

14 March 2012

## ImpediMed Company Presentation

Brisbane, Australia. – **ImpediMed Limited** (ASX: IPD) refers shareholders to the attached Company update presentation.

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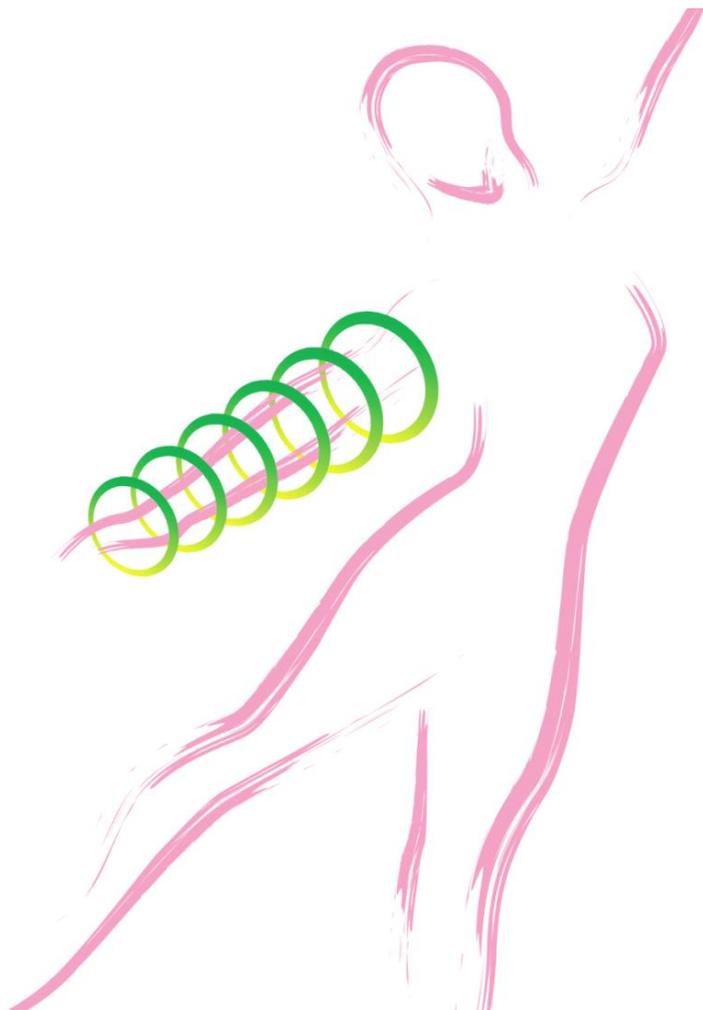
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### **About ImpediMed**

ImpediMed Limited is the world leader in the development and distribution of medical devices employing Bioimpedance Spectroscopy (BIS) technologies for use in the non-invasive clinical assessment and monitoring of fluid status. ImpediMed's primary product range consists of a number of medical devices that aid surgeons, oncologists, therapists and radiation oncologists in the clinical assessment of patients for the potential onset of secondary lymphoedema. Pre-operative clinical assessment in cancer survivors, before the onset of symptoms, may prevent the condition from becoming a lifelong management issue and thus improve the quality of life of the cancer survivor. ImpediMed has the first medical device with an FDA clearance in the United States to aid health care professionals, clinically assess secondary unilateral lymphoedema of the arm and leg in women and the leg in men.

For more information, visit: [www.impedimed.com.au](http://www.impedimed.com.au)



# **ImpediMed Limited**

## **Investor Update**

**March 2012**



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## Clinical Assessment of Unilateral Lymphoedema



- High incidence
- Underserved / early Dx
- Early Dx / prevention



- IP hurdles expanding
- FDA clearance Arm/leg
- Prospective care



- ECF differences of limbs
- ECF/TF measure
- UB500 next generation



- First mover advantage and category III code in place
- Code, payment and building coverage – critical to drive sales
- Directly commercialising the business globally – R&D, Mfr, Q&R, S&M, MC, IP



## Milestone table – Calender year 2011 / 2012

News Flow Pipeline:	1H11	2H11	1H12	2H12
Announcement of first covered lives	[Blue bar]			
Announcement of 20 million covered lives		[Blue bar]		← March 2012
Stanford registry launch and roll out		[Blue bar]		
Publication on health economic paper		[Blue bar]		[Green bar]
Announcement clinical guidelines		[Blue bar]		
Announcement of 50 million covered lives			[Blue bar]	[Green bar]
Key outcomes publication on BIS			[Blue bar]	[Green bar]
Unilateral Limb (arm & leg) FDA - U400			[Blue bar]	
250 placement of L-Dex devices				[Blue bar] [Green bar]
NCD CED resubmission				[Blue bar] [Green bar]

## Recent Progress

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1. L-Dex placements in the U.S. marketplace - 178 devices.
2. U.S. FDA notice of clearance for our L-Dex U400 device to aid in the clinical assessment of unilateral lymphoedema of the arm in women, and legs for both men and women (Nov 2011).
3. Key Pennsylvania based health plan (HMO) implemented prospective care and coverage (Dec 2011).
4. Regarding coverage metrics - we announced 1.6 million additional covered lives, bringing the total to 13.8 million; 6.2 million short of the milestone for Dec. 2011.
5. In March 2012 we report just over 23 million lives
6. Reimbursement coverage – payment information continues to be collected from doctors at both the U.S. state and local levels. Coverage continues to build, but at this point is still well short of required levels.
7. Preliminary summary report on five (5) year outcomes data from the NIH study, was presented (Dec 2012). Supports prospective care and early intervention for improving clinical outcomes in lymphoedema.
8. Stanford launched Breast Cancer Lymphoedema Registry ( Nov 2011)
9. The Company expanded its intellectual property by exclusively licensing three U.S. patents for the fields of lymphoedema, oedema and dialysis. Company considers these to be significant hurdles for BIA/BIS (Feb. 2012)

## New Regulatory Claim

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- First FDA cleared device - Indications for use/intended use:

A bioelectrical impedance analyzer/monitor for use on adult human patients, utilizing impedance ratios that are displayed as an L-Dex ratio that supports the measurement of extra cellular fluid volume differences between the limbs and is presented to the clinician on an L-Dex scale as an aid to their clinical assessment of unilateral lymphoedema of the arm and leg in women and the leg in men.

The device is only indicated for patients who will have or who have had lymph nodes, from the axillary and pelvic regions, either removed, damaged or irradiated. The device is not intended to diagnose or predict lymphoedema of the extremity



# Business Model – Reimbursement Critical to Drive Model

## Illustrative Device Economics

	Per Reading (USD)
Reimbursement <sup>1</sup>	Up to \$400
Consumables <sup>1</sup>	Up to \$85
Net Clinic/Surgeon	Up to \$315

<sup>1</sup>Reimbursement and consumable amounts are targets - indicative only

## Assumptions (based on primary target surgeon)

- Cumulative readings per patient over 1<sup>st</sup> 3yrs – 8 to 12 <sup>2</sup>
- If a clinician enrolls 8 new patients per month
- Readings after 3 years estimated to be 768 to 1,152 per year
- Readings after 5 years estimated to be 960 to 1,632 per year

<sup>2</sup> Readings per patient can vary from baseline, to 5 in the first year to annually thereafter; to baseline, quarterly for the first 3 years and 6 monthly years 4 and 5

- Approximately 250 surgeons treat 20% of all breast cancer patients
- IPD estimates top 2,000 US surgeons treat approximately 60% of patients
- IPD estimates around 800 to 1000 US surgeons treat around 40% to 45% of all patients – primary target
- IPD estimates up to 8000 US surgeons operate on the breast

# Targeting Multiple Fluid Status Markets

## Lymphoedema market - Arms

- Arms - female breast cancer
- TGA, FDA, and CE cleared (Uni only)
- Est. - US\$130m to \$220m annually
- 5 year market potential estimate
- Targeting \$65 to \$85 per reading

Today & Near Term

## Lymphoedema market - Legs

- TGA, FDA, and CE cleared (Uni only)
- 80% of market, 70% unilateral
- Est. - US\$400m to \$700m annually
- 5 year market potential estimate
- Targeting \$65 to \$85 per reading

Fluid Status  
Technology  
platform

## Dialysis market

- Fluid status monitoring in dialysis patients

Future

## Oedema market

- Venous insufficiency
- Pelvic cancers - differentiation of lymphoedema / oedema

# Reimbursement – Critical to drive business model

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## 1. Coding

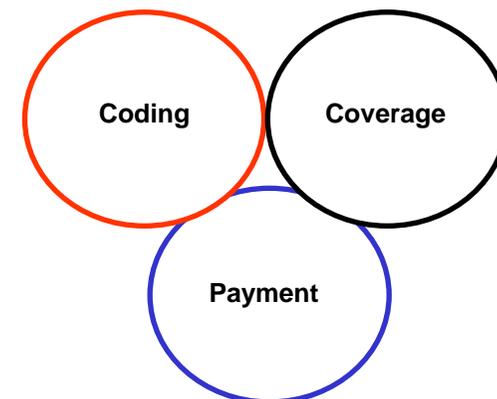
- CPT procedure codes
- ICD-9-CM diagnosis and procedure codes
- HCPCS drug, device and durable medical equipment codes

## 2. Coverage

- National vs. Regional vs. Local coverage policies
- Blue Cross and Blue Shield Technology policies
- Private insurers (National/Regional) and managed care coverage policies

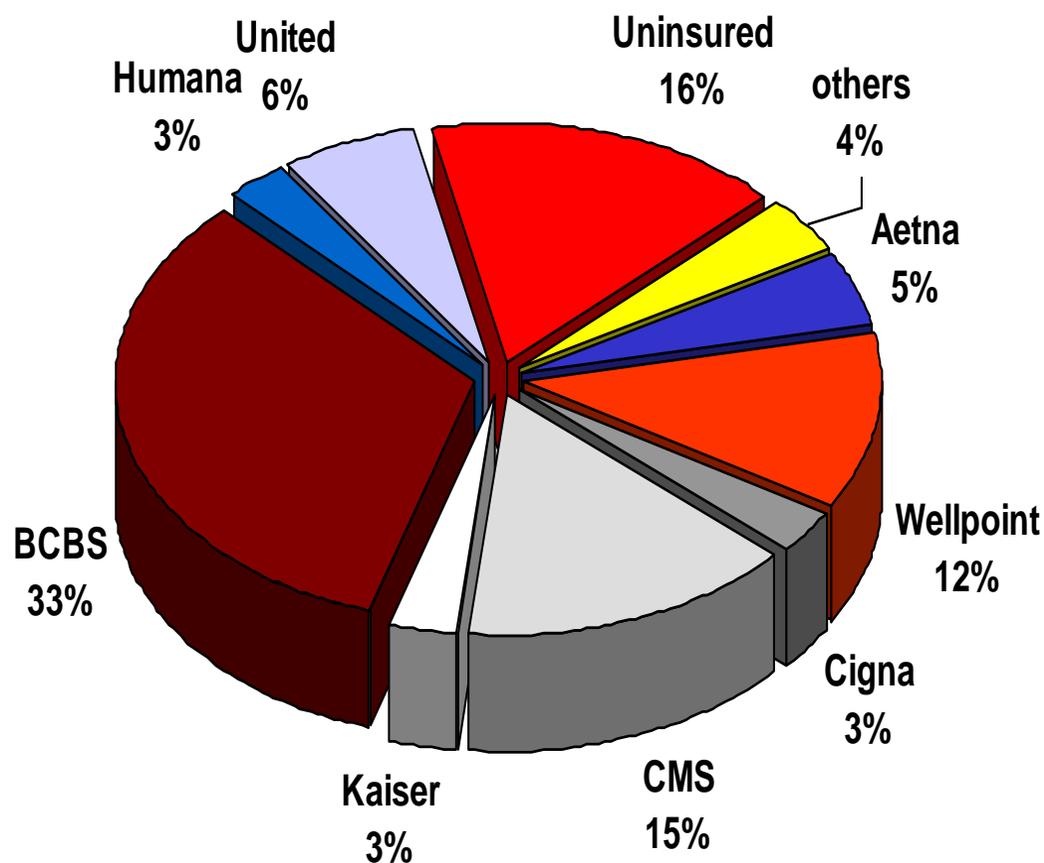
## 3. Payment

- Outpatient hospital Ambulatory Payment Classification (APC) and pass-through payment
- Physician & diagnostic test payment under the resource-based, relative value schedule (RBRVS)
- Durable Medical Equipment payment under DMERC fee schedules
- **Market metrics for showing effective reimbursement – coding, payment and coverage**
  - The best metric is sales - moving forward placements and revenue per placement important
  - Early with a new code it is useful to have a metric to show traction, the options are
    - Medical policy – covered lives
    - Managed Care – Membership



# Payment & Coverage – Delivered Through US Healthcare Payers

US Health insurers by covered lives (2007)



*Approximately 800 plus payers of US Healthcare, multiple delivery systems*

# Reimbursement Status

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## 1. L-Dex testing coverage beginning in the market

- Coverage occurring sporadically– EOB's showing reimbursement of CPT 0239T
- Examples of major private payers covering at local levels - only seen in certain states at present
- Payment is around an average of \$200 presently

## 2. Covered lives metric - medical policy

- 23.0 million covered lives announced to date
- Advancing private payers & HMO's

## 3. Membership metric - managed Care

- 5 PPO signed contracts in place for handling reimbursement claims
- Beech Street – Viant (BSV) – covering some claims (no contract)
  - ✓ BSV is an at risk PPO with 16 million members - Covering L-Dex clients at a percentage of billed charges or contracted default percentage discount when billing CPT 0239T

## 4. Key obstacles for building covered lives – medical policy

- Need clinical outcomes data for L-Dex over present conventional methods – key to health economics
  - ✓ Looking for longer term outcomes data comparing conventional intervention vs earlier detection
- Lack of understanding to the limitations of conventional methods for early assessment
  - ✓ Referenced arguments listed on website; Red Journal article in October

## Clinical studies – Payer categories for assessment

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### Early Dx/Treatment Improved Outcomes

- Key studies
  - Campisi 2002 (RCT)
  - Boccado 2009 (RCT)
  - LaComba 2010 (RCT)
    - Stout 2008

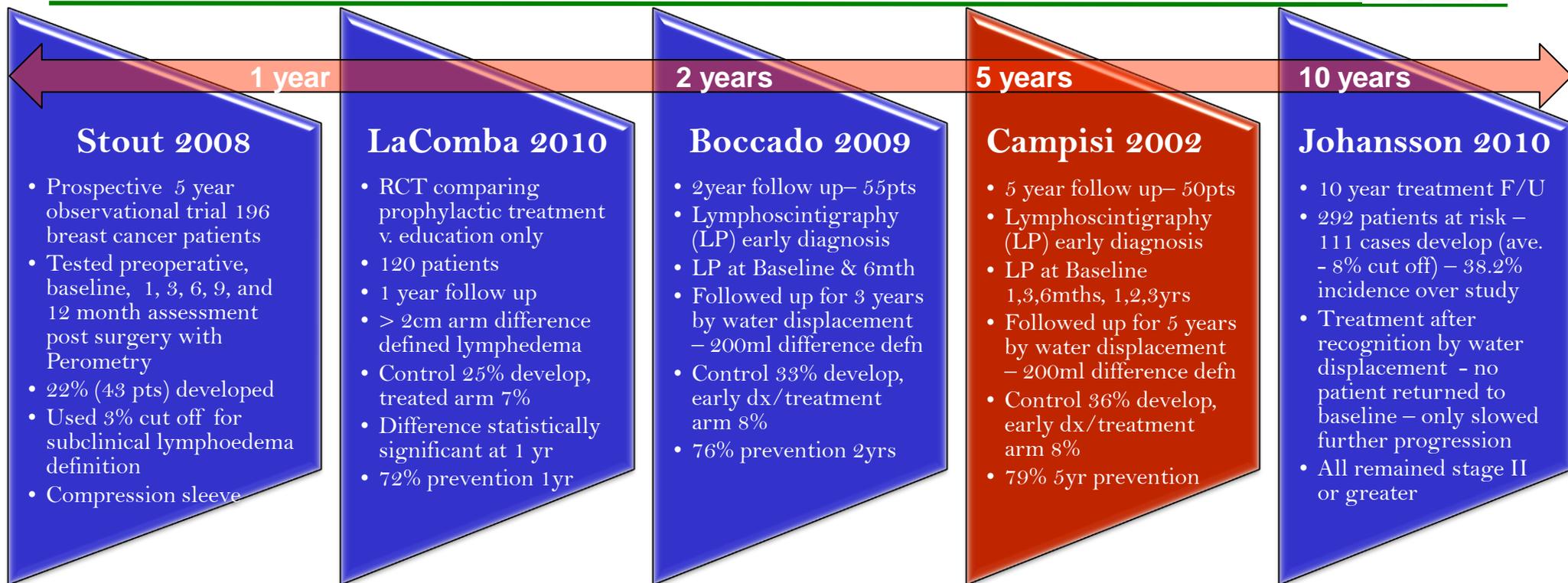
### Reactive Care Poor outcomes

- Referred/Dx at later stage (200ml difference)
- Treatment often starts after irreversible change
  - Johansson 2010
  - Dini 1998

### Clinical Assessment Aid for Doctors - BIS

- **Technical Performance**
  - Van Loan 1993,1999 (RCT)
  - Cornish 1996, Czerniec 2010
  - Hayes 2008, Czerniec 2009
- **Diagnostic performance**
  - Hayes 2005, 2008, 2011
  - Cornish 1996, 2001
    - Ward 2009

# Prospective Care / Earlier Treatment – Data supporting outcomes



Trials	Detection	Follow-Up	Control Arm	Treatment Arm
<b>Stout (Observational)</b>	Perometry >3% difference	196 patients –	22% (developed subclinical)	All returned to near baseline
<b>Campisi (RCT)</b>	Lymphoscintigraphy	50 patients – 5 years	36%	8%
<b>Boccado (RCT)</b>	Lymphoscintigraphy	55 patients – 2 years	33%	8%
<b>LaComba (RCT)</b>	Prophylaxis vs educate	120 patients – 1 year	25%	7%
<b>Johansson (Observational)</b>	Water displacement (8%)	292 patients – 5 /10yrs treated	111 patients developed	38% Dx (111pts) /no return

## Support Building for Prospective care

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1. NAPBC clinical Standard 2.15 “Support and Rehabilitation”
  - Part of the comprehensive breast cancer care program. This standard strongly recommends lymphoedema management and risk reduction practices for the treatment of all breast cancer patients. The NAPBC clinical Standard was updated and published in the “2011 Breast Center Standards Manual”
  - Under this standard, it recommends the National Lymphoedema Network (NLN) supporting guideline document, referenced under the Center Resource section of the site – this supports baseline testing at baseline and every subsequent visit for the life of the patient.
  
2. Avon Foundation White paper – calls for prospective care
  
3. Clinical based Economic Model – Gives clinical and economic potential benefits



# Medical Necessity – Does BIS meet this for aiding in the clinical assessment of unilateral lymphoedema of the arm in women?

- “Medical Necessity” - health care services that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness or its symptoms, & that are:

	Yes/No	BIS	Perometer	Tape	Water
<b>A) In accordance with generally accepted standards of medical practice</b>  <small>NAPBC 2.15 recommends lymphedema mgt &amp; risk redn.            • NLN document recommends</small>	Recommends Lymphedema mgt. & risk reduction	+++	+++	+ Minimally acceptable	+ Minimally acceptable
<b>B) Clinically appropriate, in terms of type, frequency &amp; duration, &amp; considered effective for the patient's illness</b>	Yes	+++ ECF only FDA cleared Std./objective	++ Volume only No FDA Std./Objective	- No FDA non-std. subjective	- No FDA non-std. subjective
<b>C) Not more costly than an alternative service at least as likely to produce equivalent diagnostic results or treatment of that patient</b>	Yes	+++ Clinical health economic model	+++ Clinical health economic model	- Clinical health economic model	- Clinical health economic model