Chief Executive Officer's Address
2017 Annual General Meeting
Sydney, Tuesday 24th October 2017

Good morning ladies and gentlemen

In the five months I've been at Sirtex, a lot has happened and perhaps this morning I could put some context around those events, and outline for you the strategy we are pursuing, and our progress with it.

Retirement of chairman

One recent event I'd like to mention at the start is the announcement of Richard Hill's retirement. Richard was one of the first people I met at Sirtex, and has been a helpful guide and support to me. As I have begun to realise the strengths of this business, its strong cash flow, global operations and solid market position, I have seen Richard's hand in building this business in the 11 years he's been chairman. Sirtex and its shareholders should recognise Richard for his contribution. We will miss him, but as he has said, he is also committed to board renewal and hopefully in his retirement, he will be watching us go on to achieve even greater things.

About Sirtex

Having briefly mentioned some of Sirtex's attributes, it might be worthwhile reiterating just exactly what we do and how we operate, because that helps with a better appreciation of our potential. I know that some of you already know most of this, but a refresher for those who perhaps don't know the full picture could be helpful.

Our main product is a medical device, SIR-Spheres Y-90 resin microspheres. It comprises tiny radioactive microspheres that become lodged within the capillaries supplying liver tumours, providing high doses of radiation directly to the tumour and minimising damage to normal liver cells. This form of therapy is known as selective internal radiation therapy, or SIRT.

From inception, approximately 80,000 doses of SIR-Spheres have been supplied to treat liver cancer patients in over 1,090 medical centres in over 40 countries. This therapy works, has regulatory and reimbursement approvals across most major global geographies, and is included in many international clinical guidelines.

80 per cent of sales are currently in the United States, with 16 per cent in Europe, the Middle East and Africa and 4 per cent in the Asia Pacific region.

In our view, current sales are a small percentage of the total addressable market for Sirtex's SIR-Spheres and this highlights the potential of our business.

A key feature of our organisation is our sales and marketing team. They understand our technology, how to sell it, and to whom, and are knowledgeable about the reimbursement systems in their respective markets.

Our sales and marketing effort is focused principally on hospitals and specialist interventional radiology and oncology staff who make decisions to refer and then treat patients with SIR Spheres. Payment for these sales is mostly through medical insurers in the US and principally government sources in other markets.

Supply of our product, where we have a 98% success rate of delivery within a 30 minute window of the scheduled arrival time, originates in our manufacturing facilities in Singapore to service the Asia Pacific region, our facility near Boston in the United States that supports the Americas, and our new facility in Frankfurt, Germany, which serves Europe.

Results

Let me briefly refer to Sirtex's results for FY17. The content is known to you, but I will mention a few highlights that assist understanding.

As an overview, we sold more product than in the previous year, with dose sales up 5.4 per cent along with increased revenue to $234 million and earnings at the normalised EBITDA level were down 17 per cent to $61 million.

There's also three important points to note – cash at 30 June was $118 million, and over the past year we've paid out $17 million in dividends to shareholders at 30 cents a share and our strong cash position has enabled us to complete a $30 million share buy-back. So, combining the dividend and share buy-back, we returned $47 million to shareholders during the last 12 months.

FY17 results also include a non-cash write-off, of intangible assets relating to the major clinical studies and SIR-Spheres development expenditure of $90.5 million, and additionally a restructuring provision of $4.1 million related to reducing staff numbers. The write-offs were principally because we invested significantly in clinical trials which didn't meet their primary end-points, and our staff numbers needed to be aligned with existing, not potential revenue.

Without the write offs, we would have recorded profit after tax of $42.4 million.

The upshot of all this is that we have a highly profitable business, underpinned by a stable and reliable global manufacturing and supply chain operation. The write offs have however highlighted the need for R&D work to be more closely aligned to our core business.

Research & Development

Very briefly on R&D, the one remaining non-core initiative that has continued is the histone inhibition program. Histones are intracellular proteins which are essential for DNA synthesis, and are released from cells when the cells die. When large numbers of cells die at the same time, which happens when you treat an infection, the increased presence of extracellular histones can cause, or exacerbate, sepsis. The symptoms of sepsis can persist and lead to death or long-term disability, even though the initial infection has been treated.

A product that can decrease mortality and reduce the time that patients spend in high dependency care has the potential to save healthcare systems around the world a significant amount of money, placing a high value on this therapy.

Our lead compound in this program is currently in Phase I development. We have completed the acute dosing phase in healthy volunteers and so far, the product has performed in accordance with our expectations and we have seen no unexpected safety issues. Once we have finalised Phase I development, decisions will be taken as to whether we continue development, or seek a strategic partner.

Strategy

Against the backdrop of a very challenging FY17, Sirtex's strategy needed refreshment, with a renewed focus on execution. We've been working on this over the past couple of months with our senior managers, and implementation is now under way.

Our strategy has several **operational** components, and four primary areas of organic expansion; these are **geographical expansion**, **new segments** within existing geographies, **reimbursement** and **broadening indications**. There is a marketing element of **improving our differentiation** from competitors, which is also key. Finally, will also seek to **build new revenue streams** via targeted R&D and acquisitions.

To improve existing operations, we've launched five initiatives.

First we are positioning ourselves for the future with a new focus on a more efficient business, with better business processes. Progress has been made on both these fronts, beginning with lowering staff numbers as announced in June, with that process now complete. An additional example is our new facility in Germany becoming operational during FY17, which moves us closer to our customers in Europe, the Middle East and Africa, which allows us to be more nimble, and means we can now deliver SIR Spheres to our customers on Monday's in key countries within this region.

A second initiative is a new program in the United States to reduce the time taken for doses to get to our clinician customers. This is making a difference, reducing the time lag between order receipt and delivery. We will report more on this at the half year.

Third, we have a pilot program with a key institution, again in the US, which we believe can later be spread across other organisations, where instead of a time gap of days and sometimes weeks between mapping the patient's vasculature and then having the patient return for implantation of SIR Spheres, those two procedures are completed in the same day. This is more convenient for the patient, and we believe may lead to increased patient referrals and potentially also less patient cancellations.

Fourth, we have reviewed how customers order our product and we are making improvements with respect to being easier to do business with. Soon we will offer the option for our customers to order electronically, which is intended to simplify and speed up the process, while also seeking to reduce potential errors.

Fifth is developing new business segments within existing geographies. As an example, we are leveraging the trend of healthcare moving outside the hospital in the United States, with various partnerships forming in the Office Based Laboratories, or OBL segment. We have already assisted several OBL's to gain their required licences, and a small number of patients have been treated in these "alternate site" locations, with an increasing number scheduled. Further proof of concept is required, however we are encouraged by the number of OBL's seeking our assistance in a relatively short period of time and we believe this may lead to new incremental volume, versus a transfer of cases from traditional treatment centres.

Expansion

In expanding geographically, there are two primary considerations – regulatory compliance, which requires developing submissions and working with regulatory authorities to gain approval, and qualifying for reimbursement, from either governments or insurers. Both these considerations can take a long time.

Our FDA approval in metastatic colorectal cancer in the US is a good start for achieving entry to new jurisdictions. We have a premarket approval from the FDA which is based on our safety and efficacy data, which shows our technology works.
In FY18 we expect to see new revenue from entering Canada and Brazil as well as expanding our existing coverage in France where we have improved reimbursement potential, and also Spain.

New markets like China and Japan are longer term initiatives because the registration and market entry requirements are more time consuming. We are reviewing these markets and will make progress, but this will take time, and we will do it carefully.

Indications and reimbursement expansion

As you are all aware, Sirtex announced the results of three large clinical studies between April and June this year. While the main results from these trials were not what we anticipated, there are several interesting clinical findings, which add to the growing body of evidence that SIR-Spheres can play an important role in the treatment of patients with liver tumours. We intend to pursue three of these findings.

The SARAH study, which was presented in April, looked at the benefits of SIR-Spheres in patients with inoperable hepatocellular cancer. SIR-Spheres showed a substantial improvement in Quality of Life and Safety, with no statistically significant difference in survival outcomes when compared directly to sorafenib, the global standard of care for this population.

These results are sufficiently positive to warrant an application to the FDA in the US for treatment of hepatocellular cancer, and that process has commenced with a pre-submission meeting with the FDA scheduled in the very near future. And while we have solid confidence in this submission, after I reviewed the project timelines in detail I decided to take a more conservative approach with respect to timing of the final application submission, which we want to be of the highest quality, and am now guiding that will occur prior to end of financial year 2018.

The metastatic colorectal cancer trial results also revealed some important findings. The location of the primary tumour has emerged over the last couple of years as a major factor that guides treatment for colorectal cancer which has spread, or metastasized, to other organs. It is generally accepted that the right-sided origin tumours are harder to treat, with only limited benefit from current standards of care. One finding with the FOXFIRE Global and SIRFLOX studies was that patients whose cancer started on the right side of the colon before spreading to the liver, were 36% less likely to die at any time during the study if they received SIR Spheres in addition to standard first-line chemotherapy. This group lived an average of nearly 5 months longer, and key opinion leaders agree that this data may be clinically significant. We are working with physicians to understand how this may affect first-line treatment of patients with metastatic colorectal cancer, and expect the full findings to be published in a major oncology journal by the end of this calendar year.

In addition, our RESIRT study explored the effects of SIR-Spheres in renal cell carcinoma, the most common form of primary kidney cancer.

Patients eligible for the RESIRT study had primary renal cancer that was not amenable for, or who declined, conventional therapy. The primary endpoint of the study was safety and toxicity 30 days post-SIRT, with a key secondary endpoint being tumour response. The RESIRT study demonstrated the tolerability of SIRT at all dose levels, with no dose-limiting toxicities reported. SIRT also provided excellent disease control in approximately 95% of patients treated.

While this was a small study, the results were encouraging and we are currently exploring our options and next steps in this indication.

Data and reimbursement

Two critical factors to appreciate about the strategic implementation of the Sirtex business model are the collection of data from use of our technology, and the link between this and improvement of our reimbursement position.

In simple terms, the more extensive the data, the stronger the case we have for our medical device to qualify for reimbursement from insurers and government, and to promote its benefits to potential customers.

A valuable asset Sirtex has for this process is what we call our RESiN Registry, or to give it its full name, the Radiation-Emitting SIR-spheres in Non-resectable Liver Tumour Patient Registry.

This is real-world collection of data from application of our technology, and at 30 June, we had approximately 600 patients in the registry at 34 different medical centres. We are targeting to add around 500 patients annually, with expansion to Australia and New Zealand already commenced.

The FDA supports this approach to data collection, and to ensure the validity and objectivity of the data in the registry, we have a partnership with Vanderbilt University in the United States to provide independent oversight.

In Europe, Sirtex commissioned a registry which was launched and is now managed by CIRSE, the Cardiovascular and Interventional Radiology Society of Europe. At present, 760 patients have been prospectively enrolled, and at close the registry will have around 950 patients. Following the cessation of patient enrolment, the registry will remain active for a 2-year follow-up period, accumulating valuable data.

Accumulation of data can have a powerful effect for reimbursement, supporting regulatory clearances, increasing clinician awareness and expanding the research we can publish. In addition, in many cases this is a more economical method than launching other forms of clinical trials, which are expensive.

Inorganic Growth

The next major part of our expansion strategy is looking at ways we can build additional revenue. Our growing cash flow puts us in an enviable position to consider acquisitions, but I also want to make clear we have developed a discipline around what would make a worthwhile direction for us.

For example, I can tell you what we won't be doing. We will not be going outside our focus on interventional radiology and oncology, since this is where we have the competitive advantage of our sales, marketing, regulatory, reimbursement and other functions which can add value to any acquisition within these defined market segments.

There are not a vast number of acquisition opportunities in our field, but monitoring them is now part of our process of assessing potential.

Competitive and market environment

An aspect of our marketing strategy is to improve our competitive differentiation, especially in comparing our technology with others.

For example, there are significant differences between our resin based microspheres for selective internal radiation therapy and competing glass microspheres, and our existing relationships and interactions with clinical leaders provides a basis for pointing out and capitalising on comparative differences.

Essentially Sirtex's competition comes in two primary forms – development of new alternate therapies, and other companies in our field.

In the metastatic colorectal cancer segment, there are a number of chemotherapeutic agents which are approved or recommended treatment options. We are continuing to monitor developments in this field and are partnering with industry colleagues to ensure we generate data that aids in understanding how SIR-Spheres can be complementary to existing, and emerging treatments.

In hepatocellular cancer, the glass technology has a humanitarian device exemption indication from the FDA which is based on safety data and probable benefit, while our forthcoming FDA submission for that segment of the market is to achieve a premarket approval, based not only on our robust safety data, but importantly, efficacy data as well.

If we are successful with our hepatocellular cancer market entry in the United States, our target market would see an increased market potential of up to approximately 9,000 doses per annum. Sirtex is the clear global market leader in selective internal radiation therapy and we consider our technology has yet to reach its full potential. Last year we sold 12,578 doses in the markets we currently serve today, and without the US hepatocellular cancer indication just mentioned, we have an opportunity to serve more than 180,000 patients a year within the salvage setting.

The treatment of cancer continues to evolve with the advent of immunotherapy. We are encouraged by these developments, as leading oncologists believe that immune checkpoint inhibitors are likely to perform better in the presence of, or in combination with radiation. Therefore Sirtex, and the developers and manufacturers of these immunotherapies, are exploring this potential enhanced combination effect.

The trialling of our technology with nivolumab, an immuno-oncology therapy approved for patients with metastatic colorectal cancer and the first to receive FDA approval for the treatment of hepatocellular cancer, is taking place in two global locations.

This is a new area we're working on, and it's promising.

Human Resources

Key elements in the success of any strategy are execution, and our people enthusiastically contributing all they have along the implementation journey.

We recently conducted group wide research among all our staff and the results were better than we might have expected, especially given a very challenging FY17.

A specialist research company was commissioned to test the pulse of our organisation, with a focus on our associates' views of our culture, leadership and their personal engagement.

We had over a 90 per cent response rate to the survey, which puts us in the excellent category to begin with, where a 60 per cent response rate is typically considered good.

While the survey has identified some areas to work on it essentially showed that our people like their work, believe in our mission, are committed to our organisation, and have very good peer relationships.

Perhaps because we are engaged in such meaningful work that extends people's lives, this commitment may not be surprising, but it confirms that we have terrific support from our people about the direction in which we're now moving.

We've recently conducted senior management sessions around various aspects of strategy implementation and developed the Sirtex mission and values, and I am pleased to say we've again had very positive engagement.

Our mission is to improve the quality and longevity of patients' lives by providing innovative interventional oncology solutions, underpinned by our values which are based on compassion, advancement, reputation and empowerment.

A company-wide summary of this is that we all really care about what we are doing, and this attitude should give us all great confidence as we look to the future.

First quarter FY18

Our first quarter results for FY18 are demonstrating some early favourable results from our focus on efficiency and productivity. Dose sales are effectively flat with the same quarter last year. Sales revenue is down about 5%, driven by unfavourable currency effects, rather than decreases in price. However, the important thing to note is that constant currency profit before tax is up 11.3% for the quarter versus prior corresponding period, and including the unfavourable foreign exchange impact, up 2.9%. We knew that Q1 was going to be difficult emerging from the distracting events of last year. With a more stable organisation and the events of FY17 now largely behind us, new sales & marketing leadership installed in our key US market, we expect to see a better alignment of costs to sales, and hence greater leverage on the P&L as the beginnings of increased revenue from newer markets, coupled with positive results from the newly implemented sales growth initiatives underpin earnings growth for FY18.

Conclusion

In conclusion, I want to leave you with five points.

One, Sirtex is becoming a more efficient and productive company.

Two, there is significant growth potential for our technology. It works, it extends the lives of people with liver cancer and yet we have just an approximate 5% per cent penetration of the addressable market. So, we're going to grow this. We're pursuing multiple opportunities to materially grow revenue and profitability over the medium term.

Three, we're exploring findings from recent research, not at great cost, but with potential to take us into new areas.

Four, we are working with new trends in the treatment of cancer where we can improve outcomes in combination with our product, so we are defending and expanding our territory.

And five, we have a great team of committed and enthusiastic people, to whom I'm very grateful, and who are keen to come along with us on this Sirtex journey.

Andrew McLean

Chief Executive Officer

Sirtex Medical Limited

24th October 2017

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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, 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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