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In this edition...
For some companies in the sector, business has never been better. Sirtex Medical is now adding a third manufacturing facility with sales of its product expected to continue to grow and product uptake likely to expand to other indications. On the other side is IDT, where business factors all having aligned for the worse at the moment, although IDT has shown an ability to turn around its business effectively in the past.

And companies such as Nanosonics and Impedimed that are moving through exciting stages of their commercial development. We also update readers on progress at Benitec.

The Editors
Companies Covered: BLT, IDT, IPD, NAN, 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)	72.5%
Cumulative Gain	**235%**
Av Annual Gain (9 yrs)	**21.1%**

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Bioshares

30 October 2009
Edition 335

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

Sirtex Adds Third Manufacturing Facility As Global Rollout Of Sir-Sphere Product Continues

Sirtex Medical (SRX: $6.00) has announced it will build a manufacturing facility in Singapore for its radioisotope coated silicon Sir-Sphere product for the treatment of liver cancer. This adds to the existing facilities it has access to, one in Sydney through a contract arrangement and one in the US that it owns. This third facility will cater for increased growth expected in Asia as Sirtex firmly accelerates the global rollout of what is fast becoming an accepted liver cancer therapy for which there a few other treatment options.

The third facility will also reduce manufacturing risk, being able to supply to Asia and Europe, the Australian facility to supply product globally, and the US facility to supply product to the US and Europe. Given the 64 hour half life of the radioisotope used in the cancer irradiation therapy, Singapore is very well positioned to access Asia and Europe if required.

In producing the Sir-Sphere product, the bulk isotope is purchased from the US or Europe. It is then processed in 'hot cells' in confined facilities in either Wilmington (USA), Lucas Heights (Sydney) and Singapore (in 18 months time). The Sir-Spheres product needs to be delivered to the patient at a particular concentration. The concentration from a set volume halves every 64 hours. From the three processing facilities, the right concentration of radioisotope can be prepared and packaged in vials for delivery to interventional radiologists.

There are now 140 sites in the US that utilise the Sirtex treatment, 68 in Europe and 50 in the Asia Pacific region. Next month a Medicare decision in the US is expected on continued reimbursement of the Sir-Sphere product. We expect this will occur and will see coverage at least out to 2012 before it will be reassessed.

There are currently 15 trials underway with the Sir-Sphere treatment. One trial in 318 patients is underway in Europe combining Sir-Spheres with chemotherapy, and a second similar trial in the UK in 490 patients. The trials are also looking at using the treatment for primary liver cancer, which can expand the market considerably.

Sirtex is now capitalised at $338 million. It generated a net profit in FY2009 of $18.2 million from sales of $65 million. With only a fraction of the potential market captured to date, Sirtex is positioned to deliver sustained strong growth over the next five years.

Bioshares recommendation: **Buy**

Benitec's Path to the Clinic

Benitec (BLT: 4.9 cents) is a genetic (DNA and RNA) technologies company that conducted a back-door listing through Queensland Opals in 2001 and 2002. The company's technology can be deployed to switch-off genes that give rise to proteins that are implicated in disease.

Benitec has had a chequered history since 2002, with disputes over ownership of IP a long term issue. A licensing arrangement with the **CSIRO** over various IP assets has over time become a disincentive to investors. For a period, management was located in the USA, well away from company's shareholder base in Australia. However, the company has been supported by several committed London-based investors.

In more recent times the company has made progress in dealing with some of these issues, including a conclusion to litigation with US company **Nucleonics**, with a favourable decision in the US Supreme Court in 2008. However, a re-examination of a US patent (the 'Graham' patent) is underway at the US PTO with a decision expected in 2010 Q1.

In August 2006, Benitec restructured its IP agreement with the CSIRO, which it had reached in the first instance in December 2003, so that a number of royalty provisions were reduced. Benitec had also sought from 2007 through to March 2009 to restructure an associated capital growth agreement it had with the CSIRO. However, this did not eventuate as it was thought to not be in the best interests of the shareholders in March 2009.

The capital growth provisions remain in place until December 2010. This provision awards the CSIRO 5% of Benitec's market capitalisation less its market capitalisation at the time of the deal (which was approximately $79 million) and the value of any merged entity that might transpire. (See *Bioshares* 52).

Product Development

Benitec has also expanded the number of therapeutic development programs it has an interest in. A stronger focus on the therapeutic product development is arguably the optimal way to attract the attention of large pharmaceutical firms. Although Benitec has an enabling technology for delivering RNAi, what other companies (or research outfits) often possess are validated (and unvalidated) drug targets.

Benitec's most advanced program to date has been a product designed to treat HIV infection, for which positive interim data from a Phase I safety study has emerged. This program has been conducted at the Los Angeles City of Hope Hospital. A T-cell directed project using the same lentivirus vector is expected to commence this quarter, also for HIV treatment.

Benitec has commenced a collaboration with **Biomics** (China) to identify sequences of the Hepatitis B gene that can be used to form the basis of a ddRNAi therapy.

Another product development opportunity is based on technology licensed from **the Childrens Cancer Institute Australia for**

Cont'd over

Nanosonics Update

Nanosonics (NAN: $0.50) has this year started selling its ultrasound high level disinfection system into Australia, New Zealand and most recently into Europe. There are two appealing aspects to this company. Firstly it is providing a product that will help reduce the spread of infection within the healthcare system, which has become a major issue. Secondly the business model is such that it sells affordable hardware (around $10,000 to the end user) but also sells an ongoing consumable, hydrogen peroxide canisters, for which it charges $2.50 per disinfection procedure. Under this model, consumable sales should crossover hardware sales, possibly within five to seven years.

The Trophon EPR is a compact system (see photo) that leaves no dangerous residues. The device itself should last around five years, in which time it will either be upgraded or will just simply need to be replaced due to wear, dependent on usage. A high end user will used the system 10-12 times a day, where a low end user will conduct up to three disinfection procedures, not necessarily every day. The consumable hydrogen peroxide canister sells for around $100.

It will be a pivotal 18 months ahead for Nanosonics. The company currently assembles its device in Sydney employing 44 staff. Its current capacity is 2,000 systems per year, and this can be upgraded at the current facility. Sales have just started in France, which should see solid take up, with that country banning gluteraldehyde use and with a competing technology using UV light recently failing. Sales will then start into Germany, the UK and Ireland.

Nanosonics is capitalised at $94 million.

Bioshares recommendation: **Speculative Buy Class A**

First Nanosonics product – Trophon EPR unit

Impedimed – CPT Filing, MEDCAC Review in November

Impedimed (IPD: $0.73) will submit a Category 1 filing for its lymphoedema assessment technology (as embodied in the LDEX U400 device) before the **American Medical Association's** Coding Committee in early November. This is milestone event of major importance for the company. If a code is granted, the submission is then forwarded to the Relative Units Committee (an entity separate to the AMA), which sets payment for the code. The code would not be published until January 2011.

The LDEX U400 device can aid in the early detection of lymphoedema, a condition that is treated far more effectively if it is detected early. Breast cancer patients who have mastectomies and received radiation therapy represent a sizable group with a major risk of developing lymphedema.

The device is currently being reimbursed under a miscellaneous code and use of this code would continue until a specific Category 1 is published. While a miscellaneous code does enable reimbursement to occur it is not optimal because miscellaneous codes are subject to automatic review by payors, and payment to physicians can take months. In contrast, payments through Category 1 coded procedures are usually made within a couple of weeks.

In general in the US, the AMA and the health insurance companies system looks to move procedures out of miscellaneous codes and into Category 1 codes, because procedures cannot be accurately tracked under the miscellaneous codes category.

Category 1 code applications must also be FDA cleared (e.g. where a device is used), must have a minimum of five years peer review literature, have support from colleges and societies of surgeons or specialists, and they must also be supported by evidence of widespread adoption.

If Impedimed is not granted a Category 1 Code or receives a rejection from the RUC, the company's revenue opportunities in the USA from it bioimpedance devices will be restricted.

The company appears to well placed to succeed with its application, with a leading surgeon who has strong credential making the submission on behalf of Impedimed. What is also in favour of Impedimed's commercialisation plans in the USA is a changing legislative environment at the state level, in which the mandating of insurance coverage for the diagnosis, treatment and management of lymphedema is emerging. This has already occurred in North Carolina and a bill is currently before the Senate of the State of New York.

MEDCAC Meeting

Another recent positive event for the company is that **US Center for Medicare and Medicaid's** (CMS) Medicare Evidence, Development and Coverage Advisory Committee (MEDCAC) has called a meeting on November 18 to 'discuss the adequacy of the available evidence that supports the diagnostic and treatment methods used in the management of secondary lymphedema.'

The panel will consider if there is sufficient evidence to determine if various 'diagnostic strategies can reliably identify and stratify the severity of secondary lymphedema, including subclinical disease. These strategies include imaging techniques, quantitative approaches, tissue tonometry, perometry, circumferential measurements, water displacement, bioimpedance, patient reported symptomatology and physical examination (see http://www.cms.hhs.gov/mcd/viewmcac.asp?where=index&mid=5)

A positive outcome from this meeting would be if the panel rated bioimpedance technologies as superior to other approaches. Such an action would advance Impedimed much more rapidly on the path to gaining coverage from Medicare, which represents 30%-35% of the US health insurance market. The company had anticipated that a MEDCAC review might occur in 2010, so the impending November review brings forward one element of Impedimed's commercialisation plans by about 12 months.

Impedimed is capitalised at $79 million and held cash assets of $9.5 million at September 30, 2009.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

– Benitec cont'd

Medical Research, which is associated with **UNSW**. The therapeutic goal is to design a ddRNAi construct that can knockdown beta-III tubulin and therefore increase the effectiveness of drugs that face resistance issues due to beta-III tubulin. The commercial opportunity exists where companies with tubulin targeting drugs are seeking complementary therapies that overcome the problem of drug resistance. Yet to be determined is the delivery vehicle (vector) for the RNAi constructs.

Summary

The likelihood of Benitec maturing into a fully-fledged and well funded therapeutic product developer remains low at this stage. What is more likely is that Benitec forms part of a consolidation play of RNAi assets, be they companies or programs. The company will be looking to raise funds in the medium term. However, such a fund raising would most sensibly form part of a strategy to position the company for a consolidation event.

Benitec is capitalised at $18 million and held cash assets of $1.7 million at June 30, 2009.

Bioshares recommendation: **Speculative Buy Class C**

Bioshares

IDT – Difficult Trading Conditions on Many Fronts

IDT Australia ($1.49) dropped a bombshell at its AGM this week, announcing that the company expected to make a loss of between $0.5 - $1.0 million for the first half of this financial year based on current information. This is a dramatic change from the $6.4 million net profit it recorded for financial year 2009, which was 10% lower than for the previous financial year.

IDT has been hit simultaneously by the global financial crisis, which has affected the spending patterns of pharmaceutical companies (marginally/temporarily) and smaller biotechs (significantly), and the cancellation of a major antibiotic drug development program that was in later stage testing.

The drop in drug development programs, which consequently reduces pricing and demand for services, and the continued threat from lower cost pharmaceutical producers in India are also weighing down on business activity for IDT. The stronger Australian dollar is not helping, with IDT negotiating all contracts in Australian dollars. And the merger between two of IDT's customers, Pfizer and Wyeth, has also affected IDT sales with those companies in the process of assessing their combined R&D programs.

On the positive side, the Phase I clinical trials testing facility in Adelaide, CMax, is performing well. The facility carried out the testing for CSL's swine flu vaccine this year. IDT continues to manufacture drugs, both active pharmaceutical ingredients and finished product, for existing drugs on the market, which provides a recurring revenue stream. A new drug it manufactures has been filed in the US as the first generic, which is an oncology drug that has a medium size market.

IDT has experienced difficult trading conditions in the past and has rebounded to deliver strong profit outcome. We expect that will occur again. The drug development spending patterns of pharmaceutical companies look to have returned to normal, as seen with contract flow at Cogstate and Atcor Medical, two other pharmaceutical service companies.

IDT is also in negotiations with Pfizer on the $20 million manufacturing facility installed at IDT that was making the antibiotic drug that has now been discontinued. This could provide some short term upside for IDT if it can negotiate a favourable outcome.

IDT has a strong balance sheet, with net assets of $34 million and effectively no borrowings. The company is now capitalized at $64 million. Any weakness in the company share price will be an opportunity to acquire this stock at discounted prices although it may suit investors with a medium term investment horizon.

Bioshares recommendation: **Look for price weakness to invest for medium term investment.**

Bioshares

Correction:
In last week's commentary on Atcor Medical, we incorrectly referred to a loan being repaid by the company, when in fact, other parties had repaid loaned funds to Atcor.

Bioshares Model Portfolio (30 October 2009)

Company	Price (current)	Price added to portfolio	Date added
Biodiem	$0.21	$0.15	October 2009
QRxPharma	$1.15	$0.25	December 2008
Hexima	$0.57	$0.60	October 2008
Atcor Medical	$0.21	$0.10	October 2008
CathRx	$0.60	$0.70	October 2008
Impedimed	$0.73	$0.70	August 2008
Mesoblast	$1.06	$1.25	August 2008
Circadian Technologies	$0.72	$1.03	February 2008
Patrys	$0.11	$0.50	December 2007
Bionomics	$0.34	$0.42	December 2007
Cogstate	$0.30	$0.13	November 2007
Sirtex Medical	$5.99	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.31	$0.66	September 2007
Starpharma Holdings	$0.58	$0.37	August 2007
Pharmaxis	$2.52	$3.15	August 2007
Universal Biosensors	$1.75	$1.23	June 2007
Probiotec	$2.56	$1.12	February 2007
Chemgenex Pharma.	$0.80	$0.38	June 2006
Acrux	$1.98	$0.83	November 2004
Alchemia	$0.72	$0.67	May 2004

Portfolio Changes – 30 October 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: Pharmaxis, Cytopia, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx

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