



ASX / MEDIA RELEASE

9<sup>th</sup> December 2016

## Trading Update

**Sydney, Australia; 9<sup>th</sup> December 2016** – Sirtex Medical today provides a trading update following a first half review of operations and expectations of dose sales growth throughout the remainder of the financial year ended 30<sup>th</sup> June 2017.

As a result of lower than anticipated dose sales recorded in the Americas and EMEA regions, worldwide first half dose sales growth is anticipated to be in the order of 4-6% compared to growth in the prior corresponding period (pcp) of 15.7%. As the company continues to invest ahead of the expected results of its major clinical studies next year, constant currency EBITDA<sup>1</sup> for the first half is anticipated to be in the range \$30-32 million, representing a decline of 16% to 9% versus the pcp.

On a full year basis, worldwide dose sales growth is anticipated to be in the order of 5-11% compared to growth of 16.4% achieved in FY16. Constant currency EBITDA<sup>1</sup> for the full year is anticipated to be in the range \$65-74 million, representing a decline of 12% to no growth versus the pcp.

Mr Gilman Wong, CEO of Sirtex Medical commented “We anticipated achieving double digit growth in the first half, however trading conditions have been volatile and impacted by a number of factors, including increased competition for patients with liver-directed therapies, a new drug approval in salvage metastatic colorectal cancer and restrictions in reimbursement. We have implemented a range of strategic initiatives across the regions to address the disappointing first half, which we anticipate will result in an improved second half and full year dose sales performances, irrespective of the results from our three major clinical studies that are due to report findings in the first half of calendar year 2017.”

Mr Wong continued “It is important to recognise that our SIR-Spheres<sup>®</sup> Y-90 resin microspheres business represents a long term growth opportunity, with a large contestable market, and low penetration to date. Our product has industry-leading evidence of benefit for liver cancer patients, which we will continue to leverage.”

Sirtex management will host an Investor Conference Call on the Trading Update including a Q&A session from **9:00-9:30 a.m. AEDT today** (details below).

An update on the performance of our three regions is described below.

<sup>1</sup> Constant currency was applied by restating the first half of FY17 and full year FY17 with the half year and full year FY16 average rates: Half year: AUD/USD – 0.723, AUD/EUR – 0.655, AUD/SGD – 1.012; Full Year: AUD/USD – 0.724, AUD/EUR – 0.656, AUD/SGD – 1.012. A determination of the constant currency effect for sales revenue 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.

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## Americas

Due to tougher than expected market conditions, we anticipate first half dose sales growth in the Americas of 4-6% over the pcp. The business has experienced increased competitive pressures in the medical oncology referral market as well as the Interventional Oncology (IO) market.

Patients are usually referred by their medical oncologist in order to receive SIR-Spheres microspheres and clinicians treating metastatic colorectal cancer (mCRC) have seen an additional oral therapeutic agent approved by the FDA to treat salvage patients, in direct competition with patients who, subject to eligibility, have traditionally been referred for SIR-Spheres microspheres treatment. Our medical oncology sales force is cognisant of these challenges and is proactively marketing the benefits of SIR-Spheres microspheres for these patients.

As a result of the high growth characteristics of the IO market, we have observed a significantly higher level of sales and marketing activity around liver-directed therapies including drug-eluting beads, embolization beads, and the alternate Yttrium-90 radioembolisation beads. These alternate transcatheter therapies are utilised in our existing market, and has impacted our sales growth trajectory during the first half. We continue to invest heavily in educating the oncology referring physicians to educate them on the benefits of our product to develop a preference for SIR-Spheres microspheres for their patients that are candidates for liver-directed therapy.

As previously indicated, we have seen some evidence of the utilisation of SIR-Spheres microspheres into higher treatment lines, including first-line mCRC following the results of the SIRFLOX study. However, it is now clear to us that the majority of clinicians are awaiting the Overall Survival (OS) data from the SIRFLOX/FOXFIRE/FOXFIRE Global studies in the first half of CY17, before a significant change to their referral patterns was to occur.

Recent developments we believe will positively impact discussions with referring clinicians. In late November, revised National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines in Oncology for colon and rectal cancer were published. The revised guidelines have seen SIR-Spheres microspheres re-classified from a Category 3 level of evidence and consensus to a Category 2A.

The NCCN concluded “Consensus amongst panel members is that arterially directed catheter therapy and, in particular, yttrium-90 microsphere selective internal radiation is an option in highly selected patients with chemotherapy-resistant/-refractory disease and with predominant hepatic metastases.”

SIR-Spheres Y-90 resin microspheres remain the only FDA cleared yttrium-90 microspheres for mCRC. We believe the revision to a Category 2A level of evidence by the NCCN is an important step forward in building awareness and utilisation of our innovative therapy over time in this setting.

Recently, the Centers for Medicare and Medicaid Services (CMS) issued its final payment rule for yttrium-90 therapy, which will see the payment rate increased by 3% to US\$16,501 in CY17 and provides pricing stability across the region. The CMS final rule with comment period revises the Medicare hospital outpatient prospective payment system (OPPS) and the Medicare ambulatory surgical center (ASC) payment system for CY17.

We continue to lay the foundations for long term growth within this important region, with the expansion of our sales and marketing infrastructure to build referrals and drive utilisation across our expanding footprint of treatment centres in the U.S, while also expanding our presence in Latin America and Canada. We are confident in the long term growth potential of the Americas.

## **Europe, Middle East and Africa (EMEA)**

Lower growth for the period was principally related to unexpected tightness and delays in reimbursement. As a result, our first half dose sales growth is anticipated to be in the range of 2-3% over the pcp.

Our major EMEA market Germany has experienced funding restrictions for SIR-Spheres microspheres at the regional level across several German States, leading to negligible dose sales growth in that market during the first half. Sirtex is working closely with a number of important hospital customers across these regions to educate the Krankenkassen (sick funds) on the evidence of SIR-Spheres microspheres to ensure that eligible patients with inoperable liver cancer are able to receive treatment.

In March, 2016 Sirtex received national reimbursement coverage in the Netherlands for patients with mCRC who have failed or are intolerant to previous chemotherapy. As previously indicated, SIR-Spheres microspheres was intended to be offered across an initial ten centres across the Netherlands. However, site set up, approvals and reimbursed sales has been slower than expected during the first half, though we expect dose sales in the Netherlands to accelerate commencing early in second half of the financial year.

Since September 2013, limited funding for SIR-Spheres microspheres has been available through the Commissioning through Evaluation (CtE) scheme across England. Recently, NHS England (NHSE) confirmed that the funding for SIRT within the CtE scheme would cease at the end of March 2017. A decision about whether to routinely fund SIRT by the NHSE could take up to 16 months from the end of March 2017.

Sirtex is actively engaged with clinicians, their professional societies and patient groups in arguing this decision, directly and via elected representatives, to NHSE. The aim to ensure a funding mechanism is in place to treat these patients who have limited or no other treatments available to them. The cessation of the CtE does not impact private insurance coverage of SIR-Spheres microspheres in the UK.

While we have placed considerable effort around expanding reimbursement within existing markets, at the same time we continue to expand our presence across emerging markets within the region, particularly in Eastern Europe, the Middle East and Central Asian Republics. Sirtex is adopting a proactive approach in these markets as healthcare expenditure expands, particularly in the area of oncology. We continue to await additional government reimbursement decisions for SIR-Spheres microspheres across the EMEA region. While we are confident of obtaining additional reimbursement, the timing of such decisions remains largely outside of Sirtex's direct control.

We anticipate formalising the appointment of a CEO, EMEA region prior to the end of 1Q CY17.

## **Asia Pacific (APAC)**

Across Asia, growth has generally been within management expectations, with the key market of Singapore performing to plan. We anticipate first half dose sales growth in the APAC region of 8-10% over the pcp. The additional investment into sales and marketing infrastructure into Australia flagged at the FY16 results, has seen a marked improvement in SIR-Spheres microspheres growth in the latter part of the half, which is pleasing. Australia remains an important market for Sirtex. We continue to investigate new markets across the APAC region, while acknowledging the complexities of such opportunities and the general restrictions around reimbursement.

We anticipate formalising the appointment of a CEO, APAC region prior to the end of 1Q CY17.

## **Summary/Outlook**

Though dose sales growth has been below management's expectations during the first half, Sirtex anticipates an improved second half performance, with forecast FY17 dose sales growth in the order of 5-11% over the pcg and constant currency EBITDA in the range \$65-74 million.

Sirtex's first half financial results will be released on 22<sup>nd</sup> February, 2017.

## **Conference Call Details**

Sirtex management will host an Investor Conference Call on the Trading Update including a Q&A session from 9:00-9:30 a.m. AEDT today.

Participants are encouraged to register at least 5-10 minutes prior to the commencement of the call. A recording of the call will be made available in the 'Investors' section of the Company website at: <http://www.sirtex.com/au/investors/>.

## **Conference ID: 3493 8629**

### **Toll Free Dial-in Details:**

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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 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 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. Over 67,000 doses have been supplied to treat patients with liver cancer at more than 1,000 medical centres in over 40 countries. For more information please visit [www.sirtex.com](http://www.sirtex.com).

For further information please contact:

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