**Investor Presentation** 

# Pressure BioSciences, Inc. (OTCQB: PBIO)

Discovery Starts with Sample Preparation™

**Investor Presentation** 

**August 2016** 



## Forward Looking Statements

This presentation may contain forward looking statements that reflect management's current views and opinions as to the status of the Company's products, technology and other future events and operations. These statements are neither a promise nor guarantee, but involve risks and uncertainties that could cause actual results to differ materially from those anticipated or indicated. Investors are cautioned that any forward looking statements should be considered in light of such risks and uncertainties including, without limitation, those detailed in the Company's filings with the Securities and Exchange Commission.



## Company Overview (OTCQB: PBIO)

- 9 FT Staff; Near Boston, MA; Publicly Traded (OTCQB: PBIO)
- 24 Patents: Pressure Cycling Technology ("PCT") Platform
- Develop, Mfg, & Sell PCT-based Instruments & Consumables
- Initial Focus in Sample Preparation for the Research Market
- ~ 275 PCT Systems Installed, 150 Customers, 100+ Publications
- Plan to Substantially Add to Sales & Marketing Capabilities in 2H 2016
- 28M Common Shares OS (73M CSE Fully Diluted): \$30M market cap
- Revenue: FY2014 (\$1.3M); FY2015 (\$1.8M); Q12016 (\$510K)
- Fast Out of the Gate in 2016:
  - Q1 Revenue \$510K (product sales increase 26%)
  - Closed \$5M PIPE @ \$6.3M (\$1.4M in 2016) cleaned up BS (100% VRD Paid)
  - Co-Marketing Agreement with SCIEX (WW leader in analytical technologies)
  - New Barocycler 2320EXTREME Unveiled at the June ASMS Annual Meeting

## **Experienced Senior Management & Board**

#### Management

- Mr. Richard T. Schumacher, President & CEO Boston Biomedica (CEO, Founder); Panacos Pharma (President, Co-founder); Trinity Biotech (Founding Group); CBR Labs (Gen' I Mgr) - Harvard Medical School
- Dr. Edmund Y. Ting, Senior Vice President of Engineering Avure Technologies (CSO); Flow Int' I (CSO); Grumman Aerospace; MIT (Ph.D.)
- Dr. Alexander V. Lazarev, Vice President of R&D Proteome Systems; Genomic Solutions; ESA; University of Kazan (Ph.D.)
- Dr. Nathan P. Lawrence, Vice President of Marketing Boston Biomedica; BD; Gene-Trak Systems; Yale University (Ph.D.)

#### **Board**

- Jeffrey Peterson, MS
- Kevin Pollack, Esq., MBA
- Vito Mangiardi, MBA
- Mickey Urdea, Ph.D.
- Richard T. Schumacher

Board Chairman Audit Committee Chairman Compensation Committee Chairman SAB Chairman CEO, Treasurer, Clerk

**PBI** 

## Primary Sample Preparation for Biomolecular Analysis: Cell Lysis



### Sample Input Quality = Sample Result Quality



Scientific research can be broken down to three key elements: sample preparation, analysis, & data reduction/interpretation

"Discovery Starts with Sample Preparation"

PRI

### Value Proposition: PCT-based Biological Sample Preparation

- Analysis of DNA, RNA, Proteins, & Lipids ("biomolecules") is Crucial to the Discovery of New Biomarkers – Quality of Results Depends on the Quality of Preparation
- Biological Sample Preparation is a Multi-Billion Market Comprised of an Estimated 500,000 Scientists in 80,000 Research Labs Worldwide
- Current Sample Preparation Methods are Mostly Mechanical and are Highly Inadequate: <u>Bottleneck</u>
- Proven Platform: ~ 275 PCT Systems Installed (~150 Sites)
- 100+ Publications Highlight Advantages of PCT Platform Over Other Methods



### Biomarker/Forensics Market: Estimated Size

Estimated Market

\$2.7B in 2011<sup>a,d</sup>

- Genomics (DNA/RNA)
  \$7.1B in 2015 b
- Next Gen Sequencing (DNA) \$2.7B in 2017°
- Mass Spectrometry (Proteins)
- Forensic Tools and Products (DNA) \$17.7B in 2019 e
- Sample Prep for all OMICS:
  \$8.4B in 2016 f

500,000 Scientists in 80,000 Biological Research Labs WW a

<sup>a</sup> EMMES Group <sup>b</sup> Decisive Bio-Insights <sup>c</sup> Markets & Markets <sup>d</sup> TechNavio <sup>e</sup> Transparency Market Rsh <sup>f</sup> bcc Research



### Selected Marquee Customers (150)





AND



HARVARD MEDICAL SCHOOL

STANFORD

UNIVERSITY





National Institutes of Health

MERCK

**Battelle** The Business of Innovation

PR







## **PCT** Sample Preparation System



Barocycler™ NEP2320





### Barocycler™ 2320 EXTREME



MicroTubes

PBI







PCT-dependent Kits

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## **Barozyme:** New High-throughput PCT-based System









Barozyme HT48 Evaluation (KOLs) 2014/15

### Marketing Focus Increase Planned For <u>2H 2016</u>

- Initial Application:
  High pressure digestion
- Consumable:
  - Proprietary 8-well strips
- Number of Samples:
  - 48 samples



## **PCT Platform: Enabling the Enablers**

Eight Impact Areas Where PBI's Powerful and Enabling PCT Platform is Currently Being Used... and the Early Results are Very Exciting & Significant

- 1. Agriculture/Food Science
- 3. Anti-Bioterror
- 5. Biomarker Discovery (2)
- 7. Personalized Medicine

- 2. Environmental Epidemiology
- 4. Rational Drug Design
- 6. Fecal Lipidomic Profiling
- 8. Improved Rape Kit Testing



## Anti-bioterrorism

#### **Dr. Bradford Powell**

- Director Analytical Sciences, PharmAthene
- Previously Division of Bacteriology, US Army Medical Research Institute of Infectious Diseases (USAMRIID)



Inactivation and Extraction of Bacterial Spores for Systems Biological Analysis Sample Preparation in Biological Mass Spectrometry

- PCT is useful for preparing multiple classes of analytes, including nucleic acids, carbohydrates and lipids
- PCT can be exploited for differential extraction and preparation of sub-spore components and for recovery of spores from infected host tissue

### **Conclusion**

Ultra-high pressure cycling can achieve complete inactivation of Anthrax with extraction in a single tube, useful for whole analysis of the spore proteome



## **Rational Drug Design and Development**

#### **Professor Wayne L. Hubbell**

- Distinguished Professor of Biochemistry: UCLA
- Member, National Academy of Sciences
- Fellow, American Academy of Arts and Sciences

Structure-Relaxation Mechanism for the Response of T4 Lysozyme Cavity Mutants to Hydrostatic Pressure. PNAS: April 2015



- On-going need to improve drug discovery, design & development
- Molecular structure of a protein and the conformational changes that control its function are key to better drug design and development

### **Conclusion**

Response to Pressure May Have Profound Implications in Future Drug Design & Development



## **Biomarker Discovery**

#### **Professor Jennifer Van Eyk**

- Professor of Medicine, Cedars-Sinai Med. Ctr.
- Director, Basic Science Research, the Barbara Streisand Women's HC

*Improved protein extraction and identification from archival formalin-fixed paraffin-embedded human aortas.* Proteomics Clin. Appl. April 2013



- Over 1 billion archived formalin-fixed paraffin-embedded (FFPE) samples exist, representing an unparalleled set of samples for clinical investigation
- Combination of heat and elevated pressure increased protein yield from FFPE aorta samples, resulting in significantly more proteins identified

### **Conclusion**

Results suggests that archival and often rare FFPE aortas and other tissues from patients with clinical histories that often span decades could potentially be invaluable if made available for PCTenhanced

biomarkar discovery and quantification

## Non-invasive Fecal Lipidomic Profiling

#### **Professor Bruce Kristal**

- Neuroscientist, Brigham and Women's Hospital, Boston
- Associate Professor of Neurosurgery, Harvard MS
- Molecular Biologist, Expert in Metabolomics

#### Method Development for Fecal Lipidomics Profiling Anal. Chem. 2012



- Robust methodologies for the analysis of fecal material will facilitate the understanding of gut (patho)physiology and its role in health and disease and will help improve care for individual patients, especially infants
- Pressure cycling differentially increased the yield of a number of lipids

### **Conclusions**

Non-invasive fecal lipidomic profiling to define gut function in health and disease could help physicians assess intestinal function, determine gut response to nutrition, and recognize existing inflammation/pathology... especially valuable in infants and the elderly

## Improved Rape Kit Testing

### **Professor Bruce McCord**

Professor of Analytical/Forensic Chemistry, FIU

Over 75 peer reviewed papers and 11 book chapters

The application of alkaline lysis and PCT in the differential extraction of DNA from sperm and epithelial cells recovered from cotton swabs Analytical and Bioanalytical Chemistry, In Press



#### An estimated 400,000 untested rape kits in the USA (The Dark Side of Clearing America's Rape Kit Back-log, Time Magazine 2013)

This current study presents a novel technique to extract biological fluids from cotton swabs with high recovery using pressure cycling technology

### **Conclusion**

Short extraction times, high yields, inexpensive reagents and semi-automated platform make alkaline lysis-based PCT a promising candidate for extracting DNA from rape kits with the potential additional benefit of reducing the current backlog 17

## **Personalized Medicine:** Analysis of Tissue Biopsies

### **Professor Ruedi Aebersold**

- Professor of Systems Biology, Institute of Molecular Systems Biology (IMSB), ETH Zurich
- Scientific Advisory Committee of numerous public and private research organizations; member of several editorial boards in proteomics & genomics



Rapid mass spectrometric conversion of tissue biopsy samples into permanent quantitative digital proteome maps. Nature Medicine March 2015

### **Conclusion**

Authors expect wide applications of PCT-SWATH in personalized medicine, and believe that PCT-SWATH may ultimately achieve clinical adoption

## Mr. David Weild IV

- Founder, Chairman, and CEO, IssuWorks
- CEO, Weild & Co Holdings (Inv Banking Firm)
- Former Vice-Chairman of NASDAQ
- Former Head of Global Equity Transactions, Prudential Securities
- Former President, PrudentialSecurities.com



- Former Head, Capital Markets Group of Grant Thornton LLP
- Known as the "Father of the JOBS Act", according to Forbes Magazine

Pressure BioSciences has retained IssuWorks and their management team to review strategic and financing alternatives



## Key Achievements: 2015

- Awarded Two-Year \$1M NIH Grant (DNA Shearing)
- New PCT Consumable (µPestle) for Small Tissue Biopsy Processing
- Prof Aebersold & Team Publish on PCT-SWATH in Nature Medicine
- Dr. McCord and Team Publish on Improved Rape Kit Test Progress
- Published Scientific Articles Show the Key Advantages of the PCT Platform in Drug Discovery, Cancer Detection, and Soil Testing
- Collaboration with Prestigious Research Organization India
- Everest Investment Holding Acquires 1M Shares of PBIO. Everest is Managed by One of Poland's Most Respected Fund Managers
- FY2015 Revenue Exceeds FY 2014 Revenue by Over 30%
- Company Initiates Planning for 2016 Up-List to U.S. National Exchange

## Key Achievements: 2016

- Company Closes Over-Subscribed \$5M PIPE at \$6.3M
- Q1 Products Revenue Incr. 26%, Total Revenue Incr. 16% YoY
- 100% (almost \$3M) of all Variable Rate Debt Eliminated
- Co-Marketing Partner Announced (Jan): SCIEX!
  - Global leader in life sciences analytical technologies
  - Market leader in mass spectrometry for proteomics
  - Wholly-owned subsidiary of the Danaher Corporation (NYSE: DHR)
- PBIO Added to the High-Performing Richmond Club Index
- Emerging Growth LLC Releases Report Indicating PCT-SWATH Could Result in Superior Biological Insights & Discoveries and in Rapid Growth for PBI
- Company Continues Planning for 2016 Up-List to U.S. National Exch.
- PBIO Price Increases 50%, from \$0.32 (Jan) to \$0.45 (July)

### Children's Medical Research Institute (Australia)

### SCIEX Announces Alliance with CMRI on Feb 3, 2016

### CMRI Designated Official Collaborator – US Cancer Moonshot – by VP Joe Biden on July 16, 2016

•CMRI will generate proteomic profiles on 70,000 tumor samples in 7 years

•CMRI has received a \$10M grant for testing these samples by PCT-SWATH

•CMRI has purchased four SCIEX mass specs

•CMRI purchased three PCT Barocyclers, plus consumables: June 30, 2016

•First of what could be many centers WW for "industrialized proteomics"

Dr. Phil Robinson, Co-Head of CMRI, noted that sample size has in the past limited the use of mass spec-based proteomics in clinical research and that the use of PCT will allow researchers to analyze tissue samples as small as ones provided by needle biopsies.

### Initial Commercial Application: Mass Spectrometry

#### The Following Information is for Discussion Purposes Only – Not Guidance

**Biomarker Discovery** (Enhanced Mass Spectrometry Sample Preparation)

#### We Believe:

- there are approx 16,000 MS labs worldwide (8,000 U.S.); approx 50% do protein analysis
- most MS protein analyses require extraction then digestion of proteins prior to processing
- PCT offers better protein extraction and better quality of digestion (significantly (10x) faster)

#### We Further Believe:

#### There are six major MS instrument companies, each with over 2,000 customers WW

- the Barozyme HT48 has helped promote strategic partnership discussions with MS firms
- the Barozyme HT48 integrates well with the automated robots in MS labs
- each Barozyme HT48 could generate ~ \$12,000/year in revenue to PBI
- researchers will use between one and many dozens of 8-well strips per day
- PBI could take 25% (minimum) market share over five years
- 3,000 customers x \$25,000/instrument (net) = \$75M
- 3,000 customers x \$12,000/year in consumables (net) = \$36M (recurring revenue)



## Short-term Growth Drivers

- Jan 12<sup>th</sup>: SCIEX, a Major WW Proteomics Mass Spec Player, announced an Exclusive, 2-Year, Worldwide, Co-Marketing Agreement with PBI
- 100% of Floorless Debt Eliminated "Much Cleaner Balance Sheet"
- 2H 2016 M\$S Expansion: 2-4 Additions in Sales & Marketing
- Company Expects Continued Strong Revenue Growth in 2016, and Beyond
- Company Expects Up-list to NASDAQ in 2016 (When Appropriate)
- New Computerized, Robust & Powerful Barocycler 2320EXTREME Developed: Initial Shipments made end of June to three sites, including an Australian cancer research group that is part of the US's "Cancer Moonshot" initiative
- Collaborations

FIU (Dr. McCord: Rape Kits) Inst. of Bioinformatics India (Dr. Pandy: Asian Center of Excellence, Biomarkers) Institute for Systems Biology Zurich (Prof Aebersold, European Center of Excellence, equipment/consumables/FFPE/other new applications)

 Expect Revenue Growth to be Driven by: Micro-Pestle Consumable, Barozyme HT48 & Barocycler 2320EXT Instruments, Additions to the Sales & Marketing Team, Healthier Financial Position, and the SCIEX Co-Marketing Agreement

