# impedimed®



### ASX:IPD February 2016

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**Proven, Proprietary Technology, IPD's Bioimpedance Spectroscopy (BIS)** — provides a simple, accurate, non-invasive system for precisely measuring and monitoring tissue composition and fluid status

**IPD's BIS Platform** — provides accurate and actionable data to clinicians, enabling early detection and better management of chronic disease

**First product, L-Dex®, enables early identification of lymphoedema** – affects approximately 20% to 30% of cancer survivors and significantly impacts long-term outcomes

- NCCN and ACS/ASCO Guidelines for Breast Cancer Lymphoedema management included for the first time in guidelines
- US reimbursement in place L-Dex awarded a unique, dedicated CPT<sup>®</sup> Category I code enabling physicians to seek reimbursement of US\$112 per patient assessment effective 1 January 2015. Requires ongoing engagement with the local Medicare Administrative Contractors if and when necessary
- Strong clinical endorsement premier US cancer centres and clinicians in various post-approval trials. L-Dex also increasingly incorporated into clinical practice guidelines
- US National Launch Underway commenced December 2015; 12 direct sales reps; 9 clinical education specialists; promising early momentum

Chronic Heart Failure (CHF) - positioning and preparing to pursue large and compelling opportunity in CHF

Strong IP Position - over 200 patents and patents pending

**Regulatory** — eight 510(k)s, two of which allow the use of our device in both a clinical and an at-home setting

**Highly experienced management team and Board** — highly experienced executives, previously at Medtronic, responsible for commercialisation of multiple products in the US and international markets

**Generating high level of commercial and corporate inquiry** — several potential strategic parties expressing interest in engaging in discussions with IPD

# Core Technology – Bioimpedance Spectroscopy (BIS) Simple and Sophisticated Method for Measuring Fluid and Tissue Composition

Bioimpedance spectroscopy — a rapid, non-invasive system that provides highly accurate data



### IPD's "Game Changing" Platform Technology

- Informative 256 frequency spectra provides detailed measurements of muscle, fluid, and fat
- Simple to Use easy placement of electrodes
- Fast 5 to 10 mins to measure
- Non-invasive no dyes or radiation
- Safe no safety concerns reported after tens of thousands of measurements
- Accurate precise algorithms analyse information and produce accurate, repeatable and immediate results
- Actionable allows for early detection of lymphoedema and other chronic disease progression



### First Application – L-Dex for the Early Detection of Lymphoedema

Lymphoedema is a leading post-surgical complication for many breast cancer patients and greatly impacts quality of life Simple and accurate measurement of fluid in limbs allows early detection and intervention

1. Treatment for cancer can damage the lymphatic system and result in fluid build up in the extremities





2. L-Dex is able to detect the onset of lymphoedema very early,~35 ml of fluid build up v 200 ml+ for other approaches



3. If detected early, the progression of lymphoedema can be prevented, and often reversed, by wearing a compression sleeve for ~4 weeks

If not treated, it can become an irreversible, life-long, debilitating condition that progressively gets worse

### **National Launch Progressing as Planned**

### <u>2015</u>

• US Commercial launch of L-Dex commenced December 2015

#### <u>2016</u>

- Establish integrated presence in 50 targeted high value top tier cancer centres
  - Begin with breast cancer lymphoedema screening (NCCN Guidelines)
  - Integrate into Electronic Medical Records
  - Establish complete care pathway for preclinical lymphoedema detection, education, follow-up, & treatment
- Target comprehensive breast cancer screening programs for leading NCCN Alliance Cancer Centres

### <u>2017</u>

- Expand to all cancer related lymphoedema in original 50 high value cancer centres
- Double customer footprint in top tier centres
- Continue to add NCCN Alliance Cancer Centres
- Publish first interim data from post approval study drives adoption and private payor coverage
- · Private payors begin to cover
- Apply to NCCN for inclusion of our technology (BIS) in cancer guidelines

#### 2018 and beyond

- Establish L-Dex as Standard of Care
  - Specific inclusion of our technology (BIS) in the guidelines
- Expand coverage of L-Dex by Medicare and private payors

### **Business Update**

- Current customer patient assessment trends are strong
  - $\checkmark$  Adoption continues to expand
- 50 Targeted account update
  - January showed marked increase in sales momentum with important target institutions added
  - Multiple devices ordered from a number of large target institutions
- Full field sales staff onboard 12 direct sales reps; 9 clinical education specialists; promising early momentum

# <page-header> Year Year

Launch of New Website

Website Traffic: Unique Visitors Prior to launch average 200 visitors/month Recently exceeding 6,000 visitors/month

### Public Relations Support

Two news releases distributed via PR Newswire resulted in:

- Over 400 website pickups including Yahoo!, CNBC and Reuters
- 143 referrals from PR Newswire to the website
- 84 referrals from ImpediMed social media channels to the website
- Interview by Medtech Insight
- Outreach to 450+ trade and consumer media outlets begins in Feb 2016



### Heart Failure — Large and Compelling Opportunity

### American Heart Association Definition:

**Heart failure** is a chronic, progressive condition in which the heart muscle is unable to pump enough blood through to meet the body's needs for blood and oxygen

At first the heart tries to make up for this by:

• Enlarging. When your heart chamber enlarges, it stretches more and can contract more strongly, so it pumps more blood. With an enlarged heart, your <u>body starts to retain</u> <u>fluid</u>, your <u>lungs get congested with fluid</u> and your heart begins to beat irregularly

Increasing fluid retention is an indicator of heart failure progression and the reason IPD's technology is so well suited for this disease state



"If this (BIS) technology has the ability to measure alterations in fluid levels accurately over time, it has the potential to significantly improve the delivery of care for heart failure patients." — Dr. Small

### Heart Failure is a Major Burden on US Population and Healthcare System

# CHF is among the most expensive diseases for Medicare

- Estimated 5.7 million people in the US have heart failure
- 870,000 newly diagnosed cases per year
- Heart failure costs the US an estimated US\$31 billion each year. By 2030 these costs are expected to increase to US\$70 billion
- 80% of these costs are spent on hospitalisation

Medicare (CMS) penalises hospitals for unplanned readmissions

- 24% of heart failure patients are readmitted to the hospital within 30 days
- 50% of heart failure patients are readmitted to the hospital within 6 months
- CMS Payment Reform Program
  - 76% of hospitals penalised due to readmissions
  - Penalties up to 3% of total CMS payments

Reducing CHF readmissions is a significant economic focus for the US Healthcare System

### **Current Heart Failure Monitoring Methods – Inaccurate or Invasive and Expensive**

	Method	Measurement	Brought on by
Weight Scale	Weight gain	2 kilograms gained in 2 days	Fluid burden
Implantables	Intrathoracic Impedance	Resistance	Fluid burden
	PA Waveforms	Cardiac Filling Pressure	Fluid burden

Current monitoring methods have major shortcomings:

- Weight Scale inaccurate
- Implantables invasive and expensive \$25k+

# The assessment of fluid burden is critical to the management of CHF patients

- Current practice is to monitor CHF patients daily for fluid burden in both a clinical and home setting
- Compelling clinical evidence and support for the role of BIS in monitoring fluid burden in CHF patients

### **Optimising Outcomes for Heart Failure Patients**

HF Classification	% of Patient Population (est)
Class I	35%
Class II	35%
Class III	25%
Class IV	5%

- Class III/IV HF patients account for the majority of the annual HF hospital readmissions
- Reducing these readmission rates would have a profound impact on the cost of care and improve the outcomes for these patients

BIS technology may be used as an early warning system for cardiac decompensation with the potential to optimise patient care



"BIS can detect and follow the changes in lung impedance in patients and is sensitive to extracellular volume. Since most patients with acute HF suffer not only from pulmonary edema but also from edema in the limbs, a combination of different segmental BIS measurements offers the best option to manage the course of disease." — Weyer 2014

# ImpediMed's Next Generation BIS Technology – Simple and Sophisticated Tool for CHF Patient Management

- True whole body measurement allows for complete and accurate BIS measurements
- Segmental measurements provides clinicians critical data on limb, trunk, and whole body fluid and tissue composition
- Highly accurate provides extracellular fluid, intracellular fluid, total body water, and tissue composition
- Design and development of CHF BIS system is well advanced
  - Well suited for patient workflow in clinics
  - Uniquely simple for easy at-home patient use
- Integrated Systems for robust data integration and reporting for/between clinicians and patients
  - Compliance Algorithms automatic notification if patients not regularly measured
  - Clinical Protocols automatic information and risk stratification when patients begin to trend outside established medical parameters



### Heart Failure Regulatory Pathway is Established and Achievable

### Regulatory

- FDA Clearance
  - IPD's current BIS device cleared for monitoring fluid and tissue composition in both clinical and at-home settings
  - CHF BIS device traditional 510(k) application (IPD predicate device)

#### Clinical data is for patients already diagnosed with CHF

- Trial Design to be finalised under guidance of IPD's Medical Advisory Board and Harvard Clinical Research Institute (see next slide for advisory board details)
- Currently expected to entail:
  - clear and binary end point (compared with current standard of care)
  - ease of recruitment (patients already diagnosed with CHF)
  - short trial duration (90 day end point)
  - relatively low cost (less than \$US15M)
- Aiming to complete trial and obtain FDA clearance by mid CY2017

#### Reimbursement

- Reimbursement barriers are known and manageable as remote monitoring of CHF patients is well accepted by payors and providers
- Technologies for early detection of fluid burden may result in significant cost savings to hospitals, accountable care organisations and integrated delivery systems trying to avoid costly readmissions due to CHF

### **Noted Medical Advisory Board Providing Guidance**

### Advisory Board Members and Clinical Research Team

**Paul Friedman, MD**, Vice Chair, Department of Cardiovascular Medicine, Medical Director, Remote Monitoring, Mayo Clinic

Roy Small, MD, FACC, FSCAI, Medical Director of Clinical Research, Lancaster General Hospital

J. Thomas Heywood, MD, Director, Heart Failure Recovery and Research Program, Scripps Health

Andrew Accardi, MD, Chairman of Emergency Medicine, Scripps Memorial Hospital Encinitas

Laura Mauri, MD, M.Sc., Chief Scientific Advisor, Harvard Clinical Research Institute; Recognised leader in the use of statistical methods in clinical research

Advising the company on study design, clinical utility, and implementation of remote patient monitoring

### **Potential CHF Business Model**

- Initial focus on Class III CHF patients
  - Estimated at 25% of US 5.7 million CHF patients
  - Goal is to monitor and manage the disease progression for Class III patients
- Initial phase of commercial plan focused on Class III CHF patients
  - Baseline reading will be performed in a clinical setting
  - Daily monitoring will continue in either a clinical or remote setting

Preliminary Estimate of US Addressable Market		
Estimated Initial Patient Population	~ 1.4 Million	
Preliminary Estimated Addressable Per Annum US Market (based on \$60/month subscription fee/patient over 12 months)	> US\$1.0 Billion	

### **Important Milestones Next 18 Months**

- Regular updates on US L-Dex adoption and sales
- Progress on inclusion of lymphoedema in additional cancer guidelines
- First release of post-approval clinical data to drive adoption and private payor coverage
- Private payors to begin coverage of L-Dex
- Next generation device
- Expansion into new BIS opportunities
- Enrolment and completion of CHF trial and 510(k) process
- Geographic expansion
- Broad potential for business development opportunities

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Fluid The 5th Primary Vital Sign<sup>™</sup> Appendix

### Management Team Has Deep and Broad Commercialisation Experience

Frank Vicini, MD Chief Medical Officer	<ul> <li>Joined September 2014</li> <li>25+ years as radiation oncologist</li> <li>Completed his fellowship at Harvard Medical School, has authored over 200 peer reviewed publications, and participated in 6 NIH clinical trials and the MammoSite Registry trial</li> </ul>
Morten Vigeland Chief Financial Officer	<ul> <li>Joined April 2011</li> <li>15+ years in financial management in the medical technology industry</li> <li>Experience in med-tech start-ups and emerging growth companies</li> </ul>
Jack Cosentino Chief Strategy Officer	<ul> <li>Joined November 2015</li> <li>20+ years experience in technology solutions and medical device companies</li> <li>Seasoned entrepreneur and technologist bringing innovative solutions to market</li> <li>Previously at Medtronic, Minntech Corp and LifeScience Alley</li> </ul>
<b>Ann Holder</b> SVP General Management and Operations	<ul> <li>Joined July 2015</li> <li>20+ years experience</li> <li>Extensive experience in the medical device field with focus on the cardiovascular space</li> <li>Previously at Medtronic with several years in the Cardiac and Vascular Group more recently at the corporate level focused on building new solutions for disease management</li> </ul>
<b>Catherine Kingsford</b> SVP Medical Affairs	<ul> <li>Joined January 2007</li> <li>20+ years global clinical experience with medical devices</li> <li>Previously worked as a cardiac scientist at several world-class medical institutions including St. Andrew's War Memorial Hospital, The Prince Charles Hospital, and Royal Brompton Hospital</li> </ul>
Dennis Schlaht SVP R&D and Technology	<ul> <li>Joined October 2007</li> <li>30+ years in engineering development and product marketing</li> <li>Previously Vice President of Marketing and Product Development at XiTRON's Test and Measurement Business</li> </ul>

### Board of Directors

\*

<b>Cherrell Hirst AO</b> FTSE, MBBS, BEdSt, D.Univ (Hon), FAICD Non-Executive Chairman	<ul> <li>On Board since 2005</li> <li>Appointed Non-Executive Chairman in Nov 2011</li> <li>Leading medical practitioner in breast cancer screening/diagnosis</li> <li>Currently Chairman of Tissue Therapies Ltd and Non-Executive Director of Medibank Private Ltd</li> </ul>
James Hazel BEc, SF Fin, FAICD Non-Executive Director	<ul> <li>On Board since 2006</li> <li>Expertise in investment banking (previously Chief General Manager of Adelaide Bank)</li> <li>Experienced in ASX listed companies and corporate governance</li> <li>Currently a Director of Bendigo &amp; Adelaide Bank Limited, Chairman of Ingenia Communities Group and Deputy Chairman of Centrex Metals Ltd.</li> </ul>
Michael Panaccio PhD, MBA, BSc (Hons), FAICD Non-Executive Director	<ul> <li>On Board since 2007</li> <li>Investment principal and founder of Starfish Ventures (12+ years)</li> <li>Experienced at capital raising, ASX listed companies, med/tech, M&amp;A, corporate governance</li> <li>Previously Director of numerous technology businesses in Australia and the US</li> <li>Currently a Director of MuriGen, Armaron Bio, Ofidium, dorsaVi and Mimetica</li> </ul>
Scott R. Ward MS, BSc Non-Executive Director	<ul> <li>On Board since July 2013</li> <li>Venture capitalist with 30+ years experience in healthcare industry</li> <li>Previously Senior Vice President and President of the Cardiovascular business of Medtronic</li> <li>Chairman of the Board of Creganna-Tactx Medical Devices and Cardiovascular Systems, Inc.</li> </ul>
<b>David Adams</b> BS, JD Non-Executive Director	<ul> <li>On Board since November 2013</li> <li>Background as medical device investment &amp; business development executive</li> <li>25+ years experience in tax, financial planning, and business development</li> <li>Previously Vice President, Integrations and Divestitures at Medtronic</li> </ul>
<b>Rick Carreon</b> Managing Director and Chief Executive Officer	<ul> <li>Joined July 2012</li> <li>30+ years experience</li> <li>Extensive experience in the medical device field and growth companies</li> <li>Previously Vice President at Medtronic (10 years)</li> </ul>

\* Scheduled for Board refresh

# Corporate Overview

- ASX listed (October 2007)
  - S&P/ASX 300 added March 2015
- Operations in US (San Diego) and Australia (Brisbane)
  - 55 staff (49 US and 6 AU)
- Market capitalisation ~AU\$310M (~294M shares on issue)
  - Cash on hand AU\$25.2M (31 December 2015)



ASX: IPD - 28 Jan 1.06 Price Change -0.070 (6.195%)



#### Substantial Shareholders



Allan Gray	15.5%
Starfish Ventures	8.6%
Fidelity	7.2%
Тор 20	63.9%

### Financial Year to Date (31 December 2015)

31 December – AUD (preliminary and unaudited)		1H FY2016 \$000	1H FY2015 \$000	% Change	
		·			
Lymphoedema Revenue		1,361	753	81%	1
Body Composition Revenue	)	331	396	16%	↓
Test & Measurement Reven	ue	1,019	935	9%	1
Total Group Revenue		2,711	2,084	30%	1
Operating Expenses		13,228	7,698	72%	1
Operating Loss		11,215	6,122	83%	1
		Full Year Lymphoedema Revenue (AU 000's)		1H Lymphoedema Reve (AU 000's, Preliminary for	enue FY16)
	\$2,100		\$1,400	)	
Cash Balance at	\$1,575		\$1,050	,	
31 December 2015: AU\$25.2 million	\$1,050		\$700	,	
	\$525		\$350	)	
	\$0			)	

FY12 FY13 FY14 FY15

1HFY13 1HFY14 1HFY15 1HFY16