



ASX / MEDIA RELEASE

24th February 2016

Sirtex 2016 Half Year NPAT Increases 46.9% to \$25.9 Million

- Global dose sales increased 15.7% to 5,728 units
- Revenue from sale of goods increased 40.0% to \$112.6 million
- Net Profit after Tax (NPAT) increased 46.9% to \$25.9 million
- Earnings per share increased 45.0% to 45.4 cents
- Cash and Cash equivalents increased 33.0% \$73.7 million

Sydney, Australia; 24th February 2016 - Sirtex Medical Limited (ASX: SRX) announced today a half year net profit after tax of \$25.9 million for the period ended 31st December 2015. This represents a material 46.9 per cent increase in NPAT compared to the previous corresponding period (pcp).

Mr Gilman Wong, CEO of Sirtex Medical commented “I am pleased with our record first half profit result, which reflects the significant progress we have made in continuing to grow the business. The first half result is consistent with our dose sales objectives for the full financial year. We remain focused on ensuring that SIR-Spheres[®] Y-90 resin microspheres is available to as many patients as possible through the expansion of certified treatment sites, trained clinicians, high quality clinical data and access to government or private reimbursement.”

Half Year Financial Highlights

	1H 2015 \$ thousands	1H 2016 \$ thousands	% change
Dose sales	4,950 units	5,728 units	+ 15.7%
Revenue from sale of goods	80,452	112,596	+ 40.0%
EBITDA	22,362	34,860	+55.9%
Profit before tax	23,925	33,156	+ 38.6%
Net profit after tax	17,655	25,939	+ 46.9%
Cash and cash equivalents*	55,455	73,738	+ 33.0%
Cash flow from operations	21,948	22,189	+ 1.1%
Earnings per share (cents)	31.3	45.4	+ 45.0%
Total R&D Investment**	4,125	5,443	+ 32.0%
Total Clinical Investment**	11,988	10,832	- 9.6%

** Inc. cash on deposit for >90 days. Sirtex has no debt. ** Includes capitalised and expensed items, ex amortisation*

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Continued Momentum Delivers a Strong Increase in Reported Net Profit After Tax

Net profit after tax (NPAT) in the first half of the 2016 financial year increased by 46.9 per cent to \$25.9 million, driven by strong double digit dose sales growth, measured operating expenditure growth and the transactional benefit of a lower Australian Dollar versus the US Dollar and Euro over the period, given over 95 per cent of SIR-Spheres microspheres revenues are foreign currency denominated.

Gross margins increased 60 basis points or 0.6 per cent to 84.9 per cent, reflecting improvements in manufacturing efficiencies associated with higher dose sales in the key US market, partially offset by the additional costs associated with the commissioning of the new Frankfurt manufacturing facility. Reported EBITDA increased 55.9 per cent to \$34.9 million, representing an EBITDA/sales margin of 31.0 per cent, up from 27.8 per cent in the pc. NPAT margins increased to 23.0 per cent compared to 21.9 per cent in the pc. The effective tax rate decreased to 21.8 per cent versus 26.2 per cent in the pc.

No interim dividend was declared for the period, which is consistent with previous years. The 2015 financial year final fully franked dividend of 20.0 cents per share was paid during October.

Solid Growth in Global Dose Sales and Revenues

Global dose sales of SIR-Spheres microspheres increased 15.7 per cent to 5,728 units compared to 4,950 units sold in the pc. The result is particularly pleasing in light of the very strong global growth recorded of 26.3 per cent in the first half of the 2015 financial year.

The Americas dose sales of 4,028 units rose 18.8 per cent compared to the pc with revenues growing 46.1 per cent. Dose sales in Europe, Middle East and Africa (EMEA) of 1,219 units were up 8.8 per cent compared to the pc, with revenues growing 19.0 per cent. Dose sales in the Asia Pacific (APAC) region of 481 units increased 9.3 per cent compared to the pc with revenue growth of 27.5 per cent.

The Americas continue to remain a key driver for dose sales and revenue growth into the future and now represent 70.3 per cent of our global mix by volume (up from 68.5 per cent in the pc) and 79.4 per cent by revenue (up from 76.1 per cent in the pc). The strong increase in dose sales is attributable to further awareness and utilisation of SIR-Spheres microspheres in the US market, an increase in the number of hospitals (treatment sites) certified to use our treatment by 17.7 per cent to 533 sites compared to the pc, and representing 8.1 per cent sequential growth over the second half of FY15, and a material increase in our sales and marketing infrastructure following the release of the SIRFLOX data at ASCO.

These initiatives are consistent with Sirtex's 'deep and wide' strategy in the US market to increase the number of procedures within existing treatment sites but also new treatment sites certified to use SIR-Spheres microspheres. We anticipate the benefits of these initiatives to continue in subsequent periods.

Revenue growth of 46.1 per cent to \$89.4 million materially outpaced dose sales growth during the period and was attributable to the depreciation of the Australian dollar against the US dollar, which positively impacted translated product revenues. The average US dollar price achieved per dose remained stable at US\$16,000 following the US\$1,000 price rise implemented in June, 2014.

In Europe, the Middle East and Africa (EMEA), dose sales growth of 8.8 per cent was recorded, despite the very high comparable growth of 28.1 per cent recorded in the first half of the 2015 financial year. Dose sales benefited from solid growth in several of Sirtex's well established Western European markets, including Germany and Belgium. The UK continues to perform well under the Commissioning through Evaluation (CtE) programme. We increased the number of hospitals certified to use our treatment by 10.2 per cent to 302 sites during the year compared to the pcp and 3.8 per cent sequential growth in treatment sites over the second half of FY15.

EMEA product revenues grew 19.0 per cent to \$19.1 million compared with the pcp, reflecting the benefit of a lower Australian dollar versus the Euro and positive mix effects associated with a higher proportion of sales in higher priced markets.

Sirtex remains committed to expanding reimbursement coverage for our innovative therapy across the EMEA region.

Asia Pacific (APAC) dose sales grew 9.3 per cent to 481 doses compared to the pcp. Growth reflected a solid double digit growth performance in Australia, and in several Asian countries including Singapore. However, dose sales growth was impacted by a dispute with our distributor based in South Korea. We anticipate the restoration of sales in this market during the current half. In November we announced the departure of Dr Burwood Chew, Chief Executive – Asia Pacific. Mr Nigel Lange, Chief Executive – EMEA in addition to his current role has assumed overall management responsibility for the APAC business, pending the appointment of a suitable replacement. This process remains ongoing.

Strong APAC revenue growth of 27.5 per cent to \$4.1 million was recorded versus the pcp, reflecting price increases implemented in several markets and a direct to market strategy in several Asian jurisdictions. The number of hospitals certified to use our treatment increased by 4.8 per cent to 132 sites during the year, though on a sequential basis the number of active sites slightly declined.

Operating Expenses

Sirtex's *2020Vision* involves building the internal capabilities and capacity to meet future demand. In the first half of the 2016 financial year, total operating expenses grew 38.3 per cent to \$64.1 million.

Our sales and marketing expenditure increased by 34.3 per cent to \$39.6 million, which represented 35.1 per cent of sales. Over the period, Sirtex significantly expanded its sales and marketing infrastructure particularly in the US, following the results of the SIRFLOX clinical study and presentation at ASCO in June.

Administration expenses, which grew by 23.2 per cent to \$9.5 million, represents 8.5 per cent of sales. Medical Affairs expenses grew 59.8 per cent to \$3.0 million or 2.6 per cent of sales with Regulatory and Quality Assurance expenses growing by 35.9 per cent to \$1.9 million.

As reported previously, we have commenced amortising the capitalised costs associated with the SIRFLOX study over an eight year period under AASB 138 *Intangible Assets*. Amortisation expense attributable to SIRFLOX was \$1.5 million during the period.

Global staff numbers grew 22.3 per cent to 269.

SIRFLOX Update

Initial results of Sirtex's flagship SIRFLOX study in abstract form were presented to the world's leading oncologists at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago in late May. Further presentations of SIRFLOX study data took place in July at the World Congress on Gastrointestinal Cancer (WCGIC) in early July and at the Gastrointestinal Cancers Symposium (ASCO GI) in January, 2016. The 'Best of ASCO' selection of the SIRFLOX study has seen the dissemination of the results at 34 Best of ASCO meetings in 25 countries across the globe by local medical oncologists. This was completed in November.






As previously announced, the main objective of the SIRFLOX study was to provide the oncology community with the necessary Level 1 evidence demonstrating the effectiveness and safety of SIR-Spheres microspheres in combination with modern chemotherapy for patients with colorectal cancer that has spread to the liver. We believe the study achieved this goal.

The SIRFLOX study data was submitted to the *Journal of Clinical Oncology* (JCO) in December. We were pleased to announce yesterday that the study was published in this prestigious Journal. Importantly, JCO has published the SIRFLOX study as a "Rapid Communication", which they define as a commitment to freely disseminate ground-breaking and practice-changing information so that it may benefit all readers and patients of the Journal. Publication of the study provides an important peer-reviewed assessment of the initial study findings presented as an oral abstract at ASCO and will provide our global sales force with a high impact publication to discuss with medical practitioners.

It is important to consider that the education and dissemination of SIRFLOX data remains ongoing. Until we can ascertain the additional benefits the high impact journal publication in the *Journal of Clinical Oncology* provides to our sales force and SIR-Spheres microspheres referrals, an accurate assessment on the use of SIR-Spheres microspheres in higher treatment lines is not currently possible.

All Major Clinical Studies to Complete Recruitment in FY16

Our total clinical investment of \$10.8 million (excluding SIRFLOX amortisation expense), was down 9.6 per cent compared to the pcp, reflecting the near completion of patient recruitment in the SORAMIC and SIRveNIB clinical studies and the progressive analysis and reporting of the major SIRFLOX study outcomes. As at 31st December 2015, the SORAMIC and SIRveNIB had reached the 97% and 95% recruitment level, respectively.

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STUDY NAME	START	TOTAL PATIENTS	% RECRUITMENT AT 30 JUNE 2015	% RECRUITMENT AT 31 DEC 2015	TYPE OF LIVER CANCER	
SIRFLOX	2006	530	100%	100%	mCRC	
FOXfire FOXfire GLOBAL	2010	573	100%	100%	mCRC	
SARAH	2012	460	100%	100%	HCC	
SORAMIC	2010	375	85%	97%	HCC	
SIRveNIB	2011	360	85%	95%	HCC	

mCRC – metastatic colorectal liver cancer or secondary liver cancer; HCC = hepatocellular carcinoma or primary liver cancer

Both the SORAMIC and SIRveNIB clinical studies are anticipated to complete patient recruitment during the first half of calendar year 2016.

The results of the SARAH clinical study are expected in late calendar year 2016.

We anticipate the results of the combined overall survival analysis of the FOXFIRE, FOXFIRE Global and SIRFLOX studies representing over 1,100 patients, will be available during calendar year 2017.

As our major studies approach full recruitment, Sirtex continues to investigate the potential uses of SIR-Spheres microspheres to treat cancers in other organs. Leading this program is our RESIRT study looking into the use of our therapy in renal cell carcinoma (kidney cancer) patients. To date, we have treated 20 patients with varying amounts of radiation, with minimal side-effects observed. A further one patient is required to complete recruitment, which is expected during the first quarter of this calendar year. The primary endpoint is safety and toxicity at 30 days with secondary endpoints of tumour response rate, Progression-Free Survival (PFS) and Overall Survival (OS) at 12 months.

Research & Development Update

During the reporting period we invested a total of \$5.4 million into R&D, up 32 per cent over last year.

R&D expenditure is allocated across a select number of programs which seek to improve our current SIR-Spheres microspheres product under the SIR-Spheres Evolution program, and the development of a range of different platform technologies, such as carbon cage nanoparticles, polymer coated magnetic nanoparticles and a novel radioprotector compound.

We expect to progressively update shareholders on our R&D pipeline as technologies meet important development milestones, including the commencement of first-in-man clinical studies.

Cash flow

Cash from operating activities increased 1.1 per cent to \$22.2 million. While cash from operations was strong, it was impacted by the effects of a higher comparable growth of working capital during the first half of financial year 2015 compared to the previous corresponding period due to increased Debtor days and reduced payables. We anticipate both debtors and payables will normalise over the coming period.

Sirtex remains debt free and with cash and cash equivalents¹ of \$73.7 million at the end of the first half of financial year 2016, representing an increase of 33.0 per cent over the previous corresponding period.

Capital Expenditure

Capital expenditure of \$3.5 million reflects the continued investment into our IT infrastructure, which will allow us to more adequately manage our supply chain, streamline administrative procedures, and enhances sales/customer management. Such enterprise-wide efficiency gains are crucial to effectively manage the business as we continue to grow.

¹ Includes cash on deposit for >90 days.

Our Frankfurt facility remains on track to commence commercial supply of SIR-Spheres microspheres before the end of FY16.

Dividends

The Board declared a final fully franked dividend of 20.0 cents per share for the 2015 financial year, an increase of 6.0 cents or 42.9 per cent over the previous corresponding period. The dividend was paid to shareholders on the 21st October 2015, representing a cash outlay of \$11.4 million (versus \$7.9 million in the pcp). As with previous half year results, no interim dividend was declared by the Board of Directors.

Outlook

The first half results have again highlighted the significant growth that is achievable at Sirtex Medical with positive momentum throughout the 2015 financial year continuing during the period. Record results were delivered. The growth in our global dose sales was particularly pleasing given the very high comparable dose sales growth rate of 26.3 per cent recorded in the first half of financial year 2015. The first half results are testament to our strategies developed under the 2020*Vision* plan which seeks, *inter alia*, to fully maximise the potential value of our innovative SIR-Spheres microspheres product but also further grow the value of Sirtex.

The first half result is consistent with our dose sales objectives for the full financial year which as previously indicated is anticipated to be least in-line with our five year compound annual growth rate or CAGR of 19.7 per cent.

Our Americas business is well positioned to capitalise on the positive structural changes to the operating environment including the 2.8 per cent increase in reimbursement for SIR-Spheres microspheres and the suspension of the 2.3 per cent medical device excise tax, both from 1st January 2016. The benefits of the increased sales and marketing infrastructure, treatment site footprint expansion and the overall referral base will provide additional scope to grow dose sales across this important region. Our EMEA business is expected to benefit from the further expansion in reimbursement, greater awareness following the SIRQLOX results and publication and continued geographic expansion. Our APAC business is positioned to continue to grow with our additional investment into Australian sales and marketing and the reinstatement of sales in South Korea.

Management are focussed on delivering these outcomes for shareholders for the remainder of the 2016 financial year, while at the same time ensuring we continue to progress and expand our R&D portfolio and assess new product or technology acquisitions that meet our long term strategic objectives under the 2020*Vision*.

Additional details about Sirtex's 2016 financial results are included in the Company's Appendix 4D, which have been released separately to the ASX today.

As previously announced to the ASX on 12th February 2016, Sirtex will host an Investor Conference Call to discuss the first half 2016 financial results, including a Q&A session at 9:30 a.m. AEST today. Details of which are provided below:

Toll Free Dial-in Details: Conference ID: 4152 4310

Australia Toll Free: 1800 123 296
Australia Local Dial: +61 2 8038 5221

USA: 1855 293 1544
Hong Kong: 800 908 865
Singapore: 800 616 2288
United Kingdom: 0808 234 0757
New Zealand: 0800 452 782
Canada: 1855 5616 766
Japan: 0120 477 087

Webcast Link

The slide presentation can also be viewed by pasting the following link into your browser:
<http://webcast.openbriefing.com/2628/>

A recording of the call and slide presentation will be made available in the 'Investors' section of the Company website at: <http://www.sirtex.com/au/investors/>.

About SIR-Spheres® Y-90 Resin Microspheres

SIR-Spheres Y-90 resin microspheres are a medical device used in interventional oncology and delivered via Selective Internal Radiation Therapy (SIRT), also known as radioembolisation, directly to liver tumours. SIR-Spheres Y-90 resin microspheres are approved for supply in key markets, such as the United States, European Union and Australia.

About Sirtex Medical

Sirtex Medical Limited (ASX:SRX) is an Australian-based global healthcare business working to improve outcomes in people with cancer. Our current lead product is a targeted radiation therapy for liver cancer. Approximately 61,000 doses have been supplied to treat patients with liver cancer at more than 950 medical centres in over 40 countries. For more information please visit www.sirtex.com.

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