



16 October 2008

## **ASX ANNOUNCEMENT/PRESS RELEASE**

### **IMPEDIMED BREAKS NEW GROUND WITH FDA CLEARANCE FOR CLINICAL ASSESSMENT IN FEMALE BREAST CANCER PATIENTS**

Impedimed CEO, Greg Brown today announced that ImpediMed had received U.S. FDA clearance for the company's L-Dex™ U400 device now cleared to aid in the clinical assessment of unilateral lymphoedema of the arm in female breast cancer patients.

This clearance marks the continued expansion of ImpediMed's L-Dex™ family of products and represents a major milestone achievement for the company.

Mr Brown said the FDA clearance paves the way for ImpediMed to directly launch the device into the US market.

"ImpediMed will market the L-Dex™ U400 device directly through its own US sales force and will initially target breast surgeons, oncologists and therapists", he said.

"The FDA clearance of the L-Dex™ U400 device puts us in a strong position to build increasing awareness in ImpediMed's target markets to assist in driving the adoption of the L-Dex™ technology" said Mr Brown.

"ImpediMed is positioned for expansion now with the clearance for the device in the US market This combined with the establishment of a US operations headquarters in San Diego last year, puts the company in a strong position with a strategically strong base from which to manage its US marketing campaign".

"The L-Dex™ U400 will be the first of ImpediMed's L-Dex™ products designed specifically to meet the needs of the routine clinical environment".

"The L-Dex™ U400 is the product that clinicians have been waiting for. It is a product suited to their busy practice environment, allowing them to deliver an improved level of care to their breast cancer patients."

"The increasing mantra from US experts in the area of managing breast cancer patients is the recognition that pre-operative assessment, early detection and treatment of [lymphoedema](#) is the best way to prevent and manage this important medical condition", said Mr Brown.

For personal use only

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. Recent findings from the US National Institutes of Health have demonstrated that periodic assessment and early intervention can effectively return patients to pre-surgical state and help protect their quality of life<sup>1</sup>. Please note a standardised volumetric technique was used in this study for early assessment.

Mr Brown said “the ImpediMed L-Dex™ U400 device has the potential to play a critical role in the pre-operative assessment and management of lymphedema in female breast cancer patients”.

“ImpediMed’s L-Dex™ technology utilizes the characteristics of frequency dependent current flow to quantify changes in extra-cellular fluid in the patient’s limb. These changes can aid the physician and other medical professionals in the clinical assessment of patients for the early signs of lymphoedema”.

“ImpediMed’s L-Dex™ technology has demonstrated in peer reviewed studies to be specific and sensitive in the measurement and monitoring of extra-cellular fluid associated with post operative breast cancer patient”, said Mr Brown.

Mr Brown said ‘The utilization of ImpediMed’s L-Dex™ U400 device could assist significantly in driving a new emerging clinical standard of care for medical professionals in their management of lymphedema”.

## **ENDS**

### **For further information contact:**

<b>Greg Brown</b>	<b>Impedimed CEO</b>	<b>+61-7-3860-3700</b>
<b>Stephanie Paul</b>	<b>Phillips Group</b>	<b>+61-7-3230-5000 or +61-418-753-062</b>

### **Notes**

- 1. Preoperative Assessment Enables the Early Diagnosis and Successful Treatment of Lymphedema, *Cancer* Vol 112/ Issue 12, June15, 2008 pp. 2809-2819.**

The L-Dex™ technology is further described by the recent release of an article by Dr Steven Schonholz on ‘Effective Ways of Managing Lymphedema’ published in the No 102 September 2008 Breast Center Bulletin published by the National Consortium of Breast Centers, Inc, in the United States.

L-Dex™ is a trademark of ImpediMed Limited

**L-Dex devices are not intended to diagnose or predict lymphedema of an extremity.**

**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 had 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).

For personal use only