ISSN 1443-850X

In this edition...
While patents are a key element in the biotech investment equation, perhaps what is more significant is the creation of barriers to entry. Sirtex Medical's liver cancer treatment, Sir-Spheres, is delivered by Interventional Radiologists, requiring specialised facilities and very good technique. Over the long term, Sir-Spheres may become an entrenched treatment that could be difficult for rivals to overtake.
Diagnostic technology companies Atcor Medical and Impedimed continue to battle for the take-up of their respective technologies in the US, although the paths being taken differ somewhat.
Tissue Therapies is edging closer to cutting a deal for its wound healing product VitroGro. A point to note is that Tissue intends to retain manufacturing rights.
The Editors
Companies Covered: ACG, IPD, SRX, TIS

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.0%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.3%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.3%
Year 9 (May '09 - May '10)	49.2%
Year 10 (May '10 - Current)	27.5%
Cumulative Gain	**269%**
Av Annual Gain (9 yrs)	**18.5%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd.

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Individual Subscriptions (48 issues/year)
$350 (Inc.GST)
Edition Number 399 (11 March 2011)
ISSN 1443-850X

Bioshares

11 March 2011
Edition 399

Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.

Sirtex Medical – Investing in Long Term Revenue Growth

Sirtex Medical (SRX: $5.35) conducted a briefing in Melbourne this week. In opening the briefing, the CEO of Sirtex Medical, Gilman Wong, said that the company was not about to raise capital, contradicting a news story in the *Australian Financial Review*. Wong said that he was not interviewed for the story.

For the half year ended December 31, 2010, Sirtex posted a net profit after tax of $3.6 million, which represented a 60% decrease from the $9.1 million recorded for the previous corresponding period.

Product revenue increased to $34 million by 9.1% from the same period a year ago, with dose sales increasing by 16.5% to 2,325 units.

What Curtailed Sirtex's Net Result?

Sales were impacted by increased cost of goods (but consistent with increase in volumes, but also higher because of a 100% price increase in services provided by ANSTO Radiopharmaceuticals), a foreign exchange loss of $2.1 million and an increase in clinical expenses of $2 million (to $4.9 million). The previous corresponding period also included a one-off settlement from a legal dispute with the University of Western Australia of $3 million. Sirtex has also increased staff numbers over the last 18 months from 60 a year ago to 99 currently, with the increased labour cost reflected in increases in cost of goods, and in clinical, marketing and R&D costs. The company now has 20 in-house clinical trials staff working alongside six contract research firms.

Results by Regions

The North American region accounted for 59% of dose sale and 64% of revenues in FY2011 H1, with volume growth of 12% on 1,363 reported unit sales. Of note, is the price increase obtained for Sir-Spheres treatment in the USA, where the reimbursable price is now US$15,000 (previously US$14,000). Sirtex lobbied US politicians to achieve the price increase.

The European and Middle East region accounted for 33% of dose sales and 32% of revenue. Dose sales of 760 units increased by 29.5% from the previous corresponding period. Sir-Spheres is sold for between €10-12,000 in the European area. Asia Pacific dose sales of 202 units increased by 3.6% from the same period a year ago.

The Goal of Level 1 Data

CEO Gilman Wong discussed the rationale behind the company's sponsoring of four Phase III/IV trials of Sir-Spheres, which once completed, will have enrolled close to 2,000 patients. Two studies are being conducting in patients with metastatic colorectal cancer (mCRC) that has spread to the liver trialing Sir-Spheres as a first line treatment with chemotherapy, and two studies are being conducted in patients with primary liver cancer. What is required Wong said is the establishment of Level 1 data that is generated from large scale, randomised controlled clinical trials.

Wong said that the company will experience current rates of growth for the next two to three years until evidence of the benefit of Sir-Spheres treatment emerges in other clinical settings.

The Sirtex liver cancer treatment is currently used to treat liver cancer patients as a salvage therapy for patients with secondary liver cancer that has spread from the colon, for whom surgery is not appropriate.

Sirtex has budgeted $60 million over five years to achieve its Level 1 data objective.

Trials Update

Of the four large Phase III/IV studies Sirtex is supporting (see table below) , the most advanced is the SIRFLOX study, involving 450 patients. This is now halfway through recruitment. The SIRVENIB study, which will recruit 360 patients, is still at very early stages of recruitment, being only 7% recruited. Enrolment status for the other two studies was not commented on.

The Asian challenge

One under-performing region for Sirtex has been Asia Pacific. Wong recently appointed Dr Burwood Chew to oversee the region. Chew is an Australian-born and educated medical doctor who is fluent in major Chinese dialects as well as Malay and Vietnamese. He worked formerly with **Welcome** (now GlaxoSmithKline), **Sanofi** and **Bayer**, where he was responsible for the launch of sorefinib (Nexavar) in Asia.

Despite the relative underperformance of the Asia Pacific region, the Sirtex view is that any of the three regions has the potential to be number one in terms of dose sales in the longer term.

Manufacturing

Alongside Sirtex's goal to drive sales by making it a first line therapy is the equal requirement to meet anticipated demand by installing manufacturing capacity. To this end, the company is very close to seeing a new facility in Singapore begin production, which will add to its facilities in Australian and the USA.

Wong stated that the company's new facility in Singapore is now fully fitted out and qualifying runs are being undertaken. Manufacturing of product is expected from June 2011.

Wong made the point that an additional manufacturing facility would be located so that it could supply any of the company's markets around the world.

Sirtex will make a decision on an additional manufacturing site within 6-9 months.

Impediments to Growth

One of the impediments to growth in sales has been the need to train interventional radiologists and set up treatment centres across throughout the world. Now there are over 400 treatment centres delivering the Sir-Spheres therapy and we estimate there are over 500 IRs trained in the procedure.

This entrenched network of users, and effectively promoters of the technology, should now also work in Sirtex's favour. We view the threat of competition low due to the high barriers to entry and that sales remain relatively low, at just under $70 million a year. With such an entrenched position, this therapy should be in use for at least the next 10 years, and very likely for many more years.

Summary

What makes Sirtex Medical interesting is the balance it is striking between short and long term business development. It has made efforts to learn how hospitals use Sir-Spheres and what it can do in practical ways to increase uptake at existing centres. With $60 million devoted over five years to extensive trials work in first line clinical indications, there is a strong drive to deliver sustained long term revenue growth for the business. .

Sirtex Medical is capitalised at $298 million and held cash of $41.2 million at December 31, 2011.

Bioshares recommendation: **Buy**

Bioshares

Sirtex Medical - Key Clinical Trials

Trial Name	Description	Randomisation - Drug Arm	Num. Subjects	Num. Centres	% enrolled to date	Est. study completion
Primary Liver Cancer Studies						
SIRVENIB	Study to Compare Selective Internal Radiation Therapy (SIRT) Versus Sorafenib in Locally Advanced Hepatocellular Carcinoma	Sorefinib	360	33 (APAC)	7%	Jul-15
SORAMIC	Evaluation of Sorafenib in combination with local micro-therapy enhanced MRI in patients with inoperable hepatocellular guided by Gd-EOBDTPA carcinoma	RF Ablation v Palliative Combo of Sorefinib & SirSpheres	375	>30 (EU)	NA	Feb-14
Metastatic Colorectal Cancer						
FOXFIRE	Open-label randomised phase III trial of 5-Fluorouracil, OXaliplatin and Folinic acid +/- Interventional Radio-Embolisation as first line treatment for patients with unresectable liver-only or liver-predominant metastatic colorectal cancer	FOLFOX	490	24 (UK)	NA	Feb-13
SIRFLOX	FOLFOX Plus SIR-SPHERES MICROSPHERES Versus FOLFOX Alone in Patients With Liver Mets From Primary Colorectal Cancer	FOLFOX	450	53	50%	Dec-12
		Total	1675			

Sirtex Medical – Specialists' Seminar Wrap

Sirtex has been conducting seminars this week in Australia for oncologists and interventional radiologists, a target group who prescribe and deliver the company's Sir-Sphere's cancer treatment. Attendees heard from three medical practitioners who are considered experts and regular users of the Sir-Sphere treatment. There were a number of insightful points raised during the Melbourne seminar.

Sir-Spheres is delivering data that is very consistent for use as a third line (salvage) therapy and for those patients who have failed all chemotherapy options, according to Dr Harpeet Wasan, oncologist at **Hammersmith Hospital** in the London. Dr Wasan is an expert in the clinical application of the Sir-Spheres treatment and one of the joint principal investigators of the FOXFIRE study that started last year.

Dr Wasan has been an early adopter and is now a strong supported of the technology. His first patient treated with Sir-Spheres had failed 16 cycles of chemotherapy. After Sir-Spheres treatment, that patient went on to live for an additional four and a half years.

Dr Wasan pointed to data from trials such as the 'Belgium Study' reported last year that supports the use of the treatment for patients with colorectal cancer that has spread to the liver where those patients had failed all chemotherapy options. (In that study, in 26 patients, median survival increase from 7.3 months to 10 months when Sir-spheres was added as a treatment. At the same time, data from a similar Italian study in 50 patients showed a median survival of 12.6 months when Sir-Spheres was added to chemotherapy.)

While the Sirtex therapy has made good global inroads into becoming a widely used therapy for the treatment of liver cancer, one clear point was that larger efficacy studies (Phase III trials) needed to be completed to show clear benefits of prescribing the treatment if it is to be more widely adopted as a first line therapy.

In 2007 Sirtex started a global study, called SIRFLOX, to investigate the use of Sir-Spheres in combination with three chemotherapy drugs (called FOLFOX) in 450 patients. Safety data has now been reported in the first 220 patients. The company is now enrolling 10 patients a month and expects full recruitment in 14 months time.

The safety study data has shown that gastric ulceration has occurred in 9% of patients, slightly lower than the 10% side effect rate expected. Dr Wasan indicated that it needs to be looked at how that side effect rate can be reduced. (Gastric ulceration, which is the main side effect of treatment, occurs when the radioactive Sir-Spheres are not contained in the liver during treatment.)

A second Phase III study, called FOXFIRE, was started last year in the UK. This UK study will also look at combining chemotherapy with Sir-Spheres as a first line treatment in 490 patients. Dr Wasan is one of the Principal Investigators of the study.

The feedback from some oncologists at the seminar was that they were keenly awaiting data from these two major Phase III studies, presumably before they would consider using the therapy as a first line treatment. For one oncologist, only two parameters really mattered: improvement in survival, and improvement in quality of life. Complete response measures were only good for getting drugs approved according to one skeptical oncologist.

One oncologist said that there needs to be a clear risk-reward benefit from improved patient outcomes over possible side effects from utilising the technology.

Multiple Sir-Spheres Treatments

The experts presenting said they had not used more than two Sir-Spheres treatments on any one patient. However it had been reported that it had been used up to five times on a patient in the past. One of the presenters gave an example of one patient who achieved a complete response for four years, and then following a second course, achieved a further 16 months before the disease progressed.

Input from an Interventional Radiologist

Melbourne-based interventional radiologist Dr Manfred Spanger gave a very important insight from the perspective of the interventional radiologist (IR), who delivers the Sir-Spheres treatment to patients.

Screening the patient prior to treatment with Sir-Spheres is extremely important to ensure side effects are kept to a minimum. What is also of interest is the influence that an IR has over the procedure. The IR decides on the safe dose to administer. The IR can decline treatment to a patient if they deem it is unsafe to do so. However this is rare as the IR can generally work around a non-ideal situation, for instance by administering treatment over two sessions, delivering a lower dose – the bigger the dose the more complications as a general rule – varying the delivery point of the treatment, and varying the rate of delivery of treatment. The rate of delivery is a critical parameter stressed Dr Spanger. If the rate of flow of the therapy can't be controlled then reflux is certain to occur.

Dr Spanger gave the impression of being extremely methodical and extensive in his approach to accurately visualizing the geometry of the vasculature system feeding the liver. This is perhaps why his gastric ulceration side effect rate is very low, at only 3%. Diagnostic methods used in screening patients who are suitable for Sir-Spheres treatment include angiography, CT, MRA and PET scans.

The relevance and expertise of the IR has become an important factor about the ongoing use and increased adoption of the Sir-Spheres treatment. There are over 500 IRs worldwide now trained in the procedure. The use of Sir-Spheres no doubt has become an important part of many of their practises and these medical practitioners have effectively become promoters of the technology. One IR in the US flies in deliver treatment of up to nine patients in a sitting every month.

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Impedimed – The Hunt for Covered Lives

Impedimed (IPD: $0.73) is now tackling the third arm of the commercialisation of its L-Dex lymphedema non-invasive detection technology in the USA. The company gained a Category 3 reimbursement code from the American Medical Association (AMA) in June 2010. The code specifies the use of bioimpedance spectroscopy (BIS) in the measurement of extracellular fluid differences of the limbs, significantly not the more narrow specification of arms.

The company looks to have achieved a pricing range (US$220-$240), and is now working to secure coverage decisions from health insurance organizations. The L-Dex system enables physicians to detect lymphedema at a sub-clinical stage.

The claiming of coverage by a diagnostics product (or other) company occurs when a medical product or service is recognized in the medical policy of the health insurer. The issue in the US is that there are hundreds of insurance companies, although several large ones do exist.

Covered Lives Targets

Impedimed had set a covered lives target of 20 million by April 1, 2011 and 50 million by Oct 1, 2011. By claiming coverage for a large number of people, the likelihood of even more coverage ensues, with a bandwagon effect taking place.

The company had hoped that UPMC Health Plan (offered by **UPMC**, an $8 billion health care enterprise managing 20 hospitals in the Pittsburgh area), which represents 1.5 million covered lives, would begin coverage of Impedimed's L-Dex system by January of this year. The expectation existed because the Magee-Womens Hospital of UPMC, a breast cancer hospital, has already begun screening using the L-Dex system. However, the organisation's medical policy director died, which has meant the company has to restart the process of gaining coverage. Impedimed expects further progress made during the month of March on gaining UPMC Health Plan coverage.

Impedimed has been working with **Humana**, a health services firm that accounts for 10.1 million covered lives, **United** (22 million covered lives) , **Aetna** (16 million covered lives) and **Medical Mutual** in Ohio (4 million covered lives).

However, an issue for Impedimed with Humana is that it is not treating L-Dex as a standalone coverage decision. Rather it appears to be including it as part of total breast cancer care policy, covering other items such as biopsy and radiation but also including a section on lymphedema detection. This means that a coverage decision by Humana will be limited to detection using arms rather than limbs (which includes arms and legs). Impedimed's preferred wording for be for the detection of lymphodema using limbs, including both arms and legs, so that it does not have revisit Humana's coverage policy in the future when it introduces technology supporting detection using both arms and legs

UB500

Impedimed is developing a next generation product, the UB500, which will enable detection using both arms and legs and expand lymphodema detection to include the pelvic region. A consequence will be detection of lymphedema that occurs as a result of interventions to treat other cancers in the pelvic area and greatly expand commercial opportunities for Impedimed. The UB500 is a bilateral device with active electrodes which can deal with interference from background electro-magnetic frequencies. The current U400 is a unilateral device that works by using an opposing limb as a control.

Revenue Models

The roll-out of the UB500 may also see Impedimed adopt a different revenue model, allowing Impedimed to give physicians the option to buy the device and purchase electrodes at a cheaper rate, or elect to take a device for free and pay for the electrodes at a higher rate. In other words, Impedimed may be able to operate a dual capital equipment and consumables revenue model.

Impedimed has built 20 UB500 beta-testing models for use in clinical trials.

Impedimed is capitalised at $114 million and held cash at of $19.9 million, with another $4.3 million raised in January through a share purchase plan.

Bioshares recommendation: **Speculative Hold Class A**

Bioshares

Tissue Therapies – Deal on the Way?

Tissue Therapies (TIS: $0.655) remains very confident that a licensing deal for its wound healing technology, called VitroGro, will be transacted in coming months. Negotiations are going extremely well, according to CEO Steven Mercer.

There are four groups that Tissue Therapies has narrowed down the potential partnering field down to, with three of those companies showing particularly strong interest. Tissue Therapies is maintaining it will transact a global licensing deal and will retain manufacturing control, which is a smart move, in line with many of the successful local life science companies, including **CSL**, **Resmed**, **Cochlear**, **Sirtex Medica**l, **Cellestis**, **Universal Biosensors**, **Pharmaxis** and the recently listed **Bioniche**. (**Acrux** also intended to maintain manufacturing control through a third party, **Orion Laboratories** in Finland, and no doubt that was a valuable trade off in its licensing deal for Axiron with **Eli Lilly**).

While the negotiations are progressing, Tissue Therapies has contracted third parties to develop financial models for the wound healing market for the treatment diabetic and venous ulcers. It has also commissioned a health economics analysis for the use of its product, which will presumably deliver information on the price it might be able to sustain in the market from payors.

A global licensing deal may not include some applications of the wound healing therapy, such as the lower cost potential retail products that might be sold through pharmacies.

The company is currently conducting a 40 patient registration trial for VitroGro, at two sites in Wales, two in Brisbane, and one in Perth. The company expects to report trial data by the end of June, and then submit its product for approval in Europe, in the UK through the MHRA (Medicines and Healthcare products Regulatory Agency). If the company can secure a licensing deal by August, then it anticipates a product launch in Europe by year's end.

In the US, Tissue Therapies expects it will need to conduct a small registration trial for its PMA registration, where the therapy will be registered under a medical device category. The company also anticipates it will need to conduct a small reimbursement study.

We place a high probability that Tissue Therapies will be successful in negotiating a global licensing agreement for its technology in the coming months. Although the market opportunity for its product is likely to be in excess of $1 billion, the licensing deal is unlikely to be on terms as high as for a pharmaceutical product.

Tissue Therapies is capitalised at $91 million with $3.1 million in cash at the end of last year.

Bioshares recommendation: **Speculative Hold Class A**

Bioshares

Atcor Medical – Waiting for a Step-change in Sales

Atcor Medical (ACG: 10 cents) is commercialising what should arguably be considered the global gold standard diagnostic test for central blood pressure, called Sphygmocor. Use of central blood pressure goes further then measuring the standard brachial blood pressure, which is more of an instantaneous measurement of hypertension. Central blood pressure measurement is a marker of arterial stiffness, and therefore an accurate measure of overall vasculature health.

In the first half of this financial year, the company achieved sales of just under $4.4 million, and a net loss of just under $1.4 million. Sales increased by 8% in constant currency terms (or 1% increase actual), which is still down 6% in constant currency terms on the peak sales the company achieved in the first half two years earlier.

Atcor had just under $2.1 million in funds at the end of last year. It is seeking to move into profitability in the next financial year (2012). Between 50%-60% of the company's revenues comes from pharmaceutical companies using the technology in clinical trials, primarily in the areas of kidney and cardiovascular diseases.

Another 30% of the company's revenue comes from sale into the research market and the remainder of sales come from clinical use. The end user price of the Sphygmocor instrument is around $16,000 but could be as high as $25,000 depending of software upgrades.

The company currently has over 500 installed systems in clinical trials. Atcor either sells the system to the pharmaceutical company, or it is leased. Atcor does not run the clinical trials, but trains users of the system, supplies the system, can process the data and services the equipment. Currently around half are leased to clients and half are sold in the clinical trials market.

The company is seeking double digit sales growth in the short-to-medium term, until the step change in demand occurs. Atcor is capitalized at only $13 million, which is 1.5 times sales. At some stage that step change should occur. Evidence continues to emerge that confirms the benefit of central blood pressure measurement, most recently this month from a 15 year Taiwanese study that showed non-invasive measurement of central blood pressure was a better predictor of morbidity that either brachial blood pressure of 24 hour ambulatory monitoring of peripheral blood pressure.

Atcor has only accessed only a fraction, around $5-$6 million, of what it believes is a very large pharmaceutical market for its test, valued at around $275 million a year. Central blood pressure measurement is still only used as a secondary measure. When it starts to be used as a primary measure, and when drugs are approved that dictate the use of central blood pressure measurement, it will almost certainly deliver that step change in product demand in daily clinical use by medical practitioners.

In the meantime, Atcor is well placed to deliver sustained growth and move back into profitability next year.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (11 March 2011)

Company	Price (current)	Price added to portfolio	Date added
Somnomed	$1.06	$0.94	January 2011
Phylogica	$0.069	$0.053	September 2010
Sunshine Heart	$0.035	$0.036	June 2010
Biota Holdings	$1.03	$1.09	May 2010
Tissue Therapies	$0.66	$0.21	January 2010
QRxPharma	$1.57	$0.25	December 2008
Hexima	$0.29	$0.60	October 2008
Atcor Medical	$0.10	$0.10	October 2008
Impedimed	$0.73	$0.70	August 2008
Patrys	$0.09	$0.50	December 2007
Bionomics	$0.41	$0.42	December 2007
Cogstate	$0.20	$0.13	November 2007
Sirtex Medical	$5.35	$3.90	October 2007
Clinuvel Pharmaceuticals	$2.00	$6.60	September 2007
Starpharma Holdings	$1.04	$0.37	August 2007
Pharmaxis	$2.39	$3.15	August 2007
Universal Biosensors	$1.37	$1.23	June 2007
Acrux	$3.36	$0.83	November 2004
Alchemia	$0.73	$0.67	May 2004

Portfolio Changes – 11 March 2011

IN:
No changes

OUT:
No changes

How Bioshares Rates Stocks

For the purpose of valuation, Bioshares divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, Bioshares grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks. For both groups, the rating "Take Profits" means that investors may re-weight their holding by selling between 25%-75% of a stock.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C
Sell

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