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# Annual General Meeting

ASX:IPD October 2014



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# Investment Summary

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## **Game changing technology platform**

- Bioimpedance spectroscopy (BIS) accurately measures tissue composition and fluid status

## **First product, L-Dex<sup>®</sup>, addresses a growing medical need**

- Lymphoedema affects approximately 20% - 30% of cancer survivors
- A precise and cost effective solution to detect lymphoedema at its earliest stages
- Large addressable market;
  - 900,000+ relevant cancer cases per year in the US alone
  - US\$350 million addressable market

## **Sales poised to accelerate in 2015**

- CPT<sup>®</sup> Category I code for reimbursement effective Jan 2015 (BIS)
- *All cancer* code descriptor expands market opportunity
- Seven out of top ten US cancer centres already using L-Dex
- More than 21,000 patient tests in last twelve months
- Targeting key regional oncology groups over coming 12 months

## **Strong pipeline of BIS product opportunities**

- Numerous medical and non-medical uses for our technology
- \$3 billion+ estimated addressable markets

# Recent Milestones Strengthen Our Position

## Reimbursement

- CPT Category I Code effective January 2015
- CPT descriptor for all cancer related lymphoedema expected to significantly expand the market opportunity – September 2014
- A leap forward in commercial strategy, allowing IPD to pursue maximum market for L-Dex at least one year earlier than expected

## Key appointments

- Leading US oncologist Dr Frank Vicini appointed Chief Medical Officer - September 2014
- Brings industry expertise, important advisor on clinical development and strategy

## Post approval study

- Crucial to driving market adoption
- Multiple leading international cancer centres participating
- First enrolment June 2014 – enrolment progressing well

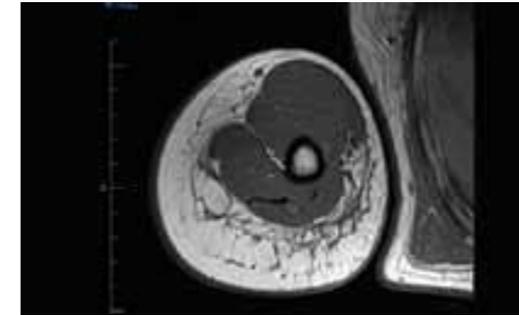
# The Need is Clear

- Fluid imbalance can have significant clinical implications
- Fluid levels are incredibly predictive (actionable information)
  - Excess fluid can lead to chronic swelling, lymphoedema, left ventricular complications, etc.
  - Excess fluid is also indicative of heart failure stage and severity
  - Fluid imbalances in dialysis patients can cause adverse events and contributes to higher mortality/morbidity rates
- Accurate fluid and body composition measurements are key components of a patient's clinical diagnosis and treatment
- Optimising fluid levels in cancer and dialysis patients is likely to have profound impact on reducing hospitalisation rates and mortality

# The Technology Gap

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- Current measurements tools are rudimentary and unreliable, or prohibitively expensive, complicated and invasive
- High-tech tools include CT scan, MRI, X-Ray absorptiometry, isotope dilution (lymphoscintigraphy) and perometry
- Low-tech tools include tape measure, “pinching” with calipers, and water displacement



Imaging\*



Perometry



Tape Measure\*



Calipers



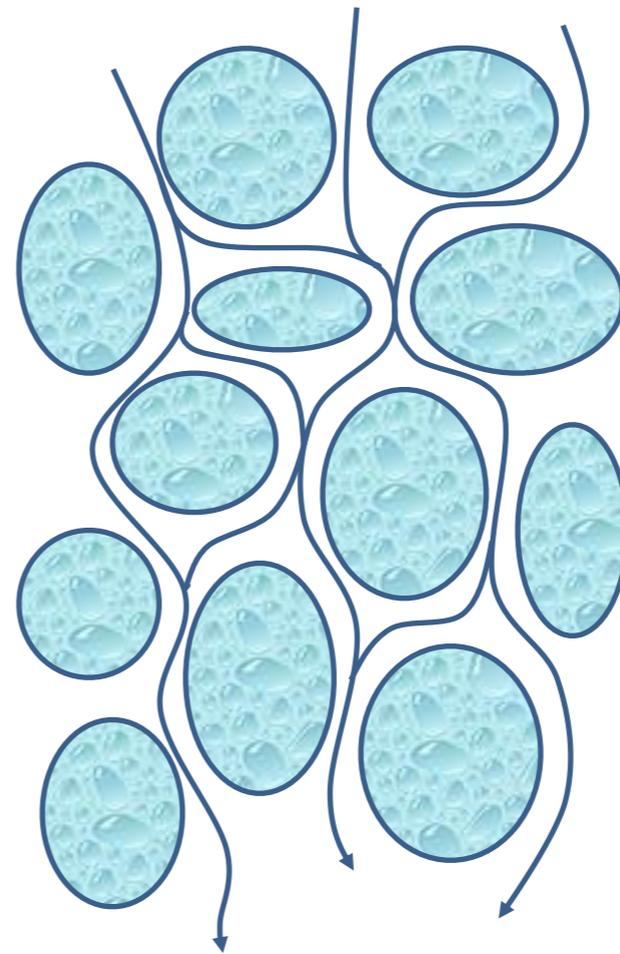
Water Displacement

\* Images courtesy of Macquarie University

# Advantages of BIS are Compelling

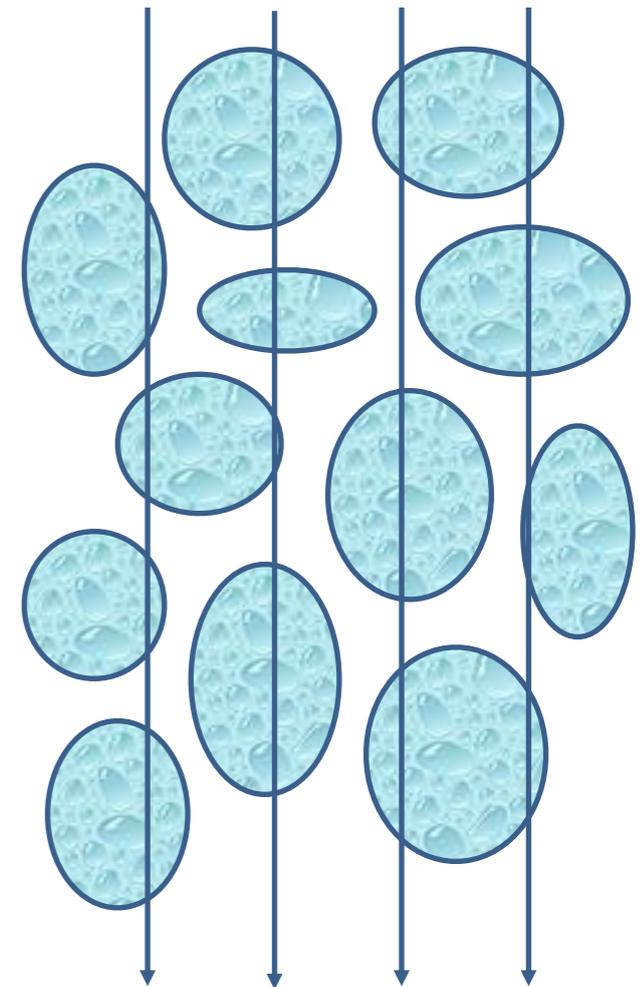
- Measurements using bioimpedance at a single frequency can be used to estimate body composition (limited capabilities)
- However, multiple frequencies are required to obtain complete information of tissue composition and fluid burden
- ImpediMed's patented technology utilises 256 frequencies effectively creating a spectrum of bioimpedance
- Using a spectrum of data obtained by BIS allows a direct and detailed measure of tissue composition (muscle, fluid, fat)

Low Frequency



Current cannot pass through cells

High Frequency



Current able to pass through cells

# A “Game Changing” Technology

- **Informative** – 256 frequency spectra provides detailed measurements of muscle, fluid, and fat
- **Simple to Use** – easy placement of electrodes
- **Fast** – 5-10 mins to measure
- **Non-invasive** – no dyes or radiation
- **Safe** – no safety concerns reported after thousands of measurements
- **Accurate** – precise algorithms analyse information and produce accurate and immediate results



# First Commercial Product: L-Dex

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- US addressable market \$350+ million per year (assumes \$30 per reading)
  - Lymphoedema affects ~1 in 3 cancer survivors
  - 900,000+ relevant new cancer cases per year
- Lymphoedema is a progressive swelling that can occur following cancer treatment due to lymph nodes being removed, damaged or irradiated
- Lymphoedema can become a chronic, debilitating, life-long condition
- Current measurements and treatments are reactive rather than proactive and actionable



# The Importance of Early Detection

- Clinical practice is moving towards early detection and early intervention
- Current techniques used to assess lymphoedema cannot detect it before it is visibly apparent
- L-Dex is able to detect minute changes in extracellular fluid (i.e. 35 mls versus other technologies 200 mls - 300 mls)
- L-Dex detects lymphoedema up to 200 days prior to current techniques

*“BIS is a significant leap in technology. It is able to detect lymphedema at the earliest possible stage of development (stage 0) where treatment is the most effective, and can potentially stabilize or even reverse the early stage lymphedema.”*

Dr. Stanley Rockson, Stanford University Medical Center,  
2013

This patient has sub-clinical lymphoedema identified by L-Dex allowing early treatment



# Potential Revenue Model for L-Dex

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|   |                |
|---|----------------|
| Annual US Relevant Cancer Incidences <sup>1</sup> | <b>939,000</b> |
|---|----------------|

| Patient Testing Protocols<br>(assuming \$30 per reading) |        |              |              |             |            |               |
|--|--------|--------------|--------------|-------------|------------|---------------|
| Per Patient  | Year 1 | Year 2       | Year 3       | Year 4      | Year 5     | Total         |
| Readings   | 5      | 1 - 4        | 1 - 4        | 1 - 2       | 0 - 2      | 8 - 17        |
| Revenue  | \$150  | \$30 - \$120 | \$30 - \$120 | \$30 - \$60 | \$0 - \$60 | \$240 - \$510 |

| Addressable Per Annum US Lymphoedema Market |                        |
|---|------------------------|
| Total                                       | <b>\$225M - \$480M</b> |

Rest of World Market<sup>2</sup> is more than 5 times the US Market

1. Estimated cases in 2013, NCI Cancer Statistics, [http://seer.cancer.gov/csr/1975\\_2010/results\\_merged/sect\\_01\\_overview.pdf](http://seer.cancer.gov/csr/1975_2010/results_merged/sect_01_overview.pdf)  
 2. New Cases 2012, International Agency for Research on Cancer <http://globocan.iarc.fr/ia/World/atlas.html>

# US Targeted Launch Plan

## **Focusing on top US oncology practices and institutions (deliberate and disciplined approach)**

- Increased opportunity for US market based on securing descriptor for all cancers
- Initial Objectives – lay foundation for long-term sustainable growth and expansion of technology
- Previous strategy focused on breast cancer related lymphoedema
- Updated Targeted Launch Strategy
  - Focus the bulk of the sales and marketing resources to building foundations for wide scale adoption in broader oncology market
  - Continue to devote resources to service core breast cancer related lymphoedema market – existing and new user base

# Oncology – Strategy

- Concentrate initial sales and support efforts on optimising uptake and processes at select large leading oncology sites
- Targeting six major oncology groups over coming 12 months
- Establish best practice at each of the six sites for:
  - Practice integration and patient flow
  - Electronic Medical Record (EMR) integration of L-Dex results
  - Data collection (publications and podium presentations)
  - Reimbursement support
- Expand to other target practices once initial data is reviewed and critical lessons learned applied

# Oncology – Supporting Activities

## Clinical

- Standardising testing protocol
- Practice integration
- Patient education
- Expand practice guidelines to National Comprehensive Cancer Network (NCCN)

## Marketing

- Expand to all cancer related lymphoedema
- Expand patient advocacy groups – key markets
- Direct to patient – in partnership with key practices

## Reimbursement expansion

- Post approval study
- Accelerate and expand publication strategy
- Enlist KOLs to educate Medicare Carrier Advisory Committees (CACs) and private payers

# L-Dex Incorporated into Clinical Guidelines

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NATIONAL ACCREDITATION PROGRAM FOR BREAST CENTERS



KAISER PERMANENTE®

Magee-Womens Hospital of UPMC

UPMC LIFE CHANGING MEDICINE

## Key position statements on early detection of lymphoedema - recommendations for BIS

- Australasian Lymphology Association (ALA), Aus
- National Lymphedema Network (NLN), US
- National Accreditation Program for Breast Centers (NAPBC), US

## Formally published guidelines

- Kaiser Permanente (the largest vertically integrated health care delivery system in the US)
- Magee-Womens Hospital of the University of Pittsburgh Medical Center (top 25 Cancer Centre)

# Third Party Trials Generating L-Dex Data

## United States

- 2 randomised controlled trials (n ~100 each site) being conducted at large teaching hospitals
- Both investigating whether early intervention, identified with BIS, halts the progression of lymphoedema
- Comparison between L-Dex and tape measure or water displacement

## Europe

- **United Kingdom**
  - Large National Health Service (NHS) study (n > 1,000) to demonstrate the equivalence of BIS with perometry
  - Small subset randomised controlled trial demonstrating efficacy of early intervention with compression sleeve
- **France**
  - Leading European oncology centre trial (n>600) conducting multi-centre randomised trial to study detection and treatment of lymphoedema related to breast cancer

# ImpediMed's Post Market Approval Trial

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- To help drive adoption ImpediMed is also sponsoring an international study
- Study commenced in June 2014 with Vanderbilt already recruiting patients. All trial sites expected to be live by year end
- Large (n=1,100), multi-centre, randomised controlled study to prove that use of BIS to enable early treatment reduces progression of lymphoedema
- Straightforward study design and low cost
  - 5 year prospective trial
  - Total cost approximately US\$3 million
- Interim results expected in 2017
  - Drives adoption of private payers



# Platform Technology – Many Applications and Markets

BIS is a platform technology for precise measurement of:

- Fluid Levels – e.g. fluid burden; fluid change; hydration; oedema
- Tissue Composition – e.g. fat mass; lean body mass

Fluid Levels and Tissue Composition are incredible predictors of health

- Fluid Levels- e.g. lymphoedema; dialysis; heart failure; hydration
- Tissue Composition – e.g. obesity; nutrition; muscle wasting; wound care; geriatric health

ImpediMed's regulatory approvals (FDA, TGA and CE Mark) cover a number of these potential applications;

- Both in the clinical and at-home settings
- Increasing engagement by physicians around various potential applications of our technology

# Looking Ahead

- CMS announces new Medicare payment rates November 2014
- CPT codes and new Medicare payment rates implemented January 2015
- Accelerating revenue in the US on the back of the CPT I code
  - Medicare reimbursement expected January 2015
- Building private payer adoption
  - Increasing profile in cancer survivorship guidelines
  - Incorporated into NCCN guidelines
  - Results of third party trials published
  - Post-approval trial continues in leading cancer centres
- Expand into new geographies
- Create new and leverage existing partnerships
- Expand into other markets



**Thank You**



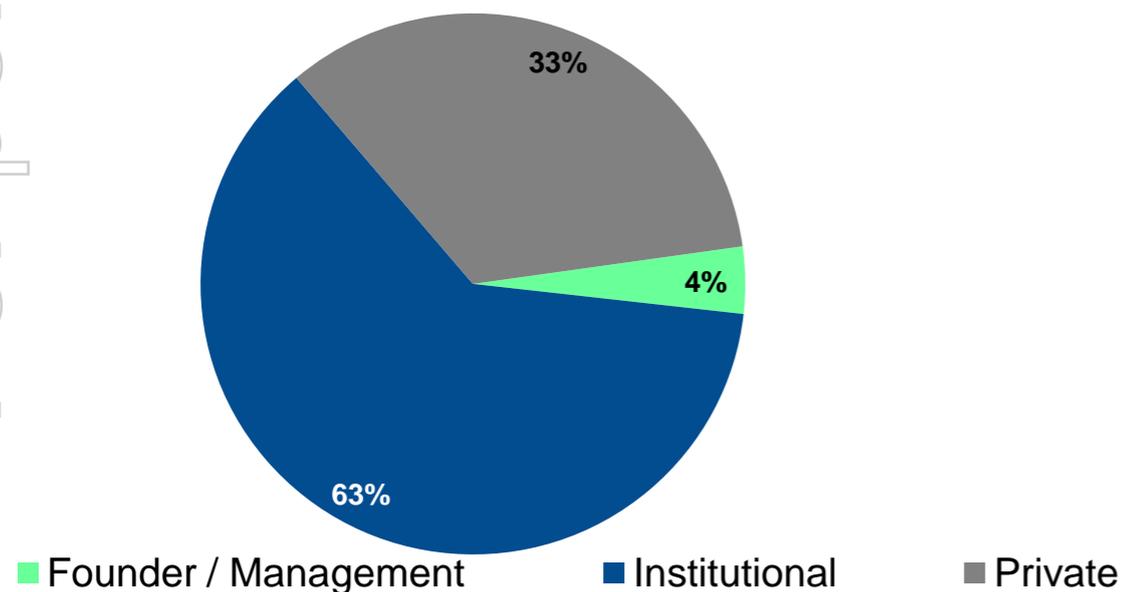
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# Appendix

# Corporate Overview

- ASX listed (October 2007)
- Operations in US (San Diego) and Aus (Brisbane)
- Transformed Board & Management in 2013
- 37 FTE staff
- Market capitalisation ~\$107M (~239M shares on Issue)
- Cash on hand \$9.5M (30 September 2014)
- Revenue FY14 – \$3.5M

## Share Register Breakdown



## Share Price Performance – CY2014

Impedimed Ltd (IPD.AX) - ASX

**0.45** 0.00 (0.00%) 3:51PM AEDT



## Substantial Shareholders

|                      |       |
|----------------------|-------|
| Allan Gray           | 19.9% |
| Starfish Ventures    | 10.2% |
| Founder & Management | 4.1%  |
| Top 20               | 56.9% |



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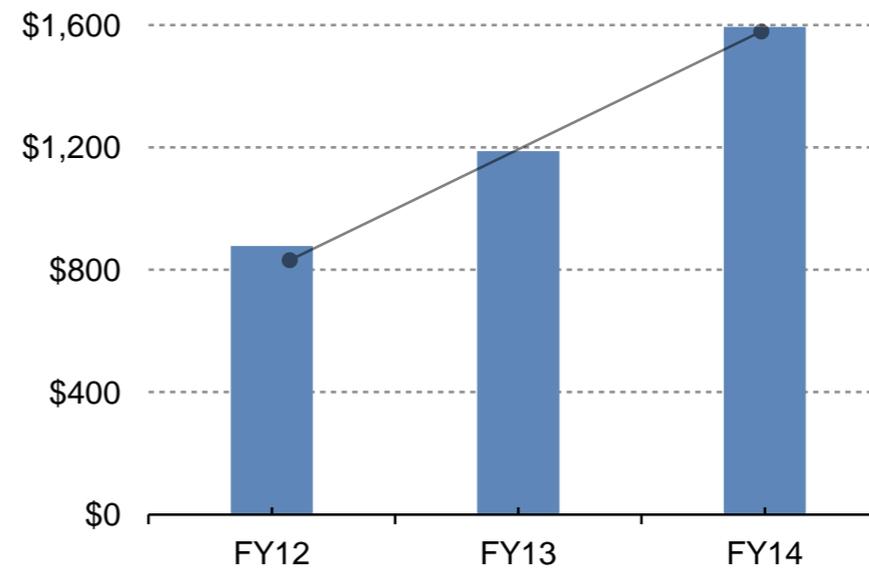
# Financials

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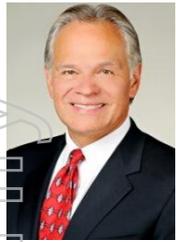
|                            | FY2014<br>\$000 | FY2013<br>\$000 | % Change     |
|----------------------------|-----------------|-----------------|--------------|
| Lymphedema Revenue         | 1,594           | 1,188           | 34% ↑        |
| Body Composition Revenue   | 891             | 728             | 22% ↑        |
| Test & Measurement Revenue | 1,036           | 817             | 27% ↑        |
| <b>Total Group Revenue</b> | <b>3,521</b>    | <b>2,733</b>    | <b>29% ↑</b> |
| Operating Expenses         | 9,967           | 10,751          | 7% ↓         |
| Operating Loss             | 7,935           | 8,464           | 6% ↓         |

Cash Balance at  
30 September 2014:  
\$9.5 million

Lymphedema Revenue  
(in thousands)



# Management Team Has Deep and Broad Commercialisation Experience



**Rick Carreon**  
President and Chief  
Executive Officer

- Joined July 2012
- 30+ years experience
- Extensive experience in the medical device field and growth companies
- Previously Vice President at Medtronic (10 years)



**Frank Vicini, MD**  
Chief Medical Officer

- Joined September 2014
- 25+ years as radiation oncologist
- 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



**Morten Vigeland**  
Chief Financial Officer

- Joined April 2011
- 15+ years in financial management in the medical technology industry
- Experience in med-tech start-ups and emerging growth companies



**Catherine Kingsford**  
VP Regulatory, Clinical  
Affairs, and Intellectual  
Property

- Joined January 2007
- 20+ years global clinical experience with medical devices
- 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



**Dennis Schlaht**  
VP Product Development,  
Quality and Marketing

- Joined October 2007
- 30+ years in engineering development and product marketing
- Previously Vice President of Marketing and Product development at XiTRON's Test and Measurement Business



**Mike Schreiber**  
VP Global  
Commercialisation

- Joined July 2013
- 20+ years in medical device arena
- Entrepreneurial business leader
- Previous founder of VendorClear



# Board of Directors



## **Cherrell Hirst AO**

FTSE, MBBS, BEdSt, D.Univ (Hon), FAICD  
Non-Executive Chairman

- On Board since 2005
- Appointed Non-Executive Chairman in Nov 2011
- Leading medical practitioner in breast cancer screening/diagnosis
- Currently a Director of Tissue Therapies Ltd and Medibank Private Ltd.



## **James Hazel**

BEC, SF Fin, FAICD  
Non-Executive Director

- On Board since 2006
- Expertise in investment banking (previously Chief General Manager of Adelaide Bank)
- Experienced in ASX listed companies and corporate governance
- Currently a Director of Bendigo & Adelaide Bank Limited, Ingenia Communities Group and Centrex Metals Ltd.



## **Michael Panaccio**

PhD, MA, BSc (Hons), FAICD  
Non-Executive Director

- On Board since 2005
- Investment principal and founder of Starfish Ventures (12+ years)
- Experienced at capital raising, ASX listed companies, med/tech, M&A, corporate governance
- Previously Director of numerous technology businesses in Australia and the US
- Currently a Director of MuriGen, NeuProtect, Ofidium, dorsaVi and Protagonist



## **Scott R. Ward**

MS, BSc  
Non-Executive Director

- On Board since July 2013
- Venture capitalist with 30+ years experience in healthcare industry
- Previously Senior Vice President and President of the Cardiovascular business of Medtronic
- Chairman of the Board of Creganna-Tactx Medical Devices, and Surmodics, Inc.



## **David Adams**

BS, JD  
Non-Executive Director

- On Board since November 2013
- Background as medical device investment & business development executive
- 25+ years experience in tax, financial planning, and business development
- Previously Vice President, Integrations and Divestitures at Medtronic

