



**ASX ANNOUNCEMENT**  
**18 April 2008**

## **HeartWare Announces Move to an Expanded, Upgraded Manufacturing Facility**

**Framingham, MA and Sydney, Australia:** HeartWare Limited (ASX: HTW) today announced that it is moving to an expanded, upgraded manufacturing facility in Miami Lakes, FL, USA. The new 59,000-square-foot facility, which is nearly twice the size of HeartWare's current facility, will enable a scaling up in manufacturing output and is expected to meet all of the Company's operational needs indefinitely.

The new facility, currently leased by Cordis Neurovascular, Inc., a division of Johnson & Johnson, includes fully-fitted offices, laboratories, wet labs, R & D facilities, conference rooms and executive meeting areas. Most importantly, it includes three clean rooms all of which are presently ISO Class 100,000 compliant and fully operational. The total clean room space exceeds 10,000 square feet.

The facility move, to be completed by the end of May, is not expected to impact the timing of HeartWare's regulatory process in the United States. HeartWare is working with the U.S. Food and Drug Administration (FDA) on the Company's application for an Investigational Device Exemption (IDE) to start a U.S. clinical trial for the HeartWare<sup>®</sup> LVAD System. Subject to approval from the FDA, HeartWare anticipates the U.S. trial to start during the current quarter.

The facility move will impact HeartWare's European regulatory timeline since the need for ISO certification is a key requirement for a CE Mark submission. HeartWare will schedule a regulatory audit of the facility as soon as practical following the completion of the move. This is expected to lead to receipt of CE Mark during the second half of 2008.

HeartWare Chief Executive Officer Doug Godshall said the new facility offered the opportunity to relocate to a high quality, purpose-built medical device facility at a significantly lower rental rate while also saving HeartWare the multi-million dollar costs and time to upgrade the clean room infrastructure at its current facility. In addition, as part of the agreement, HeartWare will acquire a number of items of specialist equipment at a nominal upfront cost.

"The decision by Cordis to relocate its neurovascular device manufacturing activities has proven extremely fortuitous for HeartWare," Mr. Godshall said. "It presents the opportunity for HeartWare to move into a fully equipped state-of-the-art medical device facility with sufficient manufacturing capacity to meet the anticipated rapid growth in demand for our products over coming years."

The new facility, located at 14000-14050 NW 57th Court, Miami Lakes, Florida, USA, is approximately 6 miles from HeartWare's current location in Miramar. HeartWare will relocate to the new facility in stages and take control of the clean rooms over a four- week period commencing on



April 28. The leasehold agreement is for an initial term of three years and includes the option to extend for two consecutive periods of five years each

### **About HeartWare**

HeartWare develops and manufactures miniaturized implantable heart pumps, or Left Ventricular Assist Devices (LVADs), designed to treat patients suffering from advanced heart failure. The Company is developing the industry's smallest and least invasive pumps, which it believes will be the key to unlocking the potential of a large and underserved market. The HeartWare<sup>®</sup> LVAD is a full-output pump designed to be implanted in the chest, avoiding the abdominal surgery generally required to implant competing devices. The device is currently the subject of an international clinical trial involving five investigational centres in Europe and Australia. A clinical trial in the U.S. is expected to begin in the first half of 2008.

For further information:

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