, 2016, when we received its initial \$250,000 advance pursuant to the Revolving Note. As a result, on the same day and pursuant to the Revolving Note, we issued to the Investor a Common Stock Purchase Warrant to purchase 625,000 shares of our common stock at an exercise price per share equal to \$0.40 per share. The Investor is obligated to provide us with advances of \$250,000 under the Revolving Note, but the Investor shall not be required to advance more than \$250,000 in any individual fifteen (15) day period and no more than \$500,000 in the thirty (30) day period immediately following the date of the initial advance. Notwithstanding the fifteen (15) day period limitation, on November 2, 2016, November 23, 2016, December 6, 2016, and December 16, 2016, we received \$1,000,000 pursuant to the Revolving Note and we issued to the Investor additional warrants to purchase a total of 2,500,000 shares of our common stock at \$0.40 per share (each warrant gives the Investor the right to purchase 625,000 shares of our common stock). The terms of the Warrants are identical except for the exercise date, issue date, and termination date. Interest on the principal balance of the Revolving Note shall be paid in full on the Maturity Date, unless otherwise paid prior to the Maturity Date.

## **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 active marketing and selling of our PCT-based instrument platform in 2012.

## **Where You Can Find More Information**

Our website address is [www.pressurebiosciences.com](http://www.pressurebiosciences.com). We do not intend for our website address to be an active link or to otherwise incorporate by reference the contents of the website into this prospectus. The public may read and copy any materials the Company files with the U.S. Securities and Exchange Commission (the “SEC”) at the SEC’s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0030. The SEC maintains an Internet website (<http://www.sec.gov>) that contains reports, proxy and information statements and other information regarding issuers that file electronically with the SEC.

## THE OFFERING

<b>Securities offered by us:</b>	An aggregate of _____ shares of our common stock and warrants to purchase _____ shares of our common stock. Each warrant will have a per share exercise price of \$ _____ per share, is exercisable immediately and will expire five years from the date of issuance. A warrant to purchase one share of common stock will accompany every two shares of common stock purchased. The shares and warrants will trade separately.
<b>Common stock outstanding before the offering</b>	31,809,839 Shares <sup>(1)</sup>
<b>Common stock to be outstanding after the offering</b>	_____ Shares <sup>(1)</sup>
<b>Option to purchase additional shares</b>	We have granted the underwriters a 45-day option to purchase up to _____ additional shares of our common stock and/or warrants to purchase _____ additional shares to cover allotments, if any.
<b>Description of the warrants offered hereby</b>	The warrants will have a per share exercise price of _____. The warrants are exercisable immediately and expire five years from the date of issuance. The exercise price and the number of shares of common stock purchasable upon the exercise of the warrants are subject to adjustment upon the occurrence of specific events, including stock dividends, stock splits, combinations and reclassifications of our common stock.
<b>Use of proceeds</b>	We intend to use the net proceeds of this offering for: the repayment of liabilities ; research and development for new products and improvements to existing products, upgrading sales and marketing capabilities, the purchase of raw materials and labor for manufacturing our products, upgrading our operations capabilities, hiring a CFO, and for general working capital purposes. See “Use of Proceeds.”
<b>Risk factors</b>	Investing in our securities is highly speculative and involves a high degree of risk. You should carefully consider the information set forth in the “Risk Factors” section beginning on page 16 before deciding to invest in our securities.
<b>Trading Symbols</b>	Our common stock is currently quoted on the OTCQB under the trading symbol “P BIO”. We intend to apply to the NASDAQ Capital Market to list our common stock under the symbol “P BIO” and our warrants under the symbol “P BIO W” and expect such listings to occur concurrently with this offering. However, there is no guarantee that our applications will be granted.
<b>Lock-up</b>	We and our directors, officers and any other 5% or greater holder of outstanding shares of our common stock have agreed with the underwriters not to offer for sale, issue, sell, contract to sell, pledge or otherwise dispose of any of our common stock or securities convertible into common stock for a period of (i) six month after the date of this prospectus in the case of our directors and

officers and (ii) three months after the date of this prospectus in the case of the Company and any other 5% or greater holder of our outstanding securities, without the prior written consent of the representative. See “Underwriting” section on page 74 .

NASDAQ listing requirements include, among other things, a stock price threshold. As a result, prior to effectiveness, we may need to take necessary steps to meet NASDAQ listing requirements, including but not limited to a reverse split of our common stock.

(1) The common stock to be outstanding before and after this offering is based on 31,809,839 shares outstanding as of April 7, 2017, and excludes the following as of such date:

7,814,250 shares issuable upon exercise of outstanding options with a weighted average exercise price of \$0.37;

656,250 shares remaining for issuance pursuant to 2005 Equity Incentive Plan;

292,500 shares remaining for issuance pursuant to 2013 Equity Incentive Plan;

977,000 shares remaining for issuance pursuant to 2015 Nonqualified Stock Option Plan;

24,449,660 shares issuable upon exercise of outstanding warrants with a weighted average exercise price of \$0.40;

26,192,288 shares issuable upon the conversion of outstanding convertible notes (including convertible debentures);  
and

shares of common stock underlying the warrants to be issued to the underwriters in connection with this offering.

**SUMMARY CONSOLIDATED FINANCIAL INFORMATION**

*The following summary consolidated statements of operations data for the years ended December 31, 2016 and 2015 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. The historical financial data presented below are not necessarily indicative of our operating results to be expected for the full fiscal year ending December 31, 2017 or any other period. You should read the summary consolidated financial data in conjunction with those financial statements and the accompanying notes and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.” Our consolidated financial statements are prepared and presented in accordance with United States generally accepted accounting principles, or U.S. GAAP. Our unaudited consolidated financial statements have been prepared on a basis consistent with our audited financial statements and include all adjustments, consisting of normal and recurring adjustments that we consider necessary for a fair presentation of the financial position and results of operations as of and for such periods.*

**SUMMARY OPERATING DATA**

	Fiscal Years Ended December 31,	
	2016	2015
Revenue:		
Products, services, other	\$ 1,794,749	\$ 1,409,991
Grant revenue	181,738	387,700
Total revenue	1,976,487	1,797,691
Costs and expenses:		
Cost of products and services	834,012	609,054
Research and development	1,183,011	1,105,295
Selling and marketing	872,365	745,574
General and administrative	2,822,752	2,902,950
Total operating costs and expenses	5,712,140	5,362,873
Operating loss	(3,735,653 )	(3,565,182 )
Other (expense) income:		
Interest expense	(4,501,186 )	(4,146,416 )
Other expense	(1,112 )	(36,879 )
Impairment loss on investment	(373,682 )	-
Gain on extinguishment of embedded derivative liabilities	-	2,555,180
Change in fair value of derivative liabilities	5,904,649	(2,222,001 )
Total other (expense) income	1,028,669	(3,850,116 )
Net loss	(2,706,984 )	(7,415,298 )

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Accrued dividends on convertible preferred stock	-	(23,194 )
Net loss applicable to common shareholders	\$ (2,706,984 )	\$ (7,438,492 )
Net loss per share attributable to common stockholders - basic and diluted	\$ (0.10 )	\$ (0.36 )
Weighted average common stock shares outstanding used in the basic and diluted net loss per share calculation	27,339,362	20,726,205

The following table presents consolidated balance sheet data as of December 31, 2016 on:

an actual basis;

an as adjusted basis, giving effect to advances from the Revolving Note in the amount of \$750,000, less financing fees of \$60,000, pursuant to the Revolving Loan in January and February 2017; and

a pro forma, as adjusted basis, giving effect to (i) the issuance of the Revolving Note in the amount of \$750,000, less financing fees of \$60,000, (ii) the conversion of 300 shares of Series D Preferred Stock into approximately 750,000 shares of common stock, the conversion of 86,570 shares of Series G Preferred Stock into approximately 865,700 shares of common stock, the conversion of 10,000 shares of Series H Preferred Stock into approximately 1,000,000 shares of common stock, the conversion of 21 shares of Series H2 Preferred Stock into approximately 2,100,000 shares of common stock, the conversion of 3,521 shares of Series J Preferred Stock into approximately 3,521,000 shares of common stock and the conversion of 6,816 shares of Series K Preferred Stock into approximately 6,816,000 shares of common stock, (iii) the conversion of \$7,803,045 of outstanding convertible notes (including convertible debentures) into approximately 26,733,955 shares of common stock and (iv) the sale by us of shares of common stock and warrants in this offering at an assumed public offering price of \$ per share and \$ per warrant after deducting underwriting discounts and commissions and estimated offering expenses.

The pro forma as adjusted information set forth below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

	As of December 31, 2016		Pro Forma, As Adjusted
	Actual	As Adjusted	
<b>Consolidated Balance Sheets Data:</b>			
Cash and cash equivalents	\$ 138,363	\$ 828,363	\$
Total assets	1,625,753	2,315,753	
Total liabilities	10,009,171	10,699,171	
Total stockholders' deficit	(8,383,418 )	(8,383,418 )	

(1) A \$1.00 increase or decrease in the assumed public offering price per share would increase or decrease our cash and cash equivalents, working capital, total assets and total stockholders' equity by approximately \$ , assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us.



## **RISK FACTORS**

*Investing in our securities involves a great deal of risk. Careful consideration should be made of the following factors as well as other information included in this prospectus before deciding to purchase our securities. There are many risks that affect our business and results of operations, some of which are beyond our control. Our business, financial condition or operating results could be materially harmed by any of these risks. This could cause the trading price of our securities to decline, and you may lose all or part of your investment. Additional risks that we do not yet know of or that we currently think are immaterial may also affect our business and results of operations.*

### **Risks Related To Our COMPANY**

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

The audit report issued by our independent registered public accounting firm on our audited consolidated financial statements for the fiscal year ended December 31, 2016 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, 2016 to cover our operating and capital requirements for the next twelve-month period; and if sufficient cash cannot be obtained, we would have to substantially alter, or possibly even discontinue, operations. The accompanying consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

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

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



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

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

We concluded that as of December 31, 2016, our disclosure controls and procedures and our internal control over financial reporting were not effective. We have determined that we have limited resources for adequate personnel to prepare and file reports under the Securities Exchange Act of 1934 within the required time periods and that material weaknesses in our internal control over financial reporting exist relating to our accounting for complex equity transactions. If we are unable to implement and maintain effective disclosure controls and procedures and remediate the material weaknesses in a timely manner, or if we identify other material weaknesses in the future, our ability to produce accurate and timely financial statements and public reports could be impaired, which could adversely affect our business and financial condition. We identified a lack of sufficient segregation of duties. Specifically, this material weakness is such that the design over these areas relies primarily on detective controls and could be strengthened by adding preventive controls to properly safeguard assets. In addition, investors may lose confidence in our reported information and the market price of our common stock may decline.

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

We have experienced significant operating losses in each period since we began investing resources in PCT and CP. These losses have resulted principally from research and development, sales and marketing, and general and administrative expenses associated with the development of our PCT business. During the year ended December 31, 2016, we recorded a net loss applicable to common shareholders of \$2,706,984, or (\$0.10) per share, as compared with \$7,438,492, or (\$0.36) per share, of the corresponding period in 2015. We expect to continue to incur operating losses until sales of PCT and CP products increase substantially. We cannot be certain when, if ever, we will become profitable. Even if we were to become profitable, we might not be able to sustain such profitability on a quarterly or annual basis.

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

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

the problems, delays, expenses, and complications frequently encountered by early-stage companies;

market acceptance of our pressure cycling technology products and services for sample preparation;  
the success of our sales and marketing programs; and  
changes in economic, regulatory or competitive conditions in the markets we intend to serve.

We expect the net proceeds from this offering, along with our current cash position, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 24 months. Thereafter, unless we achieve profitability, we anticipate that we will need to raise additional capital to fund our operations and to otherwise implement our overall business strategy. We currently do not have any contracts or commitments for additional financing. There can be no assurance that financing will be available in amounts or on terms acceptable to us, if at all. Any additional equity financing may involve substantial dilution to then existing shareholders.

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

severely limit or cease our operations or otherwise reduce planned expenditures and forego other business opportunities, which could harm our business;

obtain financing with terms that may have the effect of substantially diluting or adversely affecting the holdings or the rights of the holders of our capital stock; or

obtain funds through arrangements with future collaboration partners or others that may require us to relinquish rights to some or all of our technologies or products.

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

We currently rely on revenues from PCT 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, specifically our Chief Executive Officer, Richard Schumacher. 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 solely rely on CBM Industries, a third party contract manufacturer, to manufacture our PCT instrumentation, provide manufacturing 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 CBM to manufacture our products cost effectively, in sufficient quantities to meet our customer demand, if and when such demand occurs, and meeting our quality requirements. If CBM experiences manufacturing problems or delays, or if CBM decides not to continue to provide us with these services, our business may be harmed. While we believe other contract manufacturers are available to address our manufacturing and engineering needs, if we find it necessary to replace CBM, there will be a disruption in our business and we would incur additional costs and delays that would harm our business.

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

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

identify appropriate candidates for alliances, joint ventures or other business relationships;

assure that any candidate for an alliance, joint venture or business relationship will provide us with the support anticipated;

successfully negotiate an alliance, joint venture or business relationship on terms that are advantageous to us; or

successfully manage any alliance or joint venture.

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

***We may not be successful in growing our international sales.***

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

multiple, conflicting and changing governmental laws and regulations, including those that regulate high pressure equipment;

reduced protection for intellectual property rights in some countries;

protectionist laws and business practices that favor local companies;

political and economic changes and disruptions;



export and import controls;  
tariff regulations; and  
currency fluctuations.

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

our ability to increase our sales of our pressure cycling technology products for sample preparation on a consistent quarterly or annual basis;

the lengthy sales cycle for our products;

the product mix of the Barocycler® instruments we install in a given period, and whether the installations are completed pursuant to sales, rental or lease arrangements, and the average selling prices that we are able to command for our products;

our ability to manage our costs and expenses;

our ability to continue our research and development activities without incurring unexpected costs and expenses; and

our ability to comply with state and federal regulations without incurring unexpected costs and expenses.

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

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

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

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

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

Our ability to further develop and successfully commercialize our products will depend, in part, on our ability to enforce our patents, preserve our trade secrets, and operate without infringing the proprietary rights of third parties. PBI has 14 United States granted patents and 1 foreign granted patent (Japan: 5587770, EXTRACTION AND PARTITIONING OF MOLECULES) covering multiple applications of PCT in the life sciences field. The patents expire between 2017 and 2032. PBI also has 19 pending patents in the USA, Canada, Europe, Australia, China, and Taiwan. There can be no assurance that (a) any patent applications filed by us will result in issued patents; (b) patent protection will be secured for any particular technology; (c) any patents that have been or may be issued to us will be valid or enforceable; (d) any patents will provide meaningful protection to us; (e) others will not be able to design around our patents; and (f) our patents will provide a competitive advantage or have commercial value. The failure to obtain adequate patent protection would have a material adverse effect on us and may adversely affect our ability to enter into, or affect the terms of, any arrangement for the marketing or sale of any product.

***Our patents may be challenged by others.***

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

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

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

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

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

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

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

companies develop more technologically advanced products, our competitive position relative to such companies would be harmed.

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

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

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

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

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

***Provisions in our Restated Articles of Organization and By-laws may discourage or frustrate stockholders' attempts to remove or replace our current management.***

Our Restated Articles of Organization, as amended and By-laws, as amended, 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 RELATING TO OWNERSHIP OF OUR SECURITIES**

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

The holders of our common stock could suffer substantial dilution due to our corporate financing practices, which, in the past few years, have included private placements and a registered direct offering. As of December 31, 2016, 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, 2016, 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, 2016 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, 2016, we had 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, 2016, an additional 73,515,600 shares of common stock would be issued and outstanding. This additional issuance of shares of common stock would cause immediate and substantial dilution to our existing stockholders and could cause a significant reduction in the market price of our common stock.

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



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

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

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

our inability to raise additional capital to fund our operations, whether through the issuance of equity securities or debt;

our failure to successfully implement our business objectives;

compliance with ongoing regulatory requirements;

market acceptance of our products;

technological innovations and new commercial products by our competitors;

changes in government regulations;

general economic conditions and other external factors;

actual or anticipated fluctuations in our quarterly financial and operating results; and

the degree of trading liquidity in our shares of common stock.

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

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

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

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

As of December 31, 2016, there were 30,999,839 shares of common stock issued and outstanding. Similarly, at such time, there were no shares of Series A Junior Participating Preferred Stock; Series A Convertible Preferred Stock; Series B Convertible Preferred Stock; Series C Convertible Preferred Stock; and Series E Convertible Preferred Stock. As of December 31, 2016 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, 3,521 shares of Series J Convertible Preferred Stock issued and outstanding convertible into 3,521,000 shares of common stock, and 6,816 shares of Series K Convertible Preferred Stock issued and outstanding convertible into 6,816,000 shares of common stock.

As of December 31, 2016, there were outstanding options and warrants to purchase an aggregate of 31,728,945 shares of common stock; and convertible debt convertible into 26,733,955 shares of common stock. From time to time, we also may increase the number of shares available for issuance in connection with our equity compensation plan, we may adopt new equity compensation plans, and we may issue awards to our employees and others who provide services to us outside the terms of our equity compensation plans. Our board of directors may fix and determine the designations, rights, preferences or other variations of each class or series of preferred stock and may choose to issue

some or all of such shares to provide additional financing in the future.

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

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

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

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

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

That a broker or dealer approve a person’s account for transactions in penny stocks; and

The broker or dealer receives from the investor a written agreement to the transaction, setting forth the identity and quantity of the penny stock to be purchased.

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

Obtain financial information and investment experience objectives of the person; and

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

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

Sets forth the basis on which the broker or dealer made the suitability determination; and

That the broker or dealer received a signed, written agreement from the investor prior to the transaction.

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

Disclosure also has to be made about the risks of investing in penny stocks in both public offerings and in secondary trading and about the commissions payable to both the broker-dealer and the registered representative, current

quotations for the securities and the rights and remedies available to an investor in cases of fraud in penny stock transactions. Finally, monthly statements have to be sent disclosing recent price information for the penny stock held in the account and information on the limited market in penny stocks.

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

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

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

***Shares eligible for future sale may adversely affect the market.***

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

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

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

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

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

## **Risks Related to the Offering**

***There can be no assurances that our shares and/or warrants will be listed on NASDAQ Capital Market and, if they are, our shares will be subject to potential delisting if we do not meet or continue to maintain the listing requirements of NASDAQ Capital Market.***

We intend to apply to list the shares of our common stock on the NASDAQ Capital Market, or NASDAQ. An approval of our listing application by NASDAQ will be subject to, among other things, our fulfilling all of the listing requirements of NASDAQ. In addition, NASDAQ has rules for continued listing, including, without limitation, minimum market capitalization and other requirements. Failure to maintain our listing, or de-listing from NASDAQ, would make it more difficult for shareholders to dispose of our common stock and more difficult to obtain accurate price quotations on our common stock. This could have an adverse effect on the price of our common stock. Our ability to issue additional securities for financing or other purposes, or otherwise to arrange for any financing we may need in the future, may also be materially and adversely affected if our common stock is not traded on a national securities exchange.

***In the event that our common stock and warrants are listed on the NASDAQ our stock price could fall and we could be delisted in which case broker-dealers may be discouraged from effecting transactions in shares of our common stock because they may be considered penny stocks and thus be subject to the penny stock rules.***

The SEC has adopted a number of rules to regulate “penny stocks” that restricts transactions involving stock which is deemed to be penny stock. Such rules include Rules 3a51-1, 15g-1, 15g-2, 15g-3, 15g-4, 15g-5, 15g-6, 15g-7, and 15g-9 under the Securities and Exchange Act of 1934, as amended. These rules may have the effect of reducing the liquidity of penny stocks. “Penny stocks” generally are equity securities with a price of less than \$5.00 per share (other than securities registered on certain national securities exchanges or quoted on the NASDAQ Stock Market if current price and volume information with respect to transactions in such securities is provided by the exchange or system). Our securities currently constitute, “penny stock” within the meaning of the rules. The additional sales practice and disclosure requirements imposed upon U.S. broker-dealers may discourage such broker-dealers from effecting transactions in shares of our common stock, which could severely limit the market liquidity of such shares and impede their sale in the secondary market.

A U.S. broker-dealer selling penny stock to anyone other than an established customer or “accredited investor” (generally, an individual with net worth in excess of \$1,000,000 or an annual income exceeding \$200,000, or \$300,000 together with his or her spouse) must make a special suitability determination for the purchaser and must receive the purchaser’s written consent to the transaction prior to sale, unless the broker-dealer or the transaction is otherwise exempt. In addition, the “penny stock” regulations require the U.S. broker-dealer to deliver, prior to any transaction involving a “penny stock”, a disclosure schedule prepared in accordance with SEC standards relating to the “penny stock” market, unless the broker-dealer or the transaction is otherwise exempt. A U.S. broker-dealer is also required to disclose commissions payable to the U.S. broker-dealer and the registered representative and current quotations for the securities. Finally, a U.S. broker-dealer is required to submit monthly statements disclosing recent price information with respect to the “penny stock” held in a customer’s account and information with respect to the limited market in “penny stocks”.

Stockholders should be aware that, according to the SEC, the market for “penny stocks” has suffered in recent years from patterns of fraud and abuse. Such patterns include (i) control of the market for the security by one or a few broker-dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) “boiler room” practices involving high-pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid-ask differentials and markups by selling broker-dealers; and (v) the wholesale dumping of the same securities by promoters and broker-dealers after prices have been manipulated to a desired level, resulting in investor losses. Our management is aware of the abuses that have occurred historically in the penny stock market. Although we do not expect to be in a position to dictate the behavior of the market or of broker-dealers who participate in the market, management will strive within the confines of practical limitations to prevent the described patterns from being established with respect to our securities.

### ***Speculative Nature of Warrants***

The warrants offered in this offering do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay an exercise price of \_\_\_\_\_ per share ( \_\_\_\_\_ % of public offering price of our common stock in this offering), prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

***We have broad discretion in the use of the net proceeds from this offering and may not use them effectively.***



Our management will have broad discretion in the application of the net proceeds, including for any of the purposes described in the section of this prospectus entitled “Use of Proceeds.” The failure by our management to apply these funds effectively could harm our business.

***Sales of a substantial number of shares of our common stock following this offering may adversely affect the market price of our common stock and the issuance of additional shares will dilute all other shareholders.***

Sales of a substantial number of shares of our common stock in the public market or otherwise following this offering, or the perception that such sales could occur, could adversely affect the market price of our common stock. After completion of this offering at an assumed offering price of \$ \_\_\_\_\_ per share, our existing stockholders will own approximately \_\_\_\_\_ % of our common stock assuming there is no exercise of the underwriters’ over-allotment option.

After completion of this offering at an assumed offering price of \$ \_\_\_\_\_ per share there will be \_\_\_\_\_ shares of our common stock outstanding. In addition, our certificate of incorporation, as amended, permits the issuance of up to approximately \_\_\_\_\_ additional shares of common stock after the completion of this offering. Thus, we have the ability to issue substantial amounts of common stock in the future, which would dilute the percentage ownership held by the investors who purchase shares of our common stock in this offering.

We and our officers, directors and certain stockholders have agreed, subject to customary exceptions, not to, without the prior written consent of Joseph Gunnar & Co., LLC, the representative of the underwriters, during the period ending 180 days from the date of this offering in the case of our directors and officers and 90 days from the date of this offering in the case of us and our stockholders who beneficially own more than 5% of our common stock, directly or indirectly, offer to sell, sell, pledge or otherwise transfer or dispose of any of shares of our common stock, enter into any swap or other derivatives transaction that transfers to another any of the economic benefits or risks of ownership of shares of our common stock, make any demand for or exercise any right or cause to be filed a registration statement, including any amendments thereto, with respect to the registration of any shares of common stock or securities convertible into or exercisable or exchangeable for common stock or any other securities of the Company or publicly disclose the intention to do any of the foregoing.

After the lock-up agreements with our principal stockholders pertaining to this offering expire 90 days from the date of this offering unless waived earlier by the representative, up to \_\_\_\_\_ of the shares that had been locked up will be eligible for future sale in the public market. After the lock-up agreements with our directors and officers pertaining to this offering expire 180 days from the date of this offering unless waived earlier by the managing underwriter, up to [ ] of the shares (net of any shares also restricted by lock-up agreements with our principal stockholders) that had been locked up will be eligible for future sale in the public market. Sales of a significant number of these shares of common stock in the public market could reduce the market price of the common stock.

The foregoing list is not all-inclusive. There can be no assurance that we have correctly identified and appropriately assessed all factors affecting our business or that the publicly available and other information with respect to these matters is complete and correct. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect us. These developments could have material adverse effects on our business, financial condition, results of operations and liquidity. For these reasons, the reader is cautioned not to place undue reliance on our forward-looking statements.

***Following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price.***

The warrants offered in this offering do not confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of our common stock at a fixed price for a limited period of time. Specifically, commencing on the date of issuance, holders of the

warrants may exercise their right to acquire the common stock and pay an exercise price of 125% of the public offering price of our common stock in this offering, prior to five years from the date of issuance, after which date any unexercised warrants will expire and have no further value. Moreover, following this offering, the market value of the warrants is uncertain and there can be no assurance that the market value of the warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the warrants, and consequently, whether it will ever be profitable for holders of the warrants to exercise the warrants.

## USE OF PROCEEDS

We estimate that the net proceeds from the sale of the common stock and warrants in the offering will be approximately \$ \_\_\_\_\_ million, after deducting the underwriting discounts and commissions and estimated offering expenses, or \$ \_\_\_\_\_ million if the underwriters exercise their over-allotment option in full.

We currently expect to use the net proceeds of this offering primarily for the following purposes:

approximately \$3,260,000 for the repayment of the following liabilities : (1) \$540,000 owed to JMJ Financial (interest rate of 9% and maturity date of May 2017); (2) \$110,000 owed to Gemini Master Fund (interest rate of 0%, however, there was an original investment discount of 10% and maturity date of October 2017); (3) \$110,000 owed to Black Mountain Equities, Inc. (interest rate of 0%, however, there was an original investment discount of 10% and maturity date of October 2017); (4) \$2,200,000 owed to the Investor pursuant to the Revolving Note (interest rate of 10% and maturity date of the earlier of October 28, 2017 or on the seventh business day after the closing of a qualified offering as defined in the Revolving Note) and the \$250,000 advance received from the same investor on March 23, 2017 ; and (5) \$250,000 owed to Bellridge Capital, LLC (interest rate of 10% and maturity date of November 2017). All of these liabilities will be completely repaid with the proceeds of this offering, were incurred after April 1, 2016, and were used for working capital, except for the \$220,000 in loans from Gemini Master Fund and Black Mountain Equities, Inc which was used to repay \$200,000 owed to Vision Capital LLC;

approximately \$[ ] for research and development for new products and improvements to existing products including but not limited to hiring of key personnel, leasing of facilities, sub-contract costs associated with the design and development of robotics for the full automation of the PCT process, vitally-needed research equipment (e.g., a mass spectrometer), and material costs for research activities;

approximately \$[ ] to upgrade sales and marketing capabilities, including but not limited to professional relations, advertising, and adding additional staff;

approximately \$[ ] to pay for the purchase of raw materials and labor for manufacturing an estimated 50 Barocycler® 2320EXTREME instruments, 10 HUB440 instruments, 10 HUB880 instruments, 25 PCT Shredder units, and 10 re-designed Barozyme HT48 instruments;

approximately \$[ ] to upgrade our operations capabilities, including but not limited to hiring of key technical services and light manufacturing personnel, additions to equipment and space, and equipment;

approximately \$[ ] to hire a high level financial leader (CFO or VP of Finance) and at least one additional administrative staff member;

the remainder for working capital and other general corporate purposes.

We believe that the expected net proceeds from this offering and our existing cash and cash equivalents, together with interest thereon, will be sufficient to fund our operations for at least the next 24 months, although we cannot assure you that this will occur.

The amount and timing of our actual expenditures will depend on numerous factors, including the status of our development efforts, sales and marketing activities and the amount of cash generated or used by our operations. We may find it necessary or advisable to use portions of the proceeds for other purposes, and we will have broad discretion and flexibility in the application of the net proceeds. Pending these uses, the proceeds will be invested in short-term bank deposits.

## MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

### Market and Other Information

Our common stock is quoted on the OTC Markets Group Inc.'s OTCQB Link quotation platform (the "OTCQB") under the trading symbol "P BIO". We intend to apply to the NASDAQ Capital Market to list our common stock under the symbol "P BIO".

Immediately following this offering, we expect to have one class of common stock outstanding and one class of preferred stock outstanding. As of April 7, 2017, there were approximately 217 holders of record of our common stock, and the last reported sale price of our common stock on the OTCQB was \$0.31 per share.

Our common stock was initially quoted on the OTCQB in 2014 and the following table sets forth the high and low sales price of our common stock on the OTCQB for the last two fiscal years. These prices are based on inter-dealer bid and asked prices, without markup, markdown, commissions, or adjustments and may not represent actual transactions.

<b>PERIOD</b>	<b>High</b>	<b>Low</b>
<b>Fiscal Year Ending December 31, 2016:</b>		
Quarter Ended December 31, 2016	\$0.40	0.18
Quarter Ended September 30, 2016	\$0.46	0.28
Quarter Ended June 30, 2016	\$0.58	0.26
Quarter Ended March 31, 2016	\$0.51	0.28
<b>Fiscal Year Ended December 31, 2015:</b>		
Quarter Ended December 31, 2015	\$0.49	0.20
Quarter Ended September 30, 2015	\$0.32	0.20
Quarter Ended June 30, 2015	\$0.38	0.20
Quarter Ended March 31, 2015	\$0.45	0.17

### Dividend Policy

To date, we have not paid any dividends on our common stock and do not anticipate paying any such dividends in the foreseeable future. The declaration and payment of dividends on the common stock is at the discretion of our board of directors and will depend on, among other things, our operating results, financial condition, capital requirements, contractual restrictions or such other factors as our board of directors may deem relevant. We currently expect to use all available funds to finance the future development and expansion of our business and do not anticipate paying

dividends on our common stock in the foreseeable future.

**CAPITALIZATION**

The following table sets forth our consolidated cash and cash equivalents and capitalization as of December 31, 2016. Such information is set forth on the following basis:

an actual basis;

an as adjusted basis, giving effect to advances from the Revolving Note in the amount of \$750,000, less financing fees of \$60,000, pursuant to the Revolving Loan in January and February 2017; and

a pro forma, as adjusted basis, giving effect to (i) the issuance of the Revolving Note in the amount of \$750,000, less financing fees of \$60,000, (ii) the conversion of 300 shares of Series D Preferred Stock into approximately 750,000 shares of common stock, the conversion of 86,570 shares of Series G Preferred Stock into approximately 865,700 shares of common stock, the conversion of 10,000 shares of Series H Preferred Stock into approximately 1,000,000 shares of common stock, the conversion of 21 shares of Series H2 Preferred Stock into approximately 2,100,000 shares of common stock, the conversion of 3,521 shares of Series J Preferred Stock into approximately 3,521,000 shares of common stock and the conversion of 6,816 shares of Series K Preferred Stock into approximately 6,816,000 shares of common stock, (iii) the conversion of \$7,803,045 of outstanding convertible notes (including convertible debentures) into approximately 26,733,955 shares of common stock and (iv) the sale by us of shares of common stock and warrants in this offering at an assumed public offering price of \$ per share and \$ per warrant after deducting underwriting discounts and commissions and estimated offering expenses.

The pro forma as adjusted information below is illustrative only and our capitalization following the completion of this offering will be adjusted based on the actual public offering price and other terms of this offering determined at pricing. You should read this table together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our audited and unaudited consolidated financial statements and the related notes appearing elsewhere in this prospectus.

	<b>As of December 31, 2016</b>		<b>Pro forma, as Adjusted (1) (2)</b>
	<b>Actual</b>	<b>As Adjusted</b>	
<b>CURRENT ASSETS</b>			
Cash and cash equivalents	\$ 138,363	\$ 828,363	\$
Accounts receivable, net of \$28,169 reserve at December 31, 2016	281,320	281,320	
Inventories, net of \$20,000 reserve at December 31, 2016	905,284	905,284	
Prepaid income taxes	7,405	7,405	



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Prepaid expenses and other current assets	258,103	258,103
Total current assets	1,590,475	2,280,475
Investment in available-for-sale equity securities	25,865	25,865
Property and equipment, net	9,413	9,413
Total Assets	1,625,753	2,315,753
Current liabilities:		
Accounts Payable	407,249	407,249
Accrued employee compensation	249,596	249,596
Accrued professional fees and other	956,884	956,884
Deferred revenue	159,654	159,654
Revolving note payable, net of unamortized debt discounts of \$637,030	612,970	1,302,970
Convertible debt, net of unamortized discounts of \$2,235,839	4,005,702	4,005,702
Other debt, net of unamortized discounts of \$380	238,157	238,157
Warrant derivative liability	1,685,108	1,685,108
Conversion option derivative liability	951,059	951,059
Total current liabilities	9,266,379	9,956,379
Long term liabilities		
Related party convertible debt, net of unamortized debt discounts of \$165,611	125,523	125,523
Convertible debt, net of unamortized discounts of \$740,628	529,742	529,742
Deferred revenue	87,527	87,527
Total long term liabilities	742,792	742,792
Total liabilities	10,009,171	10,699,171

	As of December 31, 2016		Pro forma, as Adjusted (1) (2)
	Actual	As Adjusted	
Stockholders' equity (deficit):			
Series D Convertible Preferred Stock, \$.01 par value; 850 shares authorized; 300 shares issued and outstanding on December 31, 2016 (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, 2016	866	866	
Series H Convertible Preferred Stock, \$.01 par value; 10,000 shares authorized; 10,000 shares issued and outstanding on December 31, 2016	100	100	
Series H2 Convertible Preferred Stock, \$.01 par value; 21 shares authorized; 21 shares issued and outstanding on December 31, 2016	-	-	
Series J Convertible Preferred Stock, \$.01 par value; 6,250 shares authorized; 3,521 and 3,546 shares issued and outstanding on December 31, 2016	35	35	
Series K Convertible Preferred Stock, \$.01 par value; 15,000 shares authorized; 6,816 and 11,416 shares issued and outstanding on December 31, 2016	68	68	
Common stock, \$.01 par value; 100,000,000 shares authorized; 30,999,839 and 23,004,898 shares issued and outstanding on December 31, 2016	309,998	309,998	
Warrants to acquire common stock	6,325,102	6,325,102	
Additional paid-in capital	27,244,600	27,244,600	
Accumulated deficit	(42,264,190 )	(42,264,190 )	
Total stockholder's deficit	(8,383,418 )	(8,383,418 )	
Total liabilities and stockholders' deficit	\$ 1,625,753	\$ 2,315,753	\$

(1) Excludes (i) 5,269,250 shares of our common stock issuable upon exercise of outstanding stock options at a weighted average exercise price of \$0.42 per share as of December 31, 2016, (ii) 26,459,695 shares of our common stock issuable upon exercise of outstanding warrants at a weighted average exercise price of \$0.40 per share as of December 31, 2016, (iii) 26,733,955 shares of common stock underlying convertible notes (including convertible debentures), (iv) 4,470,750 shares of common stock available for issuance under our equity incentive plans, (v) shares of common stock underlying the warrants to be issued to the underwriters in connection with this offering, and (vi) shares of common stock issuable upon the exercise of the underwriters' over-allotment option.

(2)

A \$1.00 increase or decrease in the assumed public offering price per share would increase or decrease our pro forma cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately \$            assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the underwriting discount and estimated offering expenses payable by us.

**DILUTION**

The historical net tangible book value (deficit) of our common stock as of December 31, 2016 was ( \$8,383,418 ), or \$0.27 per share based upon shares of common stock outstanding on such date. Historical net tangible book value (deficit) per share represents the amount of our total tangible assets reduced by the amount of our total liabilities, divided by the total number of shares of common stock outstanding.

Our pro forma net tangible book value (deficit) of our common stock as of December 31, 2016 was ( \$8,383,418 ), or \$0.11 per share. Pro forma net tangible book value (deficit) represents total tangible assets less total liabilities. Pro forma net tangible book value (deficit) per share represents pro forma net tangible book value divided by the total number of shares outstanding as of December 31, 2016, after giving effect to (i) the issuance of advances from the Revolving Note in the amount of \$750,000 in January and February 2017, (iii) the conversion of 300 shares of Series D Preferred Stock into approximately 750,000 shares of common stock, the conversion of 86,570 shares of Series G Preferred Stock into approximately 865,700 shares of common stock, the conversion of 10,000 shares of Series H Preferred Stock into approximately 1,000,000 shares of common stock, the conversion of 21 shares of Series H2 Preferred Stock into approximately 2,100,000 shares of common stock, the conversion of 3,521 shares of Series J Preferred Stock into approximately 3,521,000 shares of common stock and the conversion of 6,816 shares of Series K Preferred Stock into approximately 6,816,000 shares of common stock, and (iv) the conversion of \$7,803,045 of outstanding convertible notes (including convertible debentures) into approximately 26,733,955 shares of common stock.

After giving effect to the sale of \_\_\_\_\_ shares of our common stock at an assumed public offering price of \$0.31 per share of common stock (the last reported sale price of our common stock on the OTCQB on April 7, 2017), and \$ \_\_\_\_\_ per warrant, after deducting the underwriting discounts and commissions and estimated offering costs payable by us, our as adjusted net tangible book value as of December 31, 2016, would have been approximately \$ \_\_\_\_\_ million, or \$ \_\_\_\_\_ per share of common stock. This represents an immediate increase in as adjusted net tangible book value of \$ \_\_\_\_\_ per share to existing stockholders and an immediate dilution of \$ \_\_\_\_\_ per share to investors purchasing shares of common stock in this offering at the assumed public offering price.

The following table illustrates this dilution on a per share basis to new investors:

	As of December 31, 2016	Pro Forma (1)
Assumed public offering price per share		
Net tangible book value per share as of December 31, 2016	\$ 0.27	\$
Increase in pro forma net tangible book value per share attributable to new investors		\$
Pro forma net tangible book value per share after giving effect to this offering		

Dilution in net tangible book value per share to new investors

(1) Calculated on a pro forma basis, giving effect to the conversion of all our outstanding shares of preferred stock into common stock.

The information above is as of December 31 , 2016 and excludes the following:

; and

If the underwriter's overallotment option is exercised, our adjusted pro forma net tangible book value following the offering will be \$ \_\_\_\_\_ per share, and the dilution to new investors in the offering will be \$ \_\_\_\_\_ per share.

A \$1.00 increase or decrease in the assumed public offering price per share would increase or decrease our pro forma as adjusted net tangible book value after this offering by approximately \$ \_\_\_\_\_, and dilution per share to new investors by approximately \$ \_\_\_\_\_ for an increase of \$1.00, or \$( \_\_\_\_\_ ) for a decrease of \$1.00, after deducting the underwriting discount and estimated offering expenses payable by us.

## CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. Forward-looking statements give our current expectations or forecasts of future events. You can identify these statements by the fact that they do not relate strictly to historical or current facts. Forward-looking statements involve risks and uncertainties and include statements regarding, among other things, our projected revenue growth and profitability, our growth strategies and opportunity, anticipated trends in our market and our anticipated needs for working capital. They are generally identifiable by use of the words “may,” “will,” “should,” “anticipate,” “estimate,” “plans,” “potential,” “projects,” “continuing,” “ongoing,” “expects,” “management believe,” “we intend” or the negative of these words or other variations on these words or comparable terminology. These statements may be found under the sections entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business,” as well as in this prospectus generally. In particular, these include statements relating to future actions, prospective products, market acceptance, future performance or results of current and anticipated products, sales efforts, expenses, and the outcome of contingencies such as legal proceedings and financial results. Such forward-looking 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 have sufficient liquidity to finance normal operations;
- 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;
- our belief that pressure cycling technology (“PCT”) has achieved initial market acceptance in the mass spectrometry and other markets;
- the expected increase in the number of PCT and constant pressure based units installed and the increase in revenues from the sale of consumable products and extended service contracts;
- 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.

We operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for us to predict all of those risks, nor can we assess the impact of all of those risks on our business or the extent to which any factor may cause actual results to differ materially from those contained in any forward-looking statement. The forward-looking statements in this prospectus are based on assumptions management believes are reasonable. However, due to the uncertainties associated with forward-looking statements, you should not place undue reliance on any forward-looking statements. Further, forward-looking statements speak only as of the date they are made, and unless required by law, we expressly disclaim any obligation or undertaking to publicly update any of them in light of new information, future events, or otherwise.



## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*The following discussion and analysis of the financial condition and results of our operations should be read in conjunction with our consolidated financial statements and the notes to those statements appearing elsewhere in this prospectus. This discussion and analysis contains forward-looking statements reflecting our management's current expectations that involve risks, uncertainties and assumptions. Our actual results and the timing of events may differ materially from those described in or implied by these forward-looking statements due to a number of factors, including those discussed below and elsewhere in this prospectus, particularly on page 16 entitled "Risk Factors".*

### Overview

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

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

In 2015, together with an investment bank, we formed a subsidiary called Pressure BioSciences Europe ("PBI Europe") in Poland. We have 49% ownership interest with the investment bank retaining 51%. As of now, PBI Europe does not have any operating activities and we cannot reasonably predict when operations will commence. Therefore, we do not have control of the subsidiary and did not consolidate in our financial statements. PBI Europe did not have any operations in 2016 or in 2015.

## Patents

PBI has 14 United States granted patents and 1 foreign granted patent (Japan: 5587770, EXTRACTION AND PARTITIONING OF MOLECULES) covering multiple applications of PCT in the life sciences field. PBI also has 19 pending patents in the USA, Canada, Europe, Australia, China, and Taiwan PCT employs a unique approach that we believe has the potential for broad use in a number of established and emerging life sciences areas, which include, but are not limited to:

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

pathogen inactivation;

protein purification;

control of chemical reactions, particularly enzymatic; and  
immunodiagnostics.

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

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

### **Primary Fields of Use and Application for PCT**

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

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

from a wide variety of plant, animal, and microbiological cells and tissues.

*Biomarker Discovery - Mass Spectrometry*

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

A mass spectrometer is a laboratory instrument used in the analysis of biological samples, often focused on proteins, in life sciences research. It is frequently used to help discover biomarkers. According to a recently published market report by Transparency Market Research, "Spectrometry Market (Atomic, Molecular and Mass Spectrometry) - Global Scenario, Trends, Industry Analysis, Size, Share & Forecast 2011 – 2017," the global spectrometry market was worth \$10.2 billion in 2011 and is expected to reach \$15.2 billion in 2017, growing at a compound annual growth rate of 6.9% from 2011 to 2017. In the overall global market, the North American market is expected to maintain its lead position in terms of revenue until 2017 and is expected to have approximately 36.2% of the market revenue share in 2017, followed next by Europe. We believe PCT and CP-based products offer significant advantages in speed and quality compared with current techniques used in the preparation of samples for mass spectrometry analysis.

### *Forensics*

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

### *Histology*

The most commonly used technique worldwide for the preservation of cancer and other tissues for subsequent pathology evaluation is 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.

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

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

We have experienced negative cash flows from operations with respect to our pressure cycling technology business since our inception. As of December 31, 2016, we did not have adequate working capital resources to satisfy our current liabilities and as a result we have substantial doubt about our ability to continue as a going concern. Based on our current projections, including equity financing subsequent to December 31, 2016, we believe we will have the

cash resources that will enable us to continue to fund normal operations into the foreseeable future.

The audit report issued by our independent registered public accounting firm on our audited consolidated financial statements for the fiscal year ended December 31, 2016, 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, 2016 states that our auditing firm has substantial doubt in our ability to continue as a going concern due to the risk that we may not have sufficient cash and liquid assets to cover our operating and capital requirements for the next twelve-month period; and, if sufficient cash cannot be obtained, we would have to substantially alter, or possibly even discontinue, operations. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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

## Results of Operations

### *Comparison for the year ended December 31, 2016 and 2015*

#### Revenue

We had total revenue of \$1,976,487, in the year ended December 31, 2016 as compared with \$1,797,691 in the prior year, a 10% increase. The increase was due to product sales growth.

*Products, Services, and Other.* Revenue from the sale of products and services was \$1,794,749 in the year ended December 31, 2016 compared with \$1,409,991 in the year ended December 31, 2015, a 27% increase. Revenue included sales of both PBI and CS's pressure-based products. Sales of instrumentation increased in 2016 by \$369,909, or 44%, from \$835,611 for fiscal year 2015 to \$1,205,520 for fiscal year 2016. Sales of consumables were \$199,873 for the year ended December 31, 2016 compared to \$146,408 for the same period in 2015, an increase of \$53,465 or 37%. Products, Services, and Other Revenue included \$63,956 from non-cash transactions in the current year while the prior year included non-cash transactions of \$78,743. Revenue from non-cash transactions was recognized on the fair value of the assets involved per ASC 845.

*Grant Revenue.* During 2016, we recorded \$181,738 of grant revenue as compared with \$387,700 in 2015. In December 2014, the Company was awarded a \$1,020,969 SBIR Phase II grant (2R44HG007136) from the National Human Genome Research Institute of the NIH. Entitled "High Pressure Sample Preparation Instrumentation for DNA Sequencing", this grant is helping to fund the development of an automated, high-throughput, high pressure system (instrument and consumables) to enable significantly better control of DNA fragmentation - a critical step in the preparation of samples for Next Generation Sequencing platforms. This system will be based on significant technological advancements over the classic hydrodynamic DNA shearing approach that has been successfully and widely used in the field of DNA sequencing for many years.

#### Cost of Products and Services

The cost of products and services was \$834,012 for the year ended December 31, 2016, compared with \$609,054 in 2015. Our gross profit margin on products and services was 58% for fiscal year 2016 vs. 66% for fiscal year 2015. The current year margin was affected by the transfer of personnel to operations from sales and marketing. 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 \$1,183,011 for 2016 compared to \$1,105,295 in 2015, an increase of \$77,716 or 7%. This increase resulted primarily from the addition of a Ph.D. level electrical engineer, costs related to the continued development of an enhanced rape kit test based on the PCT Platform, and a rent increase related to additional R&D space. Research and development expense also included \$65,500 and \$50,617 of non-cash, stock-based compensation in 2016 and 2015, respectively.

### Selling and Marketing

Selling and marketing expenses were \$872,365 in 2016 compared to \$745,574 in 2015, an increase of \$126,791, or 17%. This increase is primarily attributed to an increase in employee staffing, collaboration activities, and rental space for product demonstrations. Selling and marketing expense included \$42,314 and \$32,704 of non-cash stock based compensation expense in 2016 and 2015, respectively.

### General and Administrative

General and administrative costs were \$2,822,752 in the year ended December 31, 2016, as compared with \$2,902,950 in 2015, a decrease of \$80,198 or 3%. This decrease was due primarily to credits received from charges incurred with a former professional service provider offset by additional stock-based compensation. During the years ended December 31, 2016 and 2015, general and administrative expense included \$272,150 and \$125,668 of non-cash, stock-based compensation expense, respectively.



Operating Loss

Our operating loss was \$3,735,653 for the year ended December 31, 2016 as compared to \$3,565,182 for the prior year, an increase of \$170,471 or 5%. This increase in operating loss was due primarily to increases in R&D and Sales and Marketing expenses, off-set to a certain extent by an increase in total revenue.

Other income (expense), net

*Interest Expense.* Net interest expense totaled \$4,501,186 for the year ended December 31, 2016 as compared to interest expense of \$4,146,416 for the year ended December 31, 2015. In connection with loans issued in 2015 and 2016, we are amortizing deferred financing costs and imputed interest against the debt discount on loans.

*Other income (expense) net*

We recognized \$1,112 in expense during 2016, compared to \$36,879 of expense from the initial fair value calculation on the conversion option on our convertible debt instruments in 2015.

*Impairment loss on investment*

The value of our investment in the common stock of Everest Investments Holdings S.A. (“Everest”) has declined since the date of receipt of the stock in 2015. We evaluated the decline and considered it as an “other than temporary impairment” reduction. Thus, the impairment loss was recognized as a charge in the consolidated statements of operations. During 2016, we recorded total impairment losses related to \$373,682 which represented the reduction in value of these securities.

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, 2016, we recorded non-cash income of \$5,904,649 from warrant and conversion option liability revaluations in our consolidated statements of operations due to a decrease in the fair value of the derivative warrants and the conversion option liabilities on our debt. This decrease in fair value was primarily due to a decrease in the price per share of our common stock. During the year ended December 31, 2015, we recorded non-cash charges of \$2,222,001 for warrant and conversion option liability revaluations due to an increase in fair value of the liabilities.

Income Taxes

We did not record an income tax benefit or provision for the years ended December 31, 2016 or 2015.

Net Loss

During the year ended December 31, 2016, we recorded a net loss applicable to common stockholders of \$2,706,984 or \$(0.10) per share, as compared with \$7,438,492 or \$(0.36) per share during the year ended December 31, 2015. This decrease in net loss is primarily attributable to the current year non-cash income from warrant and conversion option liability revaluations.

**LIQUIDITY AND CAPITAL RESOURCES**

We have experienced negative cash flows from operations with respect to our pressure cycling technology business since our inception. As of December 31, 2016, 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 issued a promissory note in the aggregate principal amount of up to \$2,000,000 in October 2016 that we could draw funds from, and, through March 1, 2017, we have drawn down the entire \$2 million (\$750,000 subsequent to December 31, 2016). We have efforts in place to continue to raise cash through debt and equity offerings.

We will need substantial additional capital to fund our operations in future periods. In the event that we are unable to obtain 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.



Net cash used in operating activities was \$3,805,851 for the year ended December 31, 2016 as compared with \$3,819,746 for the year ended December 31, 2015. Our accounts payable balance was \$407,249 as of December 31, 2016, as compared with \$941,389 as of December 31, 2015, a decrease of 57% from 2015. Accounts payable should continue to become more current as we continue to secure more capital and funds from operations; this should allow for more timely payments to our vendors.

We invested \$7,203 in fixed assets during the year ended December 31, 2016 as compared with \$9,412 investment in fixed assets in the prior year.

Net cash provided by financing activities for the year ended December 31, 2016 was \$3,834,634 as compared with \$3,471,993 in the prior year.

In 2016,

A \$2,105,420 in aggregate net proceeds were raised from sales of convertible debentures and \$107,000 payments were made for convertible debt.

B Loans in the aggregate amount of \$1,022,784 were received during the year and we made payments on new and existing debt of \$947,702.

From August 29 through December 31, 2016, we completed five tranches of a private placement, pursuant to  
C which we sold and issued an aggregate of 1,525,000 shares of common stock, with a purchase price of \$0.40 per share, resulting in net proceeds to us of \$530,965.

D \$1,133,500 in aggregate net proceeds were drawn down from a revolving note facility.

E \$116,667 net proceeds were received from related party debt and we made payments of \$20,000.

### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements as of December 31, 2016 and December 31, 2015.

### **CRITICAL ACCOUNTING POLICIES AND ESTIMATES**

While our significant accounting policies are more fully described in Note 3 to our audited financial statements appearing elsewhere in this prospectus, we believe that the following accounting policies are the most critical for fully understanding and evaluating our financial condition and results of operations.

#### *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 Barocyler® instruments require a basic level of instrumentation expertise to set-up for initial operation. To support a favorable first experience for our customers, upon customer request, and for an additional fee, will send a highly trained technical representative to the customer site to install Barocyler®s 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 Barocyler® instrumentation and Constant Systems products is recognized upon shipment of the unit. In the case where the customer requests installation and training, the additional revenue related to the installation and training is recognized upon the completion of the installation and introductory training process of the instrumentation at the customer location. 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.



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

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

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

c) The transaction lacks commercial substance.

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

In accordance with FASB ASC 840, *Leases*, we account for our lease agreements under the operating method. We record revenue over the life of the lease term and we record depreciation expense on a straight-line basis over the thirty-six month estimated useful life of the Barocycler® instrument. The depreciation expense associated with assets under lease agreement is included in the “Cost of PCT products and services” line item in our accompanying consolidated statements of operations. Many of our lease and rental agreements allow the lessee to purchase the instrument at any point during the term of the agreement with partial or full credit for payments previously made. We pay all maintenance costs associated with the instrument during the term of the leases.

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

Revenue from the sale of CS’ cell disruption equipment, parts, and consumables is recognized when products are shipped.

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

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, we Company develop 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.

#### *Warrant Derivative Liability*

The warrants issued in November 2011 in connection with the registered direct offering of Series D Convertible Preferred Stock (the “Series D Warrants”) and the warrants issued in 2015 and 2016 in connection with the \$6.3 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 sale of convertible debentures in 2015 and 2016, the estimated fair value of the warrants was determined using the binomial model, resulting in an allocation of the gross proceeds of \$2,847,624 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. The down-round protection for the Series D Warrants ends in May 2017.

#### *Conversion Option Liability*

We have signed convertible notes and have determined that conversion options are embedded in the notes and it is required to bifurcate the conversion option from the host contract under ASC 815 and account for the derivatives at fair value. The estimated fair value of the conversion options was determined using the binomial model. The fair value of the conversion options will be classified as a liability until the debt is converted by the note holders or paid back by the Company. The fair value will be affected by changes in inputs to that model including our stock price, expected stock price volatility, the contractual term, and the risk-free interest rate. We 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. We have 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*

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

### *Equity Transactions*

We evaluate the proper classification of our equity instruments that embody an unconditional obligation requiring the issuer to redeem it by transferring assets at a determinable date or that contain certain conditional obligations, typically classified as equity, be classified as a liability. We record 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.

## BUSINESS

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, Boston Biomedica, Inc.'s name was changed to Pressure BioSciences, Inc. Operations began as PBI in February 2005, research and development activities in April 2006, early marketing and selling activities of our initial Barocycler® instrument in late 2007, and earnest marketing and selling of our PCT-based instrument platform in 2012.

During its early development, under the legacy business of Boston Biomedica, Inc., our scientists were researching and developing applications of the PCT platform in many areas of the life sciences, including proteomics, genomics, lipidomics, 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 the PCT platform both within and outside of the sample preparation market.

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 PCT, uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels i.e., 20,000 psi or greater to safely, conveniently and reproducibly control the actions of molecules in biological samples, such as cells and tissues from human, animal, plant and microbial sources.

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

In 2015, together with an investment bank, we formed a subsidiary called Pressure BioSciences Europe (“PBI Europe”) in Poland. We have 49% ownership interest with the investment bank retaining 51%. PBI Europe did not have any

operating activities in 2016 and we cannot reasonably predict when operations will commence. Because we don't have control of the subsidiary, we did not consolidate them in our financial statements.

## Patents

PBI has 14 United States granted patents and 1 foreign granted patent (Japan: 5587770, EXTRACTION AND PARTITIONING OF MOLECULES) covering multiple applications of PCT in the life sciences field. PBI also has 19 pending patents in the USA, Canada, Europe, Australia, China, and Taiwan PCT employs a unique approach that we believe has the potential for broad use in a number of established and emerging life sciences areas, which include, but are not limited to:

biological sample preparation – including but not limited to sample extraction, homogenization, and digestion - in such study areas as proteomics, genomics, lipidomics, metabolomics, and small molecules;

pathogen inactivation;

protein purification;

control of chemical reactions, particularly enzymatic;

immunodiagnostics.

### **Primary Fields of Use and Applications for PCT**

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

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

#### *Biomarker Discovery - Mass Spectrometry*

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

A mass spectrometer is a laboratory instrument used in the analysis of biological samples, often focused on proteins, in life sciences research. It is frequently used to help discover biomarkers. According to a recently published market report by Transparency Market Research, "Spectrometry Market (Atomic, Molecular and Mass Spectrometry) - Global Scenario, Trends, Industry Analysis, Size, Share & Forecast 2011 – 2017," the global spectrometry market was worth \$10.2 billion in 2011 and is expected to reach \$15.2 billion in 2017, growing at a compound annual growth rate of 6.9% from 2011 to 2017. In the overall global market, the North American market is expected to maintain its lead position in terms of revenue until 2017 and is expected to have approximately 36.2% of the market revenue share in

2017, followed next by Europe. We believe PCT and CP-based products offer significant advantages in speed and quality compared with current techniques used in the preparation of samples for mass spectrometry analysis.

*Forensics*

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

### *Histology*

The most commonly used technique worldwide for the preservation of cancer and other tissues for subsequent pathology evaluation is 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.

### **Other Fields of Use and Applications for PCT**

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

#### *Pathogen Inactivation*

Biological products intended for human use, such as blood, vaccines and drugs, are put through rigorous processing protocols in an effort to minimize the potential of that product to transmit disease. These protocols may include methods to remove infectious materials such as pre-processing testing, filtration or chromatography, or methods to inactivate infectious agents that are not captured in the removal steps such as pasteurization, irradiation and solvent detergent inactivation. Notwithstanding current diligence in both the removal and inactivation steps, significant concern remains that some pathogens (e.g., bacteria 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. 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 in this area.

*Control of Chemical (Particularly Enzymatic) Reactions*

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

### *Immunodiagnosics*

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

### **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.

### *Barocyler® Instrumentation*

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

Our instruments (the 2320EXT, the Barozyme-HT48, the Barocyler® NEP3229, the HUB440 and the HUB880) use cycles of high, hydrostatic pressure to quickly and efficiently break up the cellular structures of a specimen to release proteins, nucleic acids, lipids and small molecules from the specimen into our consumable processing tubes, referred to as our PULSE® Tubes and MicroTubes. Our instruments have temperature control options (on-board heating or chilling and heating via external circulating water-bath), 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 Barocyler® instruments and our consumable products make up our PCT Sample Preparation System.

Barocyler® 2320EXT - The Barocyler® 2320EXT weighs approximately 80lbs, has a maximum pressure of 45,000 psi, and can process either up to 16 MicroTubes simultaneously or 1 PULSE® Tube. The working temperature range is 4 – 95°C and is controlled via an on-board electric heating jacket or external circulating water bath. All tests are

entered and recorded on a touch screen interface. Information from each test runs (pressure profile, cycle number, and temperature) is recorded and can be stored on the instrument, on a USB drive, or networked into the user's lab. Pressure profiles can be manipulated in a number of ways, including static high pressure holds and pressure ramp programs. The Barocycler® 2320EXT is pneumatic, and requires an input air source of 100psi to reach and cycle at high pressure.

The Barocycler® 2320EXT was developed to support the PCT-HD/PCT-SWATH application. PCT-HD enables faster, less cumbersome and higher quality processing of biopsy tissues. With homogenization, extraction, and digestion of proteins occurring in a single PCT MicroTube under high pressure. This protocol can yield analytical results in under 4 hours from the start of processing tissues. PCT-HD was developed by our scientists and engineers in collaboration with Professor Ruedi Aebersold and Dr. Tiannan Guo of the Institute of Molecular Systems Biology, ETH Zurich, and the University of Zurich, both in Zurich, Switzerland. Drs. Aebersold and Guo combined PCT-HD with SCIEX's SWATH-Mass Spectrometry – calling the resulting method “PCT-SWATH”.

Barocycler® NEP3229 – The Barocycler® NEP3229 contains two units – a user interface and a power source – comprised primarily of a 1.5 horsepower motor and 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.

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

Barocyler® HUB440 –We believe the Barocyler® HUB440 is the first portable, ready to use, “plug-and-play” high pressure generator for the laboratory bench. The Barocyler® HUB440 is capable of creating and controlling hydrostatic pressure from 500 psi to 58,000 psi. It is computer controlled and runs on software that was specially-written by us in LabVIEW (software from National Instruments Corporation). We own the rights and have a license to use the specialty LabVIEW software. We believe that over the coming years, the Barocyler® HUB440 may become the main instrument in our pressure-based instrument line.

Barocyler® HUB880 - The Barocyler® HUB880 is one of our new instruments; it is expected to be available for sale during the first six months of 2017. 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 safety and vaccine industries.

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

#### *Barocyler® Consumable Products*

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

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

PCT-Micro-Pestle - PCT  $\mu$ Pestles are made from Polytetrafluoroethylene (PTFE), a synthetic fluoropolymer of tetrafluoroethylene, also known as Teflon (by DuPont Co). PTFE is practically inert; the only chemicals known to affect it are certain alkali metals and most highly-reactive fluorinating agents. PCT  $\mu$ Pestles, in conjunction with PCT MicroTubes, are designed to enhance the extraction of 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  $\mu$ L. PCT MicroTubes and PCT  $\mu$ Pestles 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  $\mu$ Pestles tip is crushed on every pressure cycle. This mechanical action, combined with the extraction ability of the buffer under high pressure, results in highly effective tissue homogenization and extraction.

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

