PRESSURE BIOSCIENCES INC
Form 10KSB
March 26, 2007
on

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

Form 10-KSB

(Mark One)

x	Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 For the fiscal year ended December 31, 2006 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.
(Name of Small Business Issuer in its Charter)

Massachusetts	**04-2652826**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
321 Manley Street, **West Bridgewater, Massachusetts**	**02379-1040**
(Address of Principal Executive Offices)	(zip code)
(508) 580-1818	
(Issuer's telephone number)	

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

Common Stock, par value $.01 per share
Preferred Share Purchase Rights
Securities registered pursuant to Section 12(g) of the Act:

(Title of Class)

Check whether the issuer is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. ¨

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

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. x

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

Pressure BioSciences Inc.'s revenues for the most recent fiscal year ended December 31, 2006 were $210,289.

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant at March 16, 2007 was $7,383,530 based on the closing price of the common stock as quoted on the NASDAQ Capital Market on that date. As of March 16, 2007, there were 2,065,425 shares of the registrant's common stock outstanding.

Documents Incorporated by Reference

Part III of this Form 10-KSB incorporates information by reference from the issuer's definitive proxy statement which will be filed no later than 120 days after the end of the fiscal year covered by this report.

Transitional Small Business Disclosure Format (check one): Yes ¨ No x

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Introductory Comment

Throughout this Annual Report on Form 10-KSB, the terms “we,” “us,” “our,” “the Company” and “our company” refer Pressure BioSciences, Inc., a Massachusetts corporation, and, unless the context indicates otherwise, also includes our wholly-owned subsidiaries.

PART I

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- our plans and expectations with respect to our pressure cycling technology (PCT) operations;
- potential growth in the market for our PCT products;
- market acceptance and the potential for commercial success of our PCT products;
- our belief that PCT provides a superior solution for sample extraction;
- the potential applications for PCT;
- our belief that we have sufficient liquidity to finance operations based upon current projections;
- our intent to sell our shares of Panacos Pharmaceuticals and the timing thereof;
- the amount of cash necessary to operate our business;
- our ability to raise additional capital when and if needed;
- general economic conditions; and
- the anticipated future financial performance and business operations of our Company.

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 Report. 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 the Report 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 II, Item 6 of this Report as well as those discussed elsewhere in this Report. We qualify all of our forward-looking statements by these cautionary statements.

ITEM 1. DESCRIPTION OF BUSINESS.

Introduction

We are an early-stage life sciences company focused on the development and commercialization of a novel, enabling, platform technology called pressure cycling technology ("PCT"). PCT uses cycles of hydrostatic pressure between ambient and ultra-high levels (up to 35,000 psi and greater) to control bio-molecular interactions.

Our pressure cycling technology uses internally developed instrumentation that is capable of cycling pressure between ambient and ultra-high levels at controlled temperatures to rapidly and repeatedly control the interactions of bio-molecules. Our instrument, the Barocycler®, and our internally developed disposable PULSE© (Pressure Used to Lyse Samples for Extraction) Tubes, together make up the PCT Sample Preparation System ("PCT SPS").

We hold 13 United States and 5 foreign patents covering multiple indications of PCT in the life sciences field. Our pressure cycling technology employs a unique approach that has the potential for broad applications in a number of established and emerging life sciences areas, including;

- sample preparation for genomic, proteomic, and small molecule studies;
- control of chemical (enzymatic) reactions;
- protein purification;
- pathogen inactivation;
- immunodiagnostics;
- DNA sequencing; and
- food safety.

We were incorporated in the Commonwealth of Massachusetts in August 1978 and commenced significant operations in 1986 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 pressure cycling technology. Pursuant to this change in business strategy, we changed our name from Boston Biomedica, Inc. to Pressure BioSciences, Inc., and commenced significant operations as Pressure BioSciences, Inc. (PBI) in February 2005.

Sample Preparation for Genomic, Proteomic, and Small Molecule Studies

Since we began significant operations as Pressure BioSciences in February 2005, we have been focusing substantially all of our research and development and commercialization efforts on sample preparation for genomic, proteomic, and small molecule studies.

Considering the platform nature of PCT, we elected to initially focus our resources in the important and rapidly growing market of genomic, proteomic, and small molecule sample preparation. We chose to focus on this application 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 and thus 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 our strongest patent protection.

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 ("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, and can thus significantly improve sample preparation.

Collaboration Programs

Throughout 2005 and 2006, our commercialization efforts have been centered on the development, and expansion, of our collaboration program. The collaboration program was initiated in June 2005 with the goal of placing our PCT Sample Preparation System in selected, strategic sites for trial periods of three months or longer, in an effort to generate data from leading, independent users of the PCT SPS. We believe that this program has provided, and continues to provide us with independent and objective data about PCT from well respected laboratories throughout the United States. Since the initiation of our collaboration program, our instruments have been evaluated by customers in approximately 20 independent laboratories. Twelve of our collaboration programs have resulted in the sale or lease of the PCT Sample Preparation System, which includes our Barocycler instrument and our single-use PULSE Tubes. Some of our other collaborations have resulted in the withdrawal of the instrument, an extension of time to use the instrument, expansion of the scope of research being performed with the instrument, and the publication and presentation of favorable third party data. In all cases, we gained valuable knowledge about our technology, our instrumentation, and various aspects of the markets that we are trying to penetrate. This knowledge is beneficial to us as we continue to expand our collaboration program, refine our instrumentation, and continue to expand our sales and marketing efforts during 2007.

Independent Third-Party Data Regarding PCT

We believe that one of the most valuable returns on our investment in the collaboration program has been, and will continue to be, the dissemination of positive third-party data about our technology. As a company with limited resources, the placement of instruments in the laboratories of our collaborators has allowed us to advance the development of our technology more quickly and efficiently than we would have been able to do on our own. These placements have also served as the basis for our commercialization efforts, which we have continued to accelerate in early 2007, as we hired a second, and began to plan for the addition of three more US sales directors. Since the initiation of our collaboration program there have been thirteen presentations and publications about PCT by our collaborators. A selected list of the areas covered by third party publications is listed below:

- Plant genomics - Improvements by PCT in the extraction of pathogen DNA in plants and soil
- Proteomics - Signal pathway analysis of human adipose tissue extracted by PCT for research in the areas of Non-alcoholic Fatty Liver Disease and Diabetes
- Human genomics - Analysis of RNA recovery and gene expression in the epidermis after PCT extraction

During the second half of 2006, we began to see early indications of market traction, such as the purchase of the PCT SPS by several of our collaborators and inquiries from several other groups about how our technology could improve their areas of research. Based on these indications we began to accelerate our marketing activities. We began to advertise in more industry periodicals and we significantly increased our participation in, and sponsorship of, industry trade shows.

The Market

According to PhorTech International Research, there are more than 200,000 nucleic acid (DNA and RNA) researchers in more than 45,000 laboratories worldwide. Frontline Strategic Consulting estimates that the worldwide nucleic acid market will exceed $16 billion in 2010 and Frost & Sullivan projects that the worldwide proteomics market will reach $3 billion by 2008. We believe that a significant portion of these researchers can benefit from the use of pressure cycling technology in their research and development efforts.

Other Applications of Pressure Cycling Technology

PCT is a platform technology by which our scientists are utilizing a bio-physical process that had not previously been used to control bio-molecular interactions. During the early developmental stages of pressure cycling technology (under the corporate structure of Boston Biomedica, Inc.), our scientists spent approximately $12 million researching the use of this bio-physical process in many areas in addition to our current work in genomic, proteomic, and small molecule sample preparation. The data generated during these early years, combined with the data generated since PBI began significant operations in February 2005, form the basis of knowledge that we believe will allow us to successfully commercialize PCT in the sample preparation market.

PCT has been shown to be beneficial in a number of significant areas of the life sciences, including: control of chemical (particularly enzymatic) reactions, protein purification, pathogen inactivation, immunodiagnostics, DNA sequencing, and food safety. The extensive research performed by our scientists has resulted in patent filings in all of these areas, and patents have been issued with approved claims that give us protection and allow us to practice PCT in all of these areas. Our pursuit of market penetration into these markets depends on a number of factors, including our success in commercializing PCT in the area of sample preparation, our view regarding the cost and the value of these markets to us, and the level of scale-up and funding required to enter these markets. Below is a brief explanation of each of these other applications and areas and how we believe PCT may be used to improve scientific progress.

Control of Chemical (Particularly Enzymatic) Reactions

Chemical reactions encompass many interactions in nature, such as the formation and cleavage of covalent and ionic bonds; the association or dissociation of two or more chemical compounds; and changes in the primary, secondary, tertiary, and quaternary structure of compounds. Chemical reactions include non-enzymatic and enzymatic reactions. Whether or not enzymes are present, a chemical reaction is usually made of several mechanistic steps or molecular interactions, including conformational changes, transition state formation, electron and proton donation/acceptance, and electron rearrangement. A series of chemical reactions may provide a useful chemical product; therefore, any method used to control a chemical reaction may 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.

Protein Purification

We believe that the technically difficult problem of isolating and recovering biopharmaceuticals can be greatly simplified through precise bio-molecular control using PCT. Additionally, through the close control of enzymatic reactions, we believe that we will be able to isolate therapeutically powerful isomers from isomeric mixtures. One of the more common and effective biopharmaceutical purification techniques employs affinity chromatography to separate compounds according to their affinity to bind to a specific binding partner and thus form a new bio-molecular complex. Currently, the existing means of controlling this binding interaction are not sufficient to enable recovery of the target molecule without causing some degree of degradation (loss). We believe PCT provides a distinct competitive advantage in this area. PCT could prove to be attractive because it may enable manufacturers to more efficiently purify drugs with limited redesign of their current process. It may also be possible to replace currently used toxic additives with PCT, thus increasing safety. Since PCT has unique properties, it may also contribute to pharmaceutical development by offering a novel method of purification. Furthermore, drugs or therapeutics that have already been developed but could not be commercialized due to difficulties in purification may be resurrected.

Pathogen Inactivation

We believe that existing inactivation methods for blood and blood plasma are inadequate because of the significant safety and cost concerns associated with them. We further believe that an inactivation method is needed that can rapidly and inexpensively inactivate pathogens in plasma or plasma fractions without the need for chemical or other potentially toxic additives, while maintaining the integrity of therapeutic proteins. We have successfully generated proof-of-concept that PCT can be a valuable solution, in our opinion, to this large need. We believe that compared to current procedures, a process that uses PCT has the potential to increase safety and yield, lower cost, and decrease the potential side effects of plasma-derived protein therapeutics such as IntraVenous Immune Globulin (IVIG).

Immunodiagnostics

We believe that PCT may be used to control bio-molecular interactions between antigens and antibodies to improve immunoassay effectiveness. Through the application of PCT, we have successfully induced association between antigens and antibodies, and also successfully dissociated pre-existing antigen-antibody complexes. Such forced immune complex dissociation may have many beneficial applications, including reducing the possibility of false positive results by revealing the presence of antigens or antibodies that were not previously detected. We believe this capability can provide a greater degree of sensitivity and quantitative accuracy in immunodiagnostics, including tests for infectious diseases, cancer, and therapeutic drug monitoring. PCT's ability to force both antigen/antibody dissociation and association could enable manipulation of existing disease markers and therapeutic drugs in patient samples, resulting in greater accuracy of immunodiagnostic-based tests, which has historically been difficult to do.

DNA Sequencing

We have generated proof of concept that PCT can be used to control the activity of DNA modifying enzymes. Through rapid cycling between inhibitory and active conditions, our scientists have shown that PCT is able to control the activity of enzymes such as exonuclease (cleaves nucleotides at a rate of about 275 base pairs per second under normal conditions) so that it should be possible to read each nucleotide base pair that is released in sequential order. We believe that this technology has considerable commercial potential because it enables base-by-base sequencing of very long fragments of DNA. In addition, sequencing DNA by PCT may also have applications for sequencing oligonucleotides. Oligonucleotides are short (typically 10-30 bases) single strands of DNA, usually made on a synthesizer. Synthetic oligonucleotides are used in biotechnology for sequencing other strands of DNA, for capture and reporter probes, and are even being developed for therapy in vivo. Sequencing, and therefore the quality control of oligonucleotides, is difficult because of their short length and because they are single-stranded. PCT used in combination with capillary electrophoresis (CE) or MALDI-TOF spectrophotometry could provide a fully automated system to rapidly sequence oligonucleotides.

Food Safety

The Centers for Disease Control (CDC) estimates that more than 5,000 people die each year due to food borne diseases. In addition to these deaths, hundreds of thousands of people are hospitalized annually and millions more become ill, all due to food borne pathogens. In an effort to reduce this debilitating economic cost and loss of lives, food processors continue to work on the development of novel, new methods aimed at improving the safety, quality, and shelf-life of the foods we eat. One such method is high pressure processing (HPP), already accepted by both the USDA and the FDA as an appropriate food processing method. With HPP, foods are subjected to high hydrostatic pressures (constant not cycled), which can kill many disease-causing pathogens while concomitantly having no deleterious effects on flavor, nutritional value, odor, or appearance. HPP is already being used in the food industry for the safe processing of a number of different kinds of food, including shellfish, orange juice, and guacamole. We believe that PCT offers distinct advantages over current HPP methods, since such methods all use constant pressure while PCT uses cycled pressure, and data generated in our laboratory and in the laboratories of our collaborators indicate that cycled pressure can be more effective in inactivating food borne pathogens than constant pressure.

Company Products and Services

Products

Our current instrument, the Barocycler NEP3229, is a high pressure laboratory instrument designed to fit on a bench top, inside a biological safety cabinet, or on the shelf of a cold room. The Barocycler NEP3229 is capable of processing up to three samples simultaneously using our specially designed, single-use PULSE Tubes. The Barocycler NEP3229 has an external chiller hook-up (to control temperature during the PCT process), automatic fill and dispensing valves, and an integrated micro-processor with an easy-to-use keypad. We believe the Barocycler NEP3229 fills an important and growing need in the sample preparation market for the safe, rapid, robust, versatile, reproducible, and quantitative extraction of nucleic acids, proteins, and small molecules from a wide variety of plant and animal cells and tissues. The NEP3229 was released for use in our collaboration programs in the third quarter of 2005 and twelve of these instruments have been sold, or leased, to our collaboration partners since that time.

We are investing a significant amount of our engineering resources towards the further improvement of the NEP3229 as well as toward the development of future generations of instrumentation. Future generation instrumentation may include portable units that can be taken into the field as well as larger, high-throughput, fully-automated instruments that could process several thousand samples per day.

Our current consumable, the PULSE Tube, is used with each and every sample that is processed by PCT. We believe that if PCT becomes widely accepted, this consumable could provide us with a significant stream of recurring, high gross-margin revenue. Our current PULSE Tube product is a plastic, single-use, processing container with two chambers separated by a small disk with about sixty small holes ("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, the PULSE Tube is placed in the pressure chamber of the Barocycler instrument, pressure chamber fluid is added, and pressurization begins. As pressure increases, a small moveable piston (the Ram) 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 (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 breaks up the cellular structures of the specimen to quickly and efficiently release nucleic acids, proteins, and small molecules.

We plan to invest a significant amount of our research and development resources towards the continued development of our PULSE Tube, as well as in the development of other consumables that can be used with the PCT Sample Preparation System.

Services

In September 2006, we received notification of an award of a National Institutes of Health ("NIH") Small Business Innovation Research ("SBIR") Phase I Grant to fund experiments to demonstrate the feasibility of using pressure cycling technology in the development of a novel method for the extraction of clinically important protein biomarkers, sub-cellular molecular complexes, and organelles from cells and tissues. The grant was for a total of approximately $150,000. During 2006, we did not work on this project and thus did not bill any costs to this grant; consequently, we expect to work on the research project and subsequently bill the government for the entire grant during the first half of 2007.

In March 2007, we received notification of an award for a second NIH SBIR Phase I Grant, this one for the purification of nucleic acids using PCT. We expect work on this grant to commence in April 2007 and to continue during the second and third quarters of 2007. This grant is also for approximately $150,000.

We view federal agency grants such as these to be an important part of our business plan. Such grants allow us to be reimbursed for work that we are planning to perform as part of the development of our technology, and we expect that such work will support our commercialization efforts. Additionally, if our work in Phase I SBIR grants is successful, then we will have the opportunity to apply for larger Phase II grants. Such larger grants are typically in excess of $750,000 and can support significant research projects in areas that we would expect to support with internal funds should Phase II SBIR grants not be awarded.

We offer extended service contracts on our instrumentation to all of our customers. These service contracts allow a customer who purchases a Barocycler NEP3229 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 typically offer one-year and four-year extended service contracts to customers who purchase Barocycler instruments. As of December 31, 2006 we had sold two of these contracts to our customers.

Occasionally, we will perform PCT services on a fee-for-service basis. We will enter into an arrangement such as this if we believe that the customer has a high likelihood of purchasing a PCT Sample Preparation System or if we believe that the customer will publish or present results of the work performed in scientific journals or in scientific meetings.