



## Investor Presentation

(ASX:IPD)

January | 2014

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# Company Snapshot



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## Corporate

Australian listed company:

- ASX: IPD

Operations:

- Brisbane (AUS)
- San Diego (USA)

Listing date:

- October 2007

Shares issued:

- 181.2 million

Options issued:

- 18.9 million

Share Price at 10 Jan 2014

- \$0.23

Market cap at 10 Jan 2014

- \$41.7 million

## Financials (at 30 Sept 2013)

Cash and cash equivalents:

- \$5.62 million

## ImpediMed - three businesses

- *Lymphoedema*
- Body Composition
- Test & Measurement

## Substantial Shareholders (as reported)

	19.9%
	13.4%
Board & Management	7.7%
Top 20	63.5%

# New Executive Team

## Proven Record of Success



### **Richard Carreon** President & CEO

Rick joined ImpediMed in July 2013 with an impressive thirty year record for building world-class organisations for global corporations in the medical technology and consumer goods industries, including a twelve year executive career at Medtronic commercialising six cutting edge therapies. He is renowned for building start-up and high-growth ventures, turning around strategic business units, penetrating new markets and delivering strong and sustainable bottom line results. Rick's expertise includes conceiving and leading innovative strategic partnership initiatives that profitably grow business in a shifting economy. Rick is driven by a personal mission to make a difference in people's lives through the delivery of superior healthcare products.

### **Morten Vigeland** Chief Financial Officer

Morten joined ImpediMed in April 2011 and was promoted to Chief Financial Officer in September 2013. His track record covers over 15 years in financial management with medical technology start-ups and emerging growth companies, both private and public. Previous roles include Chief Financial Officer of Access Scientific, Inc., where he completed multiple rounds of financing and corporate deals with C.R. Bard, Inc. and Teleflex, Inc., and Corporate Controller for both private and public medical device companies. His experience includes IPO, M&A and financial reporting for companies in the US. Morten holds an MBA from California State University, and a Bachelor of Science, Business Administration, Finance from the University of Colorado.

### **Dennis Schlaht** VP Product Development, Quality & Marketing

Dennis joined ImpediMed in October 2007 as part of the company's acquisition of XiTRON Technologies, Inc. He has over 30 years' experience in product development and technical marketing leadership, with 10 years' expertise in bioimpedance technology. At XiTRON, he was Vice President of Marketing and Product Development, then President, responsible for the execution of all key strategies for XiTRON's Test and Measurement Business. Prior to joining XiTRON, Dennis held positions as Director of Technical Business Development and Director of Technical Marketing for Insight Electronics. Previously, Dennis held positions at Lockheed Martin in RF and laser communications design, proof-of-concept development, and program management. Dennis earned a BS in electrical engineering from Colorado State University and completed post graduate work at UCLA and UCSD.

### **Catherine Kingsford** VP Clinical & Regulatory Affairs and IP

Catherine joined ImpediMed in 2007 bringing with her over 20 years of global clinical experience with medical devices. Prior to joining ImpediMed, Catherine 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. She has international experience with regulatory bodies in Australia, USA, and Europe. She has been instrumental in obtaining regulatory clearances for medical devices. Catherine has been involved with many international device trials, including implantable devices. She is co-author on a number of scientific publications, many of which she has presented at international conferences. Catherine has studied at Queensland University of Technology (Australia) and the University of London (UK).

### **Mike Schreiber** VP Global Commercialisation

Mike joined ImpediMed in July 2013. He contributes many years of experience in a wide variety of leadership and management roles for varying medical device organisations including Minnetronix, Medtronic, and Boston Scientific. Mike has extensive experience bringing new technologies from concept to commercialisation in the healthcare market.. He also has expertise in entrepreneurship. He was the Founder of President of VendorClear, a web-enabled vendor access program for healthcare systems which acquired more than 1000 hospital customers in less than four years. Mike earned an MBA from Southern Methodist University in Dallas, Texas, and a BS in Business Administration and Marketing from Marist College in New York.

# FY13 - Transformed the Business



## New Direction

- New CEO
- New executive team
- New strategy

## New Focus

- Building the core lymphoedema business
- Clear reimbursement plan of action
- Clinical requirements and regulatory pathway
- Strong financial discipline
- Expand our technology platform

## Positioning the Company for the Future

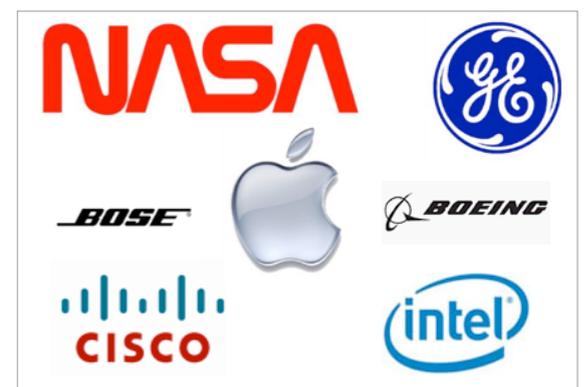
- New U.S. Board Members
- 3M exclusive agency agreement
- Pivotal clinical trial for lymphoedema
- New global business model (device/consumables)
- Next generation platform



Lymphoedema



Body Composition



Test & Measurement

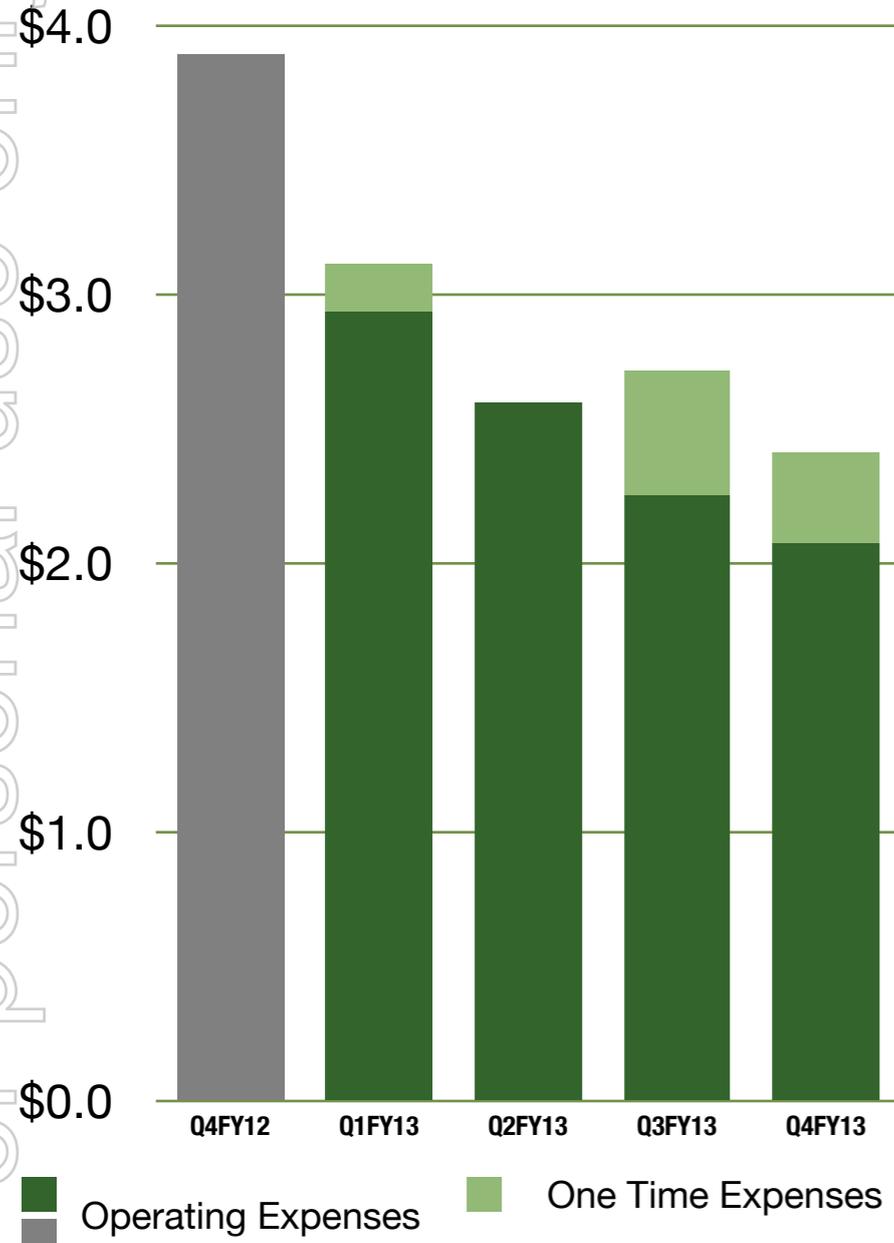
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# Dramatically Improved our Financial Position and Invested in our Future

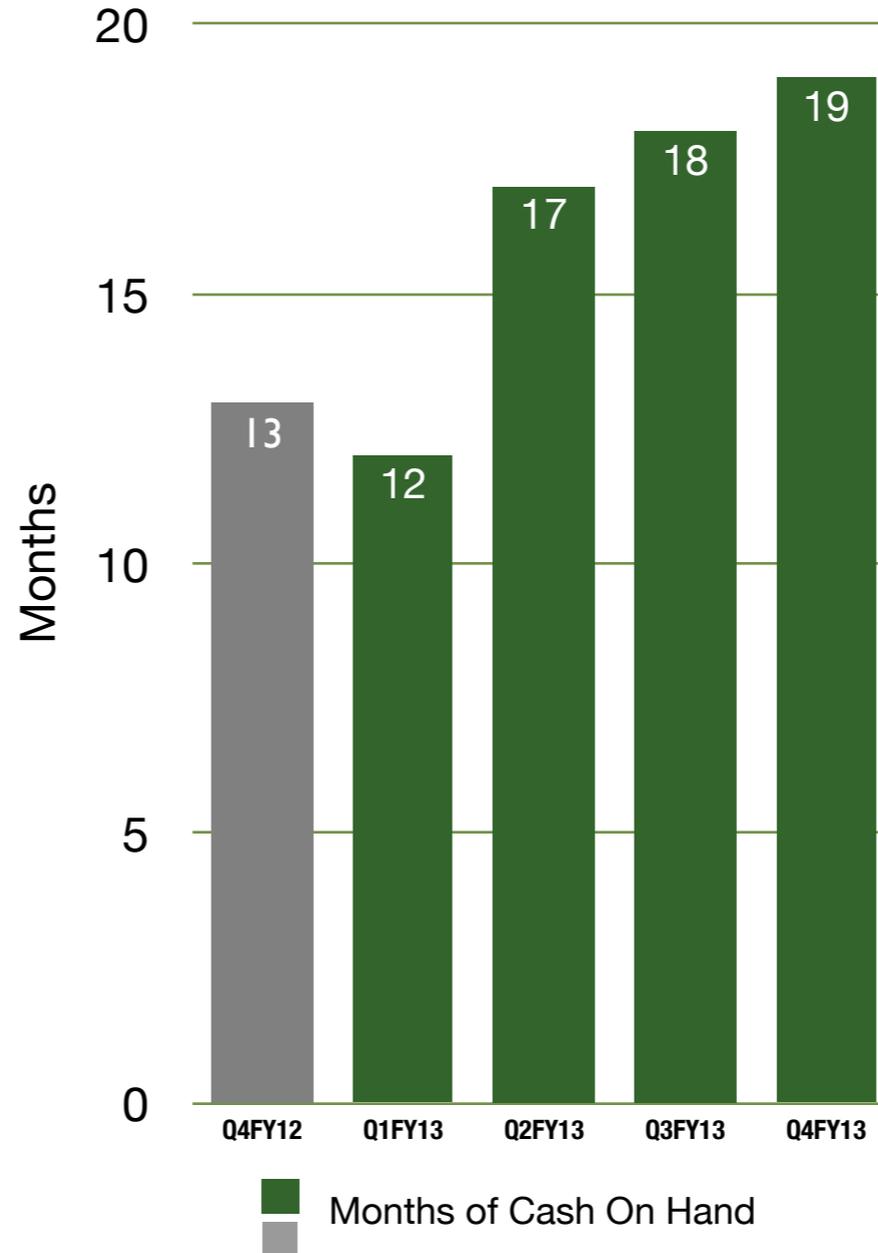


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### Expenses



### Months of Cash On Hand



Instituting strong financials controls allowed us to:

1. Reduce expenses by \$4.7 million
2. Invest in critical long-term initiatives:
  - Reimbursement
  - 510(k) Clearance
  - Payor Advisory Panel
  - Clinical Trial Design
  - Next Generation Platform

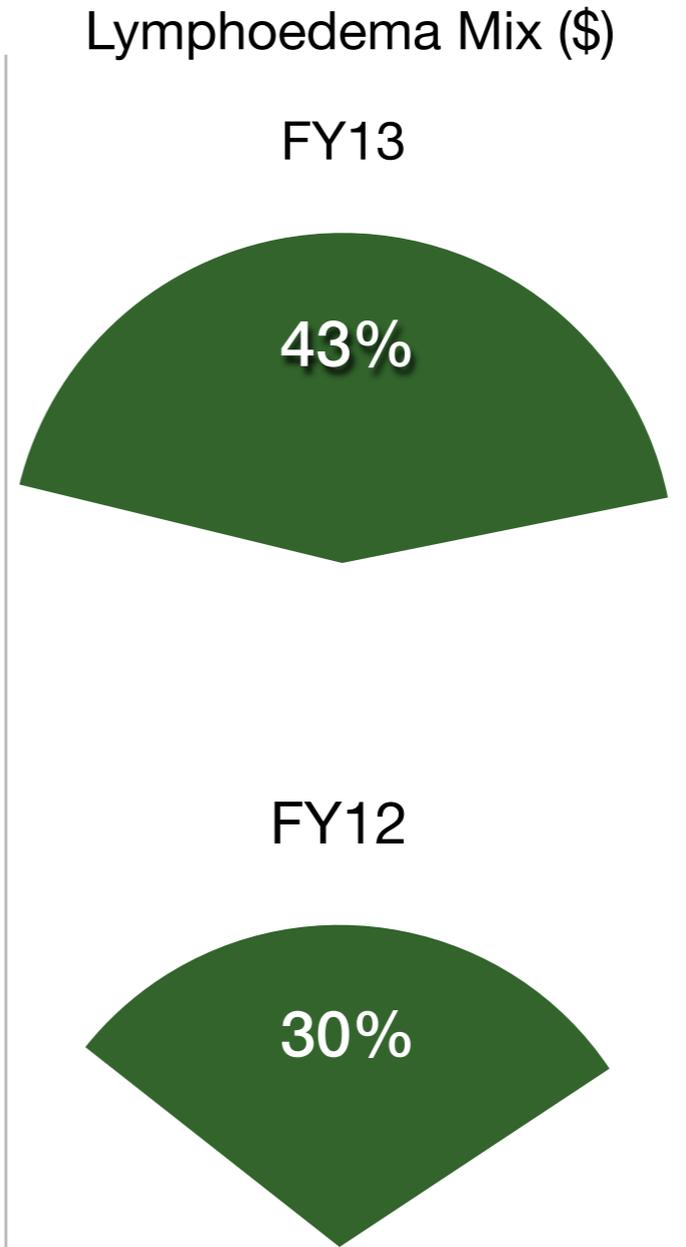
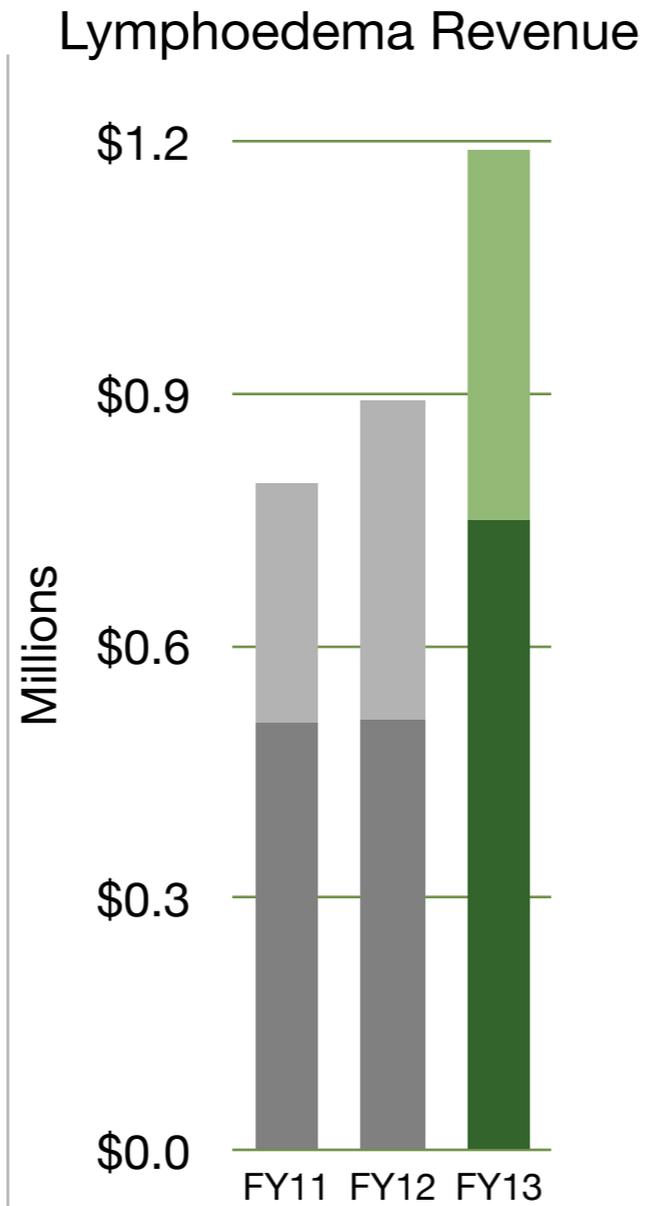
	Q4FY12	Q1FY13	Q2FY13	Q3FY13	Q4FY13
Cash On Hand	\$14.5	\$11.4	\$9.6	\$8.2	\$7.3
Operating Cash Burn per Quarter	\$3.4*	\$3	\$1.7	\$1.4	\$1.1*

\* Excluding R&D tax credit and certain one-time payments

# Focusing on the Lymphoedema Business Paid Off



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Global lymphoedema business grows 35% in FY13:

- US +51%
- International +15%

Changed global lymphoedema business model based on Australian experience

Lymphoedema
  Non-Core

US
  International



# FY2013 Significant Investments/Accomplishments

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## **U.S. - Expanded Adoption of L-Dex**

- Required for CPT Category 1 Code submission “The procedure or service is performed by many physicians across the US”
- Across healthcare channels
- Introduced new business model

## **Food and Drug Administration (FDA) 510(k) Clearance**

- Forged new relationship with the FDA
- Removal of our disclaimer was required before submission of the CPT Category 1 application
- Clarified indications for use

## **Payor Advisory Panel**

- Convened panel consisting of both Medicare and Private Payors
- Invaluable insight provided into required deliverables to achieve payment
- Detailed recommendations developed by panel members to achieve reimbursement

## **3M and Australasian Lymphology Association (ALA) Partnership**

- New business model developed in conjunction with both 3M and the ALA
- New business model being implemented globally
- Improved patient outcomes through more frequent measurements

## **Clinical Trial Design Panel**

- Trial designed by global Key Opinion Leaders
- US Private Payors are reviewing the protocol and providing constructive feedback
- This clinical trial will help to establish L-Dex as the standard of care

# Lymphoedema is a Significant Unmet Medical Need



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An estimated 3 million people develop secondary lymphoedema each year due to cancer

One out of every three survivors of breast, pelvic (including gynaecological and prostate), or melanoma cancer will develop lymphoedema

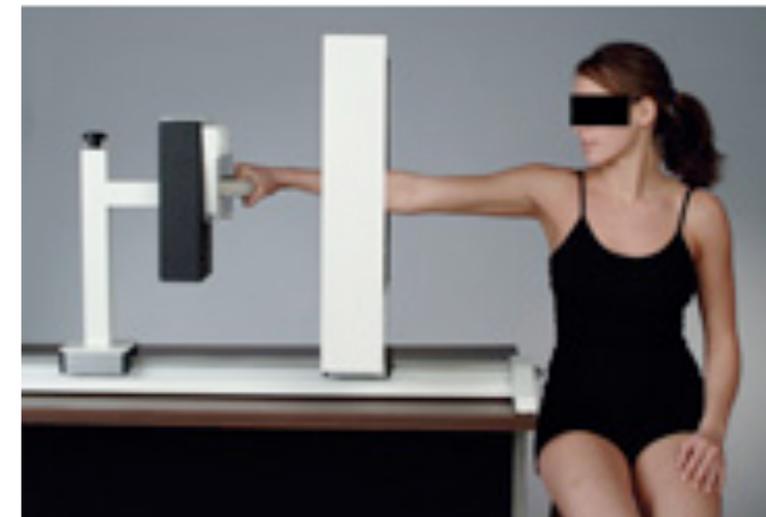
Current detection methods are subjective and have changed very little over the years



Tape Measure



Water Displacement



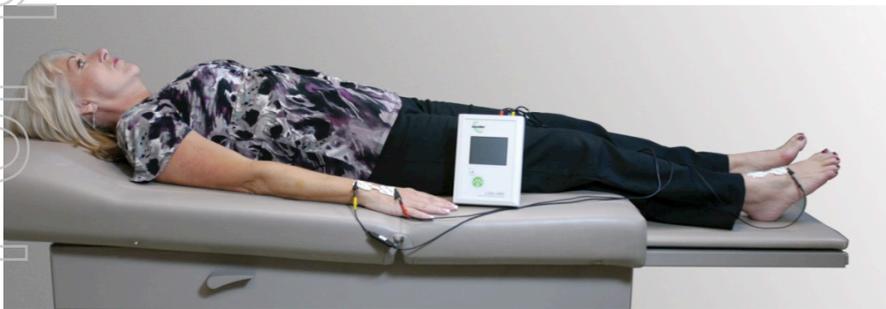
Perometry

# L-Dex: The only FDA Cleared Technology for the Assessment of Lymphoedema



**L-Dex**<sup>®</sup>

- A hand held device designed specifically to assist in clinical assessment and monitoring of lymphoedema
- Bioimpedance Spectroscopy (BIS), Class II Medical Device
- FDA cleared, ARTG listed, CE marked
- L-Dex<sup>®</sup> is a registered trademark of ImpediMed

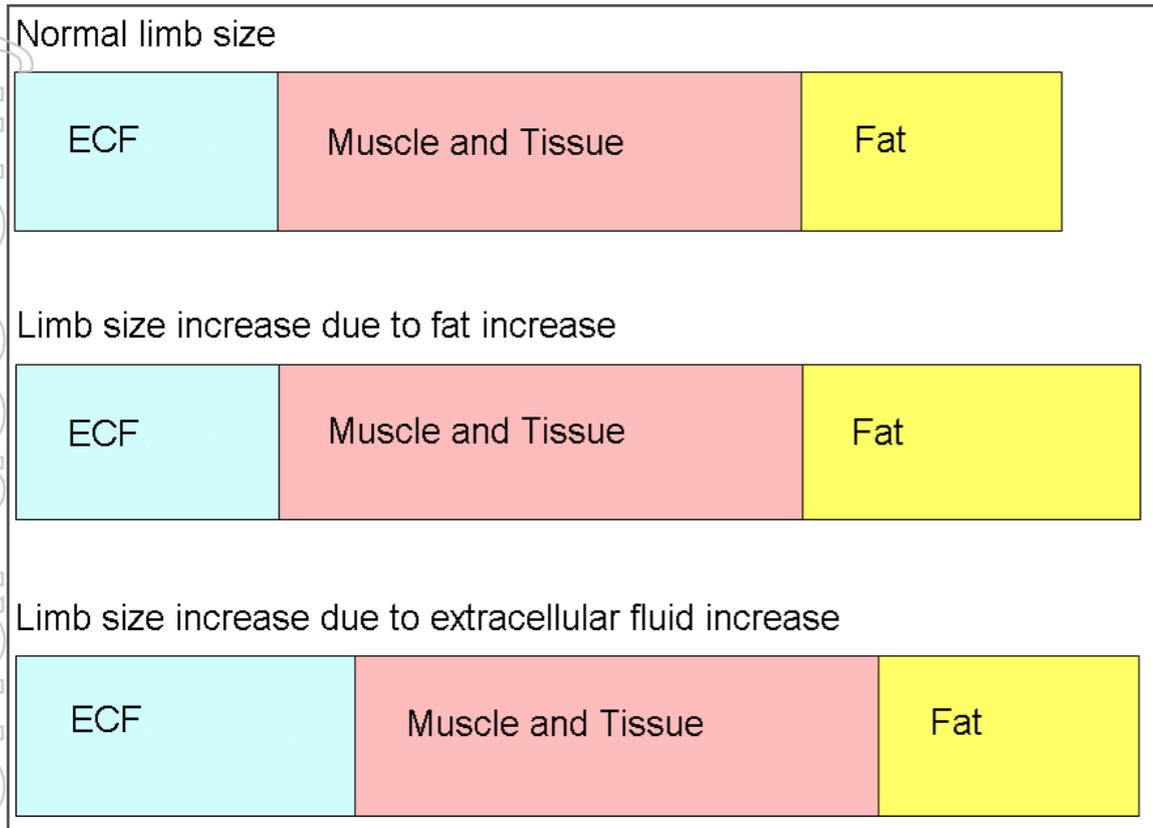


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# L-Dex: Key to Early Detection of Lymphoedema



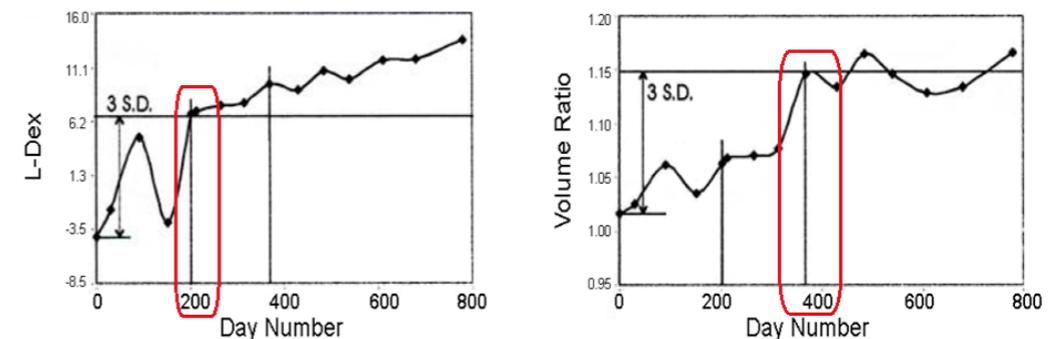
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L-Dex technology (BIS) is a direct measure of extra cellular fluid (ECF), all other techniques used today measure volume

Bioimpedance spectroscopy detects lymphoedema up to 200 days prior to volume measurements such as a tape measure

Figures demonstrate the advantage in longitudinally monitoring extracellular fluid levels versus total limb volume



Patient T10 - Variation in volume ratio and L-Dex (impedance ratio) over 2 years  
Adapted from Cornish *et al* 2001

**BIS clinically detects nearly 200 days prior to volume**

# L-Dex Provides Significant Advantages



ImpediMed  
 L-Dex  
 Tape Measure  
 Water Displacement  
 Perometry

Method	Direct Measure of Extracellular Fluid	Detects Sub-Clinical (Stage 0)	Volume Change Required for Detection	Standardised Detection Criteria	Easily Reproducible	Regulatory Clearance	Ease for Patients, Non-invasive	Portable	Standard of Care
	✓	✓	35 mls	✓	✓	FDA, CE Mark, TGA	✓	✓	
			200 - 300 mls					✓	✓
			200 mls						
			200 mls						

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

*-Dr. Stanley Rockson,  
Stanford University Medical Center, 2013*

# Value Proposition



## Early Detection

- Enables early treatment
- Enhances treatment options

## Because...

- Emerging data from the University of Pittsburgh Medical Center shows a 97% reduction in lymphoedema progressing beyond stage 0 if detected early and treated effectively

## Which...

- Improves patient outcomes
- Improves quality of life for cancer survivors
- Dramatically reduces healthcare costs

# Lymphoedema Market Potential



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Current Clinical Practice for L-Dex Readings	
Time and Protocol	Total Number of L-Dex Readings
<u>Year 1</u> Base line plus quarterly readings	5
<u>Years 2-4</u> Annual or quarterly readings**	3 to 12
Total L-Dex Readings	8 to 17

Cleared Markets	Incidence Rates	
	Cancer*	Lymphoedema
	8,245	2,720
	46,723	15,419
	582,200	192,126
	1,104,776	364,576
Total	1,741,944	574,841

At Standard of Care the total annual lymphoedema consumable market potential in the geographies we have regulatory clearance ranges from \$416 million to \$884 Million

\*\*Annually, unless L-Dex increases by 10 points

\*Breast, pelvic (including gynaecological and prostate), and melanoma

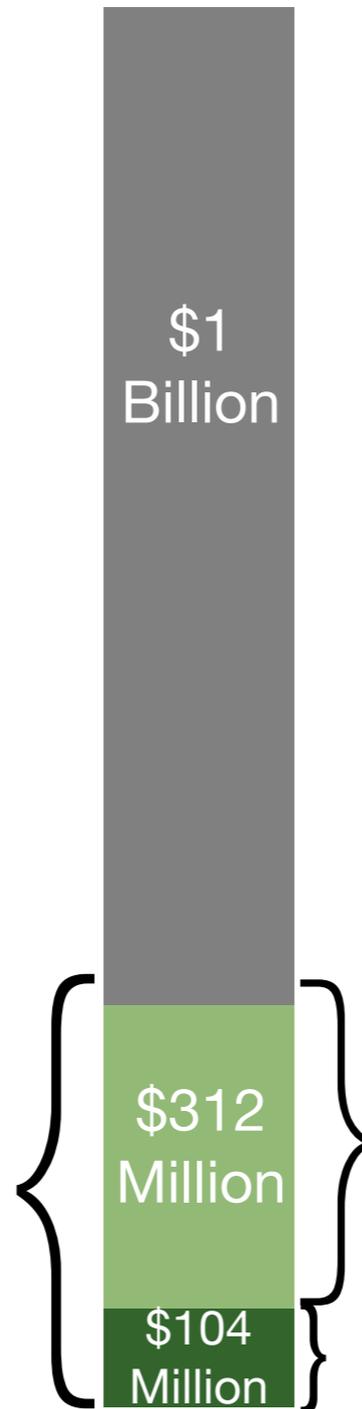
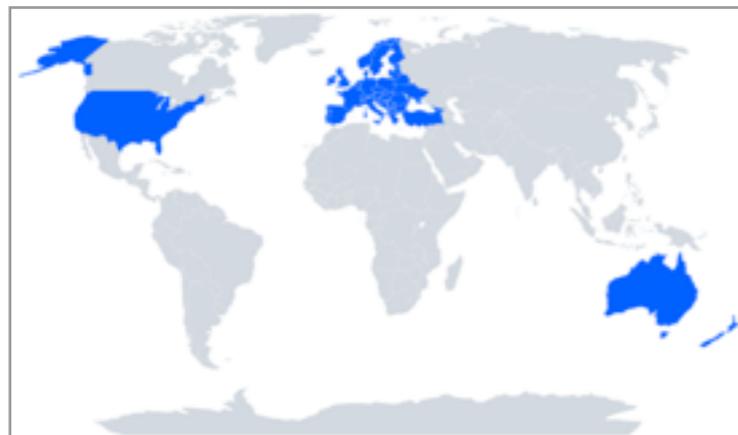
# Significant Growth Opportunities



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Regulatory Cleared Markets



## Lymphoedema Consumable Market

**Phase III** - Expand into High Potential Geographies

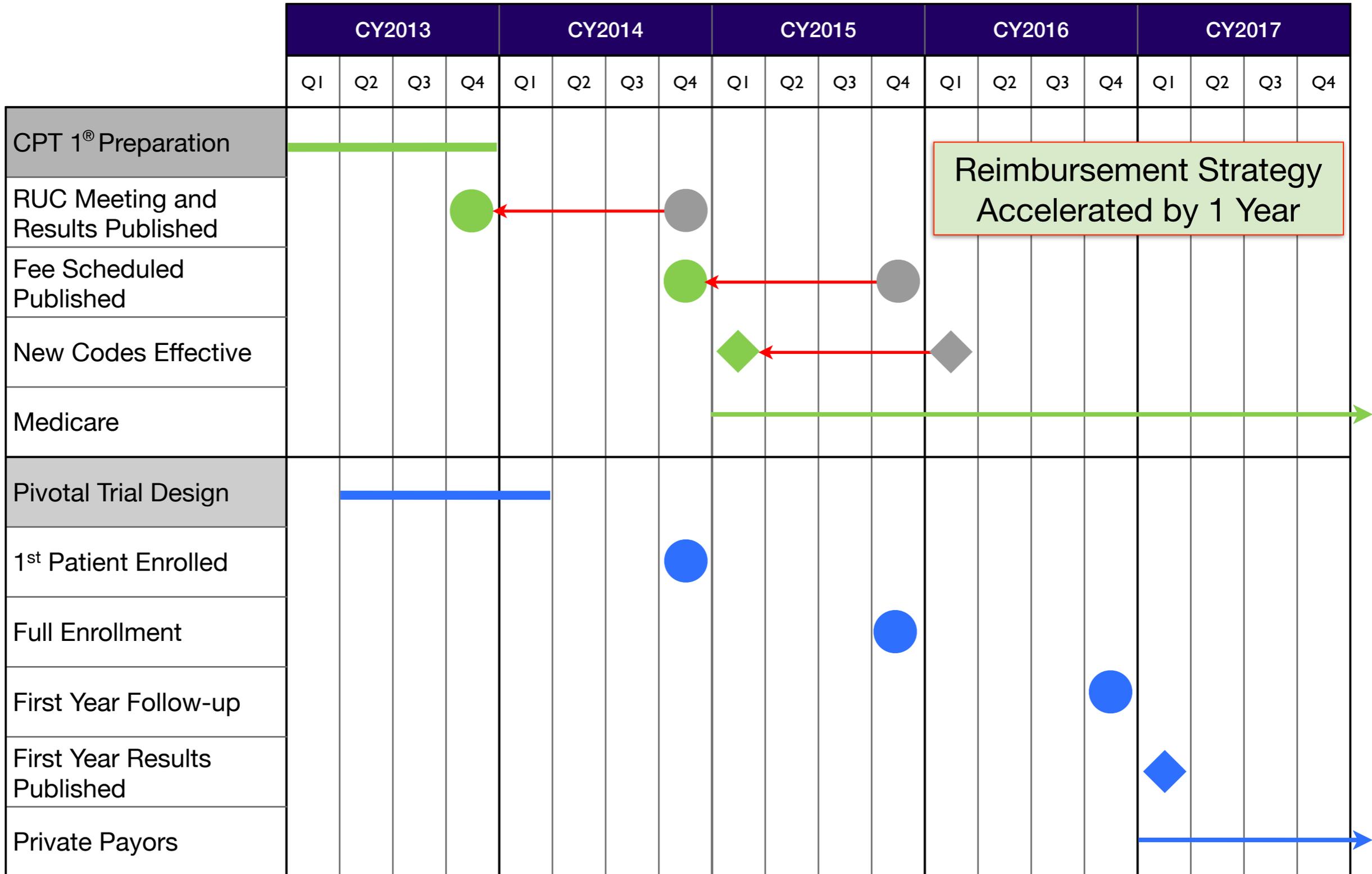
**Phase II** - Lower Limb and Melanoma Cancers (underway)

**Phase I** - Breast Cancer (executing)

# Key Reimbursement Milestones



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Reimbursement Strategy Accelerated by 1 Year



# Pivotal Trial - Principal Investigators

## Sheila Ridner, PhD, FAAN

- Professor with Tenure: Vanderbilt University School of Nursing
- Member National Lymphoedema Network since 2001; member of its Research Committee since 2003; Research Committee Chair since 2010; member of its Medical Advisory Committee since 2004
- Lymphatic Research Foundation (Board Member) since 2005; chair of LRB Patient Registry/Tissue Bank Sub-Committee since 2005
- Author on over 50 peer reviewed articles, the vast majority on lymphoedema

## Frank Vicini, MD, FACR

- Chief Academic Officer for Michigan Healthcare Professional and 21st Century Oncology
- Professor of radiation oncology
- Developed a breast cancer related lymphoedema programme at The William Beaumont Hospital
- He is currently principal investigator on two large multi-center trials supported by the National Cancer Institute
- Author on over 200 articles on breast and prostate cancer including papers on breast cancer related lymphoedema

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17 December 2013

**ASX ANNOUNCEMENT**

Nutrition and Body Composition

**ImpediMed, Fonterra, University of Auckland and University of Queensland  
Working Together to Improve Nutritional Health**

Brisbane, Australia – **ImpediMed Limited** (ASX: IPD) (“the Company”) today announced that we are working with Fonterra, University of Auckland and University of Queensland to improve our understanding of how to assess the impact of nutrition on the composition of the body. ImpediMed has provided their next generation bioimpedance spectroscopy (BIS) device for this important initiative.

Dr Leigh Ward, University of Queensland, said “I am very excited to be leading the development of this next generation technology platform as part of this world-renowned team.”

Professor Sally Poppitt, University of Auckland, said “We are very pleased to have the opportunity to collaborate on this project with Associate Professors Leigh Ward and Lindsay Plank, both renowned experts in the assessment of body composition”

“At ImpediMed, we are committed to maximising the potential of scientific discoveries relevant to the development of new bioimpedance spectroscopy applications”, said ImpediMed President and CEO, Richard Carreon. “We look forward to working with this innovative group in the application of our technology focusing on improving people’s lives through better nutrition.”

**For further information contact:**

**Richard Carreon, ImpediMed CEO  
Morten Vigeland, ImpediMed CFO  
T: +1 (760) 585-2100**

**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)

# Next Generation BIS Platform

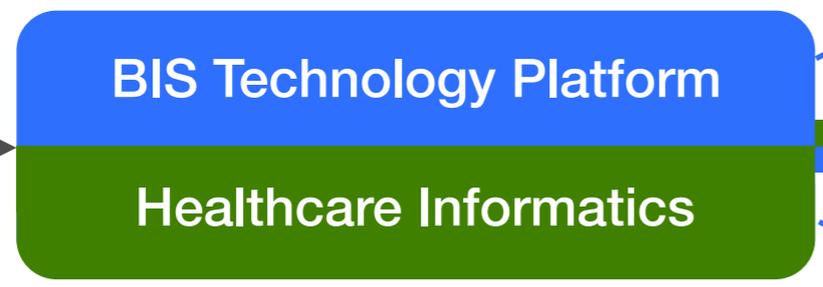


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- | Technology   |
|--|
| <ul style="list-style-type: none"> <li>• BIS Platform - Strong IP position</li> <li>• Robust data integration and reporting - Treatment optimisation</li> <li>• Longitudinal monitoring - Integrated into the patient treatment continuum</li> <li>• Form Factor - Depending on application</li> <li>• Design for manufacturability - Lower costs and higher quality</li> <li>• Precision</li> </ul> |

## In Clinical Testing

Devices  
BIS/BIA



Medical

Commercial

At Home

- | Capabilities  |
|---|
|  <ul style="list-style-type: none"> <li>• Extracellular fluid</li> <li>• Intracellular fluid</li> <li>• Total body water</li> <li>• Fat free mass</li> <li>• Fat mass</li> <li>• Muscle mass</li> <li>• Active tissue mass</li> <li>• Extracellular mass</li> <li>• Hydration index</li> <li>• Whole body measurement</li> <li>• Segmental measurements</li> </ul> |

# Current and Future Opportunities

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## Medical

## Commercial

Lymphoedema

Dialysis

Elite Athletes

Obesity

Geriatric Health

Venous Insufficiency

General Health

Wound Care

Nutrition

Muscle Wasting



 Core Business (IP Protected)

 Presence (IP Protected)

 Opportunity (IP Protected)

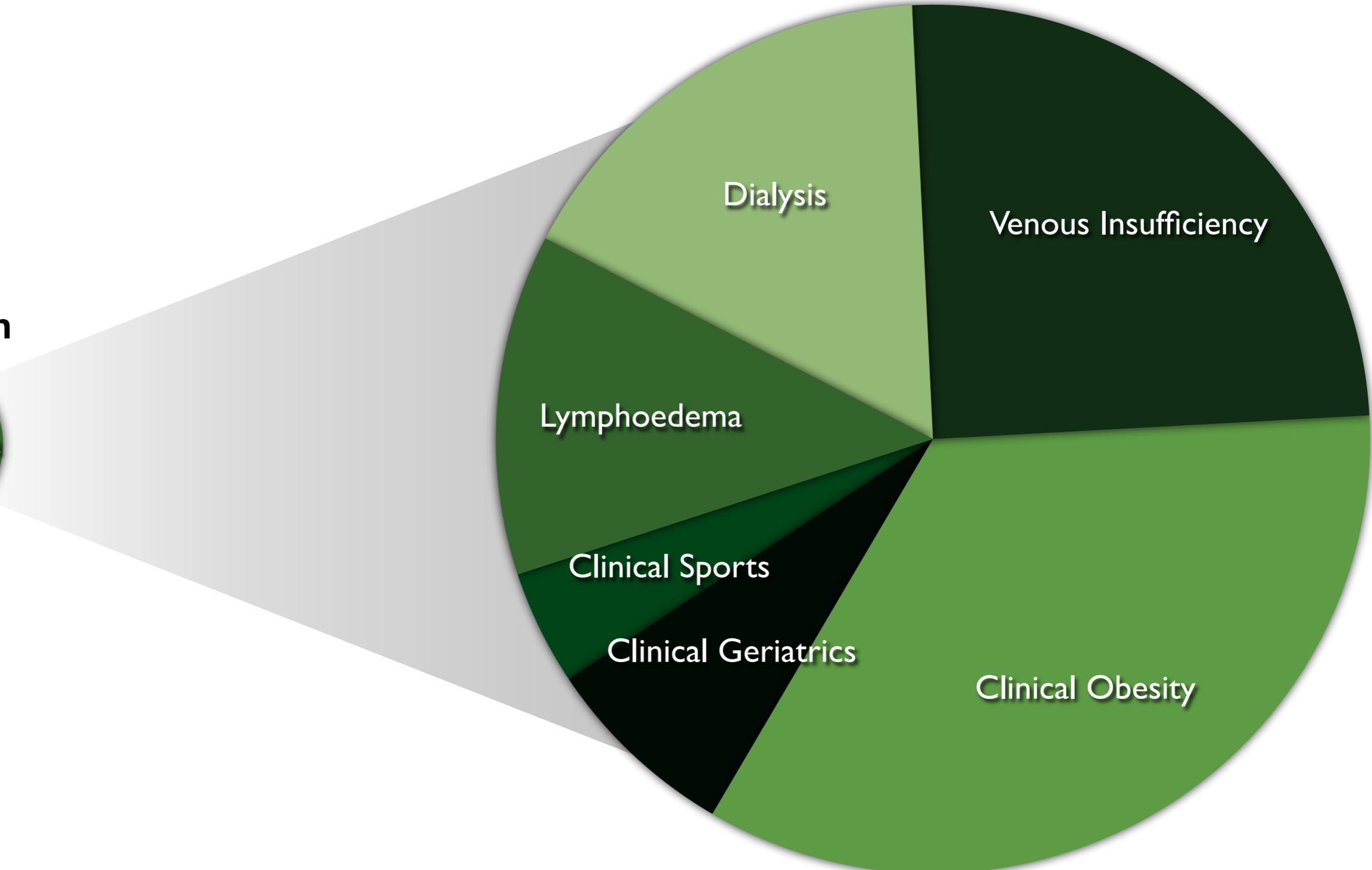
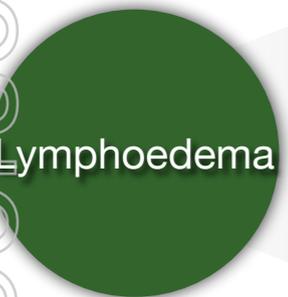


# Current and Future Opportunities

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**\$3.3 Billion**

**\$0.4 Billion**



# Key Objectives and Milestones



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Add U.S. Healthcare experienced board members

15



CPT Category 1 Code - January 2016~~6~~



• Pivotal Clinical Trial - first enrollment 2014



Develop new and / or expand existing strategic partnerships



• Expand use of our devices for drug and / or therapeutic clinical trials

# Investment Case



- Highly experienced executive team
- Acceptance of a CPT Category 1 Code effective 1 January, 2015
- Regulatory clearances in AU, US, and EU
- First mover advantage in lymphoedema market
- Substantial IP portfolio
- Proven technology
- L-Dex is the assessment tool, the metric, and ImpediMed's registered trademark
- Low valuation with significant potential

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# Appendix

# Board of Directors

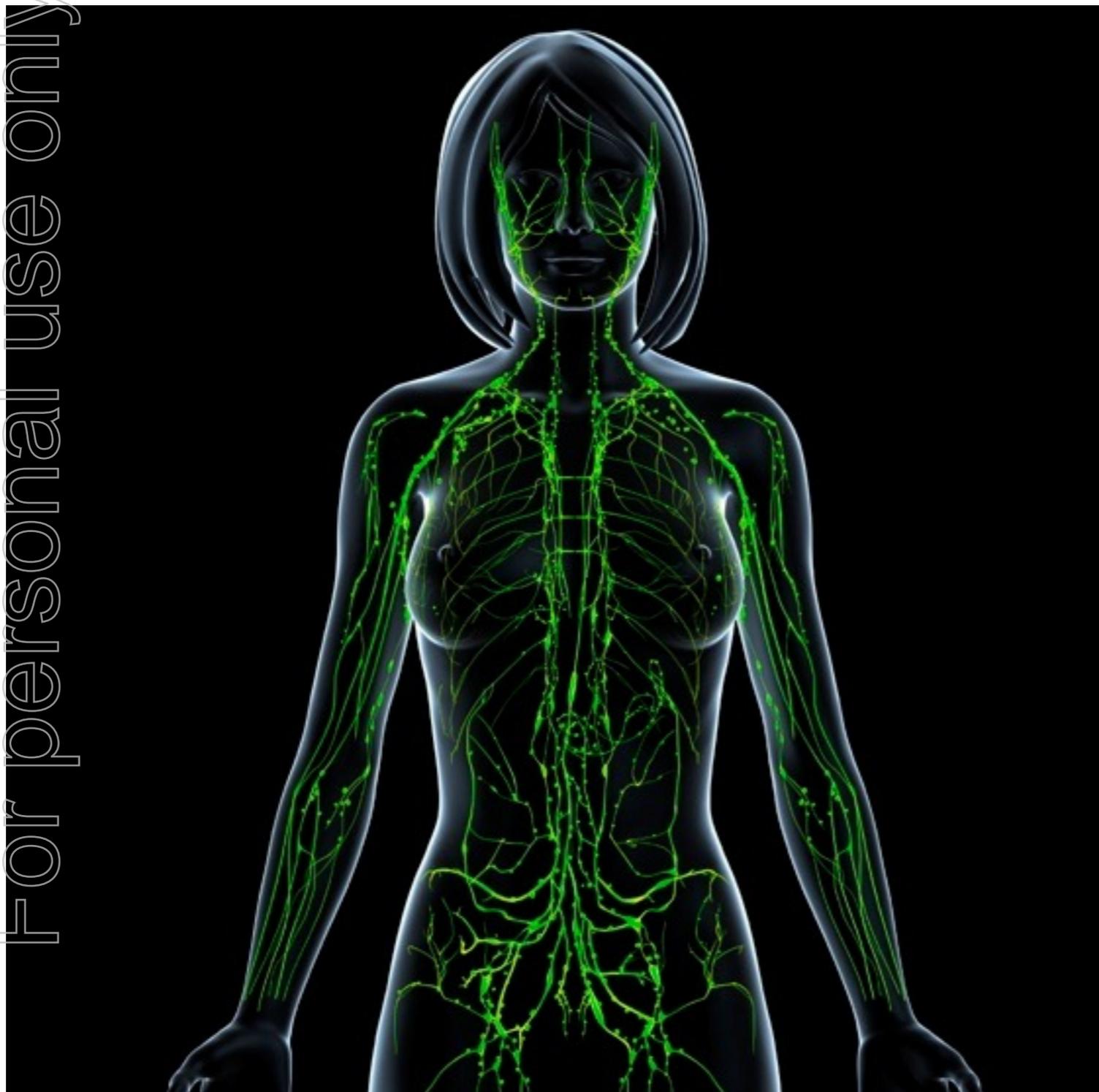
## Experienced and Influential



<p><b>Cherrell Hirst, AO FTSE MBBS BEdSt DUniv FAICD Non-executive Chairman</b></p>	<p>Cherrell Hirst is a medical doctor and was a leading practitioner in the area of breast cancer screening and diagnosis. Cherrell serves as the Chairman of the Board. Cherrell was appointed Deputy Chairman on 12 July 2011 and Chairman on 8 November 2011. Presently, she is also the Chair of ImpediMed Limited's Nomination Committee and serves on the Remuneration Committee and the Audit and Risk Committee. She is a Non-executive Director of Tissue Therapies Limited, Avant Insurance Ltd, Medibank Private Ltd and Telesso Ltd. Cherrell is the (part-time) Chief Executive Officer of QIC BioVentures.</p> <p>Cherrell's areas of experience include medical practice, with extensive experience as a breast cancer clinician, the medical/biotechnology industry and corporate governance.</p>
<p><b>David Adams, BS, JD Non-executive Director</b></p>	<p>David Adams is an experienced medical device business development and investment executive. His years in budgeting, ventures, divestitures and diligence give him an ability to review transactions and strategic planning from several different aspects of the transaction. His Medtronic career, in which he performed roles as VP Cardiovascular Business Development and VP Vascular Business Development and Ventures, included managing cross functional teams which integrated new businesses into the Company. The business model was applied successfully in 8 acquisitions and 4 divestitures.</p> <p>David has over 25 years of experience in tax, financial planning, and business development.</p>
<p><b>James Hazel, B.Ec, F Fin, FAICD Non-executive Director</b></p>	<p>Jim Hazel chairs the Audit and Risk Committee and serves on the Remuneration Committee and Nomination Committee. Jim had an extensive career in retail and investment banking and was formerly Chief General Manager of Adelaide Bank Limited. Jim is a Director of Bendigo &amp; Adelaide Bank Limited, Rural Bank Limited, Centrex Metals Limited, Coopers Brewery Limited and Motor Accident Commission. Jim is the Chairman of the Board of Ingenia Communities Group.</p> <p>Jim's areas of experience include finance and accounting, ASX listed companies, former CEO, chairman of audit committees and corporate governance.</p>
<p><b>Michael Panaccio, PhD, MBA, B.Sc (Hons), FAICD Non-executive Director</b></p>	<p>Michael Panaccio was appointed Chairman of the Remuneration Committee in July 2013, and serves on the Audit and Risk Committee and the Nomination Committee. Michael is an investment principal and founder of leading Australian venture capital firm Starfish Ventures, a venture capital manager focusing on investments in medical devices, therapeutics and IT companies. Michael and entities he is associated with including funds managed by Starfish Ventures hold approximately 13.6% of ImpediMed Limited's ordinary shares.</p> <p>Michael's experience includes more than five years with Singapore based venture capital firm Nomura/JAFCO investment (Asia) Limited and 12 years at Starfish Ventures. Michael has experience in capital raising, ASX listed companies, medical/biotechnology industry, mergers and acquisitions and corporate governance.</p>
<p><b>Scott R. Ward, MS, B.Sc Non-executive Director</b></p>	<p>Scott R. Ward is a Managing Director at SightLine Partners, a venture capital firm focused on direct, secondary investments in later stage medical device companies. He is also President of Raymond Holdings, a firm founded in 2011, with activities in venture capital, strategy and transactional advisory services. Mr. Ward has over 30 years of experience in the healthcare industry, including 15 years as an operating business leader. He was most recently Senior Vice President and President of the CardioVascular business of Medtronic Inc., responsible for all worldwide operations of the CardioVascular Business including the Coronary, Peripheral, Endovascular, Structural Heart Disease and Revascularization and Surgical Therapies Businesses. Previously, Mr. Ward served as Senior Vice President and President of Medtronic Neurological and Diabetes, with responsibility for the global Neurological, Neurologic Technologies, Diabetes, Gastroenterology and Urology businesses; Vice President and General Manager of the Medtronic Drug Delivery Business; and Director of Medtronic NeuroVentures.</p> <p>Mr. Ward is Chairman of the Board of Creganna-Tactx Medical Devices, Gillette Children's Specialty Healthcare, and Surmodics, Inc.</p>

# Lymphoedema

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**Lymphoedema is the build-up of fluid in soft body tissues when the lymph system is damaged or blocked.**

Lymphoedema occurs when the lymph system is damaged or blocked. Fluid builds up in soft body tissues and causes swelling. It is a common problem that may be caused by cancer and cancer treatment.

Lymphoedema usually affects an arm or leg, but it can also affect other parts of the body. Lymphoedema can cause long-term physical, psychological, and social problems for patients.



# Stages of Lymphoedema



**Stage 0** (or Ia) which refers to a latent or sub-clinical condition where swelling is not evident despite impaired lymph transport. It may exist months or years before overt oedema occurs (Stages I-III).

**Stage I** represents an early accumulation of fluid relatively high in protein content (e.g., in comparison with “venous” oedema) which subsides with limb elevation. Pitting may occur. An increase in proliferating cells may also be seen.

**Stage II** signifies that limb elevation alone rarely reduces tissue swelling and pitting is manifest. Late in Stage II, the limb may or may not pit as excess fat and fibrosis supervenes.

**Stage III** encompasses lymphostatic elephantiasis where pitting can be absent and trophic skin changes such as acanthosis, further deposition of fat and fibrosis, and warty overgrowths have developed.

International Society of Lymphology., The diagnosis and treatment of peripheral lymphedema. 2009 Consensus Document of the International Society of Lymphology. Lymphology, 2009. 42(2): p. 51-60