

# **Pressure BioSciences, Inc.**



*“Discovery Starts with  
Sample Preparation”*

**August, 2012**

**Not Confidential**

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# Executive Summary

Pressure BioSciences, Inc.

August, 2012

Pressure BioSciences, Inc. (“PBI”) is a publicly-traded company (OTCQB: P BIO) focused on solving the challenging problems inherent in biological sample preparation, a crucial laboratory step performed by nearly all scientists worldwide working in biological life sciences research.

Sample preparation is a term that refers to a wide range of activities that precede virtually all forms of scientific analysis. Sample preparation is often complex, time-consuming, and one of the most error-prone steps of scientific research. It is none-the-less a ubiquitous laboratory undertaking whose requirements drive a large and growing market, worldwide.

We have developed and patented a novel, enabling technology platform that can exquisitely control the sample preparation process. It is based on harnessing the unique properties of an entirely new dimension in thermodynamics – cycled hydrostatic pressure. This cutting-edge process, called pressure cycling technology (“PCT”), uses alternating cycles of hydrostatic pressure between ambient and ultra-high levels (up to 58,000 psi) to safely, conveniently, and reproducibly control the actions of molecules in biological samples (e.g., cells and tissues from human, animal, plant, and microbial sources).

We began operations in 2006. Initial sales of our instruments began in late 2007 and into 2008, and consisted of prototype and first generation units. From 2008 to present, with the information continuously gleaned from the customers of our early generation instruments, we have developed a number of PCT-based products for use by the life sciences’ market, including three pressure generating instruments (“Barocyclers”), a unique patent-pending sample homogenization device (the “PCT Shredder”), five types of single-use processing containers (PULSE Tubes, MicroTubes, and Shredder Tubes), six different reagent kits, and a number of ready-to-use, application-specific protocols. Many of these products and protocols are covered by claims in our 24 issued US and foreign patents. We have many additional patent applications on file.

We believe the overall market for biological sample preparation products is very large. As indicated, virtually every laboratory engaged in any form of biological research is faced with the necessity of routinely preparing samples prior to testing and analysis. The Emmes Group (2008) estimated that this market is comprised of up to 80,000 laboratories and 500,000 researchers worldwide. A report produced by Strategic Directions International, a well regarded provider of market intelligence, estimated that the global sample preparation market would reach \$6 billion by 2009.

There are a number of existing methods used by scientists for biological sample preparation, including mortar and pestle grinding, sonication, homogenization, and bead beating. We believe that PCT offers significant advantages over these methods, including safety, speed, reproducibility, versatility, and ease-of-use, often with a substantial increase in the quality of the final results. There are a growing number of scientific publications and presentations from independent laboratories that we believe highlight and confirm these clear advantages of PCT over other current methods.

Our primary efforts are focused on the development and sale of PCT-based products and applications for the preparation of samples for mass spectrometry, a powerful laboratory instrument that is playing an increasingly important role 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.

Other strategic areas in biological sample preparation where we have seen encouraging market penetration of PCT and our PCT-based products, and where we are focusing the remainder of our efforts, are in PCT-enhanced enzymatic digestion applications outside of the mass spectrometry area, biomarker discovery, soil and plant biology, forensics, histology, and counter-bioterror applications.

We derive our sources of revenue from the sale, lease, or rental of our Barocycler instruments, as well as from the recurring purchase of consumables required for the PCT process, including single-use processing containers (PULSE Tubes, MicroTubes, and Shredder Tubes) and reagent kits. We also derive revenue from instrument service contracts, replacement instrument parts, and grants.

We believe that there are approximately 80,000 laboratories worldwide that require the extraction of DNA, RNA, proteins, lipids, and small molecules from biological samples for their research studies. Based on market research, our results to date, and the fact that PCT is a novel, cutting-edge technology currently uncontested in the field of high pressure, we believe that a large number of these laboratories will benefit from the advantages of the PCT Sample Preparation System. We believe that we can capture a reasonable share of this existing market over the next 3-5 years, and that by doing so, we will become a highly respected and profitable life sciences tools provider during this time.

We have installed approximately 225 PCT Sample Preparation Systems (Barocycler instruments plus required consumables, or “PCT Systems”) through June 30, 2012. Revenue for FY 2011 was approximately \$1.0 million. Revenue for the first six months of June 2012 was \$631,000 (a 70% increase over revenue for the same period in 2011). We have achieved annual revenue of approximately \$1.0 million each of the past three years, even though we have not had a concerted sales and marketing program to support the effort. During this time our focus was not in the achievement of revenue, but in making significant improvements in our instrumentation and consumables, in the development of applications for our PCT Platform, in filing patents, and in working with clients to support their efforts in publishing and presenting PCT generated data.

Our current customers include government agencies and research institutions, such as the Food and Drug Administration (FDA), Federal Bureau of Investigation (FBI), National Institutes of Health (NIH), Centers for Disease Control (CDC), US Department of Agriculture (USDA), the VA Hospital System, US Army Medical Research Institute of Infectious Diseases (USAMRIID), and Pacific Northwest National Laboratories (PNNL). We also have customers in academia, such as Harvard Medical School, Harvard School of Public Health, Harvard School of Dental Medicine, UC – San Diego, UCLA, George Mason University, Thomas Jefferson University School of Medicine, the Barnett Institute of Northeastern University, Broad Institute at MIT, Mississippi State University, the University of New Hampshire, and Lawrence Berkeley National Laboratory. In addition, we also have diagnostic, biotechnology, and pharmaceutical customers, including Amgen, Novartis, Regeneron, Lilly, Merck, Monsanto, Bristol Myers-Squibb, Thermo Fisher Scientific, and Target Discovery, Inc.

Recently, important data have been presented by independent scientists from the US and international research communities on the advantages of PCT compared to existing, competitive methods for biological sample preparation. These presentations have been in the areas of cancer biomarker discovery, drug development, stroke, forensic sciences, counter-bioterror, soil and plant biology, extraction of biomolecules from microorganisms (i.e., oil-eating bacteria), and PCT-enhanced protein digestion. Data from these various applications have been presented at scientific meetings by researchers from Thermo

Fisher, PNNL, Amgen, USAMRIID, the USDA, Harvard School of Public Health, Lawrence Berkeley National Lab, the University of North Texas, Merck, and Target Discovery. These presentations can be found on our website.

In 2011, we unveiled four key instruments that represent an important addition to the Company's existing PCT platform. We believe that these new products will make a significant impact in the way that research scientists prepare their samples for analysis, particularly scientists working in the estimated \$2 billion mass spectrometry market (based upon the findings of the Emmes Group, April 2008). The Company believes that proof-of-concept has been demonstrated. Data have been generated and patents filed on these very exciting new products, which include:

1. Barocyler HUB440. A manual or computer controlled, compact, portable, and versatile high pressure generator for multiple bioscience applications. Released: Q3 2011.
2. Barocyler FFPE Protein Extraction Service. A service offering the enhanced extraction of proteins from formalin-fixed, paraffin-embedded (FFPE) samples using a modified Barocyler instrument that combines the advantages of pressure cycling, high temperature, and certain reagents. Estimated release: 2013.
3. XstreamPCT™ HPLC Digestion Module. For automated, in-line, on-demand PCT-enhanced protein digestion; the first module in PBI's PCT-based HPLC platform. Estimated release: 2014.
4. Barocyler HT Multiwell (48-384). For high throughput, PCT-enhanced biomolecule extraction/accelerated enzymatic digestion; process 48 - 384 samples. Estimated release: 2014.

We have a sharp, strategic focus that we believe gives us a realistic opportunity to successfully reach our short and long-term business goals, which include:

A significant increase in the installed base of PCT Systems

Consistent revenue growth

A significant strategic alliance with one or more marketing/distribution partners in 2011

Strong, growing presence in the mass spectrometry, PCT-enhanced enzymology applications, biomarker discovery, soil & plant biology, forensics, histology, and the counter-bioterror markets

Continued market acceptance of PCT through the publication and presentation of independent data by scientific leaders who are both collaborators and customers

Increased shareholder value

Profitability

Although we expect to maintain a sharpened focus on our short and long-term business goals going forward, we believe that our strong IP and proprietary positions in other areas, such as the potential of using enhanced enzymatic reactions in the area of bio-fuel development, using PCT for the inactivation of pathogens, and using PCT in other important areas of sample preparation, lend themselves well for licensing possibilities. We plan to pursue this avenue during late 2012 and beyond.

In 2012, we began to aggressively commercialize our PCT Platform. During the first six months of the year, we announced agreements with distribution companies representing 11 countries, as well as with four US-based strategic partners. We expect to continue to add both domestic and international distribution capabilities – and strategic partners - throughout the rest of the year. We expect revenue to continue to increase significantly during the remainder of 2012, and beyond.

On July 6, 2012, we closed on the first tranche (\$600,000) of a \$1.2 million Series G Private Placement. Deal terms included the purchase of Series G preferred stock at a common stock equivalent above-market

price of \$0.50/share, plus 50% warrant coverage. On April 9, 2012 we closed on a \$500,000 S-3 Registered Direct with Ironridge BioPharma. Deal terms included the purchase of preferred stock at \$1.02/share, 10.5% interest on the preferred, no warrants, no re-sets, and no shorting. In February 2012, we closed on an \$800,000 PIPE, which included the conversion of \$400,000 in loans into equity. Deal terms included the purchase of restricted common stock at market. In 2009-2011, we completed five additional transactions, four of which were done above-market.

We believe that our estimated, current average cash burn is approximately \$600,000 per quarter. We further believe that we will close on a financing of approximately \$3million or more before the end of 2012. With the cash from this financing, we believe we will have sufficient capital to fund our continuing operations, achieve our strategic business goals, and reach profitability in the near future.

Investment highlights include:

- Novel, enabling, powerful patent protected technology
- Highly experienced management team, Board of Directors, and support staff
- Core technology developed and field proven
- Product pipeline (2011-2014) includes instruments that offer the advantages of PCT in automated, on-demand, in-line, and /or high throughput systems
- Future products greatly expand current fields of use, e.g., FFPE
- Early market traction with approximately 225 revenue-generating installations through June 2012 in academia, government, biotechnology, and pharmaceutical companies
- Barocycler instrumentation is CE registered and ETL certified
- An increase in independently generated data from scientific thought leaders highlighting the significant advantages of PCT compared to other current methods of biological sample preparation supporting the advantages of PCT has been seen recently and is expected to continue
- Large and growing market for biological sample preparation products
- Strong strategic alliance opportunities with marketing/distribution partners
- Successful collaborations on-going with recognized thought leaders in the field
- Attractive business model with upfront sales and a recurring revenue stream
- Sharp, focused, and achievable business goals in 2012 and beyond

As we work to further develop pressure cycling technology and the PCT-based product line with our collaborators and customers, we believe that our efforts will increase the quality of research and speed the time to scientific discovery, which in turn will improve healthcare and save lives, worldwide.