

## **ASX ANNOUNCEMENT**

**24 July 2009**

### **Status of trials and progress towards commercialisation in Europe**

As previously advised, the National Health Service of Italy (Unit ASLto5) has announced the completion of their first independent trial of the Fermiscan Test. The results achieved were 83% sensitivity (ability to accurately detect cancer) and 76% specificity (ability to accurately detect the absence of cancer) on a population base of 3,508 people, with 123 participants.

The Breast Screening Coordinator for the unit in Turin Italy, Dr S. Polizzi commented, *"This is a good preliminary result, well within the European Guidelines. We are proceeding now with a multi Centric Trial in France and Italy to further demonstrate the use of the Fermiscan Test, in particular to study its initial use as a pre menopause screening system in Europe, and as a pre screening tool to increase the coverage and efficiency of regular Mammographic screening"*.

Two larger coordinated trials are ongoing with the Piedmont Region National Health Service (ASLto5) and the Iserre Department National Health Service in France (ODLC). Results are expected in November 2009. The trials are being managed by the Piedmont Region Centre for Oncological Prevention (CPO) and have been approved by the relevant Ethics Committees.

A trial is currently ongoing in Egypt (Mansoura University Hospital) to evaluate the utility of the Fermiscan test in a low income setting.

Legal advice has been received that the Fermiscan Test is a "Diagnostic Procedure" and therefore, should not require further individual licensing in the European Union.

With completion of these trials, and the expected publication of their results in relevant medical publications, work is now commencing to automate the Fermiscan testing operations on our beam line at ESRF Grenoble, with the goal to facilitate European commercialisation.

Gary Garton

Chairman

Visit Fermiscan's website at [www.fermiscan.com.au](http://www.fermiscan.com.au)

## **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 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 [www.fermiscan.com.au](http://www.fermiscan.com.au)

Visit Sydney Breast Clinic's website at [www.sydneybreastclinic.com.au](http://www.sydneybreastclinic.com.au)