

PRESSURE BIOSCIENCES INC
Form 10-K
February 27, 2012

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

Form 10-K

(Mark One)

Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the fiscal year ended December 31, 2011 or
 Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934
For the transition period from _____ to _____

Commission file number 000-21615

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

Massachusetts 04-2652826
(State or Other Jurisdiction of Incorporation or Organization) (I.R.S. Employer Identification No.)
14 Norfolk Avenue
South Easton, Massachusetts 02375
(Address of Principal Executive Offices) (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
Preferred Share Purchase Rights The Nasdaq Stock Market, LLC

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 No

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

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

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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 No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(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 No

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant as of June 30, 2011 was \$2,609,837 based on the closing price of the common stock as quoted on the NASDAQ Capital Market on that date.

As of February 15, 2012, there were 7,974,321 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 Pressure Biosciences, Inc., a Massachusetts corporation, and, unless the context indicates otherwise, also includes our wholly-owned subsidiary.

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our need for, and our ability to raise, additional equity or debt financing on acceptable terms, if at all;
 - our need to take additional cost reduction measures, cease operations or sell our operating assets, if we are unable to obtain sufficient additional financing;
 - our belief that we have sufficient liquidity to finance normal operations until April 2012;
 - 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 pressure cycling technology (“PCT”) operations;
 - our belief that PCT has achieved initial market acceptance in the mass spectrometry market;
 - the expected increase in number of PCT units installed and the increase in revenues from the sale of consumable products and extended service contracts;
 - the expected development and success of new product offerings;
 - the potential applications for PCT;
 - 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 sample extraction and for other applications;
 - the capabilities and benefits of our PCT sample preparation system and consumable products;
- our belief that laboratory scientists will achieve results comparable to those reported to date by certain research scientists who have published or presented publicly on PCT;
 - 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.

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 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 Report. We qualify all of our forward-looking statements by these cautionary statements.

ITEM 1. BUSINESS.

Throughout this document we use the following terms: Barocycler®, PULSE®, and BioSeq®, which are registered trademarks of the Company. We also use the terms ProteoSolve™, ProteoSolveLRSTM, the Power of PCT™, the PCT Shredder™, 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 (35,000 psi or greater) to safely, conveniently and reproducibly control the actions of molecules in biological samples, such as cells and tissues from human, animal, plant, and microbial sources.

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

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, including;

- Biological sample preparation, which includes sample preparation for genomic, proteomic, lipidomic, metabolomic, and small molecule studies;
- pathogen inactivation;
- protein purification;
- control of chemical (particularly enzymatic) reactions; and
- immunodiagnosics (clinical laboratory testing).

Within the broad field of biological sample preparation, we focus the majority of our product development efforts in three specific areas: mass spectrometry, forensics, and histology.

- Mass Spectrometry.** A mass spectrometer is a laboratory instrument used in the analysis of biological samples in life sciences research. We believe that mass spectrometry is a multi-billion dollar market, and that PCT offers significant advantages in speed and quality compared to 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, 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 but untested 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

(“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.

Since we began operations as Pressure BioSciences in February 2005, we have installed 209 Barocycler instruments through the end of December 31, 2011, of which 132 have been purchased or are currently being leased by our customers. 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.

	2005	2006	2007	2008	2009	2010	2011
Units installed in year	5	8	20	41	54	50	31

We have experienced negative cash flows from operations with respect to our pressure cycling technology business since our inception. As of December 31, 2011, 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, 2011, we believe our current cash resources will enable us to extend our cash resources until April 2012.

As a result, the audit report issued by our independent registered public accounting firm on our audited financial statements for the fiscal year ended December 31, 2011 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, 2011 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, 2011 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.

Such an opinion from our independent registered accounting firm could adversely affect our ability to obtain additional financing on favorable terms, if at all, as such an opinion 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.

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 in February 2012, in which we sold units consisting of shares of restricted common stock and warrants to purchase shares of common stock for net aggregate proceeds of approximately \$765,000, which included the conversion of \$387,547 in principal and accrued interest from convertible promissory notes. Although we have successfully completed equity financings and reduced expenses in the past, we cannot assure you that our plans to address these matters in the future will be successful. Additional financing may not be available to us on a timely basis, if at all, or on terms acceptable to us. In the event we are unable to raise sufficient funds on terms acceptable to us, we may be required to:

- severely limit or cease our operations or otherwise reduce planned expenditures and forego other business opportunities, which could harm our business. The accompanying financial statements do not include adjustments that may be required in the event of the disposal of assets or the discontinuation of the business;
- obtain financing with terms that may have the effect of diluting or adversely affecting the holdings or the rights of the holders of our capital stock; or

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

Developments

Despite the uncertainty in the capital markets since 2009 and the concomitant decrease in the capital budgets of our existing and prospective customers and despite our limited financial resources during this time, we reported a number of accomplishments during 2011, including the following:

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2011

- Sale of Series C Convertible Preferred Stock in a Private Placement. We received approximately \$1.1 million from the sale of securities in a private placement to accredited investors in April and June.
- Worldwide e-Commerce Distribution Deal Signed. We signed a worldwide, non-exclusive agreement with KeraFAST LLC for the e-commerce distribution of our Shredder SG3, related Shredder consumables, our IEF buffer.
- Product Pipeline for 2011 – 2013 Announced. We announced our targeted schedule for the release of four new PCT-based products: the Barocyler HUB440 (released in July 2011), the FFPE Extraction Service (Q4 of 2012), the XstreamPCT HPLC Digestion Module (Q4 of 2013), and the High Throughput Multi-well System (Q4 2013).
- Multiple Presentations on the Advantages of PCT at National and International Meetings. Researchers from academia, government, pharma, and the biotechnology industry reported advantages when using our PCT Platform in their sample preparation processes at four scientific conferences between May and December 2011.
- 100% Conversion of Series A Convertible Preferred Stock and Series B Convertible Preferred Stock. All 87 holders of our Series A Convertible Preferred Stock and Series B Convertible Preferred Stock voluntarily converted their shares into our common stock.
- We Were Awarded \$810,000 in National Institutes of Health and Department of Defense Grants. We were awarded approximately \$160,000 from the National Institutes of Health to help fund the development of a high pressure-based system to improve the processing of cancer and other samples, and approximately \$650,000 from the Department of Defense to help fund the development of a PCT-based system to improve the processing of pathogenic organisms, specifically viruses and bacteria.
- Co-Marketing/Selling and Research and Development Agreement with Digilab Inc. (“Digilab”) Under this agreement with Digilab, a provider of products for life sciences, analytical chemistry and diagnostics markets, we intend to co-market and sell 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 also intend to explore ways to co-develop new instrumentation, accessories/modules for existing instrumentation, and consumables that combine the robotics and high throughput capabilities of Digilab products with the extraction, protein digestion, and other advantages of our PCT platform.
- Registered Direct Offering with Net Proceeds of Approximately \$843,000. We raised approximately \$843,000 through the sale of Series D Convertible Preferred Stock and warrants to purchase shares of our common stock in a registered direct offering.
- Second half of 2011 Results. We reported an approximate 65% increase in total revenue for the second half of 2011 compared to the first half of 2011, with concomitant reductions in operating loss and cash burn.

In February 2012, we raised an aggregate of \$800,000 in a private placement of units consisting of a total of 971,867 shares of restricted common stock and 485,937 warrants to purchase restricted common stock. Seven current investors, including our President and Chief Executive Officer, our Chairman of the Board of Directors, and two investors from our November 2011 registered direct offering, participated in the private placement. The price per unit was \$0.8025 for units consisting of 789,350 shares and 394,677 warrants, and was \$0.9125 for units consisting of the remaining 182,517 shares and 91,260 warrants. Of the \$800,000 invested in the private placement, \$412,453 was received in cash and \$387,547 was from the conversion of outstanding principal and interest on convertible

promissory notes we issued in 2011.

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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 the Boston Biomedica 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., or PBI, and commenced operations as Pressure BioSciences in February 2005.

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") including our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. These SEC reports can be 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, 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, 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
- is the area in which we currently have strong patent protection.

We believe that our existing Barocycler instrumentation, and PCT 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.

Mass Spectrometry

Mass spectrometry is frequently used by research scientists to evaluate proteins and nucleic acids (DNA and RNA). We believe that mass spectrometry is one of the most powerful laboratory tools used today and that it is playing an increasingly important role in the analysis of biological samples in life sciences research. A number of companies and research laboratories in this market are currently our customers, or are in the process of evaluating our technology for use in their laboratories.

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

Forensics