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## ASX ANNOUNCEMENT

### 22 July 2009

# Fermiscan Breast Cancer Test now "CE Marked"

Fermiscan is pleased to announce that 'The Fermiscan Breast Cancer Test' has now been "CE Marked". The CE Mark indicates that the test can be freely marketed anywhere in the European Union and that the company has satisfied the relevant Essential Requirements in the EU's Medical and Healthcare Products Regulatory Agency directives that its product conforms and that it is fit for its intended purpose.

Fermiscan has begun to establish the necessary infrastructure in Europe to drive a commercial roll out of the test.

Gary Garton Chairman Visit Fermiscan's website at <u>www.fermiscan.com.au</u>

### About Fermiscan

Fermiscan's principal activity is the commercialisation of an innovative non-invasive diagnostic test for the detection of breast cancer.

The Fermiscan Breast Cancer Test is based on the discovery by an Australian scientist that a change can be detected in the molecular structure of hair from women with breast cancer and this change can be identified by using diffraction of X-rays generated in a synchrotron.

Fermiscan completed a major clinical trial of the Fermiscan Test in May 2008, with sensitivity (ability to accurately detect cancer) of 74% in women under 70, and with a higher sensitivity for younger women; and specificity (ability to accurately detect the absence of cancer - negative predictive value) of 99.5%.

Fermiscan is developing opportunities to licence and sell the Fermiscan Test internationally, particularly in Australia, Europe, Japan, South East Asia, and the United States.

Fermiscan owns and operates the Sydney Breast Clinic, one of the largest diagnostic breast clinics in Australia that for more than 30 years has been caring for over 10,000 women annually.

With clinical trials successfully concluded, commercialisation of the Fermiscan Test is progressing to plan in 2009.

#### **Recent announcements**

- Patents granted in Japan and European Community countries
- Exclusive option agreement to licence the Fermiscan Test to Hitachi Chemical in Japan and Korea granted in March 2009
- Italian independent study (123 patients) completed in March 2009 with sensitivity (ability to accurately detect cancer) of 83% and specificity (ability to accurately detect the absence of cancer) of 76%
- Independent European multi-centre trial of the Fermiscan Test is underway and will support commercialisation in Italy and Europe
- European CE Mark registration of the Fermiscan Test completed in July 2009
- Australian Synchrotron agreement signed in February 2009 securing beamline access for two years
- Named 2008 'Australian Innovator of the year' at the Austrade sponsored annual 'Innovation Day Shoot Out' competition in New York.

Fermiscan is a member of the Australian Technology Showcase, a national program aimed at promoting and developing export markets for innovative technology based products. Fermiscan has received support from the NSW Department of State and Regional Development through its various programs such as BioBusiness and BioFirst

Visit Fermiscan's website at <u>www.fermiscan.com.au</u>

Visit Sydney Breast Clinic's website at www.sydneybreastclinic.com.au