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## **ASX / PRESS RELEASE**

### **IMPEDIMED REAFFIRMS GROWTH PROSPECTS FOR THE US**

At today's AGM, Chief Executive Officer, Greg Brown announces to shareholders that with the recent U.S. FDA clearance for the Company's L-Dex™ U400 device, the company was now in a position to begin to grow revenues in the US market.

Mr Brown said now that the U400 was cleared to assist in the clinical assessment of unilateral lymphoedema of the arm in female breast cancer patients, this paves the way to roll out our marketing program across the US using ImpediMed's own sales force. This clearance marks the continued expansion of ImpediMed's lymphoedema index (L-Dex™) family of products and represents a major milestone achievement for the company, Mr Brown added.

ImpediMed's Chairman, Mel Bridges is upbeat about the company's prospects for growth in the next year, having almost doubled sales over the preceding financial year. The company will initially target breast surgeons, oncologists and therapists throughout the United States with its newly cleared device, Mr Bridges said.

We have already received strong signals from surgeons in relation to the adoption of Impedimed's L-Dex™ technology. The clearance for the U400 puts us in a position to focus our resources into the US market to build revenues ,” Mr Brown added.

With clearance for a range of devices in Australia, Europe and now the US, ImpediMed is positioned for expansion, Mr Brown said. The acquisition last year of San Diego based Xitron Technologies has given the company a strategically strong US base from which to manage its US roll out marketing campaign.

Mr Brown said “The L-Dex™ U400 is the product that has been designed for clinicians. It is a product with the improved features to assist in integrating into their busy practice environment, allowing them to deliver an improved level of care to their breast cancer patients. Through reimbursement schedules already in place – the patient and the healthcare provider both benefit from ImpediMed's technology.

The increasing belief from US experts in the area of managing breast cancer patients is that the early recognition of [lymphoedema](#), with prompt treatment,

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is the best way to assist in preventing and managing this important medical condition from progressing.

Lymphoedema can be an extremely debilitating medical condition, and if not detected early, may progress to an irreversible condition. Treatment often involves exercise, compression bandaging, pumps and manual lymph drainage. A recent finding from the US National Institutes of Health have demonstrated that preoperative assessment, using a standardised volumetric technique, can lead to an early intervention that effectively returns patients to a pre-surgical state, helping to protect their quality of life. The ImpediMed cleared U400 device has the potential to play a critical role in the management of breast cancer patients.

Mr Brown said the utilization of ImpediMed's U400 device and the associated L-Dex assessment could help facilitate preoperative assessment and ongoing surveillance as a standard of care globally for cancer professionals.

The company update presentation to be delivered at today's AGM is attached herewith.

To learn more, please visit [www.impedimed.com](http://www.impedimed.com) and [www.l-dex.com](http://www.l-dex.com).

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L-Dex™ is a trademark of ImpediMed Limited

#### **About ImpediMed**

ImpediMed Ltd. 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 to clinically assess patients for the potential onset of secondary lymphoedema. Pre-operative clinical assessment in breast 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 lymphoedema of the arm in female breast cancer patients. For more information, visit.

[www.impedimed.com](http://www.impedimed.com)

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**ImpediMed Limited**  
Surviving cancer without compromising lifestyle

October 2008 AGM business update

healthy lifestyle

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## Targeting Multiple Fluid Status Markets

**Fluid Status Market**

**Current Target Markets**

- Lymphedema markets**
  - Breast cancer focused
  - 4000-5000 breast surgeons
  - Also oncologists, therapists
- Medical Hydration market**
  - Fluid status device – assist DW
  - FDA denovo denied
  - RRI studies for Hy-Dex

**Future**

- Lymphedema markets**
  - Pelvic cancers
- Edema markets**
  - Venous insufficiency

healthy ImpediMed Ltd - Surviving Cancer Without Compromising Lifestyle lifestyle

## Key milestones and updates

- Publications this year – JCO, Lymphology (on BIS), Cancer publication on early detection benefit (Perometer)
- Xitron acquisition completed and new San Diego office base for operations
- Regulatory U400 filed in March 2008 and clearance in October 2008
- Reimbursement – Miscellaneous code being covered
  - Market analysis report completed
  - Doctors are using miscellaneous code and being covered
  - Miscellaneous codes can be lost overnight – serious implications
  - ImpediMed filing category one code in July 2009 for December 2010
- European distribution
  - Separating from the EDN agreement– key markets were not being covered
  - Progressing both European wide and country specific arrangements
- Northern Ireland guidelines and progress with trust hospitals
- Japan Distribution
  - Second largest market and progressing distribution options

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## Key milestones and updates

- Changing business model
  - L-Dex agreements – longer term impact
  - Initially moving away from sale of instruments
- Know your L-Dex Campaign & Media coverage
  - Houston, Dallas, San Diego, Chicago, Tucson
  - New York Times, LA Times, TV media
- Increasing direct US sales team – USD impact both on revenues and costs
  - California, Dallas, Chicago, Philly, Florida, Boston
  - Wanting NY and DC representatives and more technical support
- Activist Support
  - NPAF
    - Surgeon education initiatives, CMS and RUC support
    - Federal law update
    - reimbursement hotline
  - Susan Koman “Race for the Cure”
  - Avon Foundation – 80 reference hospital mailing
- Metagenics Contract



## Reimbursement - Women's Health and Cancer Rights Act of 1998 Requires Coverage for Lymphedema Care

### COVERAGE OF LYMPHEDEMA TREATMENT (HR 4328 (Public Law 105-277))

- Required coverage for reconstructive surgery following mastectomies, SEC. 713:
  - Payers must provide a mastectomy patient, coverage for "prostheses and physical complications of mastectomy, including lymphedemas"
  - The payer may not deny patient eligibility or limit reimbursement of an attending provider
  - These provisions do not block any State laws or ERISA
- In addition to this federal law, there are now 22 state laws with similar requirements

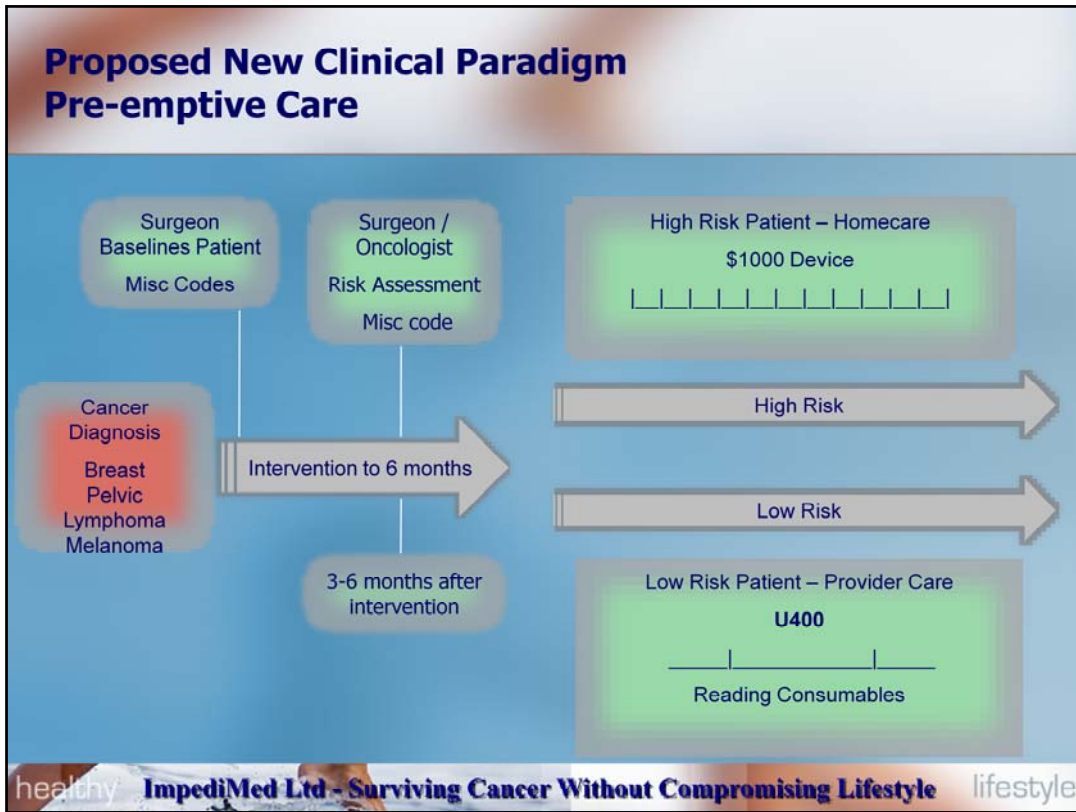
## Reimbursement Category 1 Code Submission July 09

Requirements for submission – progressing well

- US peer reviewed data – on early detection and benefit of early detection
- U400 FDA clearance in place
- Placing U400 from July 2009 to support submission requirements – targeting 150 accounts
- Use of miscellaneous codes supports CPT application
- Lobbying support from Society Coding & Reimbursement Committees
- RUC process – CMS role for setting payment



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## Commercial and Regulatory Status Uni-lateral Arm

### L-Dex XCA



- First **FDA cleared** medical device for the clinical assessment for uni-lateral lymphedema of the arm
- Single low frequency – patented
- Uni-lateral arm only – control limb
- Distribution models for home
- Longer term homecare product

## Commercial and Regulatory Status Uni-lateral Arm

### L-Dex U400



- BIS Device
- Development complete
- Targeting the clinical assessment for uni-lateral lymphedema of the arm
- Uni-Leg submission target FY09
- FDA submission filed March 08, clearance October 08
- Over 10 years of peer reviewed science since 1996 built on BIS

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## Moving to Beta version Unilateral and bilateral arms and legs



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## Results Financial Year 2008

	<b>FY2008</b>	<b>FY2007</b>
Sales	2.213M	1.195M
Revenue	2.994M	1.418M
EBITDA	(7.639M)	(6.628M)
NPAT	(9.754M)	(10.126M)

- Sales up 92.9% versus FY2007
- Increased operating loss a reflection of investments in creating a market for L-Dex products in the key United States market.