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.