PRESSURE BIOSCIENCES INC
Form 10-K
March 31, 2014

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

(Mark One)

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

For the fiscal year ended December 31, 2013 or

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

For the transition period from _____ to _____

Commission file number 000-21615

PRESSURE BIOSCIENCES, INC.
(Exact Name of Registrant as Specified in its Charter)

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

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

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

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

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

_____

(Title of Class)

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

Yes o No þ

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that registrant was required to submit and post such files. Yes þ No o

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

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

Large accelerated filer	o	Accelerated filer	o
Non-accelerated filer	o	Smaller reporting company	þ
(Do not check if smaller reporting company)			

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

The aggregate market value of the voting and non-voting Common Stock held by non-affiliates of the registrant as of June 30, 2013 was $3,640,182 based on the closing price of $0.34 per share of Pressure BioSciences, Inc. Common Stock as quoted on the OTC Markets QB exchange on that date.

As of March 31, 2014, there were 12,624,267 shares of the registrant's Common Stock outstanding.

Documents Incorporated by Reference

N/A.

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Introductory Comment

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

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

our need for, and our ability to raise, additional equity or debt financing on acceptable terms, if at all;
our need to take additional cost reduction measures, cease operations or sell our operating assets, if we are unable to obtain sufficient additional financing;
our belief that we have sufficient liquidity to finance normal operations until August 2014;
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 PCT has achieved initial market acceptance in the mass spectrometry and other markets;
the expected increase in the number of pressure cycling technology ("PCT") and constant pressure ("CP") based units installed and the increase in revenues from the sale of consumable products and extended service contracts;
the expected development and success of new instrument and consumables product offerings;
the potential applications for our instrument and consumables product offerings;
the expected expenses of, and benefits and results from, our research and development efforts;
the expected benefits and results from our collaboration programs, strategic alliances and joint ventures;
our expectation of obtaining additional research grants from the government in the future;
our expectations of the results of our development activities funded by government research grants;
the potential size of the market for biological sample preparation;
general economic conditions;
the anticipated future financial performance and business operations of our company;
our reasons for focusing our resources in the market for genomic, proteomic, lipidomic and small molecule sample preparation;
the importance of mass spectrometry as a laboratory tool;
the advantages of PCT over other current technologies as a method of biological sample preparation in biomarker discovery, forensics, and histology and for other applications;
the capabilities and benefits of our PCT sample preparation system, consumables and other products;
our belief that laboratory scientists will achieve results comparable with those reported to date by certain research scientists who have published or presented publicly on PCT and our other products;
our ability to retain our core group of scientific, administrative and sales personnel; and
our ability to expand our customer base in sample preparation and for other applications of PCT and our other products.

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

A. ITEM 1. BUSINESS.

Throughout this document we use the following terms: Barocycler®, PULSE®, and BioSeq®, which are registered trademarks of the Company. We also use the terms ProteoSolveTM, ProteoSolveLRSTM, the Power of PCTTM and the PCT ShredderTM, all of which are unregistered trademarks of the Company.

Overview

We are focused on solving the challenging problems inherent in biological sample preparation, a crucial laboratory step performed by scientists worldwide working in biological life sciences research. Sample preparation is a term that refers to a wide range of activities that precede most forms of scientific analysis. Sample preparation is often complex, time-consuming and, in our belief, one of the most error-prone steps of scientific research. It is a widely-used laboratory undertaking – the requirements of which drive what we believe is a large and growing worldwide market. We have developed and patented a novel, enabling technology platform that can control the sample preparation process. It is based on harnessing the unique properties of high hydrostatic pressure. This process, called pressure cycling technology, or PCT, uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels i.e., 35,000 pounds per square inch ("psi") or greater to safely, conveniently and reproducibly control the actions of molecules in biological samples, such as cells and tissues from human, animal, plant and microbial sources.

Our pressure cycling technology uses internally developed instrumentation that is capable of cycling pressure between ambient and ultra-high levels at controlled temperatures and specific time intervals, to rapidly and repeatedly control the interactions of bio-molecules, such as deoxyribonucleic acid ("DNA"), ribonucleic acid ("RNA"), proteins, lipids and small molecules. Our laboratory instrument, the Barocycler®, and our internally developed consumables product line, which include our Pressure Used to Lyse Samples for Extraction ("PULSE") tubes, and other processing tubes, and application specific kits such as consumable products and reagents, together make up our PCT Sample Preparation System ("PCT SPS").

We hold 14 United States and 10 foreign patents covering multiple applications of PCT in the life sciences field. Our pressure cycling technology employs a unique approach that we believe has the potential for broad use in a number of established and emerging life sciences areas, which include:

- biological sample preparation in such study areas as genomic, proteomic, lipidomic, metabolomic and small molecule;
- pathogen inactivation;
- protein purification;
- control of chemical reactions, particularly enzymatic; and
- immunodiagnostics.

We are also the exclusive distributor throughout all of the Americas for the Constant Systems cell disruption equipment, parts, and consumables. Constant Systems, Ltd ("CS"), a British company located about 90 minutes northwest of London, England, has been providing niche biomedical equipment, related consumable products, and services to a global client base since 1989. CS designs, develops, and manufactures high pressure cell disruption equipment required by life sciences laboratories worldwide, particularly disruption systems for the extraction of proteins. The CS equipment provides a constant and controlled cell disruptive environment, giving the user superior, constant, and reproducible results whatever the application. CS has nearly 900 units installed in over 40 countries worldwide. The CS cell disruption equipment has proven performance in the extraction of cellular components, such as protein from yeast, bacteria, mammalian cells, and other sample types.

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

Within the broad field of biological sample preparation, 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.

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

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

Forensics. The detection of DNA has become a part of the analysis of forensic samples by laboratories and criminal justice agencies worldwide in their efforts to identify the perpetrators of violent crimes and missing persons. Scientists from the University of North Texas and Florida International University have reported improvements in DNA yield from forensic samples e.g., bone, and hair, using PCT in the sample preparation process. We believe PCT may be capable of differentially extracting DNA from sperm and female epithelial cells in swabs collected from rape victims and stored in rape kits. According to the Joyful Arts Foundation's website, an organization focused on bringing justice to all victims of rape cases that remain unsolved (http://endthebacklog.org/whatisthebacklog.htm), "Experts in the federal government estimate that there are hundreds of thousands of untested rape kits in police and crime lab storage facilities throughout the United States." We believe this backlog exists for reasons such as cost, processing time and quality of results. We further believe that the ability to differentially extract DNA from the sperm while not extracting DNA from the female epithelial cells could reduce the cost of such testing, while increasing quality, safety and speed.

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

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

We have experienced negative cash flows from operations with respect to our business since inception. As of December 31, 2013, we did not have adequate working capital resources to satisfy our current liabilities. Based on our current projections, including equity financing subsequent to December 31, 2013, we believe our current cash resources will enable us to extend our cash resources until August 2014.

As a result, the audit report issued by our independent registered public accounting firm on our audited consolidated financial statements for the fiscal year ended December 31, 2013, 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, 2013 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 qualify its opinion in the future. If we cannot successfully continue as a going concern, our stockholders may lose their entire investment in us.

Developments

Despite the continued uncertainty in the capital markets during 2013 that negatively affected the overall capital budgets of our existing and prospective customers, and notwithstanding our limited financial resources during such time, we reported a number of accomplishments during 2013 including:

2013

On December 12th, we filed a current report on Form 8K relating to the close of the first tranche ($1 million) of a $1.5 million Convertible Preferred Stock and Common Warrant transaction.

On November 7th, we announced Q3 2013 financial results, including record quarterly total revenue, record quarterly products and services revenue, record quarterly consumable sales, and record quarterly Shredder Systems sales.

On August 1st, we reported that scientists from UCLA presented data at an international scientific symposium on an advanced pressure-based instrument system for biomarker discovery and rational drug design that we believe could offer new insights into protein structure and function.

On June 14th, we announced the close of the third and final tranche of our Series J $2.0 million Private Placement of Preferred Stock and Warrants; we also announced the closing of a $500,000 one-year convertible debenture with an institutional investor.

On June 4th, we announced a core technology breakthrough; that we had succeeded in reaching a pivotal development in our PCT platform that will allow the processing of the high throughput multiwell format found in research (and clinical) laboratories worldwide and that we expected this novel design would have a significant impact on our future growth.

On May 21st, we announced financial results for Q1 2013: total revenue increased 21% over the Q1 2012, consumable sales increased 64% over Q1 2012, and operating loss decreased 24% compared to Q1 2013.

On May 20th we closed the third and final tranche of an over-subscribed $1.5 million Convertible Preferred Stock and Common Warrant transaction, in which the Company received a total of $2,034,700.

On May 16th, we reported the publication of a breakthrough method for lipid analysis in fecal material, developed by a team led by Dr. Bruce Kristal (Harvard Medical School and the Brigham and Women's Hospital). We believe that this new method can help increase the understanding of diseases and disorders related to gastrointestinal (GI) disorders.

On April 4th, we announced that further advances had been made in the development of an improved method for rape kit sample testing using PBI's PCT Platform by Dr. Bruce McCord and his team at the International Forensic Research Institute of Florida International University.

On March 19th, we announced that the use and advantages of PBI's PCT Platform had been highlighted in cancer, stem cell, and heart disease studies at an important protein research conference. We believe that the FDA data indicate that PCT can be used to extract proteins from stem cells with consistency and quality; the Johns Hopkins data indicate that combining PCT with heat might be a way to recover significantly more proteins from FFPE tissues compared to standard (heat) methods, especially membrane proteins (this could be very important with scientists looking for disease biomarkers); and the ETH Zurich data might be significant for extracting proteins

from small, needle biopsy samples, something that we believe is vitally needed today yet not well satisfied at the present time, and (we believe) a significant market opportunity.

On February 12th, we announced that Dr. Mickey Urdea had been appointed to the Board of Directors of PBI. Dr. Urdea is one of the most well-known entrepreneurs and leaders in biotechnology today, having founded two successful companies (Halteres Associates and Tethys Bioscience) over the past ten years. Earlier in his career, Dr. Urdea led the infectious diseases R&D groups at Chiron Corporation and Bayer Diagnostics. He has also been on the Scientific Advisory Boards of numerous life sciences companies and has been an advisor and consultant to the Bill and Melinda Gates Foundation Diagnostic Forum.

Liquidity

Management has developed a plan to continue operations. This plan includes reducing expenses, streamlining operations, and obtaining capital through an equity and/or debt financing including our most recently completed financing on February 28, 2014 (the "Series K Private Placement"). In the Series K Private Placement, we sold units consisting of Preferred Stock convertible into the Company's Common Stock ("Common Stock") and warrants to purchase shares of Common Stock for net aggregate proceeds of approximately $2,849,110 in three tranches of $1,000,000, $1,218,750 and $630,360, respectively. Although we have successfully completed equity financings and reduced expenses in the past, we cannot assure our investors that our plans to address these matters in the future will be successful. Additional financing may not be available to us on a timely basis or on terms acceptable to us, if at all. In the event we are unable to raise sufficient funds on terms acceptable to us, we may be required to:

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

Corporate Information

We were incorporated in the Commonwealth of Massachusetts in August 1978 as Boston Biomedica, Inc. In September 2004, we completed the sale of Boston Biomedica's core business units and began to focus exclusively on the development and commercialization of the PCT platform. Following this change in business strategy, we changed our legal name from Boston Biomedica, Inc. to Pressure BioSciences, Inc. ("PBI"). We began operations as PBI in February 2005, research and development activities in April 2006, early marketing and selling activities of our Barocycler instruments in late 2007, and aggressive marketing and selling of our PCT-based instrument platform in 2012.

Available Information

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

You may read and copy any materials we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy and information statements and other information regarding Pressure BioSciences and other issuers that file electronically with the SEC. The SEC's Internet website address is http://www.sec.gov.

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

The Market

Since February 2005, we have focused substantially all of our research and development and commercialization efforts on sample preparation for genomic, proteomic, lipidomic, and small molecule studies. This market is comprised of academic and government research institutions, biotechnology and pharmaceutical companies, and other public and private laboratories that are engaged in studying genomic, proteomic and small molecule material within plant and animal cells, and tissues. We elected to initially focus our resources in the market of genomic, proteomic and small molecule sample preparation because we believe it is an area that:

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

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

Biomarker Discovery - Mass Spectrometry

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

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

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

Forensics

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

Histology

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

Sample Extraction Process

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

Collaboration Program

Our collaboration program is an important element of our business strategy. Initiating a collaboration with a researcher involves the installation of a Barocycler instrument for an agreed upon period of time of approximately three to six months, and the execution of an agreed upon work plan. Our primary objectives for entering into a collaboration agreement include:

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

Since we initiated our collaboration program in June 2005, third party researchers have cited the use of our PCT platform in publications and presentations. We believe that this program has provided and continues to provide us with independent and objective data about PCT from well-respected laboratories in the United States and throughout the rest of the world.

Company Products

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

Barocycler Instrumentation

Our Barocycler product line consists of laboratory instrumentation that subjects a sample to cycles of pressure from ambient to ultra-high levels and then back to ambient; all in a precisely controlled manner. Our instruments, the Barocycler NEP3229 and Barocycler NEP2320, use cycles of high, hydrostatic pressure to quickly and efficiently break up the cellular structures of a specimen to release nucleic acids, proteins, lipids and small molecules from the specimen into our consumable processing tube, referred to as our PULSE Tubes. Our Barocycler instrumentation is designed to fit on a laboratory bench top, inside a biological safety cabinet, or on the shelf of a laboratory cold room. Our instruments have an external chiller hook-up (to control temperature during the PCT process), automatic fill and dispensing valves, and an integrated micro-processor keypad. The microprocessor is capable of saving up to 99 specific PCT protocols; so, the researcher can achieve maximum reproducibility for the extraction of nucleic acids, proteins, lipids, or small molecules from various biological samples. Our Barocycler instruments and our consumable products make up our current PCT Sample Preparation System (See below).

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

Barocycler NEP2320 – The Barocycler NEP2320 is a smaller, more compact version of our NEP3229 unit. It weighs approximately 80 pounds (with accessories), and works on compressed air (pneumatic) instead of hydraulics like the larger NEP3229 unit. Because this instrument is pneumatic, the NEP2320 can be easily attached by an air hose to a

typical 85 psi air compressor found in most scientific laboratories as well as many consumer-sold portable compressors or even to bottled gas. This instrument is used by our sales directors as a demonstration instrument and is marketed as a second instrument alternative to our PCT SPS. The Barocycler NEP2320 is capable of processing one sample at a time using our specially designed, single-use PULSE Tubes and up to 16 samples simultaneously using our specially-designed MicroTubes.

Barocycler HUB440 – The Barocycler HUB440 was introduced to collaborators in the electron paramagnetic resonance ("EPR") market in 2011 for testing in a laboratory environment, and to elicit feedback from research scientists on performance and capabilities. The Barocycler HUB440 is capable of creating and controlling hydrostatic pressure from 35 Bar (500 psi) to 4,000 Bar (58,000 psi). It is computer controlled, and runs on software that was specially-written by PBI in LabVIEW (by National Instruments Corporation). PBI owns the rights and has a license to use the specialty LabVIEW software. The Barocycler HUB440 is the first portable, ready to use pressure generator for the laboratory bench. We believe that over the coming years, the Barocycler HUB440 will be the main instrument in the Company's pressure-based instrument line.

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

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

Cell Disruption Instrumentation

We are also the exclusive distributor throughout all of the Americas for the Constant Systems cell disruption equipment, parts, and consumables. Constant Systems, Ltd ("CS"), a British company located about 90 minutes northwest of London, England, has been providing niche biomedical equipment, related consumable products, and services to a global client base since 1989. CS designs, develops, and manufactures high pressure cell disruption equipment required by life sciences laboratories worldwide, particularly disruption systems for the extraction of proteins. The CS equipment provides a constant and controlled cell disruptive environment, giving the user superior, constant, and reproducible results whatever the application. CS has nearly 900 units installed in over 40 countries worldwide. The CS cell disruption equipment has proven performance in the extraction of cellular components, such as protein from yeast, bacteria, mammalian cells, and other sample types.

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

Baracycler Consumable Products

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

Non-Disk PULSE Tubes (FT500-ND) – The FT500-ND PULSE Tube is a specially-designed, plastic, single-use, processing container with one chamber separated by a small disk with small holes. The FT500-ND is similar to the

FT500 in look and feel, except there is no Lysis Disk separating the body of the processing container into two chambers, as in the FT500. The design change was based on market demand for a PCT consumable for the rapid and reproducible processing of solutions and suspensions that do not require partial homogenization by passage through a Lysis Disk and for a consumable that could accept smaller sample volumes. The FT500-ND offers variable sample volumes with a range five times that of the existing FT500.

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

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

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

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

Company Services

Government Grants and Contracts

We view federal agency grants to be an important part of our business plan. These types of grants allow us to bill the federal agency for work that we are planning to perform as part of the development and commercialization of our technology. We generally start by submitting initial grant requests that are in response to requests for proposals (“RFPs”) from the federal government through their Small Business Innovation Research (“SBIR”) program. Initial (“SBIR Phase I”) grants are meant to fund approved research projects for six months, and generally have budgets of approximately $100,000 to $150,000. Because our work in SBIR Phase I grants has been successful, we have applied, and may in the future apply for larger National Institutes of Health (“NIH”) SBIR Phase II grants. Such larger grants are typically for a two-year period and can offer as much as $1,000,000 to support significant research projects in areas we would otherwise expect to support with internal funds should SBIR Phase II grants not be awarded. To date, we have been awarded three NIH SBIR Phase I grants and one SBIR Phase II grant. The data on one of the NIH SBIR Phase I grants was the basis for the submission, and subsequent award, of the NIH SBIR Phase II grant awarded to us in the approximate amount of $850,000 in August 2008. This NIH SBIR Phase II grant was for work in the area of using PCT to extract protein biomarkers, sub-cellular molecular complexes, and organelles, with the expectation that these studies might ultimately lead to the release of a new, commercially available PCT-based system, with validated protocols, end-user kits, and other consumables intended for the extraction of clinically important protein biomarkers, sub-cellular molecular complexes, and organelles from human and animal tissues. All three of the NIH SBIR Phase I grants and the NIH SBIR Phase II grant have been completed.

In October 2011, we were awarded a contract for approximately $850,000 from the Department of Defense (“DoD”) to help fund the development of a PCT-based system to improve the processing of pathogenic organisms, specifically viruses and bacteria. The contract funded studies until September 2013.

Extended Service Contracts

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

Other Applications of Pressure Cycling Technology

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

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

Pathogen Inactivation

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

Protein Purification

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

Control of Chemical (Particularly Enzymatic) Reactions

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

Immunodiagnostics

Many tests used in the clinical laboratory today are based on the formation of a complex between two proteins, such as an antigen and an antibody. Such “immunodiagnostic” methods are used for the detection of infectious agents such

as the human immunodeficiency virus ("HIV"), hepatitis viruses, West Nile virus, and others, as well as for endocrine, drug testing and cancer diagnostics. We have generated proof-of-concept that PCT may be used to control biomolecular interactions between proteins, such as antigens and antibodies. We believe this capability may provide a greater degree of sensitivity and quantitative accuracy in immunodiagnostic testing than that offered by methods that are available today. We have been issued U.S. and European patents in this area.

Customers

Our customers include researchers at academic laboratories, government agencies, biotechnology companies, pharmaceutical companies and other life science institutions in the United States. Our customers also include 11 foreign distribution partners. Our goal is to continue our market penetration in these target groups and releasing products in our publicized product pipeline. We also believe that there is a significant opportunity to sell and/or lease additional Barocycler instrumentation to additional laboratories at current customer institutions.

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

Competition

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

labor reduction	versatility
temperature control	efficiency
precision	simplicity
reproducibility	safety

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

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

Manufacturing and Supply

BIT Group USA, formerly Source Scientific, LLC, currently provides all of the manufacturing and assembly services for our Barocycler NEP2320 and Barocycler NEP3229 instrumentation products under an informal, unwritten understanding. We currently manufacture and assemble the Barocycler HUB440, the Shredder SG3, and the MicroTubes at our South Easton facility. We plan to continue to utilize BIT Group USA as our primary assembler

and contract manufacturer of our current, and future, Barocycler NEP 2320 and 3229 instruments. Until we develop a broader network of manufacturers and subcontractors, obtaining alternative sources of supply or manufacturing services could involve significant delays and other costs and challenges, and may not be available to us on reasonable terms, if at all. The failure of a supplier or contract manufacturer to provide sufficient quantities, acceptable quality and timely products at an acceptable price, or an interruption of supplies from such a supplier could harm our business and prospects.

Research and Development

Our research and development activities are split into two functional areas, applications and engineering.

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

2. Engineering Research and Development: Our engineering research and development team is focused on the design and development of new and improved instrumentation and consumable products to support the commercialization of PCT. Our engineering department is led by Dr. Edmund Ting, our senior vice president of engineering. The primary focus of our engineering group is to ensure seamless production processes, perform installations and field service, and work with our application scientists to complete the development of a high throughput sample processing system for the mass spectrometry market.

Product Pipeline

The following instruments are in our research and development pipeline:

Barocycler FFPE Protein Extraction Instrument System - A PCT-based system offering the enhanced extraction of proteins from formalin-fixed, paraffin-embedded (“FFPE”) samples using a modified Barocycler instrument that combines the advantages of pressure cycling, high temperature and certain reagents.

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

Barocycler HT Multiwell (24-384) - For high throughput, PCT-enhanced biomolecule extraction/accelerated enzymatic digestion with the capability of processing 48 - 384 samples.

Barocycler HUB880 High Pressure - The next in the line of modular, high pressure generating instruments, the Barocycler HUB880 will be capable of creating and controlling hydrostatic pressure from 35 Bar (500 psi) to approximately 7,000 Bar (100,000 psi). The higher pressure limit of the Barocycler HUB880 will be nearly two times the upper limit of its’ sister instrument, the Barocycler HUB440. This higher limit will allow users to study the effects of pressure on substances (e.g., certain proteins) that do not react to pressures below 58,000 psi. Like the Barocycler HUB440, the Barocycler HUB880 will be computer controlled and run on software specially-written by PBI in LabVIEW. (by National Instruments Corporation). The Barocycler HUB880 will be the first portable, ready to use pressure generator for the laboratory bench that can reach pressures between 60,000 and 100,000 psi. We believe that over the coming years, the Barocycler HUB880 will be one of the main instruments in the Company’s pressure-based instruments line.

Sales and Marketing

Our sales and marketing efforts are centered on using the independent data developed and disseminated by our collaboration partners to help drive the installed base of our PCT Sample Preparation System. The development of scientific data by our partners and our internal researchers provides our sales and marketing staff with additional tools that are essential in selling a new technology such as PCT.

Sales

Direct US Sales Force

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

Foreign Distributor Network

Currently, we have 11 distribution arrangements covering 22 countries in Europe, Asia and Australia. In June 2008, we entered into a distribution agreement with Veritas Corporation ("Veritas") of Tokyo, Japan pursuant to which we granted Veritas exclusive distribution rights to all of our products in Japan. This agreement extends through December 31, 2013. In October 2011, we entered into a distribution agreement with IUL Instruments GmbH ("IUL") of Germany pursuant to which we granted IUL exclusive distribution rights to all of our products in Germany and Switzerland through March 31, 2014. In November 2011, we entered into a distributor agreement with Oroboros Instruments Corp. ("Oroboros") of Austria pursuant to which we granted Oroboros non-exclusive world-wide distribution rights to the PBI Shredder SG3 System and related products through December 31, 2013. In March and July 2012, we entered into a distribution agreement with six companies pursuant to which we granted non-exclusive distribution rights to certain PCT products in six European and Asian countries and Australia through December 2013. In October 2012, we entered into a supply agreement with Cole Parmer Corporation pursuant to which we granted Cole Parmer non-exclusive, worldwide distribution rights to our PBI Shredder SG3 System and related consumables through December 2014. In November 2012, we entered into a distribution agreement with UK-based Constant Systems ("CS"), pursuant to which we granted Constant Systems non-exclusive distribution rights to certain of our PCT SPS product line in 12 European and Asian countries. This Agreement terminates on May 31, 2014. In June 2013, CS and PBI signed an expanded Distribution Agreement that made PBI the exclusive distributor of CS products throughout all of the Americas; this Agreement also terminates on May 31, 2014. CS and PBI began discussions in January 2014 to extend both agreements for a minimum of two years.

Marketing and Sales

Our marketing and sales function is led by Dr. Nathan Lawrence, our vice president of Marketing and Sales. Dr. Lawrence oversees and directs marketing and sales activities such as trade show attendance and sponsorship, on-line advertising, website maintenance and improvement, search engine optimization, creation and dissemination of a PCT newsletter, market research initiatives, the arrangement of on-location seminars, lectures, and demonstrations of PCT capabilities, and the supervision of our two-person sales force. Dr. Lawrence is also responsible for the overall coordination of our collaboration programs, from initial set-up, research plan design, and training, service, and data analysis. Some of these responsibilities are shared with other PBI departments such as Research and Development, but marketing and sales drives the collaborative process. Dr. Lawrence is also responsible for the continued coordination and support of our foreign and domestic distribution partners.

In January and May 2012, we entered into co-marketing/selling and research and development agreements with Digilab, a provider of products for life sciences, analytical chemistry and diagnostic markets, and LEAP Technologies, a provider of automation equipment for the genomic and proteomic industries. Under these agreements, we are co-marketing and co-selling our respective product lines worldwide, including in industry publications, at scientific meetings, on each company's website, through common collaborator studies, at key industry trade shows, and in visits to customer sites. We are also exploring ways to co-develop new instrumentation, accessories/modules for existing instrumentation, and consumables that combine the robotics and high throughput capabilities of these companies' products with the extraction, protein digestion, and other advantages of our PCT platform.

Intellectual Property

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

To date, we have been granted 14 United States and 10 foreign patents. Our issued patents expire between 2015 and 2027. Our failure to obtain and maintain adequate patent protection may adversely affect our ability to enter into, or affect the terms of, any arrangement for the marketing or sale of any of our PCT products. It may also allow our competitors to duplicate our products without our permission and without compensation.

License Agreements Relating to Pressure Cycling Technology

BioMolecular Assays, Inc.

In 1996, we acquired our initial equity interest in BioSeq, Inc., which at the time was developing our original pressure cycling technology. BioSeq, Inc. acquired its pressure cycling technology from BioMolecular Assays, Inc. under a technology transfer and patent assignment agreement. In 1998, we purchased all of the remaining outstanding capital stock of BioSeq, Inc., and at such time, the technology transfer and patent assignment agreement was amended to require us to pay BioMolecular Assays, Inc., a 5% royalty on our sales of products or services that incorporate or utilize the original pressure cycling technology that BioSeq, Inc. acquired from BioMolecular Assays, Inc. We are also required to pay BioMolecular Assays, Inc. 5% of the proceeds from any sale, transfer or license of all or any portion of the original pressure cycling technology. These payment obligations terminate in 2016. During the years ended December 31, 2013 and 2012, we incurred approximately $23,785 and $23,634, respectively, in royalty expense associated with our obligation to BioMolecular Assays, Inc.

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

Battelle Memorial Institute

In December 2008, we entered into an exclusive patent license agreement with the Battelle Memorial Institute ("Battelle"). The licensed technology is the subject of a patent application filed by Battelle in 2008 and relates to a method and a system for improving the analysis of protein samples, including through an automated system utilizing pressure and a pre-selected agent to obtain a digested sample in a significantly shorter period of time than current methods, while maintaining the integrity of the sample throughout the preparatory process. In addition to royalty payments on net sales on “licensed products,” we are obligated to make minimum royalty payments for each year that we retain the rights outlined in the patent license agreement and we are required to have our first commercial sale of the licensed products within one year following the issuance of the patent covered by the licensed technology. The minimum annual royalty for 2012 was $10,000. Our only obligation for 2013 was a minimum royalty payment of $4,025.

Regulation

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

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

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

We self-certified that our Barocycler instrumentation was electromagnetically compatible, or “CE” compliant, which means that our Barocycler instruments meet the essential requirements of the relevant European health, safety and environmental protection legislation. In order to maintain our CE Marking, a requirement to sell equipment in many countries of the European Union, we are obligated to uphold certain safety and quality standards.

Employees

At December 31, 2013, we had 9 full-time employees and 3 part-time employees. All employees enter into confidentiality agreements intended to protect our proprietary information. We believe that our relations with our employees are good. None of our employees are represented by a labor union. Our performance depends on our ability to attract and retain qualified professional, scientific and technical staff. The level of competition among employers for skilled personnel is high. Subject to our limited financial resources, we attempt to maintain employee benefit plans to enhance employee morale, professional commitment and work productivity and provide an incentive for employees to remain with us.

ITEM 1A RISK FACTORS.

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

As of March 25, 2014, we had available cash of approximately $314,896. We require additional capital to fund our operations and cannot ensure that additional capital will be available on acceptable terms or at all.

We have experienced negative cash flows from operations from our pressure cycling technology business since we commenced our pressure cycling technology operations. As of March 25, 2014, we had available cash of approximately $314,896 which, based on current projections, including additional fund raising, will be sufficient to fund operations until August 2014. We need substantial additional capital to fund our operations beyond August 2014.

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, 2013 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, 2013 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 further reductions in expenses and obtaining equity or debt financing including our most recently completed financing on February 28, 2014 in which we sold units consisting of shares of convertible preferred stock and warrants to purchase shares of Common Stock for net proceeds of approximately $630,360. 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 qualify its opinion in the future. If we cannot successfully continue as a going concern, our stockholders may lose their entire investment in us.

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, 2013, our disclosure controls and procedures and our internal control over financial reporting were not effective. As described in Item 9A of this Annual Report on Form 10-K, we have determined that we have limited resources for adequate personnel to prepare and file reports under the Securities Exchange Act of 1934 within the required time periods and that material weaknesses in our internal control over financial reporting exist relating to our accounting for complex equity transactions. If we are unable to implement and maintain effective disclosure controls and procedures and remediate the material weaknesses in a timely manner, or if we identify other material weaknesses in the future, our ability to produce accurate and timely financial statements and public reports could be impaired, which could adversely affect our business and financial condition. We identified a lack of sufficient segregation of duties. Specifically, this material weakness is such that the design over these areas relies primarily on detective controls and could be strengthened by adding preventive controls to properly safeguard assets. In addition, investors may lose confidence in our reported information and the market price of our Common Stock may decline.

We will need a greater amount of additional capital than we currently expect to need if we experience unforeseen costs or expenses, unanticipated liabilities or delays in implementing our business plan, developing our products and achieving commercial sales.

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

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

To satisfy our potential capital requirements to cover the cost of implementing our sales distribution strategy for our current products and services and to develop and commercialize future products and services using our pressure cycling technology relating to sample preparation and other life science applications, we need to raise additional funds in the public or private capital markets. We may seek to raise any necessary additional funds through the issuance of warrants, equity or debt financings or executing collaborative arrangements with corporate partners or other sources, which may be dilutive to existing stockholders or otherwise have a material effect on our current or future business prospects. Additional financing may not be available to us on a timely basis, if at all, or on terms acceptable to us. If adequate funds are not available or if we fail to obtain acceptable additional financing, we may be required to:

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

Our actual results and performance, including our ability to raise additional capital, may be adversely affected by current economic conditions.

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

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

We have experienced significant operating losses in each period since we began investing resources in PCT and CP. These losses have resulted principally from research and development, sales and marketing, and general and administrative expenses associated with the development of our PCT business. During the year ended December 31, 2013, we recorded a net loss applicable to common shareholders of $5,247,450, or ($0.44) per share, as compared with $4,400,215, or ($0.43) per share, of the corresponding period in 2012. We expect to continue to incur operating losses until sales of our PCT and CP products increase substantially. We cannot be certain when, if ever, we will become profitable. Even if we were to become profitable, we might not be able to sustain such profitability on a quarterly or annual basis.

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

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

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

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

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

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