



Sirtex Medical Limited

Results for the full year ended 30 June 2017

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23 August 2017



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FY 2017 overview

- ↗ Underlying constant currency EBITDA of \$70.2 million
- ↗ Underlying NPAT versus prior year declined 20.9% due to lower dose sales growth and higher expenditures ahead of clinical study data
- ↗ Decisive action taken in June to become more efficient
- ↗ Reported net loss after tax driven by asset impairments and restructuring costs
- ↗ Cash on hand of \$118.3 million, up 10.6% and no debt
- ↗ 30.0 cent per share final dividend declared and \$30 million share buy-back, as cash generation remains strong
- ↗ Structure optimised to capitalise on growth opportunities within the core SIR-Spheres® Y-90 resin microspheres business globally

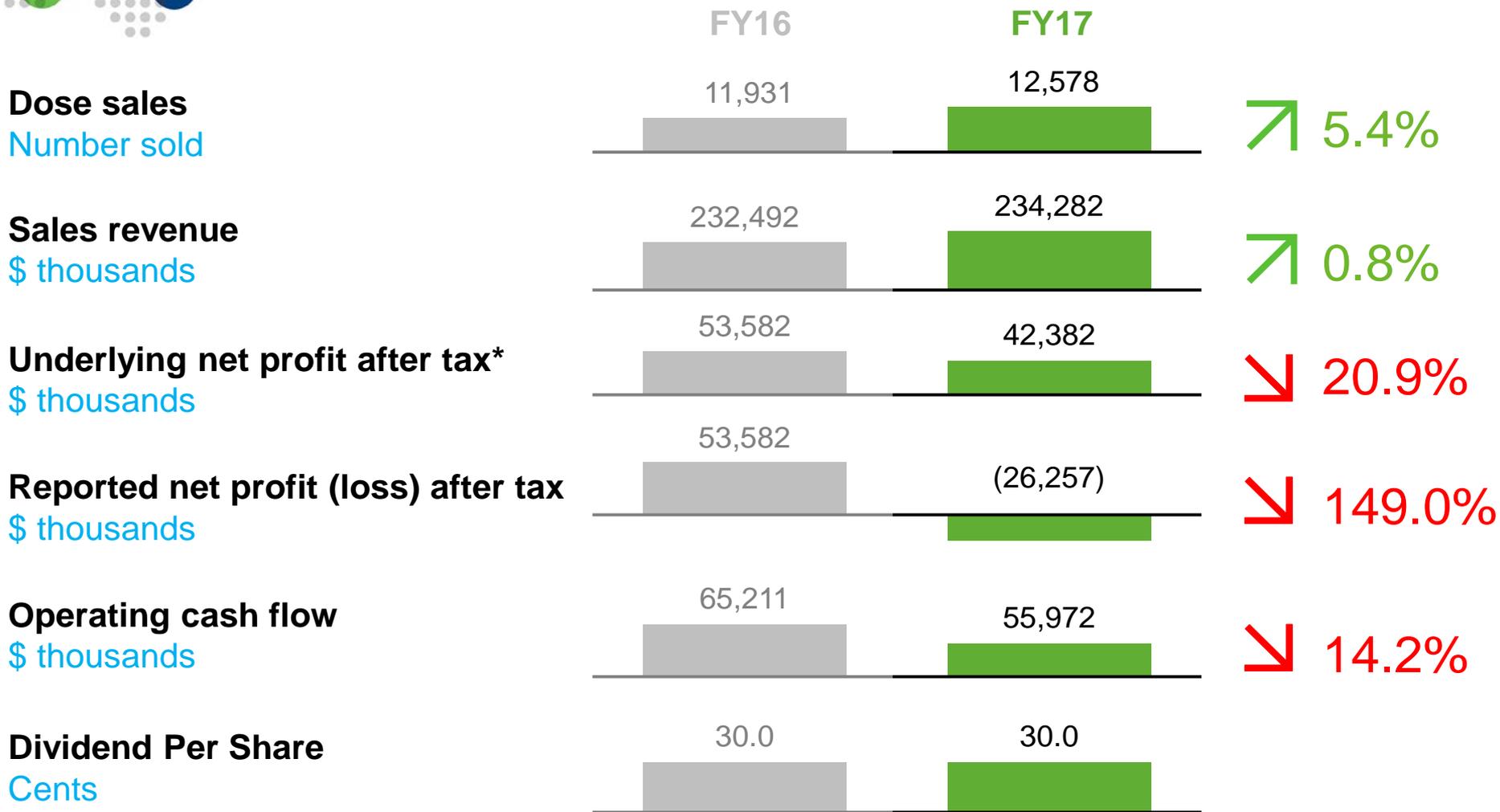


FY 2017 overview (cont.)

- Reported clinical results from the combined SIRQLOX/FOXFIRE/FOXFIRE Global study in first-line mCRC at ASCO in June
- Reported clinical results from SARAH study at EASL in April and SIRQveNIB study at ASCO in June (both studies in HCC)
- Though the studies did not meet their primary endpoints, valuable new information on the effectiveness of SIRQ-Spheres was generated



Financial results





Underlying/Reported NPAT reconciliation

Underlying Net Profit After Tax (NPAT)	\$42.4 million
<i>Less Impairment of Intangible Assets¹</i>	<i>(\$90.5 million)</i>
<i>Less Impairment/Write-Off of Receivables</i>	<i>(\$3.6 million)</i>
<i>Less Restructuring Costs²</i>	<i>(\$4.1 million)</i>
<i>Add Tax Effect of Adjustments</i>	<i>\$29.5 million</i>
Reported Net Loss After Tax	(\$26.3 million)

¹ 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.

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



Constant currency revenue, EBITDA and NPAT

➤ Summary Sales Revenue

➤ Constant currency adjusted sales revenue:	\$246.6 million, up 6.1%
➤ Currency effect:	(\$12.3 million)
➤ Reported sales revenue:	\$234.3 million, up 0.8%

➤ Summary Underlying EBITDA

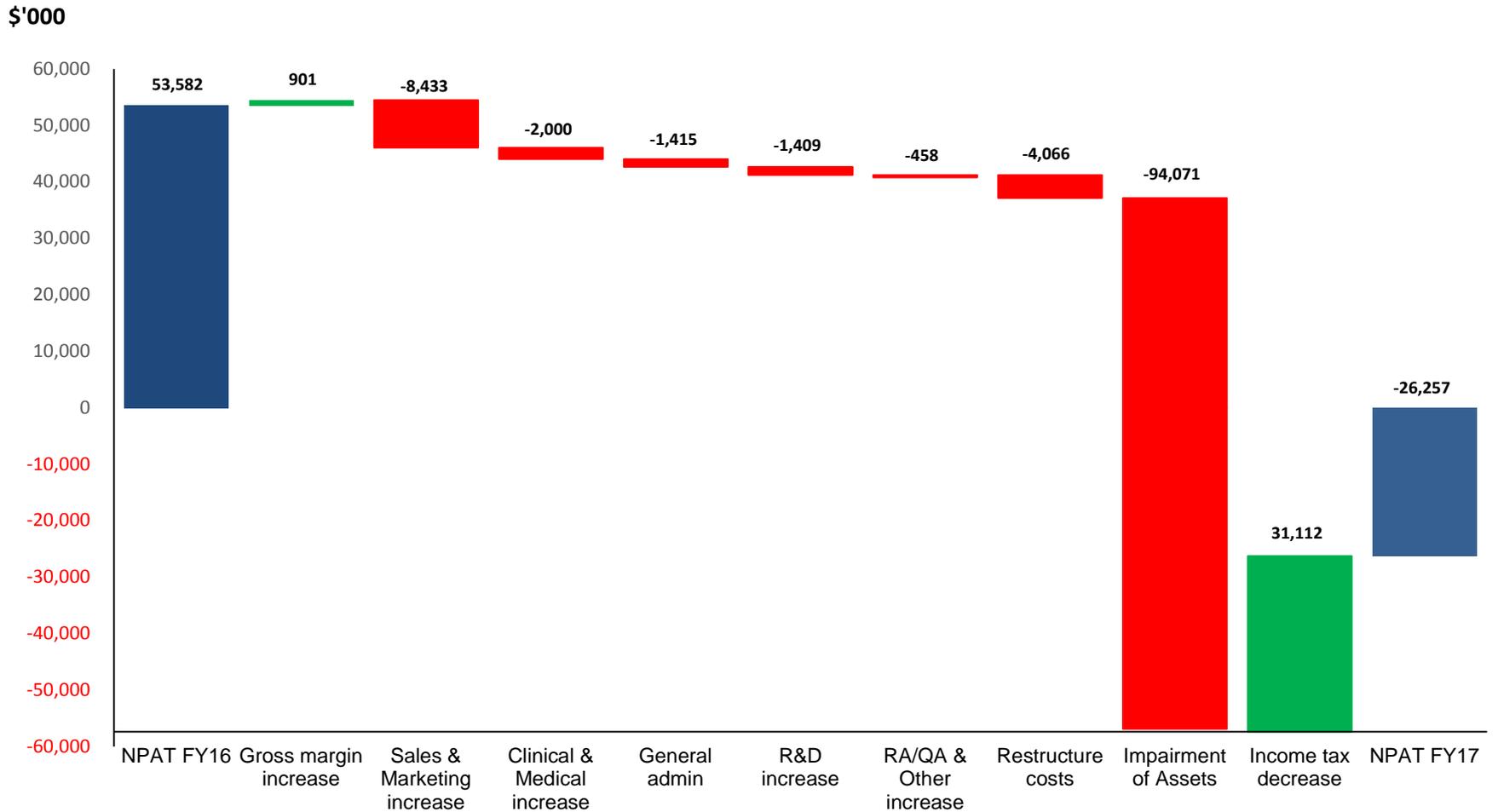
➤ Constant currency adjusted underlying EBITDA:	\$70.2 million, down 5.6%
➤ Currency effect:	(\$8.7 million)
➤ Underlying EBITDA:	\$61.5 million, down 17.3%

➤ Summary Underlying Net Profit After Tax

➤ Constant currency adjusted underlying NPAT:	\$48.3 million, down 9.9%
➤ Currency effect:	(\$5.9 million)
➤ Underlying NPAT:	\$42.4 million, down 20.9%

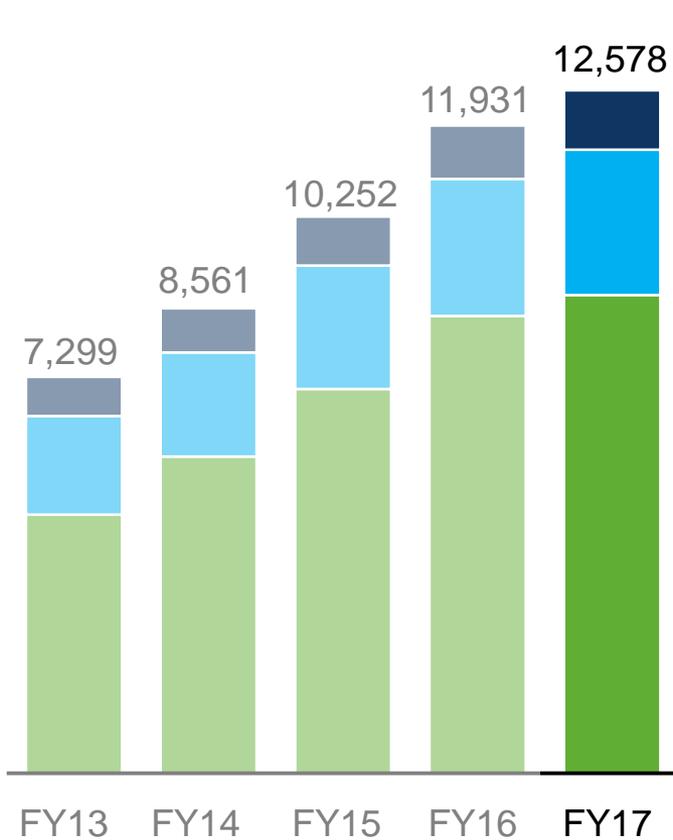
Constant currency was applied by restating full year FY17 expectations with the full year FY16 average rates: AUD/USD – 0.724, AUD/EUR – 0.656, AUD/SGD – 1.012. A determination of the constant currency effect for revenues, EBITDA and NPAT has not been subject to external review or audit or prepared in accordance with Australian Accounting Standards, IFRS or the Corporations Act 2001. Constant currency provides one measure of comparability between the periods. Underlying EBITDA and NPAT excludes asset impairments, write-offs and restructuring provisions.

FY16-FY17 reported NPAT reconciliation

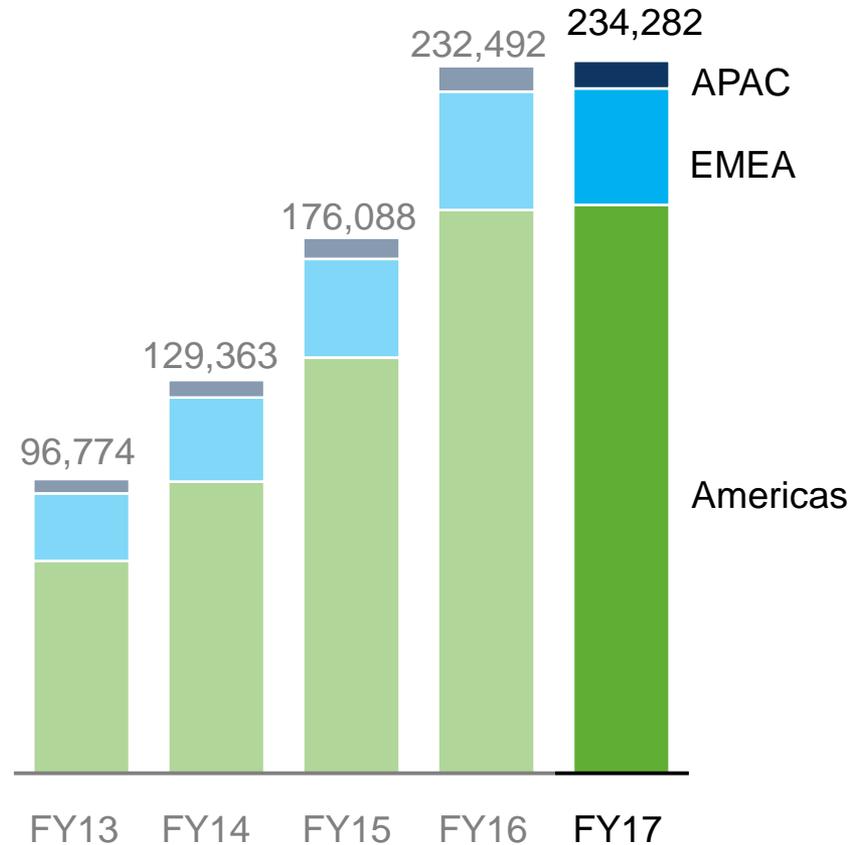


Dose sales and reported sales revenue

Dose sales
Number of units



Reported sales revenue
\$'000

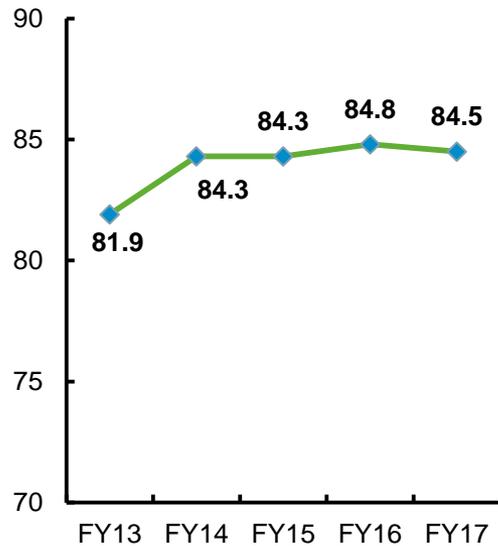




Margins

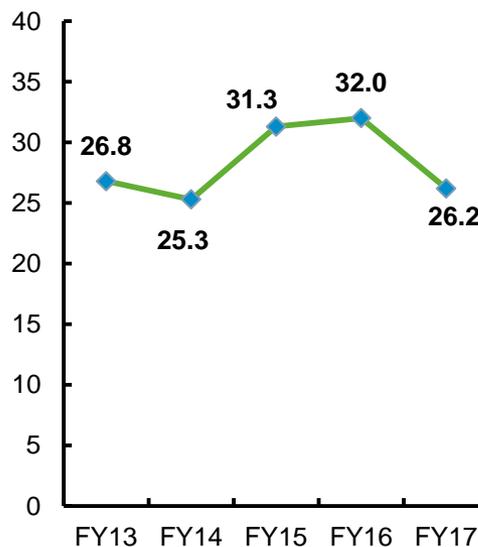
Gross margin

%



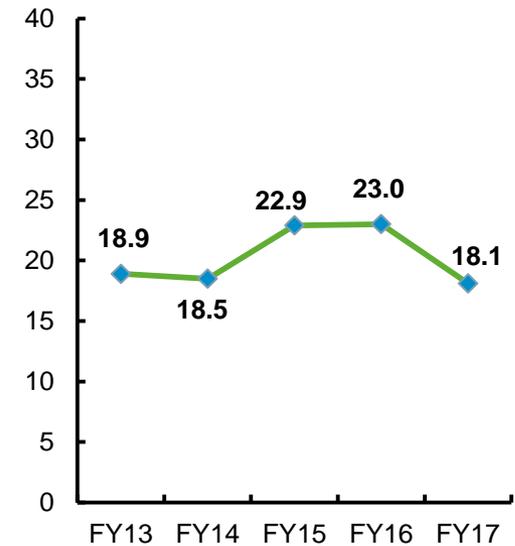
Underlying EBITDA margin

%



Underlying NPAT margin

%



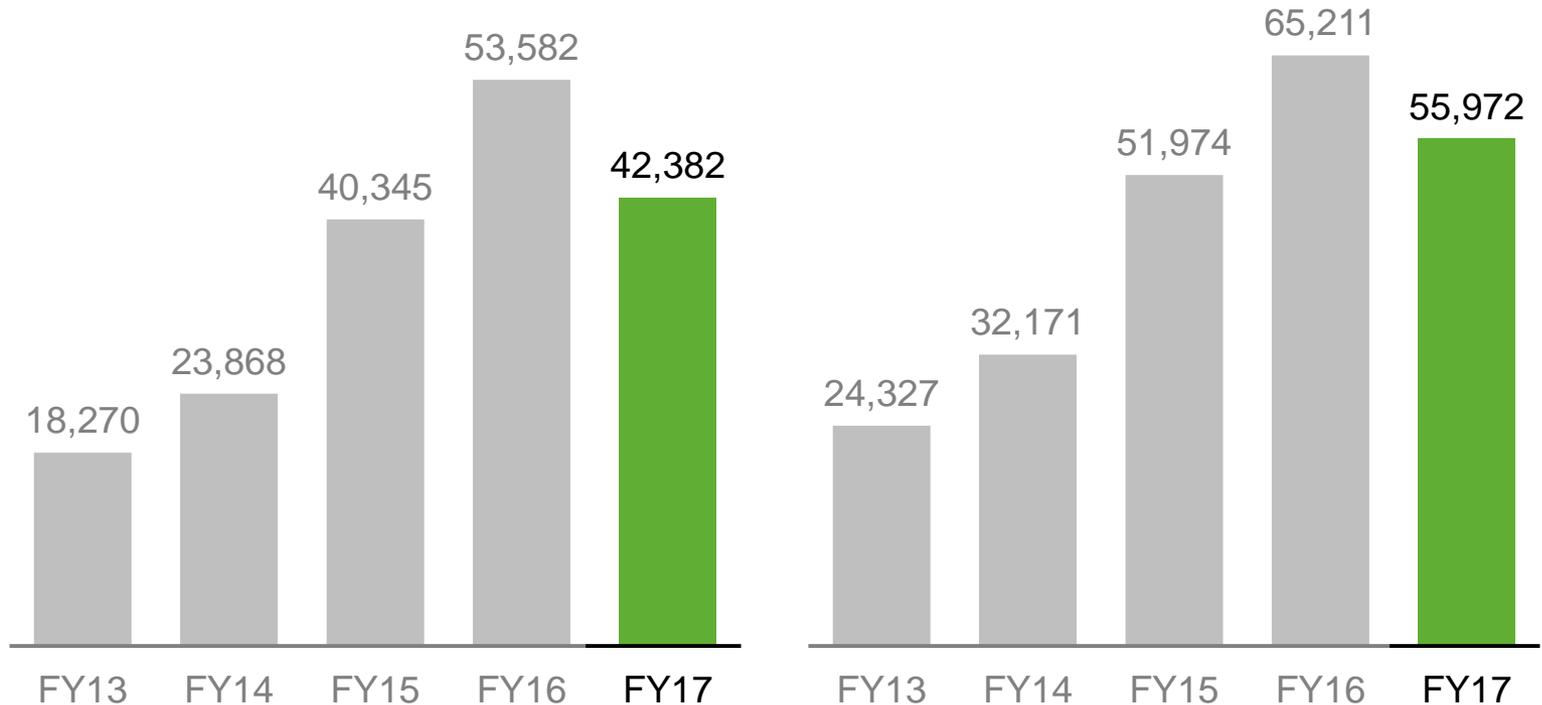
- ↗ Gross margin relatively stable at 84.5%
- ↗ Underlying EBITDA margin, down 580 bps – higher op. expense as % sales
- ↗ Underlying NPAT margin, down 490 bps



Net profit after tax and operating cash flow

Underlying net profit after tax*
\$'000

Operating cash flow
\$'000

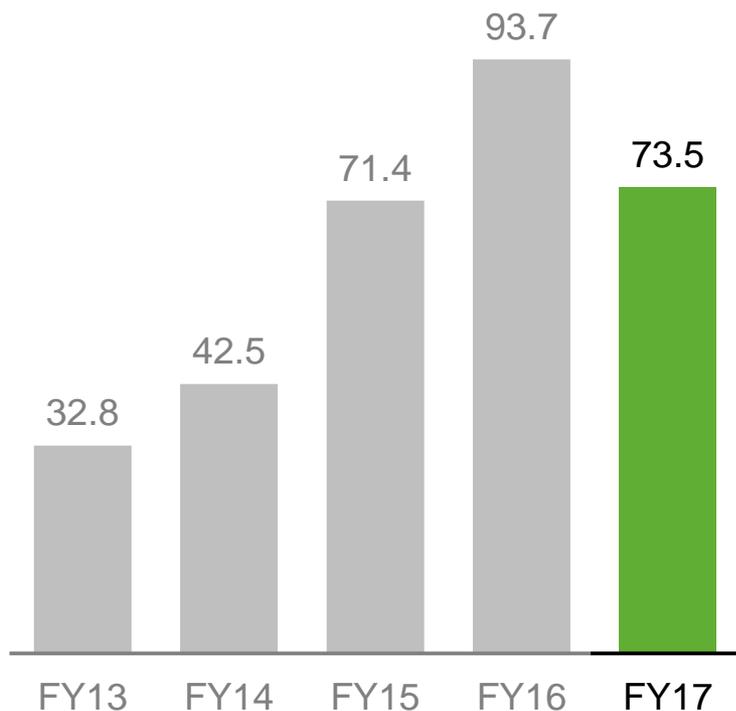


* Excludes clinical and R&D asset impairments, restructuring costs and impairment/write-off of receivables

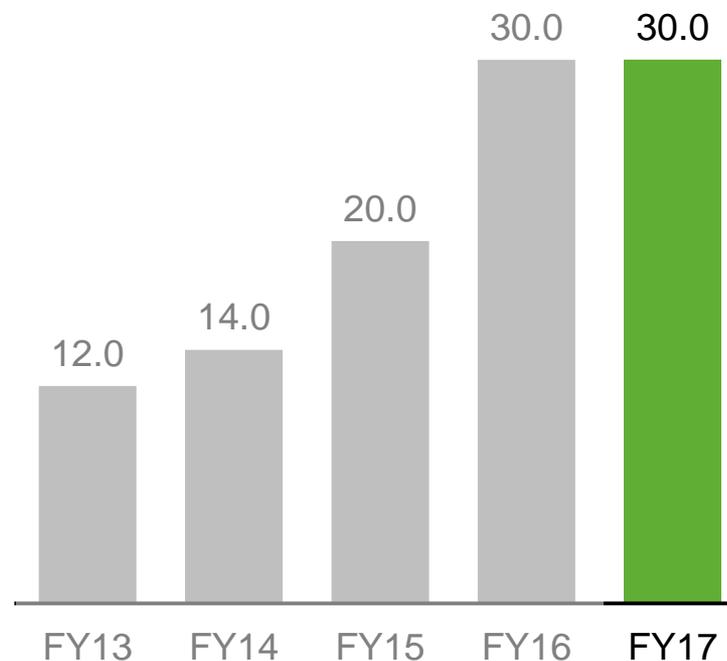


Earnings per share and dividend per share

Underlying earnings per share*
Cents



Dividend per share
Cents



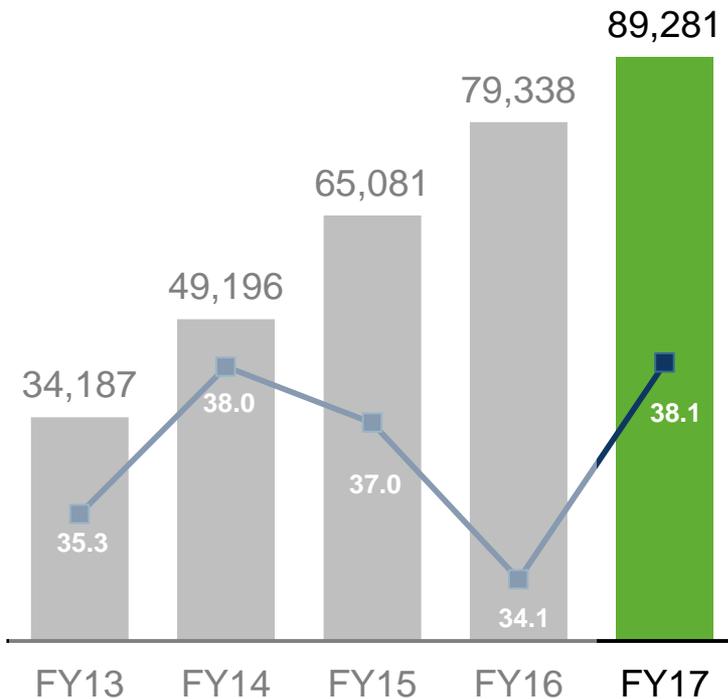
* Excludes clinical and R&D asset impairments, restructuring costs and impairment/write-off of receivables

Investment in sales and marketing

Sales and Marketing

\$'000

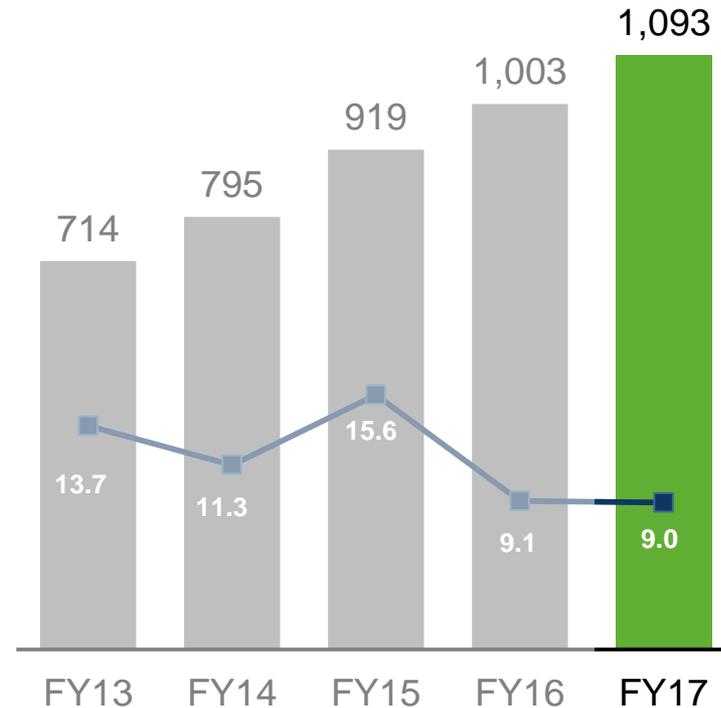
■ % sales



Geographic footprint expansion

Number of sites globally

■ % growth

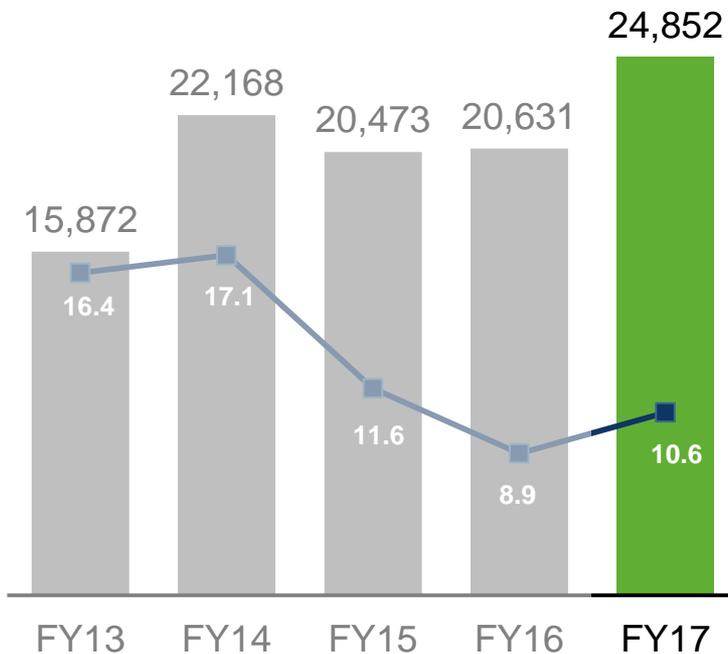


Clinical investment

Total Clinical investment *

\$'000

■ % sales



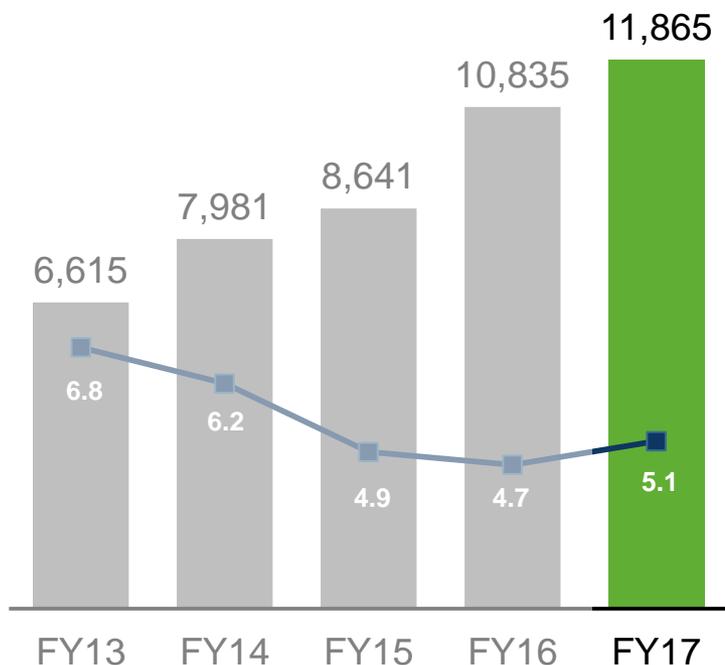
- ↗ Completion and reporting of all major clinical studies, except SORAMIC
- ↗ Targeted, smaller Company sponsored & Investigator-Initiated Trials (IITs) to continue
 - ↗ e.g. SIRCCA in cholangiocarcinoma 
- ↗ Clinical, R&D Assets written-off (\$90.5 million)
- ↗ Material reduction in expenditure in FY18

R&D investment to be aligned with core business

Total R&D investment *

\$'000

■ % sales

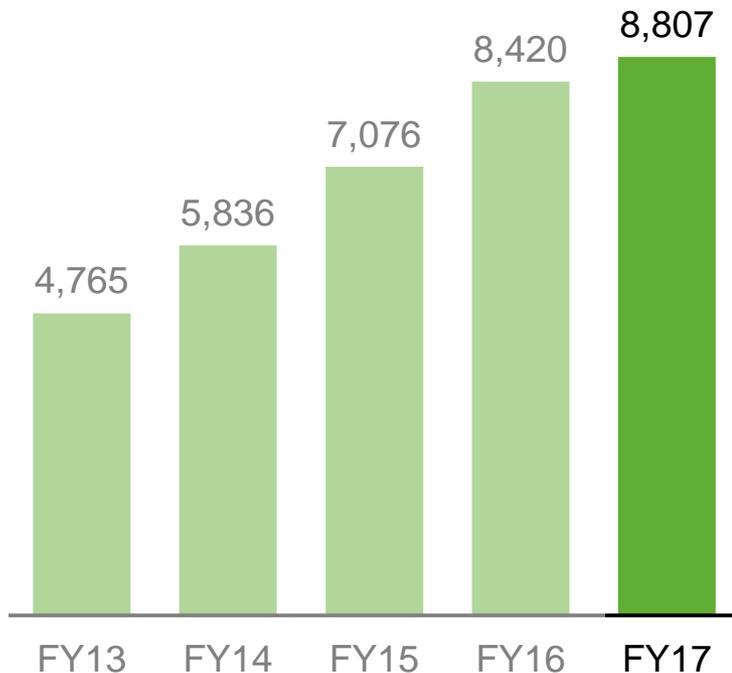


- Programs related to carbon-cage nanoparticles, polymer-coated nanoparticles and radioprotector discontinued, as announced at 1H17
- Programs dedicated to product and user interface enhancements associated with SIR-Spheres, maintained
- Histone Inhibition Program (HIP) funded to Phase 1
 - Results expected 2H18
 - Commercial options post-results



Americas

Dose Sales

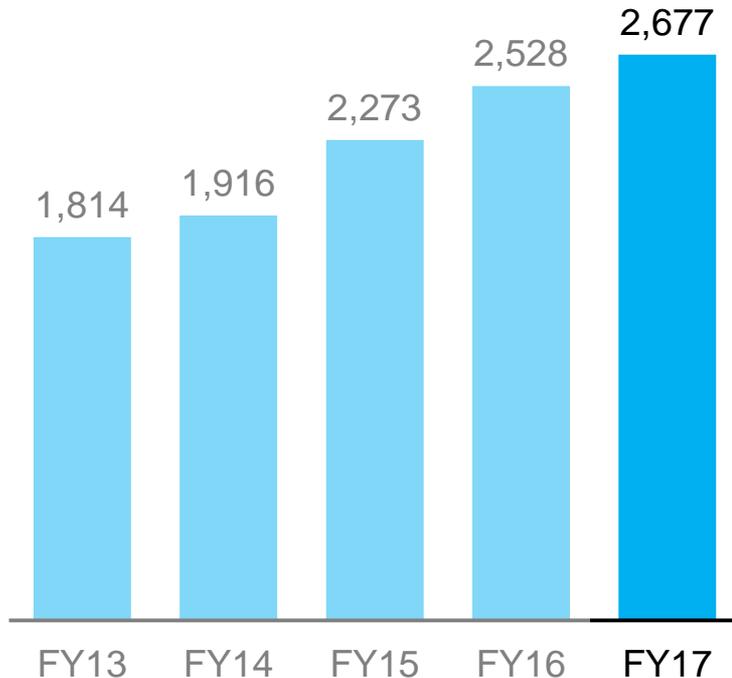


- ↗ Dose sales of 8,807, up 4.6%
- ↗ CC Revenue of \$195.7 million, up 4.7%
 - ↗ Reported revenue of \$186.9 million, up 0.9%
- ↗ 639 treatment sites, up 13.3% on pcp
- ↗ FY Highlights:
 - ↗ Positioning more deeply into mCRC markets
 - ↗ RESiN crossed 600 patients, 34 centres
 - ↗ Continued to leverage NCCN Cat. 2A
- ↗ Outlook
 - ↗ CMS reimbursement anticipated to remain stable through CY18
 - ↗ US FDA PMA Supplement filing in 1H FY18
 - ↗ New EVP, Sales & Marketing appointed



Europe, Middle East & Africa (EMEA)

Dose Sales

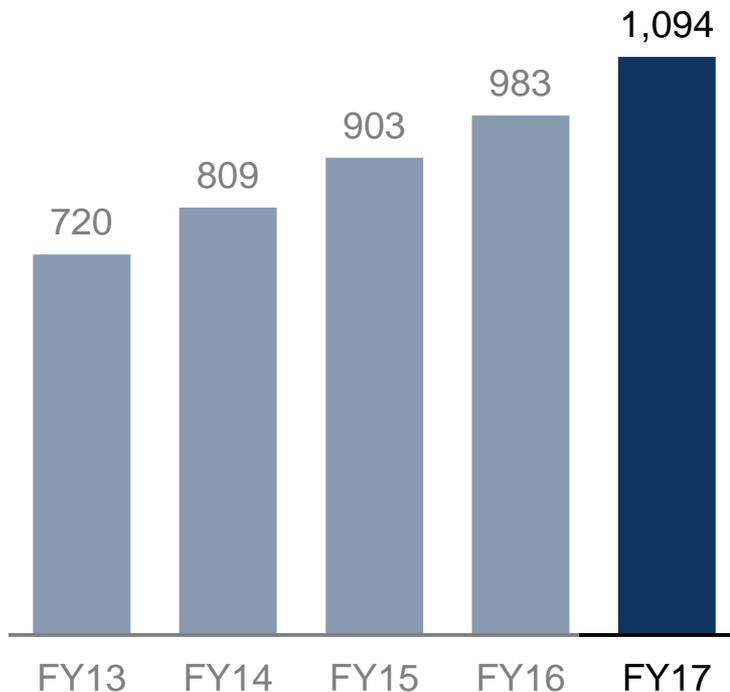


- ↗ Dose sales of 2,677, up **5.9%**
- ↗ CC Revenue of \$40.8 million, up **6.4%**
 - ↗ Reported revenue of \$38.3 million, down **1.6%**
- ↗ 308 treatment sites, up **0.7%** on pcp
- ↗ FY Highlights:
 - ↗ Reimbursement in France for refractory mCRC
 - ↗ Improved market access in Spain
 - ↗ Continued focus on referrers, users and payers
- ↗ Outlook:
 - ↗ Positioning for HCC post SARA
 - ↗ Further reimbursement submissions in Europe
 - ↗ New market entries planned



Asia Pacific (APAC)

Dose Sales



- ↗ Dose sales of 1,094, up **11.3%**
- ↗ CC Revenue of \$10.1 million, up **11.5%**
 - ↗ Reported revenue of \$9.1 million, up **8.6%**
- ↗ 146 treatment sites, up **9.8%** on pcp
- ↗ FY Highlights:
 - ↗ Solid 20%+ growth in Asia
 - ↗ Public funding for HCC in AU in 3 states
 - ↗ Pleasing growth in Taiwan and India
- ↗ Outlook
 - ↗ New reimbursement in Asia
 - ↗ HCC messaging post SIRveNIB/SARAH
 - ↗ Focus on throughput from key centres



Capital Management & Efficiency

- On-market share buy-back program commenced early June
- Buy-back for up to \$30.0 million to early Sept 2017 - \$6.8 million remaining
- \$2.9 million bought back by end of FY17
- \$27.1 million remaining, on track for completion date as planned, with accretion benefits flowing in FY18
- Buy-back, coupled with FY17 declared dividend, will mean Sirtex will return approximately \$47 million to shareholders during CY17



Clinical Studies – Results in HCC

SIRveNIB

SARAH
SorAfenib versus Radioembolization
in Advanced Hepatocellular carcinoma

- Both studies showed statistically significant safety and toxicity benefits for SIR-Spheres versus the standard of care chemotherapy agent, with no statistically significant difference in survival outcomes
- Over 25% of patients randomised to receive SIR-Spheres did not ultimately receive treatment and time to treatment was higher than real world setting
- Based on these results, the addressable opportunity in HCC within currently contested markets is 61,000 patients annually
- Additional regulatory filings in the USA on track for submission in 1H FY18
- Sales and Marketing efforts on results (ex-USA) have commenced



Clinical Studies – Results in mCRC

SIRflox

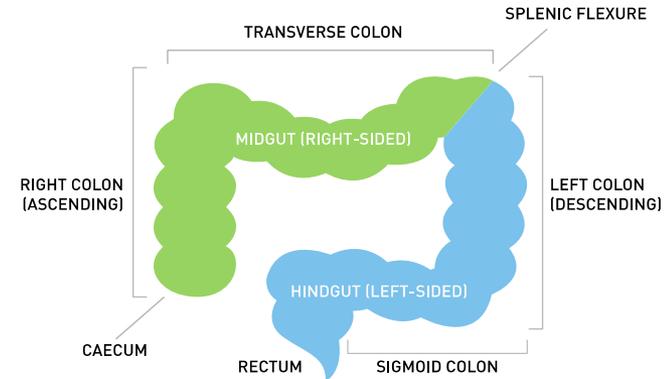


FOXFIRE
Global

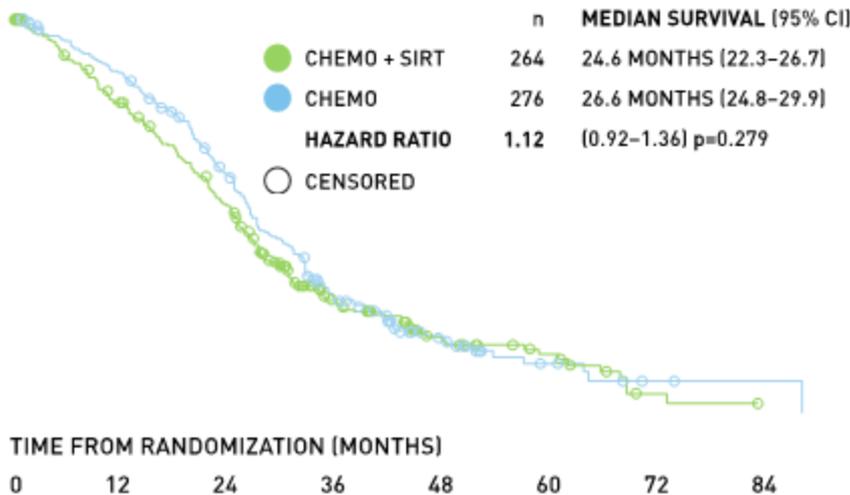
- Combined SIRFLOX/FOXFIRE/FOXFIRE Global (n=1,103) failed to show a statistically significant Overall Survival (OS) benefit when SIR-Spheres combined with standard chemotherapy in first-line metastatic colorectal cancer (mCRC) patients
- No statistically significant difference in survival outcomes was observed within key sub-groups, including liver-only and liver-dominant patient groups
- Exploratory analysis from pooled SIRFLOX and FOXFIRE Global studies showed a statistically significant survival benefit in patients with a right-sided primary colon cancer who received SIR-Spheres microspheres + chemotherapy

Right-side survival data

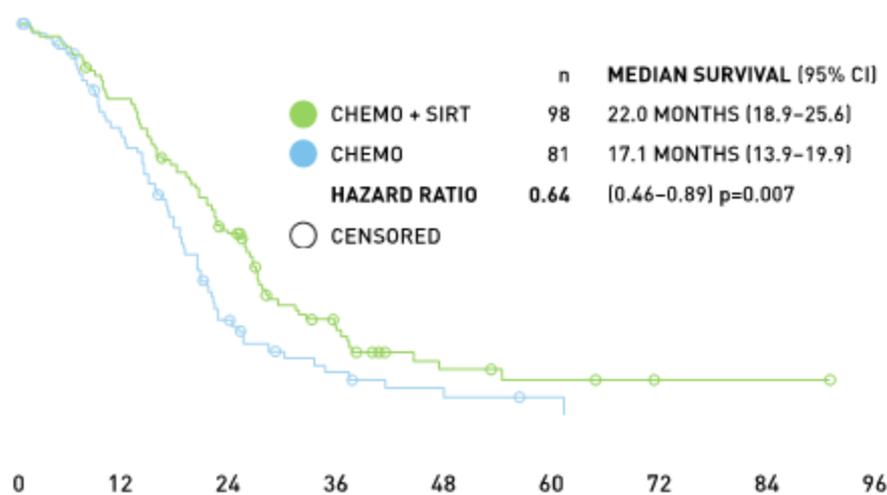
- 4.9 month OS benefit (36% reduction in risk of death) in Right-Sided patients treated with SIR-Spheres + chemo
- Patient baseline characteristics were well balanced (no statistically significant differences)
- Next Steps: (1) Confirm benefit from FOXFIRE (n=364) and (2) Assessment of tissue genetic profile
- Incidence of right-side primary cancers is ~38%, with patients harder to treat, and lower survival versus left-side



LEFT-SIDED PRIMARY TUMOURS



RIGHT-SIDED PRIMARY TUMOURS





RESiN Registry

**Radiation-Emitting SIR-Spheres in Non-resectable
(RESiN) Liver Tumor Patient Registry¹**



- Multi-centre US patient registry that prospectively enrolls patients who are scheduled for treatment with SIR-Spheres Y-90 resin microspheres as part of their care plan – examining US treatment patterns and long term outcomes
- Exceeding initial expectations, with approx. 600 patients enrolled across 34 centres at 30 June
- Targeting 500 patients annually, with expansion into Australia and NZ commenced
- Considerable benefits: reimbursement support, regulatory clearances, clinician awareness, real-world clinical data, structured publication strategy



Short term initiatives

- Optimise sales efficiency and effectiveness within the Americas and EMEA, with focus on markets where reimbursement is more widely available
- Prudent management of operating expenditures
- Maximise SIR-Spheres utilisation within the salvage market opportunity, representing approximately 184,000 patients per annum in existing markets
- Leverage the findings from SARA, SIRveNIB studies in existing HCC markets, representing approximately 61,000 patients per annum
- Product and user enhancements



Outlook – FY18

- Preparations for additional FDA submissions on track - filing during 1H18
- Secure further reimbursement across the Americas, EMEA and APAC
- Measured expansion within higher growth markets, e.g. France
- Leverage clinical findings at the level of treatment guidelines (NCCN, ESMO, Other) and government payers
- Market conditions experienced in FY17 expected to persist through FY18
- SORAMIC clinical study results expected 2H18 (1H CY18)
- In focusing on a more efficient core business that is more effective in targeting new and existing clinicians and their patients, the Company will be better positioned to grow within its under-penetrated salvage market

