

# Sirtex Medical Limited

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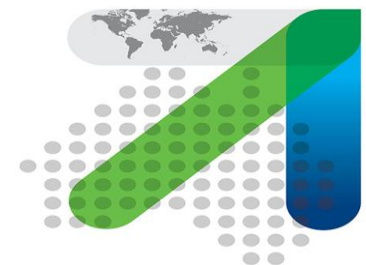


# About Sirtex

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- Australian headquartered, global healthcare business
- Listed on the ASX since 2000 (ASX:SRX); S&P / ASX 200 Index
- Focus on Interventional Radiology & Oncology Market – a rapidly growing sub-set of cancer market that utilises minimally invasive techniques to diagnose and treat solid tumours
- Main product is SIR-Spheres® Y-90 resin microspheres
  - Tiny radioactive microspheres that provide high dose radiation directly to the tumour while minimising damage to normal healthy cells
  - Regulatory clearances in most major markets for the treatment of inoperable liver cancer
- Approximately 80,000 doses of SIR-Spheres supplied to treat liver cancer patients in over 1,090 medical centres in over 40 countries
- Current sales are a small percentage of the total addressable market for SIR-Spheres, which highlights the potential of the product





## Our Mission

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*To improve the quality and longevity of patients' lives by providing innovative interventional oncology solutions*

# Liver-Specific Treatment Options are Limited



## Surgery

- Liver resection
- Curative intent
- Possible in minority of cases



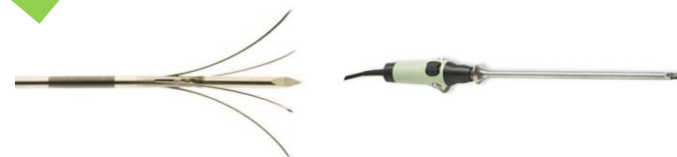
## Liver Transplant

- Replaces diseased liver
- Curative intent
- Lifelong immunosuppression



## Selective Internal Radiation Therapy (SIRT)

- Targeted, high dose radiation
- Palliative intent
- Substantial evidence of effect



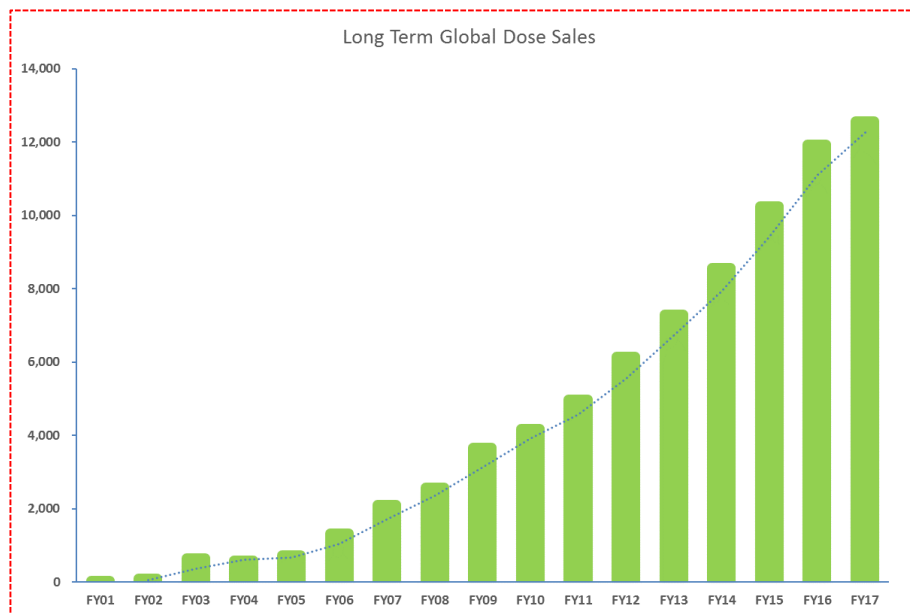
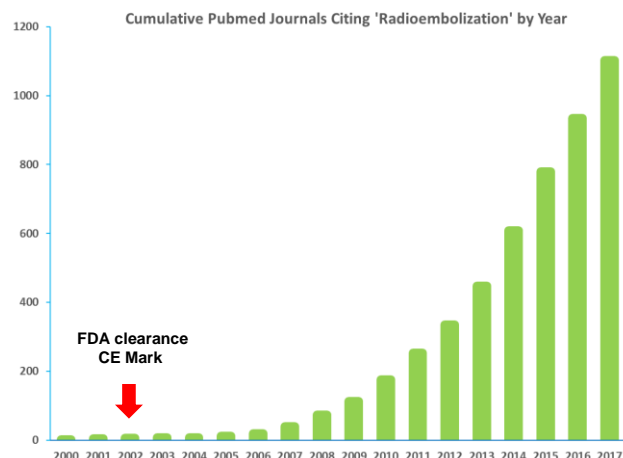
## Ablation

- Heat (radiofrequency or microwave)
- Cold (cryotherapy) or chemical (ethanol)
- Palliative intent, percutaneously 'through the skin'

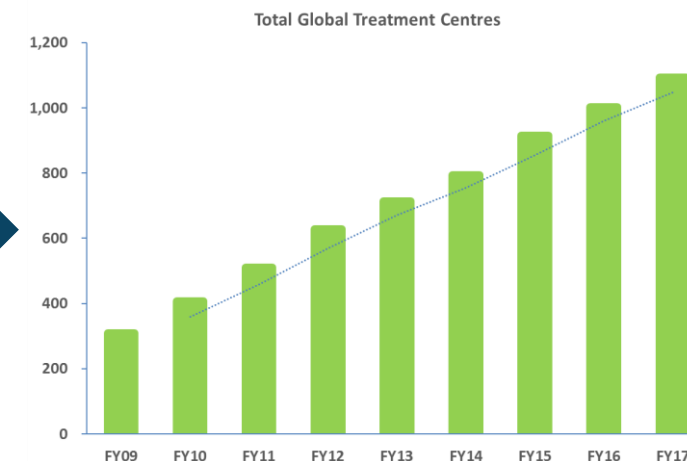
# Clinician Adoption of SIR-Spheres Continues to Grow

Long term growth for SIR-Spheres has been achieved through a multi-faceted strategy with 3 main elements

## Clinical/Scientific Evidence



## Geographic Expansion



## Reimbursement & Consensus Treatment Guidelines

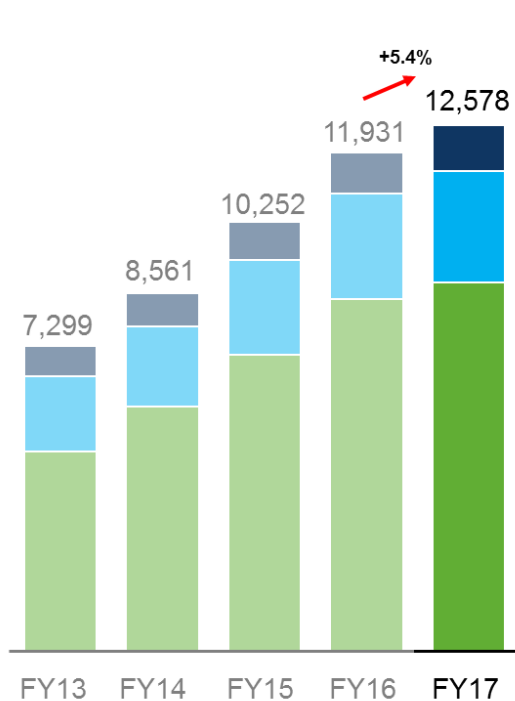


SIRTeX

# FY17 Results

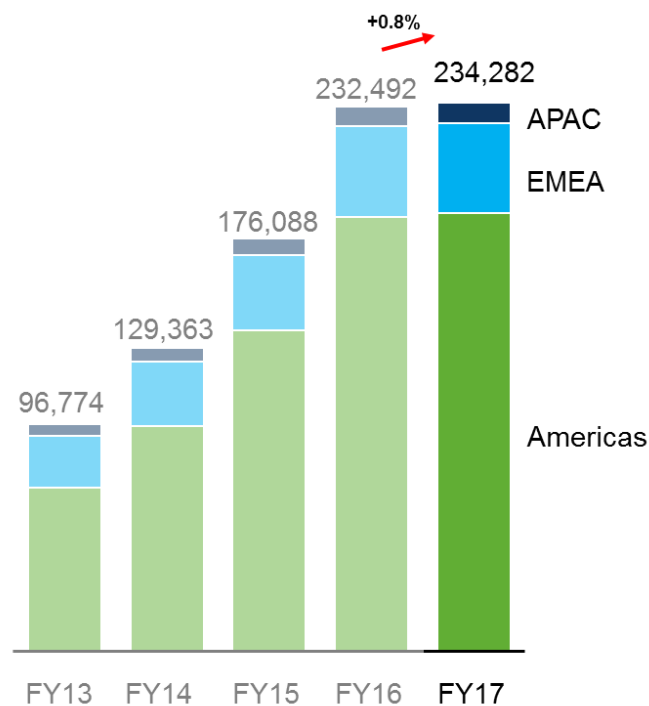
## Dose Sales

Units



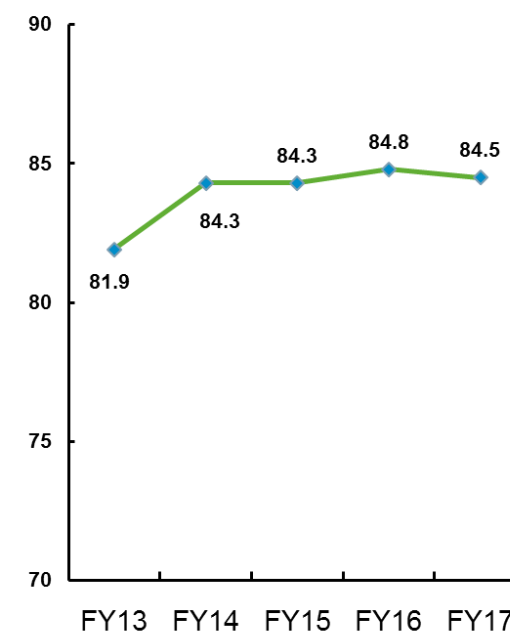
## Revenues

\$'000



## Gross Margin

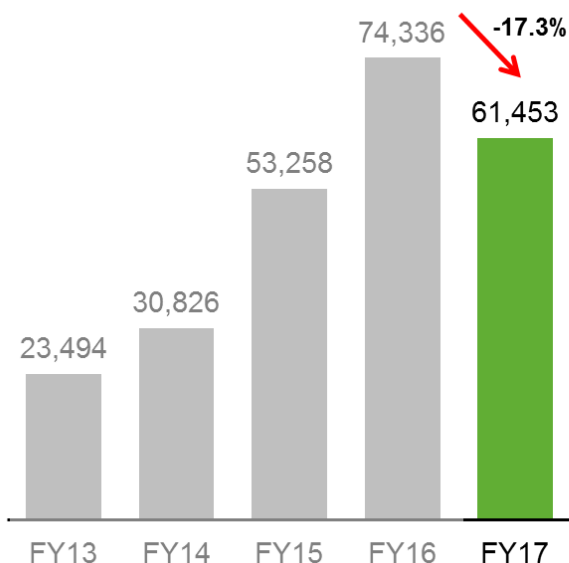
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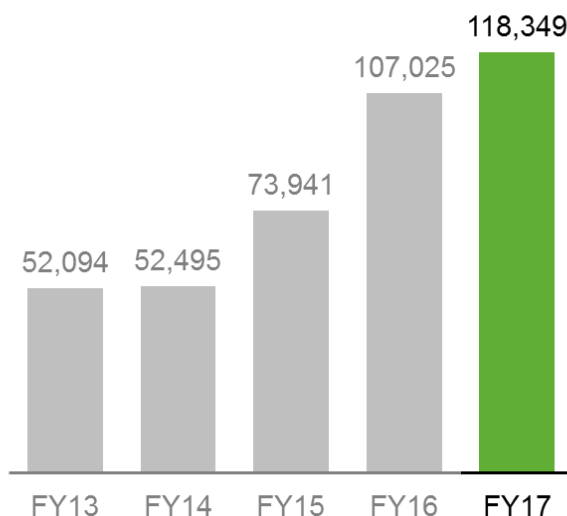


## FY17 Results (cont.)

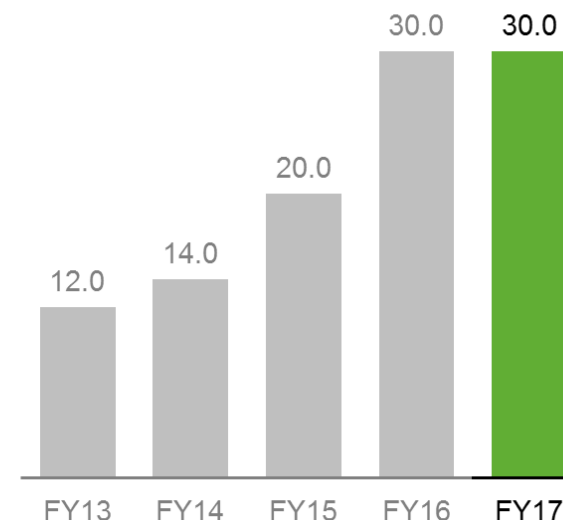
**Underlying EBITDA\***  
\$'000



**Cash on Hand**  
\$'000



**Dividend per share**  
Cents



Share Buy-Back + Dividend: **\$47 million returned to shareholders in CY17**





## FY17 Results (cont.)

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<b>Underlying Net Profit After Tax (NPAT)</b>	<b>\$42.4 million, down 20.9%</b>
<i>Less Impairment of Intangible Assets<sup>1</sup></i>	<i>(\$90.5 million)</i>
<i>Less Impairment/Write-Off of Receivables</i>	<i>(\$3.6 million)</i>
<i>Less Restructuring Costs<sup>2</sup></i>	<i>(\$4.1 million)</i>
<u><i>Add Tax Effect of Adjustments</i></u>	<u><i>\$29.5 million</i></u>
<b>Reported Net Loss After Tax</b>	<b>(\$26.3 million)</b>

- Highly profitable business – stable and reliable global manufacturing & supply chain operation
- Write-off highlights need for R&D investment to be more closely aligned to core business

<sup>1</sup> Internally generated intangible assets related to the major clinical studies of SIRFLOX/FOXFIRE/FOXFIRE Global in mCRC; SARAH, SIRveNIB and SORAMIC in HCC and development expenditure associated with SIR-Spheres microspheres.

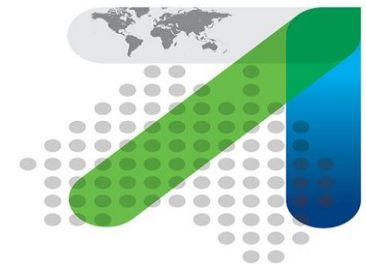
<sup>2</sup> Restructuring costs are principally related to provisioning for employee redundancies in clinical, R&D and global sales & marketing



## Trading Update – First Quarter FY18

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- ↗ 1Q FY18 worldwide dose sales flat versus the prior corresponding period (pcp)
  - ↗ Organisation distraction from FY17 coupled with competitive pressures
  - ↗ New growth initiatives in place, more to come
  
- ↗ Reported 1Q FY18 sales revenue of \$53.3 million, down 4.8%
  - ↗ Pricing remains stable; increased currency headwinds (principally USD)
  
- ↗ Unaudited 1Q FY18 constant currency profit before tax (PBT) up 11.3%
  - ↗ Reported PBT up 2.9%



# Our Strategy

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## ↗ Operational

- ↗ Efficiency and productivity gains
- ↗ Becoming easier to do business with

## ↗ Four core areas of organic expansion

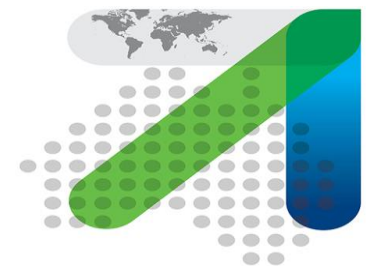
- ↗ Geographical
- ↗ New segments within existing geographies
- ↗ Reimbursement
- ↗ Indication expansion



## Our Strategy (cont.)

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- Operational highlights during the year
  - Reduction of staff by approximately 15% announced June
  - Frankfurt facility became operational
  - Improvements in supply logistics within the US
  - Pilot Program: same day vasculature mapping and SIR-Spheres implantation
  - Becoming easier to do business with via electronic ordering
  - Partnerships with Office-Based Laboratories (OBLs) in the US, leveraging trend in healthcare moving outside of traditional hospital setting



# Expansion

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- ↗ Two primary considerations for geographic expansion
  - ↗ Regulatory
  - ↗ Reimbursement
- ↗ New revenues anticipated in Canada and Brazil
- ↗ Expansion within France following reimbursement in refractory metastatic colorectal cancer (mCRC)
- ↗ China and Japan are longer term initiatives



# Indications and Reimbursement Expansion

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**SARAH**  
Sorafenib versus Radioembolization  
in Advanced Hepatocellular carcinoma

HCC - French Study  
(reported in April)

**SIRveNIB**

HCC - Asian Study  
(reported in June)

**SIRflox**  **FOX FIRE**  
Global

mCRC (reported in June)

- Sirtex announced the results of three large clinical studies during FY17
- The SARAH study forms part of our regulatory submissions to the US FDA to obtain regulatory clearance to market for hepatocellular carcinoma (HCC) – expected before end of FY18
- For SIRFLOX/FOX FIRE/FOX FIRE Global, Sirtex continues to investigate the survival benefit conferred and the 36% reduction in the risk of death in patients with a right-side primary colon cancer who received our therapy in the SIRFLOX and FOX FIRE Global studies

**SIRTeX**



## Data and Reimbursement

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➤ The Radiation-Emitting SIR-Spheres in Non-resectable (**RESiN**) Liver Tumor Patient Registry

➤ As at 30 June, approx. 600 patients in the registry at 34 different medical centres

➤ Target enrolment rate is 500 per annum, with expansion into AU and NZ having commenced

➤ FDA supportive of real world patient registries

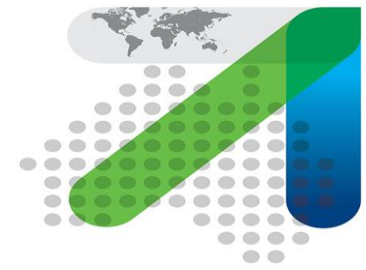


# Inorganic Growth

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- Focus on interventional radiology and oncology
- Sirtex has competitive advantages across sales, marketing, regulatory and reimbursement that could add value to any acquisition
- Careful monitoring of opportunities allows the Company to assess potential





# Competitive and Market Environment

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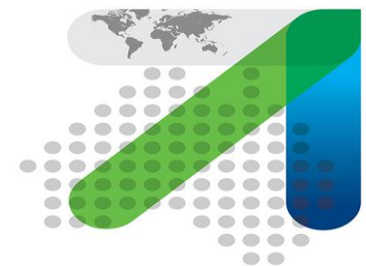
- ↗ Improvement in competitive differentiation
  - ↗ Resin (SIR-Spheres) versus glass
  - ↗ US regulatory status (PMA versus HDE)
  - ↗ PMA supplement filing in hepatocellular carcinoma (HCC) prior to the end of FY18
  
- ↗ Large addressable market in salvage
  - ↗ >180,000 patients per annum in currently contested markets
  
- ↗ PMA supplement approval enables promotion of SIR-Spheres in HCC in the key US market
  - ↗ Significant body of evidence via SARA-H & other smaller studies



## Competitive and Market Environment (cont.)

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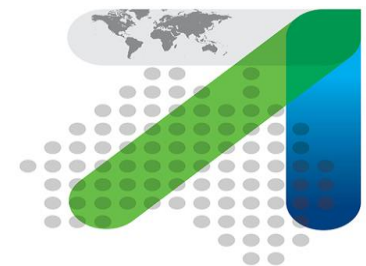
- Treatment of cancer continues to evolve with advent of immunotherapy
- Leading oncologists believe immune checkpoint inhibitors in combination with radiation therapy likely to confer additional benefits to the patient
- Two combination studies of nivolumab and SIR-Spheres microspheres in HCC have commenced in Singapore and more recently, Spain
- Nivolumab recently received FDA approval in second-line HCC



## Conclusion

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- More efficient and productive company
- Significant potential of technology – approx. 5% penetration of addressable market
- Exploring three findings from recent research
- Working with new treatments of cancer to improve outcomes in combination with our product
- Team of committed and enthusiastic people



**Thank you**