



ASX / MEDIA RELEASE

23 August 2017

Sirtex Records Underlying Full Year NPAT of \$42.4 Million

- FY17 global dose sales increased 5.4% to 12,578 units
- Underlying constant currency EBITDA¹ of \$70.2 million
- Underlying Net Profit After Tax (NPAT) of \$42.4 million
- FY17 Reported Net Loss After Tax of \$26.3 million, driven by \$90.5 million in non-cash, one-off clinical and R&D asset impairments and additional restructuring charges

Sydney, Australia

Sirtex Medical Limited (ASX: SRX) today announces its financial results of the full year ended 30 June 2017. The Company recorded a Net Loss After Tax of \$26.3 million, compared to the previous corresponding period (pcp) Net Profit After Tax (NPAT) of \$53.6 million.

Mr Andrew McLean, Chief Executive Officer of Sirtex Medical commented “The 2017 financial year was a challenging one for Sirtex, reflecting the dual fiscal impact of a lower dose sales growth profile and a high level of committed expenditure in anticipation of positive clinical data, which drove down our underlying financial performance. However, we have now taken decisive actions to improve our financial performance through targeted cost reductions, which are expected to deliver a more focussed and efficient organisation that improves our effectiveness in realising the potential of our SIR-Spheres[®] Y-90 resin microspheres business across the globe. I look forward to updating shareholders on our progress throughout the year.”

Full Year Financial Highlights

	FY16 \$'000	FY17 \$'000	Change
Dose sales	11,931	12,578	5.4%
Product revenue	232,492	234,282	0.8%
Underlying EBITDA	74,366	61,453	(17.3%)
Reported EBITDA	74,366	(36,684)	(149.3%)
Underlying earnings per share (cents)	93.7	73.5	(21.6%)
Reported earnings per share (cents)	93.7	(45.5)	(148.6%)
Dividend per Share (cents)	30.0	30.0	0.0%
Cash flow from operations	65,211	55,972	(14.2%)
Cash and cash equivalents*	107,025	118,349	10.6%

* Inc. cash on deposit for >90 days. Sirtex has no debt. Underlying EBITDA, EPS clinical and R&D asset impairments, restructuring costs and impairment/write-off of receivables.

¹ 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 clinical and R&D asset impairments, restructuring costs and impairment/write-off of receivables.

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Clinical and R&D Asset Impairment, Restructuring and NPAT

Following the dissemination of clinical findings at major oncology conferences during the 2H17 period, the Board assessed the carrying value of the combined SIRFLOX/FOXFIRE/FOXFIRE Global study in metastatic colorectal cancer (mCRC) and the SARAH/SIRveNIB studies in hepatocellular carcinoma (HCC). In all instances, the primary endpoint of the studies was not met.

Additionally, the carrying value of certain development costs related to product and user enhancements for SIR-Spheres microspheres were also assessed by the Board.

As a result, the Board decided to impair the entire carrying value of those assets and the SORAMIC study, representing a pre-tax, one-off, non-cash impairment charge of \$90.5 million for FY17.

Following results of recent clinical studies, an extensive review of the business was also undertaken to identify areas where greater efficiencies could be implemented.

The Company announced in June that certain identifiable resource inefficiencies and a focus on the core business would result in headcount reductions of approximately 15% across the business primarily in the clinical, R&D and global sales & marketing functions. Accordingly, Sirtex has recorded a pre-tax restructuring charge of \$4.1 million, mostly relating to provisions for employee redundancies. An additional \$3.6 million charge was taken for the impairment and write-off of receivables, relating to an EMEA distributor and a US hospital entering bankruptcy.

These asset impairments and restructuring charges materially impacted Sirtex's statutory financial results, with the Company reporting a Net Loss After Tax of \$26.3 million versus an NPAT of \$53.6 million in the previous corresponding period (pcp).

Excluding these one-off significant items, the Company recorded an underlying NPAT of \$42.4 million, which was down 20.9% on the pcp.

Margins

Gross margins remained relatively stable at 84.5%. Commercial supply commenced from our manufacturing plant in Frankfurt during the 2H17. Underlying EBITDA declined 17.3% to \$61.5 million (down 5.6% in constant currency), representing an EBITDA/sales margin of 26.2%. The decline in underlying EBITDA was largely attributable to higher sales and marketing to support future growth and in preparation for the reporting of major clinical studies, which occurred in the latter part of the financial year. Admin costs were higher due to the class action legal fees.

The underlying NPAT margin fell to 18.1% from 23.0% in the pcp.

Regional Performance

Global dose sales of SIR-Spheres microspheres increased 5.4% to 12,578 units compared to the pcp. The number of treatment centres globally certified to use our product increased 9.0% to 1,093 centres, versus the pcp.

Dose sales in the Americas of 8,807 units increased 4.6% compared to the pcp while Americas revenue growth was up 0.9% (up 4.7% in constant currency) to \$186.9 million. Pricing remained stable for the period. The Americas region will continue to remain a key driver for dose sales and revenue growth into the future, and represents 70.0% of our global mix by volume and 79.8% by revenue.

The slowdown in full year growth achieved by the Americas relative to that achieved in the pcp was the result of a general decline in referrals to SIR-Spheres microspheres in salvage metastatic colorectal cancer due to drug-based therapies and competition for patients with clinical studies, a reduction in referrals for first-line patients prior to and post our clinical data from SIRFLOX/FOXFIRE/FOXFIRE Global, a general uptick in competition for patients with liver-directed therapies, and a generally tighter reimbursement environment.

In June, we announced changes to the organisational structure which included changes in our sales and marketing infrastructure in the key US market to allow our sales staff to more efficiently and effectively engage our key clinician referrers and user group, while enhancing our patient-specific focus. We anticipate the benefits of this restructure will begin to flow through the organisation in FY18.

We continued to grow our presence in the region with an increase in the number of treatment sites certified, growing 13.3% to 639 sites compared to the pcp.

In Europe, the Middle East and Africa (EMEA), dose sales growth of 5.9% to 2,677 was recorded, which represents 21.3% of our global mix by volume. We increased the number of treatment sites certified to use SIR Spheres by 0.7% to 308 sites during the year compared to the pcp.

EMEA product revenues were down 1.6% (up 6.4% constant currency) to \$38.3 million compared with the pcp, reflecting mix impacts from lower growth recorded in higher priced markets and currency impacts. We were pleased to achieve reimbursement for our product in France for refractory metastatic colorectal cancer, with reimbursed sales commencing in the last quarter of FY17.

Disappointingly, government reimbursement in the UK via the Commissioning through Evaluation (CtE) program ceased at the end of March, which materially impacted dose sales in that market with sales limited to private patients only. The Company continues to work with a number of different groups to re-establish funding in that market as soon as practicable. A decision as to whether to routinely fund SIR-Spheres microspheres could take up to 16 months from the end of March.

Asia Pacific (APAC) dose sales grew 11.3% to 1,094 doses compared to the pcp. APAC represents 8.7% of our global mix by volume. APAC revenues of \$9.1 million were up 8.6% on the pcp (up 11.5% in constant currency). We saw continued sales momentum in Australia, and sales growth across a number of South East Asian markets. The number of hospitals certified to use our treatment across the region was 146 sites, up 9.8% on the pcp.

Operating Expenses

In FY17, total operating expenses grew 12.7% to \$146.4 million, driven by sales and marketing expenditure that increased by 12.5% to \$89.3 million, representing 38.1% of sales (34.1% in pcp). The increase was largely the result of an infrastructure build-out in anticipation of the clinical studies, targeted marketing campaigns and costs associated with a major European symposium held in Rome.

Administration expenses grew by 7.6% to \$22.5 million or 9.6% of sales, reflecting the legal costs associated with the ongoing class action. Medical expenses grew 20.5% to \$7.7 million (3.3% of sales), due to the continued excellent recruitment of the RESiN liver tumour patient registry in the US and costs to service the expanding clinician base. Regulatory and Quality Assurance expenses grew 18.9% to \$4.6 million (2.0% of sales).

Global staff numbers grew 5.0% to approximately 300, reflecting additions across predominately the sales and marketing infrastructure in the US during the period. In June, we announced a reduction of approximately 15% of our global workforce following the release of the clinical studies and the slowdown in growth for SIR-Spheres microspheres.

Majority of Clinical Studies Have Now Reported Findings

Our total clinical expenditure in FY17 was \$24.9 million, up 20.5% and represented 10.6% of sales. During the year, we reported the clinical findings from the combined SIRFLOX/FOXFIRE/ FOXFIRE Global clinical study in metastatic colorectal cancer (mCRC) representing 1,103 patients and the SARAH and SIRveNIB studies in hepatocellular carcinoma (HCC), which recruited 467 and 360 patients, respectively. Unfortunately, none of the studies met their primary endpoint of Overall Survival (OS) superiority when SIR-Spheres was combined with, or compared against, the current standard(s) of care within each disease indication. However, the data does not change SIR-Spheres usage, and our current US and European treatment guidelines supporting salvage use are expected to remain unchanged.

In May, the results of SIRFLOX/FOXFIRE/FOXFIRE Global, were released in abstract form and the results presented as an oral abstract at the American Society of Clinical Oncology (ASCO) annual meeting in June. We were disappointed that the combined analyses did not meet the primary endpoint of an OS benefit in these first-line patients and that no statistically significant survival benefit was observed in the pre-specified sub-groups, including those patients with metastatic disease confined to their liver.

However, an exploratory analyses of the combined SIRFLOX and FOXFIRE Global studies showed that for patients with a right-sided primary tumour, median OS was significantly improved, with a statistically significant 4.9 month benefit observed in patients who received SIR-Spheres microspheres plus chemotherapy versus chemotherapy alone. The patient baseline characteristics were also well balanced, with no statistically significant difference observed. The result is considered clinically meaningful but is subject to further confirmatory analyses, coupled with additional supporting evidence of this OS benefit from the FOXFIRE study. Such additional evidence may support consideration of right-sided liver-only or liver-dominant mCRC patients for SIR-Spheres microspheres treatment. At this juncture, Sirtex does not believe another large clinical study to confirm this finding is appropriate.

The SARAH study was the largest Interventional Oncology study ever to compare the current (and only) standard of care chemotherapy agent sorafenib with a liver-directed therapy in HCC. While SIRveNIB, which was of a similar design to SARAH, was the largest ever study to examine a liver-directed therapy versus sorafenib in a predominately Asian population. In both studies while superiority against the standard of care sorafenib was not demonstrated, the data indicated that there was no statistically significant difference in OS between those patients treated with SIR-Spheres microspheres and those treated with sorafenib.

Pleasingly, in patients who were randomised to receive SIR-Spheres microspheres, there were a large number of statistically significant safety, toxicity and tolerability benefits to these patients versus sorafenib across a range of different clinical parameters examined and significantly better Quality of Life scores (SARAH only).

Overall, we were pleased with the SARAH/SIRveNIB results, and we can now market these important findings globally, excluding the USA and Taiwan where we are not approved for HCC. We plan on filing for FDA clearance in the first half of FY18 in support of these results. When granted, the FDA clearance will allow Sirtex to promote SIR-Spheres microspheres for HCC in the USA.

A single remaining major study in HCC, known as SORAMIC, which is examining the combination of SIR-Spheres microspheres with sorafenib in 420 patients across Europe, is due to report findings in the first half of the 2018 calendar year.

We were pleased to launch a new clinical study (SIRCCA) in unresectable, first-line intrahepatic cholangiocarcinoma (iCCA) during the year, which will compare standard of care chemotherapy plus SIR-Spheres microspheres versus standard of care chemotherapy alone. Survival rates for patients suffering from this disease remain poor, with limited treatment options. Recruitment of the 180 patients is expected to be completed by the end of CY18, with overall survival at 18 months the primary endpoint.

In February, the National Cancer Centre Singapore (NCCS) announced an Investigator Initiated Trial (IIT) of SIR-Spheres microspheres plus nivolumab (Opdivo[®], Bristol Myers Squibb) in up to 40 Asian patients with hepatocellular carcinoma (HCC). This study is expected to take up to two years.

Progress in the Sirtex US RESiN Registry has been strong, with approximately 600 patients recruited at the end of the FY17 with 34 sites now active. The RESiN registry has recently been expanded to include sites within Australia and New Zealand. This registry provides a significant number of benefits, including building awareness among clinicians, supporting reimbursement initiatives and providing regulators with real-world evidence of benefit.

Cessation of Most Non-Core R&D Activities and Focus on Outcomes

During the reporting period we invested a total of \$11.9 million into R&D, up 9.5% over the pcp (5.1% of sales versus 4.7% in pcp). As previously announced, Sirtex has reviewed its R&D activities to focus more closely on alignment with the core business. As a result, the majority of the non-SIR-Spheres related expenditure has now ceased.

With regard to the Histone Inhibition Program (HIP), Sirtex intends to complete the Phase 1 safety and toxicity study for its lead compound STC314, which is expected to report findings in 2H FY18. Once these results are available, we will conduct an evaluation of our commercial options for this program.

Solid Financial Position

Cash from operating activities decreased 14.2% to \$56.0 million in the period. Gross operating cash flow to underlying EBITDA (GOCF/EBITDA) was 100%. Cash and cash equivalents² of \$118.3 million, represented an increase of 10.6% on the pcp. The Company has no debt.

Share Buy-Back

In June, we commenced a \$30 million on-market share buy-back. At the end of the FY17 period, we bought back \$2.9 million worth of our stock, representing approximately 231,000 shares. A further \$27.1 million remains to be bought back which is expected to be completed by 8 September 2017. Accordingly, the expected earnings accretion from the buy-back will be skewed towards the FY18 period.

Dividend

The Board declared a final unfranked dividend of 30.0 cents per share for the 2017 financial year, which is identical to the prior year. The record date for the dividend is the 27th of September and the payment date is the 18th of October.

The Board remains committed to maximising shareholder returns where possible. It is important to note that inclusive of the \$30 million share buy-back and the approximately \$16.8 million in expected dividend payments to be made in October, the Company will have returned approximately \$47 million to shareholders during the current calendar year.

Class Action

In January, the Company received a letter and draft statement of claim, foreshadowing the commencement of a representative proceeding against the Company in the Federal Court of Australia. The statement of claim alleged breaches by the Company of its continuous disclosure obligations, and alleged misleading and deceptive conduct. The statement of claim was subsequently filed at the Federal Court of Australia, Victoria Registry in early February and the proceeding commenced. The matter is set down for trial commencing late October 2018.

The statement of claim alleges breaches by the Company of its continuous disclosure obligations, and alleged misleading and deceptive conduct. Sirtex will continue to vigorously defend the proceeding.

The Company is aware of a further two legal groups attempting to commence a class action against the Company on similar grounds as the initial class action, but to date no such action has commenced.

Outlook

Sirtex remains committed to exploiting the underpenetrated market opportunity for SIR-Spheres Y-90 resin microspheres, globally. We plan to undertake measured expansion in those markets which have high growth potential, such as France given the reimbursement which is now available for our product.

² Includes cash on deposit for >90 days.

We do anticipate the market conditions that manifested in FY17 may persist through FY18, though the resetting of the business means we are now better positioned and more focussed on growing our core SIR-Spheres microspheres business.

While FY17 was a tough year for Sirtex, it is important to note that the addressable market for our therapy in salvage markets we currently contest is 184,000 patients per annum, while the SARAHSIRveNIB results allow us to contest an HCC annual opportunity in our existing markets of approximately 61,000 patients. Our FY17 dose sales imply we are significantly underpenetrated relative to the annual market opportunity.

- ENDS -

Additional details about Sirtex's 2017 full year financial results are included in the Company's Appendix 4E, Annual Report, Appendix 4G and 2017 Corporate Governance Statement, which have been released separately to the ASX today.

As previously announced to the ASX on 9 August 2017, Sirtex will host an Investor Conference Call and Webcast to discuss the full year financial results, including a Q&A session at 9:15 a.m. AEST today. Details of which are provided below.

Participants are encouraged to register at least 5-10 minutes prior to the commencement of the call, using the details provided, below.

Conference ID: 6202 4007

Toll Free Dial-in Details:

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 and audio can also be viewed by pasting the following link into your browser:
<http://webcast.openbriefing.com/3900/>

A recording of the call and slide presentation will be made available in the 'Investors' section of the Company website shortly after the conclusion of the call 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, Canada and Australia.

About Sirtex Medical, www.sirtex.com

Sirtex Medical Limited (ASX:SRX) is an Australian based medical device company with global market coverage. Its core revenue producing technology, which has regulatory approvals, is a selective internal radiation therapy (SIRT), with clinically proven applications for liver cancer with approximately 80,000 doses supplied and administered over 1,090 medical centres in more than 40 countries.

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