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In this edition...
In a year when many economic sectors are suffering, biotech has provided several shining lights when it comes to outstanding revenue performance. One such company is Sirtex Medical which has advised that its full year results are based on a 72% increase in sales. With the latest data at hand we have conducted a valuation of Sirtex, which indicates the stock continues to represent very good buying.
We also note a very successful fund raising conducted by Impedimed. Impedimed is following Sirtex Medical's path in obtaining reimbursement in key markets. Although the task is not without expense, effort and struggle, it is well worth it when the revenues do start to flow in later years as Sirtex can now attest. And Tom Williams contributes some tips on managing a biotech company.
The Editors
Companies Covered: IPD, SRX

	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 - Current)	11.6%
Cumulative Gain	**117%**
Av Annual Gain (8 yrs)	**14.7%**

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Bioshares

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Edition 319

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

Sirtex Medical Flags Strong FY2009 Results

Sirtex Medical (SRX: $4.20) has released preliminary earnings guidance for the financial year ending June 30, 2009. The company reported Sir-Spheres revenues of $65.6 million, an increase of 72%. Unit sales however rose 42% following a 23% increase in the prior year. Unit sales in the US rose 28% (previous year - 25%), Europe 117% (37%) and Asia/Pacific 18% (-3%). The company identified new production capacity at the Wilmington, USA plant as a contributor to improving gross margins from 74% to 80%.

Sirtex Medical expects to post a net profit *before* tax of $22.8 million for FY2009, up from $2.5 million for the previous corresponding year. Sirtex is currently capitalised at $234 million.

Valuation

We have prepared a DCF valuation of Sirtex Medical. Our valuation of $**6.30** per share is based on the following assumptions:

Shares on issue: 55.768 million
Cash at hand, June 30, 2009: $26.7 million
Discount rate: 10%
Corporate tax rate: 30%
Exchange rate (l/t ave): AUD/USD 75 cents
US and EU average revenue per treatment to Sirtex: US$14,000
Gross Margin: 80%

Treatment only of unresectable liver cancer that has metastasized from the colon/rectum (CRC - colorectal cancer)

US CRC pool 2010: 75,000 pts (CAGR 3.5% p.a)
Percentage patients with liver metastases (CRC): 30%
Sir-Spheres 2010 share: 13%, rising to 20% by 2013, declining to 10% for 2017-2019

German CRC pool 2010: 26,000 pts (CAGR 3.4% p.a)
Percentage patients with liver metastases (CRC): 30%
Sir-Spheres 2010 share: 11%, rising to 20% by 2013, declining to 10% for 2016-2019

Asia/Pac volumes treated left constant at forecast 2010 levels of 500 pts per annum at an average revenue per treatment of US$6,000.

Marketing expenses: 2010 - 30% sales; 2011 - 20% sales, 2012-2016 10% sales, thereafter 5% sales
Development expenses: 5% sales

Bioshares recommendation: **Buy**

Impedimed Secures Valuable Funding

Impedimed has successfully conducted a valuable funding round, raising $12 million through a fully underwritten placement and an entitlement offer to shareholders. The funds were raised at 64 cents a share, a 15% discount, with the stock price having held up well over the last year. The funds will help the company with the goal of building a secure and proprietary position as a global provider of technology for use in the aid of clinical diagnosis of lymphedema progression.

As seen with several companies in the Australian biotech sector, bringing about a global change in the way healthcare is practised is a long and expensive process, however one that can place companies in a commanding commercial position.

Patient registry

Use of the funds raised will go towards expanding the company's sales and support team in the US and in funding the establishment of a lymphedema patient registry with 200 breast surgeons. The registry will record details of lymphedema occurrence and treatment with data from the registry to be used to help form best clinical practice for treatment and prevention of lymphedema. The surgeons on the registry will be targeted to use the Impedimed technology, the L-Dex U400 system. The establishment and maintenance of this registry is expected to cost Impedimed between $3-$4 million.

For Impedimed, establishment of a surgeon registry increases the awareness of the need to monitor breast cancer sufferers for early progression of lymphedema, which is fully preventable if detected earlier enough. The registry will also increase the level of usage of this technology to over 250 surgeons, which is one of the key parameters in gaining a specific reimbursement code for the device (Category One Reimbursement).

Re-imbursement

One of the key outcomes for the company over the next 18 months is to gain a Category One Reimbursement Code for the L-Dex U400. This will ensure any use of the L-Dex U400 system is reimbursed by private insurers in the US. The company is expected to file its reimbursement code submission in November this year, with a decision then to be returned in December 2010.

Currently procedures using the Impedimed systema are covered under a miscellaneous code. However, there is no guarantee that the assessment procedure will be covered by private insurers. Miscellaneous code payments can also take three to four months to be paid, and it is a manual processing system. Category One reimbursements are paid within two weeks and are automatic.

One of the challenges to gaining widespread adoption of testing for post breast cancer resection lymphedema is the unwillingness by surgeons to accept this condition, because of the belief by some (or many) that good surgeons don't have patients who develop lymphedema after breast cancer resection i.e. that it's only a problem that poor surgeons have. It is estimated at 6% - 40% of breast cancer survivors will develop lymphedema at some point. That wide variation in itself highlights the need to create registries of the type that Impedimed is seeking to establish.

In Impedimed's favour is that some breast cancer societies around the world have become very effective lobby groups. These groups are highly motivated to push for the introduction of improved healthcare tools for breast cancer patients as they become available.

Impedimed sells its product into the US to breast cancer surgeons and oncologists by establishing L-Dex agreements. Under such agreements with the L-Dex U400 product, Impedimed receives payment from use of consumables used in the procedure. It is estimated that one user will generate annual sales of US$20,000 in consumable sales. At the moment the company has at least 50 such agreements in place with users in the US.

Cost savings

For Impedimed, reimbursement should not be a difficult point to argue, given the recent information which has emerged about healthcare cost savings from introducing regular lymphedema checks, patient benefits aside. Breast cancer patients who develop lymphedema in the first two years after surgery (the most likely period) have on average US$19,000 in extra costs over this time, whereas overall costs to the healthcare system could be reduced significantly if regular lymphedema screening were introduced, as well as providing enhanced patient care.

Summary

In the US there are 2.8 million breast cancer survivors. Up to 40% of breast cancer patients develop lymphedema, mainly in the first two years post surgery, however the condition is completely preventable if its subtle progression can be promptly detected.

In October last year Impedimed was the first company to received FDA approval for its product, the L-Dex 400, to aid in the assessment of lymphedema in women following breast cancer surgery. The company has developed its own lymphedema index, called the 'L-Dex', and will now look to form a lymphedema registry for breast cancer patients in conjunction with the American Society of Breast Surgeons.

Impedimed with likely need to raise further funds before it becomes profitable although now has at least 12 months of funding. However its investment in gaining acceptance and reimbursement for the screening of women following breast cancer surgery will allow the company to cement its position at the forefront of lymphedema prevention services.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Contributed Discussion

The Golden Rules of Biotech Management

by Tom Williams (formerly CEO of Biodiem)

With apologies to Winston Churchill, you might say that regarding the development of the Australian biotech sector, while we are not at the end, or even the beginning of the end, perhaps it could be said we are at the end of the beginning.

We now have several biotech companies who have battled through everything from investor ignorance, regulatory prevarications, federal indifference and the GFC to get their home-grown drugs into late stage clinical trials, having raised most of their money in Australia. On the other hand we have a bunch of little companies running out of survival money who some say should be left outside the tent to die. In between are a group with a mixture of promising projects, though arguably, not many with sufficient critical mass or a sharp enough strategy to meet the goal of becoming sustainable businesses.

So what have we learnt so far? Are there any golden rules? While everyone will have their own opinions, I think there are a dozen or so shining rules and here are four of them.

1. Forget dilution – Seize any money raising opportunity with both hands

Significant existing investors will want you to raise the smallest possible amount of money at the highest possible price. They'll say, "Just raise what you need now to get to the next milestone and then you can raise more at a higher price." They worry about the dilution of their control and the perceived dilution of value of their shareholding. What they should be worried about is the diluted prospects of surviving let alone thriving if you don't have the capital to drive towards building a sustainable business in a timely and properly resourced manner.

If you want to build a company, rather than just get a single project to the next stage, raise more than you think you'll need, whenever you can. And where did the idea of raising money at the highest possible price get such a hold? How about giving new investors a discounted entry and letting them have some upside in the share price afterwards. That will keep interest in the stock going far better than watching it fall after a high priced funding round. Also, some chairmen and board members with backgrounds in larger companies don't seem to understand how marginal life can be for most biotechs, where the window for capital raising can slam shut without warning. They expect you'll be able to raise money anytime and want you to wait three months or so for the next milestone or next exciting announcement. Don't wait. Your announcement may not eventuate, or the news may not shift the price, or the market might tank. If it's there take it now. And take two to three times what you think you'll need.

2. If it doesn't have a pretty dose response curve, your drug's a dud

Yes, someone will tell you it's just unusual. It's got a rare bell shaped curve or a series of waves and you just happened to be in between waves and that's why it looks random. Sorry. It probably is random. As in if you are a small biotech and not a giant pharma, you probably shouldn't spend the shareholder's money on more advanced trials until and unless you can obtain a normal looking dose response curve. If the response plotted against the log dose of your drug doesn't look like a nicely rising S of classical sigmoidal dimensions then the chances are Buckley's and none that any subsequent clinical trial will have a happy outcome. Think of Metabolic's fat pill or Progen's cancer treatment. In neither case did rising doses produce appropriately rising responses. In other words this is a gate you need to go through before proceeding further.

3. Never give up

This may seem like a paradox given the diatribe above to down tools without an appropriate dose response curve. But while you might quit on that indication, or that molecule, or that series of compounds, unless that is the only thing in your cupboard, don't give up. If it is, then you are in deep dooh-dooh, because there's another golden rule relating to risk management that you haven't paid sufficient attention to. But, if you have faith in your product (based on solid prior evidence) and you come to a roadblock, regroup and re-route. After years of work Avastin failed its first phase III clinical trial in breast cancer in 2002.

Genentech was persuaded by some committed scientists to keep going and were suitably rewarded. Avastin made US$2.6 billion in 2008. When Peplin had their treatment for pre-cancerous skin conditions handed back to them by pharmaceutical partner Allergan they turned around and raised the money to pursue clinical trials on their own. At BioDiem, when Merck in the US handed back our novel influenza vaccine, we went and found another partner in

Cont'd over

Golden Rules conr'd

Europe. Then we went back to the US and partnered with the CDC to develop the world's first mammalian cell candidate vaccine for pandemic influenza. Of the half dozen qualities, and more than a dozen competencies that biotech CEOs need, in my opinion, perseverance is top of the list.

4. Treat scientists like the divas they are

They say trying to get scientists to follow a corporate product development path is like trying to herd cats. But I think they're like big cats. Treat them sweetly with respect and lots of positive attention from the beginning of your relationship and they'll be as co-operative as Christian the lion. Treat them brusquely without understanding what motivates them and you can get mauled. Research scientists are not necessarily goal orientated in the same way you are. They're driven by curiosity, their love of science and (let's be honest) by fame. Being out on the leading edge and getting published in top journals, or presenting to the cream of their peers is still their game. But if you are willing to give them star status and see that their needs are met – they will understand that you have corporate objectives and work unstintingly in highly creative ways to see you both get what you want.

Getting the best scientists to come and work for the company and keeping them happy when they were there, according to Amgen's second CEO Gordon Binder, was the main reason for the company's success. Perhaps 80% of problems with founding scientists and other research stage scientists are due to poor human resource management. In a few cases however, your big cat or your lion tamer and their relationship may be too far-gone to be re-trained or re-trieved. In which case, you need a smart and legally well researched way to part company with as little rancour as possible before the circus audience takes fright and runs out of the tent, taking their money with them.

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Notice

Sixth round VISTECH (Victoria-Israel Science and Technology R&D Fund) project applications are now open and will close on 17 September 2009.

The scheme provides matching grants of up to US$500,000.

To apply for VISTECH grants visit www.business.vic.gov.au/vistech and contact roland.diggens@iird.vic.gov.au or call 03 9651 8170

Bioshares Model Portfolio (10 July 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	$0.28	$0.30	December 2008
QRxPharma	$0.39	$0.25	December 2008
Hexima	$0.38	$0.60	October 2008
Atcor Medical	$0.22	$0.10	October 2008
CathRx	$0.40	$0.70	October 2008
Impedimed	$0.65	$0.70	August 2008
Mesoblast	$0.80	$1.25	August 2008
Cellestis	$2.96	$2.27	April 2008
IDT	$1.53	$1.90	March 2008
Circadian Technologies	$0.75	$1.03	February 2008
Patrys	$0.14	$0.50	December 2007
Bionomics	$0.23	$0.42	December 2007
Cogstate	$0.24	$0.13	November 2007
Sirtex Medical	$4.20	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.30	$0.66	September 2007
Starpharma Holdings	$0.33	$0.37	August 2007
Pharmaxis	$2.30	$3.15	August 2007
Universal Biosensors	$0.94	$1.23	June 2007
Biota Holdings	$1.38	$1.55	March 2007
Probiotec	$2.01	$1.12	February 2007
Peplin Inc	$0.60	$0.83	January 2007
Chemgenex Pharma.	$0.51	$0.38	June 2006
Cytopia	$0.09	$0.46	June 2005
Acrux	$1.16	$0.83	November 2004
Alchemia	$0.35	$0.67	May 2004

Portfolio Changes – 10 July 2009

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.

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

Corporate Subscribers: Phylogica, Pharmaxis, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical

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