



# **Fermiscan Holdings Limited**

ABN 51 000 689 725

**Managing Directors Report  
Annual General Meeting  
May 2007**

# Significant milestones achieved

- **Original discovery replicated in scientific and validation trials**
- **Validation trials progressed**
- **Patent and trademark protection enhanced**
- **International licensing commenced**
- **Financial position strengthened**
- **Synchrotron operations commenced**

## Discovery replicated in trials

**In December 2006 Fermiscan announced that using two different beam lines scientists were able, on each beam line, to successfully replicate the results obtained by the original inventor**

**In April 2007 Fermiscan announced the initial results from the 2000 patient study. The announcement said**

**“Fermiscan has recently completed initial trial results from a small sample of only 107 of the 2,000 patient trial, which whilst inconclusive due to the small sample size, are however encouraging with regard to Fermiscan’s ability to identify patients as being positive for breast cancer and importantly also being able to correctly identify women with no sign of breast cancer”**

**These initial trial results, together with the results of previously published research, suggest that the Fermiscan test has the potential to be used as both a positive indicator and a negative predictor for breast cancer.**

# Clinical trials

- **In January 2007 Fermiscan commenced a 2,000-patient validation trial with the support of major radiology and diagnostic groups**
  - **Approximately 1300 samples from 12 clinics have been collected**
  - **Patient enrolment continues to progress and it is anticipated the trial will be completed in the middle of 2007**
  - **Results of 107 samples have been released with plans for completion on track**
- **This trial is designed to assess the effectiveness of the Fermiscan breast cancer test in a screening situation by testing the hair of women referred to radiologists for mammograms**
- **Results will compare mammogram and pathology results with the results from the Fermiscan breast cancer test**

## Clinical trials - continued

- **A trial on the potential of the Fermiscan breast cancer test for monitoring of breast cancer patients undergoing treatment is underway in a leading hospital in Australia**
- **Negotiations are currently taking place to carry out International trials on known cancer patients in Italy and the USA**
- **Beam time access in the USA has been secured for all trials**
- **Successful trial completion will enable commercialisation through a pilot rollout in the last quarter of 2007**
- **the Fermiscan Ethics Committee was established as an independent body to protect patient welfare and govern the company's clinical trials.**
- **The Fermiscan Ethics Committee has been approved and registered by The National Health and Medical Research Council.**

# Patent and trademark protection

**Patents on the intellectual property have been granted in Australia, NZ and the USA, and have around 18 years to run.**

**Our Patent and Trademark has been significantly strengthened since Fermiscan was listed.**

**Significant events include:**

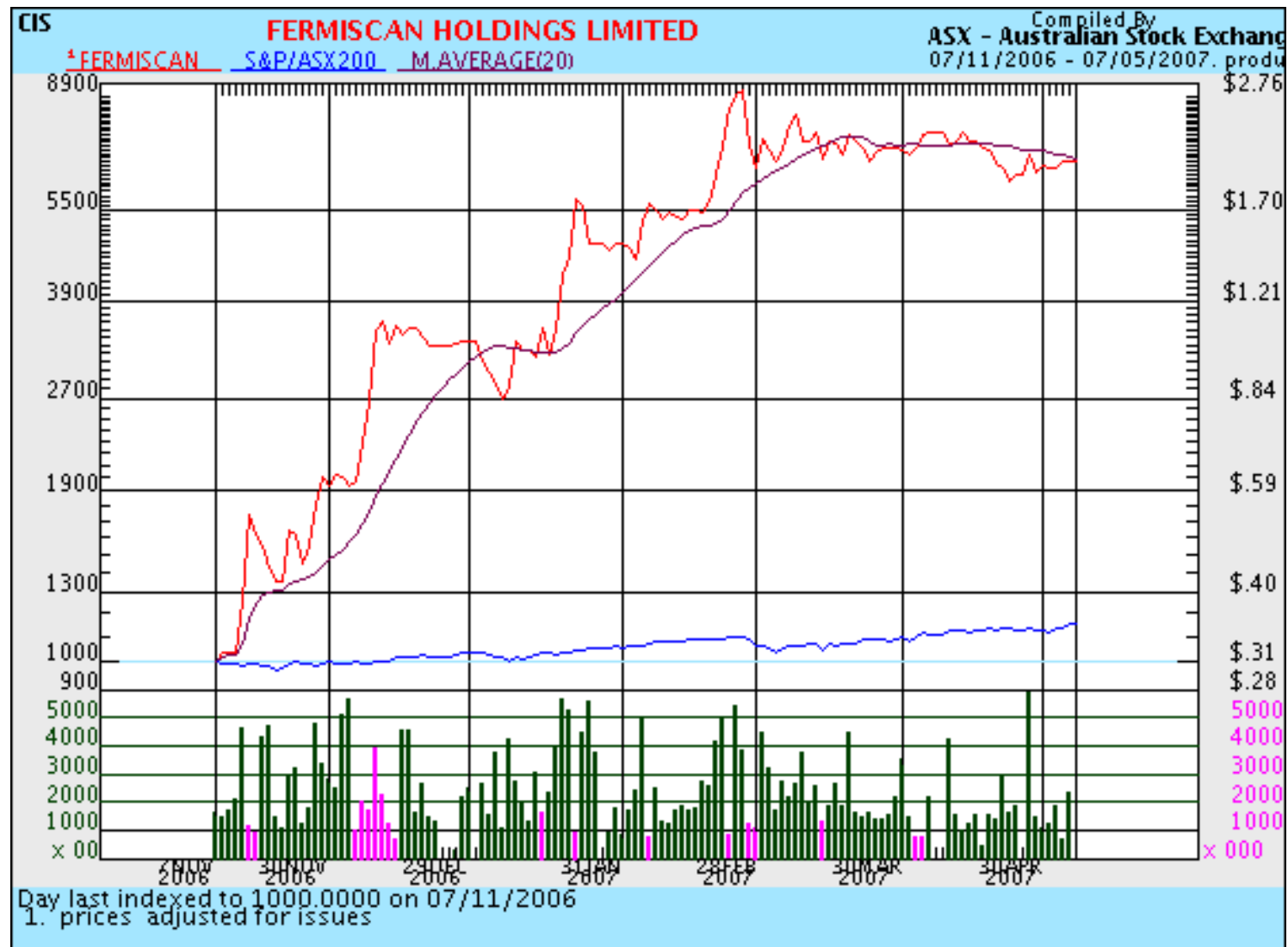
- **Registration of the trademarks “Fermiscan” and “Fiberscan” in Australia**
- **International application for Fermiscan trademark**
- **European patent application progressing well towards granting**
- **Japan patent application has entered examination phase**
- **Canadian application pending**
- **Three new patent applications have been lodged which add protection to the entire commercial operations from hair collection to processing of sample and production of result**

# International licensing progress

## **Fermiscan commenced international licensing initiatives**

- **Avia Reed International Pte Ltd has been granted rights to market and sell the Fermiscan test in Singapore, Hong Kong, Indonesia, Malaysia, Thailand and Vietnam. Avia Reed International management has extensive medical experience, including ownership and management of medical centres, and pathology and outpatient clinics.**
- **Fermiscan announced a feasibility study with leading merchant banking and asset management group Crosby Capital Partners Inc. to commercialise its non-invasive test for breast cancer in Japan. 14 million mammograms are performed every year in Japan with a potential relevant population for the Fermiscan breast cancer test estimated at 38 million women.**

# Financial status





# Financial status

**Several significant events have occurred since the previous shareholder meeting in January**

- **\$22.5 million raised in a share placement on 16 February 2007 and issued 15 million new shares at \$1.50 strengthening both the balance sheet and share register**
- **Synchrotron beam time negotiations have resulted in confirmation of costs and contracts for 2007**
- **Licensing agreements for six Asian countries have been put in place**
- **Operational costs have been reviewed and this, together with the points above, provides reasonable grounds by which the company can now provide a sensitivity analysis which compares the assumed cost and profitability models at various volume thresholds**

# Financial sensitivity analysis

**The following sensitivity analysis is provided on the basis that it is dependant upon the successful completion of the current trial and that the company can not assess at this time the market penetration of the test globally.**

**Given a potential global market in excess of the 100 million mammogram's conducted annually and the knowledge now at hand regarding pricing, regulatory approvals, costs and potential profitability, the sensitivity model contains conservative potential test volumes which are considered by the company to be reasonable**

- Fermiscan would like to point out that a sensitivity analysis by it's very nature**
- Is predictive in character**
- May be affected by inaccurate assumptions or known or unknown risks and uncertainties**
- May materially differ from the results ultimately achieved**

# Key sensitivity analysis assumptions

## The sensitivity analysis

- Shows a range of Fermiscan breast cancer test volumes for a fully operational year including 100k, 300k and 500k test volumes for a national roll out in Australia
- Shows a 1 million test volume which includes 500k roll out in Australia and 500k through international licences
- Implies a successful outcome from clinical trials
- Implies public and medical acceptance and uptake of the Fermiscan breast cancer test in Australia and internationally
- Is based on a full year where the business is established for the volumes indicated and therefore includes regular annual expenditure
- Shows EBITDA and does not include capitals costs, depreciation or amortisation
- Does not include any government subsidies
- Includes 2.5% of gross sales allocated to research and development
- Includes in cost of sales inventor royalty payments, retail margin, distribution and administration, packaging and data storage

# Key sensitivity analysis risk factors

- **Successful outcome from Clinical trials**
- **Regulatory risks in countries where the Fermiscan breast cancer test is to be commercialized**
- **Public and medical acceptance and uptake of the Fermiscan breast cancer test**
- **Synchrotron operational issues or significant cost increases**
- **Development by third parties of a competitive alternative breast cancer test**
- **Normal and usual business and intellectual property risks**
- **Managing the growth and expansion of operations and facilities**
- **Ability to attract and retain suitably qualified staff**

# Financial sensitivity analysis

<b>Fermiscan tests</b>	<b>100k</b>	<b>300k</b>	<b>500k</b>	<b>1,000k **</b>
	\$'s millions	\$'s millions	\$'s millions	\$'s millions
Gross revenue	22.6	67.9	113.2	181.6
Cost of sales	5.7	14.5	21.4	42.5
<b>Gross profit</b>	<b>16.9</b>	<b>53.4</b>	<b>91.8</b>	<b>139.1</b>
Corporate costs	3.8	5.6	8.3	9.0
Sales & marketing	3.1	5.6	7.3	7.6
Business operations	1.3	2.4	3.6	3.8
Research & development	0.6	1.7	2.8	5.7
Laboratory	4.8	8.1	9.1	9.7
<b>Expenses</b>	<b>13.6</b>	<b>23.4</b>	<b>31.1</b>	<b>35.8</b>
<b>EBITDA</b>	<b>3.3</b>	<b>30.0</b>	<b>60.7</b>	<b>103.3</b>
** Includes 500k tests via licencees				

# Synchrotron operations

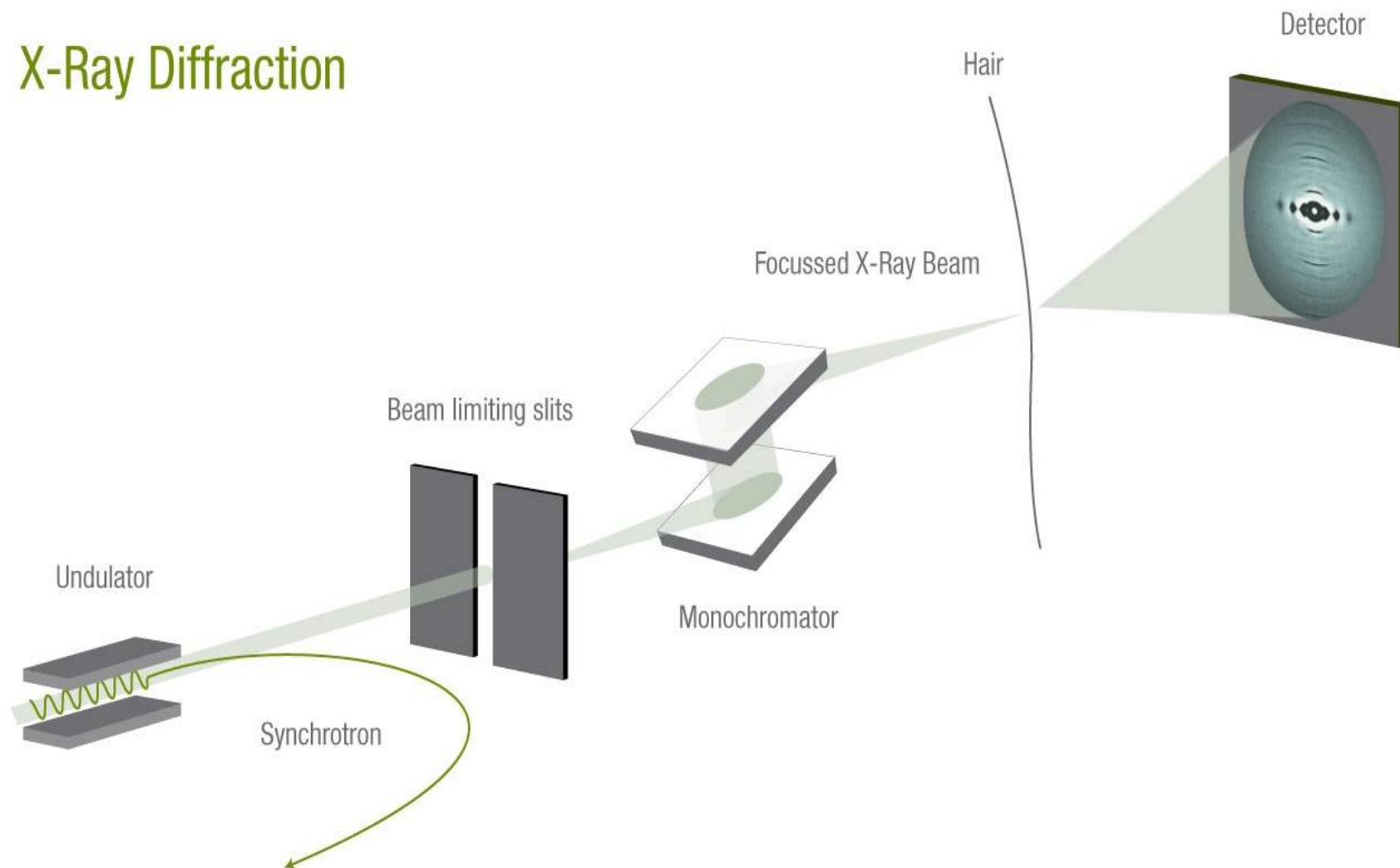
- The beam line on which the recent trial analysis was conducted has now been secured for the remainder of 2007 and has sufficient capacity to complete trials and the initial commercialisation roll out
- Negotiations are nearing completion for access time which will enable test volumes at the upper end of the sensitivity analysis as early as 2008
- Automation enhancements are showing considerable potential for substantially higher productivity rates than currently forecast
- Support teams are in place utilising both Fermiscan staff and beam line partner teams in the USA
- Discussions are underway with the Monash Synchrotron in Melbourne
- Video

# USA testing facility- Argonne Chicago



The Advanced Photon Source at the Argonne National Laboratories, USA

# X-Ray Diffraction





**Thank you  
for your attendance and  
support**