

# Sirtex Medical Limited

## Market Update

### 2011 Half Year Results

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9-10 March 2011

*SIR-Spheres® is a registered trademark of Sirtex SIR-Spheres Pty Ltd.*

SIRTeX

# Understanding the Sirtex growth story....

## Background

- Sirtex is an Australian medical device company, ASX listed with a unique product for the treatment of liver cancer
- SIR-Spheres microspheres use highly targeted radiation to treat liver tumors in a procedure called Selective Internal Radiation Therapy (SIRT)
- SIR-Spheres microspheres were developed in Australia by Dr Bruce Gray
- Liver cancer now the third most common cause of cancer mortality
- First commercial sale in 2002 after approval by the FDA, CE Mark and TGA.
- SIR-Spheres microspheres are now sold globally in over 25 countries

# Understanding the Sirtex growth story ...

## The past six years

- SIR-Spheres microspheres market acceptance has been constrained by insufficient Level 1 clinical data
- SIR-Spheres microspheres are still in their infancy and used primarily in a “salvage” setting addressing less than 1% of the liver cancer market
- By applying good management practices Sirtex has transformed from a loss making company into a profitable business
  - Revenue grew from \$11.8 million in FY05 to \$64.3 million in FY10
  - Market cap grew from \$78 million (June 05) to \$273 million (June 10)
  - Cash reserves grew from \$6.8 million (June 05) to \$41.4million (June 10)
  - Paid first dividend of \$3.9 million in 2009 and again in 2010

# Understanding the Sirtex growth story ...

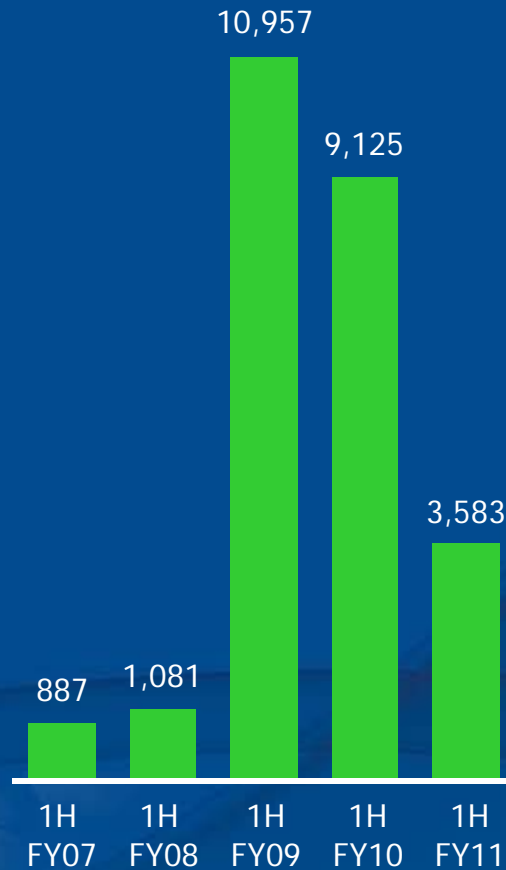
## Today

- Sales growth will continue at similar if not accelerated rates in the next few years then will see a step change increase as Level 1 clinical study data is released
- Investing today to enable both short term and long term growth
  - Sales & Marketing – Increased direct sales and support structures, building the referral base and entering new markets
  - Operations – Strengthening the supply chain, installing capacity to improve service Sirtex's growing market
  - Support teams – Building infrastructure to enable global growth
  - Clinical Studies – Established a portfolio of Level 1 clinical studies to enable a step change in acceptance of SIR-Spheres microspheres
  - R&D – Increasing investment in a pipeline portfolio of new technologies
- Growing awareness and acceptance of SIR-Spheres microspheres evidenced by 73 peer reviewed medical papers published in 2010 compared to 15 in 2005

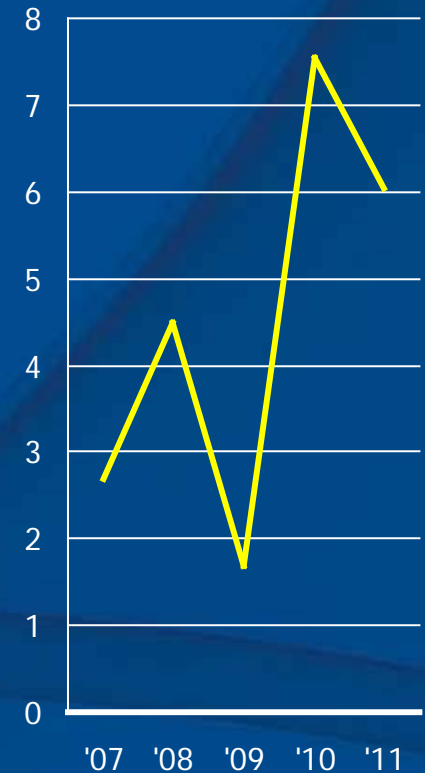
# Selected financial snapshot at 1H FY11

- ASX: SRX
- Market cap: \$314 million
- Stock on issue: 55.8 million
- 1HY product sales: \$34.0 million
- 1HY NPAT: \$3.6 million
- Cash @ 31 Dec 10: \$41.2 million
- Top-20 holders: 84.4%
- Major holders:
  - Hunter Hall 31%
  - ACN132442114 26%
  - Platypus 11%
  - Citicorp Nom. 4%
  - Equity Trustees 2%









Net profit after tax  
\$ thousands



Share price  
\$ price at 31 Dec



# Summary of First Half FY2011 result

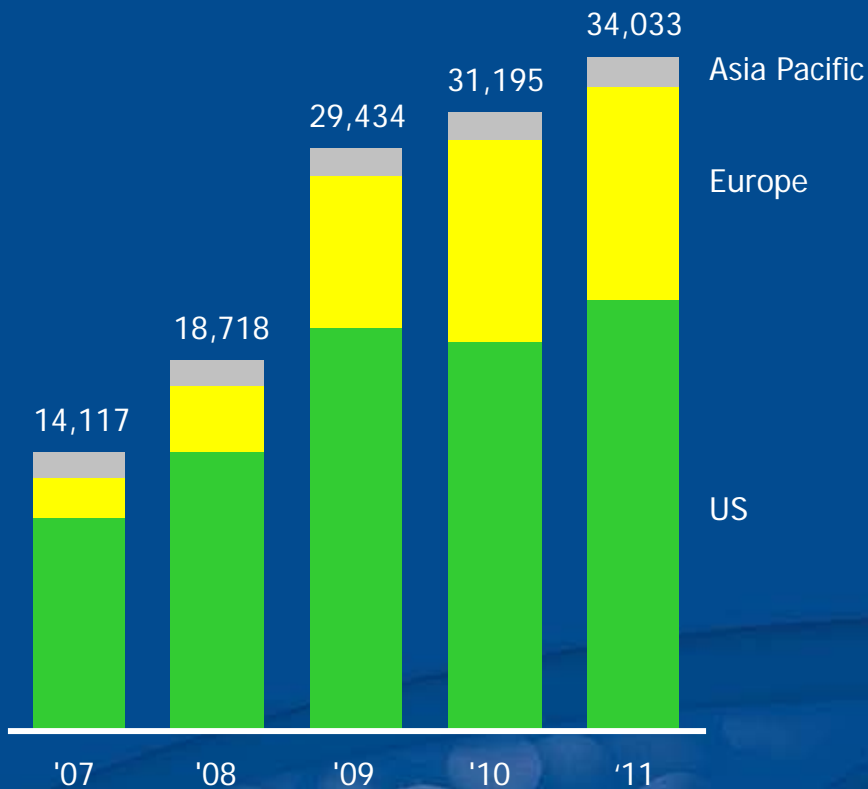
Key measure of dose sales	2,325 units	 16.5%
Product revenue	\$34 million	 9.1%
Operating profit	\$5.7 million	 39.4%
Profit before tax	\$6.6 million	 59.7%
Net profit after tax	\$3.6 million	 60.6%
Earnings per share	6.4 cents	 61.0%
Operating cash flow	\$6.4 million	 45.3%
Cash on hand	\$41.2 million	 20.5%

# Summary of key drivers behind 1H FY11 result

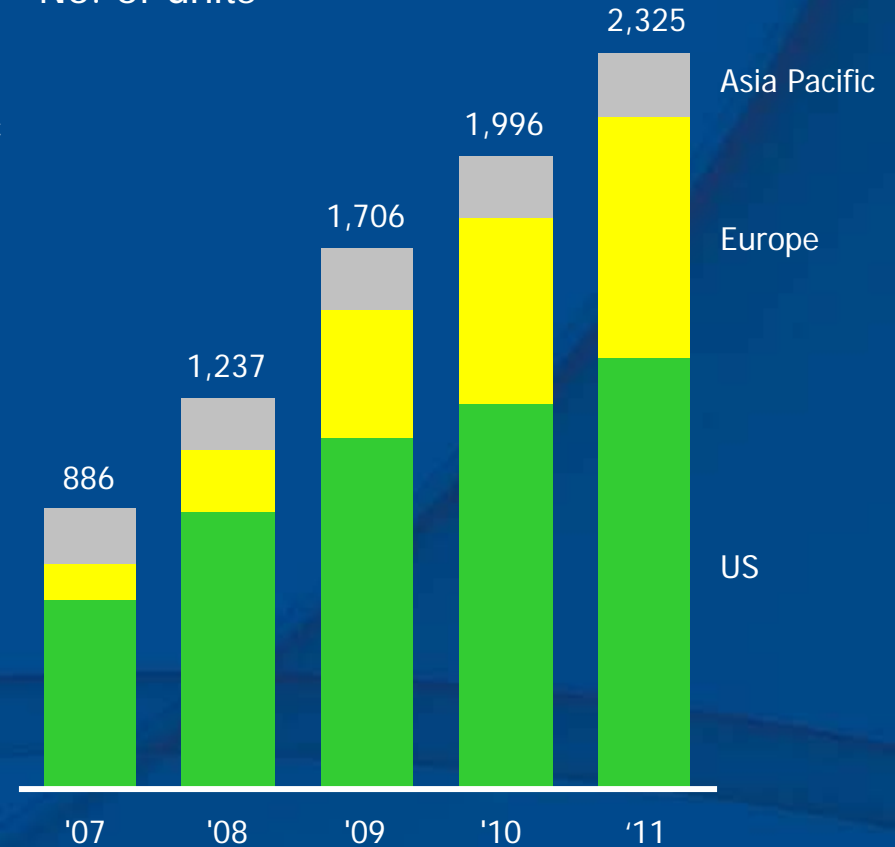
- **Product dose sales growth remains strong across all regions**
  - Europe up 29%, US up 12.3%, Asia Pacific up 3.6%
- **Strategic increased investment in sales, clinical, marketing, R&D**
  - In line with our long term global growth strategy
  - Staff numbers up 30% as we build capacity and capabilities
- **Foreign Exchange (USD/EUR) remains a challenge for all AU exporters**
  - \$2.1 million FX loss vs \$1.6 million 1H FY10
  - AUD up 12 % against USD and 23% against Euro
- **Clinical awareness expanding in all geographic markets**
  - Clinical support teams doubled
  - SIRFLOX global study recruitment up 62%
- **Significant increase in cost of goods by key Australian supplier**
  - 100% price hike by ANSTO Radiopharmaceuticals (ARI)

# 1H FY11 key metric of dose sales remains strong

Sales revenue  
\$ thousands



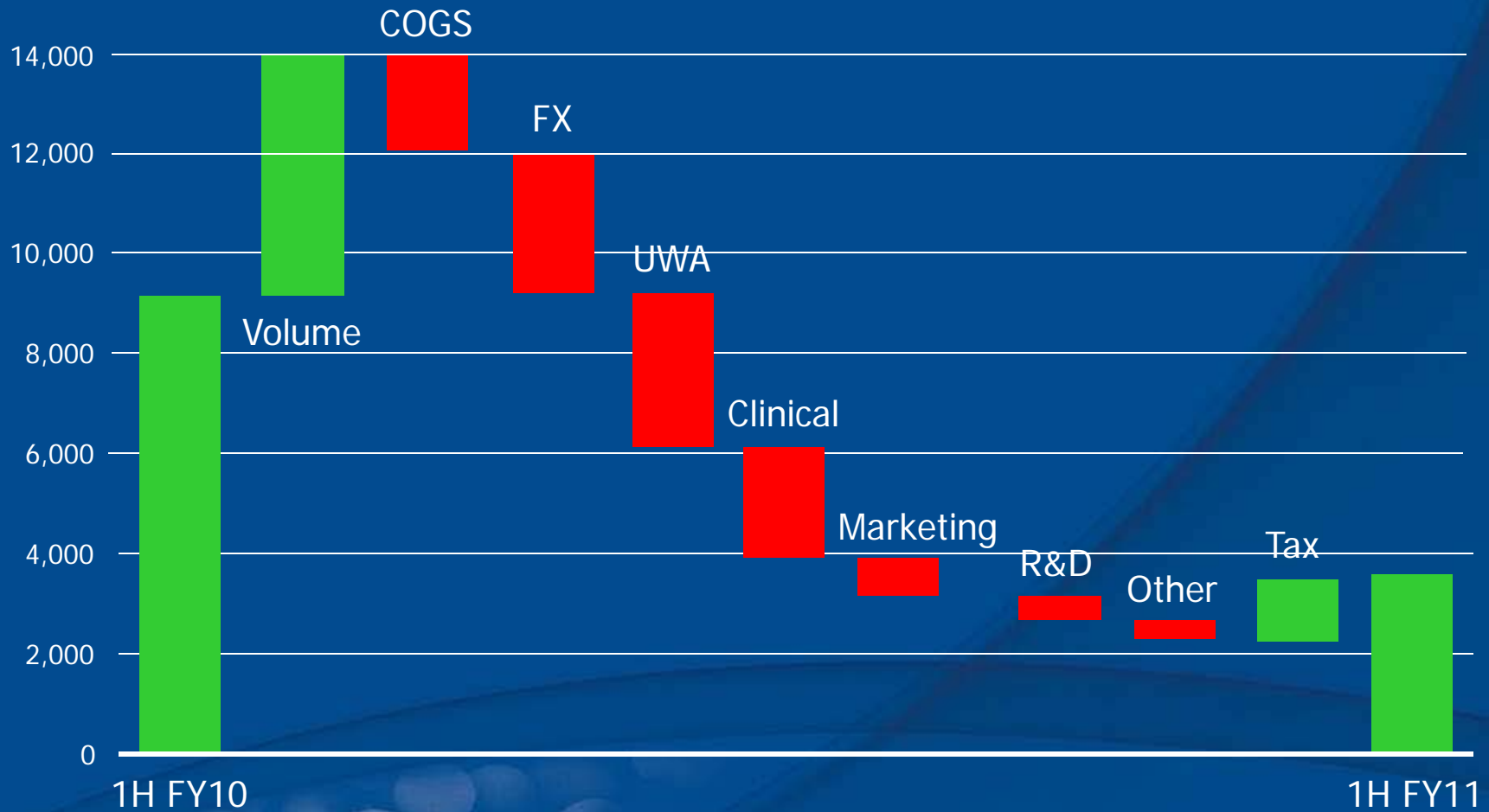
Dose sales  
No. of units





# 1H FY11 NPAT reconciliation

\$ thousands



# Legal update

- Sirtex was successful in the UWA Proceedings against UWA and Dr Gray. Sirtex incurred in excess of \$5.5 million in legal costs and expenses and have recovered \$3.25 million from UWA and \$2.57 million from Dr. Gray. These amounts have been paid by UWA and Dr Gray and the UWA proceedings have been concluded.
- Dr Gray filed an appeal against the assessment of damages in Sirtex's favour. Sirtex is defending the appeal which was heard by the Full Court on 23 February 2011. We expect judgment of the Full Court to be delivered in 3 to 4 months.

# Understanding the Sirtex growth story ...

## Sales & marketing

- Investment in sales & marketing grew to \$10.3 million in 1H FY11
- Limited Level 1 clinical data continues to restrict greater acceptance of SIR-Spheres microspheres
- Strategies have been developed to continue sales growth including:-
  - Increasing Sirtex's direct sales and support resources
  - Entering new geographic regions
  - Providing support to hospitals and patients to obtain reimbursement
  - Building awareness in the referral community through targeted small group meetings, symposiums and education
  - Building awareness with patient advocacy groups

# Sales & marketing – USA

- 59% of dose sales and 64% of sales revenues in 1H FY11
- Added several new treatment centres, expanded sales and clinical support teams
- Focused on supporting higher volume treatment centres
- Educating the national referring physician base and raising visibility among clinical community and KOLs
- Assisting patient support groups and using media to drive greater awareness and interest
- Expanding into Canada and planning entry to Latin American market

# Sales & marketing – Europe

- 33% of dose sales and 32% of sales revenue in 1H FY11
- Active program to drive public and private reimbursement and expand referral base and treatment centres
- Raising visibility among KOLs and EU clinical community with Bayer Pharmaceuticals and Oxford University clinical collaborations
- Program to have SIR-Spheres microspheres included in all treatment guidelines for mCRC, HCC and NNETs
- Reimbursement in France will take longer than expected
- Improving customer service and support
- Expect sales to remain very strong and demand to increase.

## Sales & marketing – Asia Pacific

- 8% of dose sales and 4% of sales revenues in 1H FY11
- Highly experienced former Bayer Healthcare executive appointed in January 2011 to manage the region
- Asia Pacific Regional office opened in Singapore
- Region still in early stages of development, strategies being developed to ensure significant growth in next few years
- Significantly expanding sales, marketing, clinical and treatment centre support teams
- Regulatory and reimbursement approvals in some countries taking much longer than anticipated
- Feasibility studies underway ahead of China and Japan market entry

# Understanding the Sirtex growth story ...

## Manufacturing & logistics

- Investment in the Singapore facility of approximately \$4 million
- The Singapore facility is now fully fitted out with equipment installed and qualifying trials are now being conducted
- Commercial doses will be manufactured and supplied once regulatory audits and approvals process is completed, expected late June
- Total manufacturing capacity at Wilmington, Singapore and Sydney is adequate, however investment in additional capacity will be required soon to cater for expected growth

# Understanding the Sirtex growth story ...

## Clinical studies

- Investment in clinical studies will provide the Level 1 data required by the medical community to gain widespread acceptance of SIR-Spheres microspheres and will underpin long term shareholder value by creating the foundations for significant business growth worldwide
- Excellent Level 1 clinical data will move SIR-Spheres microspheres from a treatment of last resort today to a first line standard of care in the future
- Expect a significant step change in sales and global medical opinions once the Level 1 study data starts to be published, expected from early 2015



# Clinical data will drive a step change in growth

- Investment in Clinical up 79% to \$5 million in 1H FY11
- 4 major studies; 120 world leading institutions and 2,000 patients
- Investment of approximately \$60 million over 5 years
- Support team of 20 in-house experts working with six CROs
- Recruitment accelerating globally due to increased investment
- Clinical data outcomes will be coordinated with sales and marketing to maximise clinical awareness among KOLs and clinical community
- Clinical data also supports regulatory approvals and reimbursement
- Increased recognition through collaborations with key institutions such as Oxford University, Singapore General Hospital, University of Magdeburg and Bayer Pharmaceuticals

# Understanding the Sirtex growth story ...

## R&D

- Investment in innovation underpins long term shareholder value and provides the opportunity for a further step change in growth of Sirtex worldwide. R&D is in two main sections, SIR-Spheres microspheres evolution and new technology
- Evolution of SIR-Spheres microspheres
  - Improved dose administration systems for clinicians
  - Imageable diagnostic microspheres
  - Imageable therapeutic microspheres
  - Patient treatment planning system
  - Next generation product
- When proven, these enhancements to SIR-Spheres microspheres will improve use and acceptance further driving sales

# Understanding the Sirtex growth story ...

## R&D

- Several exciting new technologies are well into development including:
  - Radioprotector technology
  - Therapeutic nanotechnologies
  - Diagnostic nanotechnologies
- When proven, Sirtex intends to commercialise these technologies as appropriate, either by licensing, collaboration or direct sale

# Innovation provides a further opportunity for a significant step change in growth

- Investment in R&D up 35 % to \$1.8 million in 1H FY11
- Will continue to ramp up investment to bring innovations online
- Continually and actively assess new opportunities for product development or possible acquisition
- Close and active collaborations with Australian National University, Peter MacCallum Cancer Centre, University of Sydney, University of New South Wales and the National Cancer Centre of Singapore strengthens research capabilities and is more cost effective
- Once proven each of these new technologies have a similar market potential to SIR-Spheres microspheres making Sirtex a significantly larger business

# Acquisition provides a further opportunity for a significant step change in growth

- Sirtex continues to evaluate suitable acquisition prospects
- Utilises Sirtex's proven ability to effectively manage all aspects of a biotechnology organisation including:
  - Sales & marketing
  - Reimbursement
  - Regulatory Affairs and QA
  - Operations
  - Corporate Structure and Administration
- Acquisition of a commercialised product would provide further opportunity for a step change in growth

# Summary

- Sirtex is a well managed solid business investing to create significant long term business growth and shareholder value
- 1H FY11 shows fundamentals of the business remain positive
- Current sales growth is not representative of future growth potential (low market penetration, large unmet clinical need, limited Level 1 clinical data)
- Clinical awareness and acceptance is growing, momentum is building
- Investment in clinical studies will drive a significant step change in demand worldwide

# Understanding the Sirtex growth story ...

## THE FUTURE

### SIR-Spheres microspheres

- Continued organic growth over the next few years through greater awareness, acceptance and geographic expansion
- Release of Level 1 clinical data providing a step change in demand

### New technology

- Exciting pipeline of several new technologies under development each of which has the potential to be at least equal in market value to SIR-Spheres microspheres

### Acquisitions

- Strategic acquisitions could leverage Sirtex's business strengths providing the opportunity for a further step change to the growth of Sirtex

Thank you