



ASX / MEDIA RELEASE

13<sup>th</sup> August 2015

## Sirtex 2015 Full Year NPAT Increases 69.0% to \$40.3 Million

- Global dose sales increased 19.8% to 10,252 units
- Revenue from sale of goods increased 36.1% to \$176.1 million
- Cash flow from operating activities increased 61.6% to \$52.0 million
- Earnings per share increased 67.8% to 71.4 cents
- Directors declare a Fully Franked Dividend of 20.0 cents per share, an increase of 42.9%

**Sydney, Australia; 13<sup>th</sup> August 2015** - Sirtex Medical Limited (ASX: SRX) today announces an audited full year net profit after tax of \$40.3 million for the period ended 30<sup>th</sup> June 2015. This represents a substantial 69.0 per cent improvement on the prior financial year (\$23.9 million).

Mr Gilman Wong, CEO of Sirtex Medical commented “The strong financial performance of Sirtex in 2015 was driven by an acceleration in global demand for our SIR-Spheres<sup>®</sup> Y-90 resin microspheres targeted radiotherapy treatment for inoperable liver cancer, with all regions delivering double-digit growth in dose sales. This, coupled with price rises in key markets, favourable exchange rates and controlled growth in operating expenditures over the period resulted in our full year earnings growth materially outpacing volume growth as measured by dose sales.”

### Full Year Financial Highlights

	2014 \$ thousands	2015 \$ thousands	% change
<b>Dose sales</b>	8,561 units	10,252 units	+ 19.8%
<b>Revenue from sale of goods</b>	129,363	176,088	+ 36.1%
<b>EBITDA</b>	32,702	55,147	+68.6%
<b>Profit before tax</b>	31,110	52,768	+ 69.6%
<b>Net profit after tax</b>	23,868	40,345	+ 69.0%
<b>Cash and cash equivalents*</b>	52,495	73,941	+ 40.9%
<b>Cash flow from operations</b>	32,171	51,974	+ 61.6%
<b>Earnings per share (cents)</b>	42.5	71.4	+ 67.8%
<b>Dividend per share (cents)</b>	14.0	20.0	+ 42.9%
<b>Total R&amp;D Investment**</b>	7,981	8,641	+ 8.3%
<b>Total Clinical Investment**</b>	22,168	20,724	- 6.5%

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

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## **Significant Increase in Full Year Net Profit After Tax**

Net profit after tax (NPAT) in the 2015 financial year increased by 69.0 per cent to \$40.3 million, materially exceeding revenue growth of 36.1 per cent.

Reported EBITDA increased 68.6 per cent to \$55.1 million, representing an EBITDA/sales margin of 31.3 per cent, up from 25.3 per cent in the previous corresponding period. Gross margins remained stable at 84.3 per cent. NPAT margins increased to 22.9 per cent versus 18.5 per cent in the previous corresponding period. The effective tax rate increased 20 basis points to 23.5 per cent in 2015.

## **Acceleration in Global Dose Sales and Revenues**

Global dose sales of SIR-Spheres microspheres increased 19.8 per cent to 10,252 units compared to 8,561 units sold for the same period last year. The acceleration in growth over the prior year highlights the greater acceptance of our product by the oncology community, coupled with increased investment into our sales and marketing infrastructure.

The Americas dose sales of 7,076 units rose 21.2 per cent with revenues growing 42.5 per cent compared to the same period last year. Dose sales in Europe, Middle East and Africa (EMEA) of 2,273 units were up 18.6 per cent compared to the same period last year, with revenues growing 17.3 per cent. Dose sales in the Asia Pacific (APAC) region of 903 units increased 11.6 per cent compared to the same period last year with revenue growth of 20.5 per cent.

The Americas remain a key driver for dose sales and revenue growth into the future and now represent 69.0 per cent of our global mix by volume and 77.6 per cent by revenue. The strong increase in dose sales reflects the growing awareness and utilisation of SIR-Spheres microspheres in the US market, coupled with an increase in the number of hospitals certified to use our treatment by 17.7 per cent to 493 sites.

Materially higher revenue growth was attributable to the full year impact of the 6.7 per cent increase in our US selling price to US\$16,000 implemented in June 2014 and the depreciation of the Australian dollar against the US dollar, which positively impacted translated product revenues.

In Europe, the Middle East and Africa (EMEA), strong dose sales growth was recorded, reflecting the full year benefit from the restoration of funding for SIR-Spheres microspheres through the Commissioning through Evaluation (CtE) process in the UK. Dose sales also benefited from good growth achieved in several of Sirtex's well established Western European markets and several Middle Eastern markets. We increased the number of hospitals certified to use our treatment by 11.5 per cent to 291 sites during the year.

The recommendation of SIR-Spheres microspheres into the published European Society for Medical Oncology (ESMO) clinical guidelines for the treatment of metastatic colorectal cancer in patients who have failed to respond to available chemotherapy options also significantly improved awareness and interest among European clinicians.

Asia Pacific (APAC) dose sales growth reflected a solid performance in Australia, and new direct market entries. Our revenue growth exceeded dose sales growth resulting from price increases implemented in several markets and the top line benefit of a direct sales model approach. The number of hospitals certified to use our treatment increased by 17.4 per cent to 135 sites during the year.

## **Operating Expenses**

Sirtex's *2020Vision* involves building the internal capabilities and capacity to meet future demand. In 2015, total operating expenses grew 25.6 per cent to \$99.6 million.

Our sales and marketing expenditure increased by 32.3 per cent to \$65.1 million, which represents 37.0 per cent of sales. This included \$6.4 million specifically targeted at educating and building awareness within the medical oncology and interventional radiology community both prior to and immediately following the release of the SIRFLOX study. Sirtex committed a total \$10.0 million to this initiative.

Administration expenses which grew by 12.4 per cent to \$15.2 million representing 8.7 per cent of sales. Medical Affairs expenses grew 69.1 per cent to \$4.7 million with Regulatory and Quality Assurance expenses growing by 28.1 per cent to \$3.2 million.

Global staff numbers grew 15 per cent to 246 during the period.

## **SIRFLOX Study Reports Strong Liver Benefits**

The detailed results of Sirtex's flagship SIRFLOX study were presented to the world's leading oncologists at the American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago in late May.

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.

The SIRFLOX study data showed that SIR-Spheres microspheres plus chemotherapy in first-line metastatic colorectal cancer (mCRC) extended the amount of time it took for the tumours to progress or 'grow' in the liver by 7.9 months. The results also showed that patients who received SIR-Spheres microspheres plus chemotherapy had a 31 per cent lower risk of the tumours in their liver progressing compared to patients who received chemotherapy alone, and were three times more likely to have their liver tumours disappear altogether. These very strong results were deemed clinically meaningful and significant in the liver.


Sirtex is now focused on helping educate and inform as many oncology professionals as possible so they are able to use the valuable insights from the SIRFLOX study to improve the clinical outcomes for their patients facing the challenge of this disease.

It is clear the Level 1 clinical data generated by the SIRFLOX study and the ongoing dissemination of these data will help facilitate an increase in the use of SIR-Spheres microspheres at an earlier stage of patient treatment. Accordingly, we expect that adoption of SIR-Spheres microspheres into earlier treatment lines, including the first-line treatment of mCRC patients with liver tumours, will gain momentum over time.

As the SIRFLOX study has now completed and reported key findings at ASCO, under AASB 138 *Intangible Assets* Sirtex will now amortise the capitalised costs of the SIRFLOX study over a period of eight years.

## Other Major Clinical Studies Progress Considerably

Our total clinical investment during the financial year was \$20.7 million, down 6.5% on the previous year, reflecting the progressive completion of patient recruitment in the FOXFIRE and FOXFIRE Global studies in January and the SARAH study in March, coupled with the release of the final SIRFLOX results.

					
STUDY NAME	START	TOTAL PATIENTS	% RECRUITMENT AT 30 JUNE 2014	% RECRUITMENT AT 30 JUNE 2015	TYPE OF LIVER CANCER
SIRFLOX	2006	530	100%	100%	mCRC
FOXFIRE FOXFIRE GLOBAL	2010	573	94%	100%	mCRC
SARAH	2012	460	92%	100%	HCC
SORAMIC	2010	375	63%	85%	HCC
SIRveNIB	2011	360	69%	85%	HCC

*mCRC – metastatic colorectal cancer; HCC – hepatocellular carcinoma*

Our remaining two major studies, SORAMIC and SIRveNIB reached the 85% recruitment level by the end of the financial year. The results of the SARAH 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 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. Our RESIRT pilot study has continued to show great promise with minimal side-effects in patients treated with high doses of SIR-Spheres microspheres. To date, we have treated 18 patients, with promising results delivered. Patient recruitment is expected to be complete by early calendar year 2016.

## New product development

During the reporting period we invested a total of \$8.6 million into R&D, up 8.3 per cent over last year. Over the past five years we have invested \$34.5 million into developing and expanding our R&D portfolio.

R&D expenditure is allocated across a select number of programs which seek to improve our current SIR-Spheres microspheres product under the 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. All of which have multiple oncology applications through a direct therapeutic effect, increasing the power of existing treatments or reducing side-effects.

SIR-SPHERES® EVOLUTION (in house & various collaborators)	CARBON CAGE TECHNOLOGY (Australian National University)	NANOPARTICLE DEVELOPMENTS (University of Sydney)	RADIOPROTECTOR PROJECT (Peter MacCallum Cancer Centre)
<ul style="list-style-type: none"> <li>• New delivery apparatus</li> <li>• Imaging for treatment planning</li> <li>• Imageable Spheres</li> </ul>	<ul style="list-style-type: none"> <li>• Safely deliver radioactive substances to specific cancer sites deep within the body</li> <li>• Therapeutic agent for intra-peritoneal micrometastases from ovarian cancer (also with NCCS)</li> </ul>	<ul style="list-style-type: none"> <li>• Cellular targeting to improve the effectiveness of chemotherapy</li> <li>• Enhancement of external beam radiation therapy</li> </ul>	<ul style="list-style-type: none"> <li>• Topical agent to prevent oral mucositis during radiotherapy for head &amp; neck cancer</li> <li>• Oral/systemic radioprotector for military and/or civilian use</li> </ul>

Recognising the inherent risk in new technology development, the majority of R&D investment comprises active collaborations with leading international research institutions, with the capability and infrastructure to accelerate technology development. Our collaborators include the Australian National University, the Peter MacCallum Cancer Centre, the University of Sydney, and the National Cancer Centre of Singapore (NCCS).

## Cash flow

Cash from operating activities increased 61.6 per cent to \$52.0 million. Sirtex remains debt free and with cash and cash equivalents<sup>1</sup> of \$73.9 million at the end of the 2015 financial year, representing an increase of 40.9 per cent over the prior corresponding period.

## 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 prior corresponding period. The record date for the dividend is 30<sup>th</sup> September 2015 and the payment date is 21<sup>st</sup> October 2015.

## Outlook

We believe dose sales growth will continue in-line with historic trends, driven by a large unmet medical need for our liver cancer therapy, where we have penetrated less than 2 per cent of the addressable global market.

The Level 1 evidence generated from the peer-review process and presentation of the SIRFLOX results further enhances our key marketing and reimbursement initiatives. Adoption into earlier treatment lines, including first-line, will therefore gain momentum over time.

During the 2016 financial year, we expect our remaining major clinical studies SORAMIC and SIRveNIB will complete patient recruitment.

We are also pleased with our progress under the *2020Vision* during the year, which will ensure the long term expansion and growth of the Company.

<sup>1</sup> Includes cash on deposit for >90 days.

Additional details about Sirtex's 2015 financial results are included in the Company's Appendix 4E and Annual Report which have been released separately to the ASX today.

As previously announced to the ASX on 3<sup>rd</sup> August 2015, Sirtex will host an Investor Conference Call to discuss the 2015 financial results, including a Q&A session at 11:00 a.m. AEST today. Details of which are provided below.

**Conference ID: 9533 0484**

**Toll Free Dial-in Details:**

Australia Toll Free: 1800 123 296  
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USA: 1855 293 1544  
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Singapore: 800 616 2288  
United Kingdom: 0808 234 0757  
New Zealand: 0800 452 782  
Canada: 1855 5616 766  
Japan: 0120 985 190

**About SIR-Spheres<sup>®</sup> Y-90 Resin Microspheres**

SIR-Spheres Y-90 resin microspheres are a medical device used in interventional oncology to deliver Selective Internal Radiation Therapy or SIRT (also known as radioembolisation), a proven technology for inoperable liver tumours that delivers substantial, targeted doses of radiation directly to the cancer. Key SIR-Spheres Y-90 resin microspheres regulatory approvals include Pre-Market Approval (PMA) from the US FDA, European Union (CE Mark) approval and Australian TGA approval.

**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 called SIR-Spheres<sup>®</sup> Y-90 resin microspheres. More than 55,000 doses have been supplied to treat patients with liver cancer at more than 900 medical centres in over 30 countries. Please visit [www.sirtex.com](http://www.sirtex.com).

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