ISSN 1443-850X

In this edition...
When a company looks to add encouraging detail rather than quickly gloss over matters of underperformance at its AGM, then the message is clear that the company is confident about its future. Nanosonics has made major inroads into the ANZ market for Trophon EPR, is working proactively with North American sales partner GE Healthcare, is adding staff in Europe and has it eyes on Asia.
Impedimed has achieved a clearer understanding of why it has received pushback from insurers and will work with the FDA to change its product label.
Osprey Medical has introduced an improvement to its CINCOR system that should make surgery requiring the use of contrast media even safer for chronic kidney disease patients.
Companies Covered: ADO, BIT, CGP, IPD, NAN, PBT, OSP, RHT

	Bioshares Portfolio
Year 1 (May '01 - May '02)	21.2%
Year 2 (May '02 - May '03)	-9.4%
Year 3 (May '03 - May '04)	70.6%
Year 4 (May '04 - May '05)	-16.3%
Year 5 (May '05 - May '06)	77.8%
Year 6 (May '06 - May '07)	17.4%
Year 7 (May '07 - May '08)	-36%
Year 8 (May '08 - May '09)	-7.4%
Year 9 (May '09 - May '10)	50.2%
Year 10 (May '10 - May'11)	45.4%
Year 11 (May '11 - May '12)	-18.0%
Year 12 (May '12 - current)	-10.1%
Cumulative Gain	**210%**
Av. annual gain (11 yrs)	**17.8%**

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

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Individual Subscriptions (48 issues/year)
$375 (Inc.GST)
Edition Number 480 (9 November 2012)

Bioshares

9 November 2012
Edition 480

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

Nanosonics AGM Report

The CEO of Nanosonics (NAN: $0.56), Dr Ron Weinberger, said the year had been transformational for the company, as it moved from an R&D company that manufactures, to a sales and marketing business with a customer focus.

In May last year, GE Healthcare started selling the company's Trophon EPR system in North America. With the help of inventory stocking orders from GE, Nanosonics generated a record revenue of $12.3 million for FY2012, up from $2.2 million in the previous year. Its net loss decreased from $11.2 million to $4.7 million. Its manufacturing capacity increased by 50% and cash reserves were $29.3 million at the end of June.

Existing Processes 'Almost Prehistoric'

Weinberger said that currently the cleaning processes for disinfecting ultrasound probes are 'almost prehistoric'. It involves disinfection with toxic liquids, and sometimes the intra-cavity ultrasound probes are only wiped down and sprayed for use in between patients. If the toxic cleaning agents are not rinsed off, they can cause anaphylactic shock.

Nanosonics' Trophon EPR uses hydrogen peroxide, which once the sealed cleaning process is complete, is converted to water and oxygen through a catalytic converter.

The Trophon unit is not only environmentally friendly and safer to use, but it delivers operational efficiencies according to the company. A recent study has shown that the incumbent chemical baths take 32 minutes to complete the disinfection process between uses, compared to 14 minutes for the Trophon system.

Weinberger explained that in the US the 'fundamental competition' is from Johnson & Johnson's chemical cleaning system. The following sign is displayed on the door leading into the probe disinfection room: "Danger, CIDEX OPA, irritant and potential cancer hazard, Authorised personnel only". This compares to the Trophon unit which can be used for disinfection in the doctor's surgery. Another advantage of Trophon is that it gets rid of human error, said Weinberger.

2012 Focus: Building Traction in the US

Weinberger said the focus over the last year has been gaining traction (in the US) and driving sales. In the US the company has put on six new sales staff, to bring the total to eight staff. These sales staff are working alongside GE. Although the 121 GE ultrasound sales staff are skilled at selling ultrasound probes, Nanosonics sales staff have become involved in the education on the issue of infection control. They are supporting the GE sales team, but they will also get access to non-GE markets in the US.

The results to date from Nanosonics having its own sales team working alongside GE has been more than encouraging the company said.

Cont'd over

Currently GE has 35% of the ultrasound market in the US. Importantly the Trophon is a vendor neutral product said Weinberger, with no GE label. Competing Siemens and Phillips accounts have purchased the Trophon product.

In Australia, Singapore and Hong Kong, Chairman Maurie Stang said the Trophon is already the gold standard of care, with a lot of interest found in Indonesia as well.

In Australia the company expects to shortly have 700 units installed (around 30% market penetration) with around 100 units also installed in New Zealand. If it can replicate this penetration on a world scale, the company said it will become very successful.

KOLs Established

In the US the company focused on key opinion leaders (KOLs) from leading hospitals to adopt the technology first. So far Trophon units have been sold to Massachusetts General Hospital (26 units), John Hopkins (20 units), Walter Reed National Military Medical Center which looks after the President of the US (eight units), Mount Sinai Hospital (eight units) and Calgary Radiology in Canada which has purchased 52 Trophon units. A KOL network has now been established according to the company.

Customer satisfaction is very high according to Stang. Not one customer has ever regretted purchasing a Trophon unit said Stang, which is a very rare thing in any industry. The company often operates by having health centres trial the Trophon product first. This has resulted in an average 2.5 units being sold for each device trialed.

A 'Return to Trend' in Sales Growth Expected

In the September quarter, Nanosonics generated sales of just under $1.2 million. This was down from the previous quarter due to inventory build-up by GE in FY2012. The company now anticipates a 'return to trend' in its sales growth path. The company believes it will now see a dramatic change from having its own US sales team on board to support GE. In the US, 93% the 121 GE ultrasound sales staff have to date sold at least one Trophon unit. The US market currently accounts for 80% of total sales.

One aspect the company has been working on in the last year is financing options for customers. It is looking to provide a facility where customers can purchase the product from the operating budget rather than the capital expenditure account.

In Australia, New Zealand and Europe, the company provides its own customer support and service. In the US this function is provided by GE. Remaining close to the customer through service contracts is fundamental, said Weinberger, if you want to generate return sales.

Infection Incidents Drive Major Operating Changes

Over the last year, a lot of focus for the company has been on the US. It has recently employed some 'quality staff' in France, Germany and the UK. Requirements around disinfection of probes vary from country to country. The US market is well primed with Trophon EPR the ‘only product that meets FDA best practice and ultrasound manufacture recommendations’. Guidelines are expected to be tightened in the UK following a death in June of this year in Scotland from a cross infection from an ultrasound probe. That death has triggered a nationwide revision of disinfection processes. Such incidents drive major operating changes said the company.

Business Model

Nanosonics business model is structured such that currently it generates 52% of its revenue from consumables. This is the heart of the business model according to Weinberger. One Trophon unit sold to a distributor for $5,000, is expected to generate $18,000 of revenue from the unit over four years, including the upfront capital equipment cost.

The company generates revenue from servicing, a new printer, software, a trophon cart and wall mount, proprietary hydrogen peroxide bottles, and chemical indicators (which tell the operator the disinfection process has been successful).

Weinberger said the company continues to innovate with new products for applications such as small and large endoscopes.

2013 Outlook

For 2013, the company is looking to leverage its investment from the sales teams installed in North America. Approval in South Korea is anticipated by the end of this year. And the company is looking to be selling the product into larger Asian countries by mid 2013.

The company says there is growing awareness of Nanosonics amongst investors in Hong Kong and Singapore. It has also committed to a stronger investor relations program. Chairman Stang said there has been an overhang in the stock which has now probably passed.

For the company to reach profitability, it needs to sell 3,000 units a year although it has a cumulative revenue stream from sales of consumables and servicing.

The company's production capacity is 6,000 units a year at the moment, on one shift. The company will focus on a predictable ramp-up in manufacture. It owns its own product tools. It the future the company may outsource the manufacture of components maintaining in-house assembly. Keeping the technical and manufacturing sections together is a good thing Weinberger said.

Nanosonics is capitalised at $146 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

A Subdued Impedimed Faces a Strict Timetable for a 2016 CPT Cat I Code

After three months into the new job as CEO of Impedimed (IPD: 14 cents), Richard Carreon is very clear on what the deficiencies are in the business and is enacting a process to resolve issues which have been the cause of poor reimbursement uptake and thereby slow sales penetration into the US market.

One of the key issues for Impedimed is an instruction from the FDA that the company's lymphoedema measurement technology, called the L-Dex, cannot be used to diagnose or predict lymphoedema; it can only be used to "assist in the clinical assessment of lymphoedema by a medical provider" and the label specifically exclude diagnosis.

The exclusion clause is one of the leading reasons why payors in the US are dodging reimbursement of an assessment that makes use of L-Dex systems. One of the major goals of the company is to get the FDA to change the label claim on the L-Dex device by dropping the exclusion clause. Impedimed is arguing its case to the FDA, and will seek to provide additional data, either from new trials or from more extensive assessment of current clinical data, to support its request to have this onerous label claim removed.

Impedimed working on a number of fronts to get better and faster market adoption of its test. It is seeking to get its Category III reimbursement coding changed to a Category I code, which would deliver more effective reimbursement. It will contact the nine medical societies associated with breast cancer in the US with a view to getting one or more of these groups to sponsor the Category I coding. At the moment, four of the past eight Presidents of the American Society of Breast Cancer Surgeons are using the device. To achieve an inclusion in AMA CPT codes effective from the January 1, 2016, Impedimed must support a society sponsored submission by either July or November 2014.

The company will also need to show wide spread adoption before it can gain Category I reimbursement coding.

The company has little margin for error in building adoption and gaining the support of a society by mid 2014.

Product Champion at Kaiser Permanente

On another front, two Health Maintenance Organisations (HMOs), Kaiser Permanente and 21st Century Oncology, are trialing the device in a number of their clinics. What the company has done right is that it has the support of some key opinion leaders such as Dr Ernie Bodai, who is Chief of Surgery for Kaiser Permanente.

HMO's such as Kaiser Permanente have gained a place in the medical health system in the US, where they seek to deliver an improved healthcare outcome an a lower cost. That Kaiser Permanente is not necessarily seen as an early adopter but is interested in the Impediment technology bodes well for the company.

Six centres at 21st Century Oncology have now been trained and two centres at Kaiser Permanente are using the technology. Success will be judged by when Kaiser Permanente expands the use of the L-Dex system to more of its 41 cancer centres across the US.

Cost Reductions

Impedimed has cut 31% of the costs out of the business and will focus now on its core activities, that being L-Dex adoption. Its lymphoedema business grew by 43% globally in the September quarter over the previous corresponding period, and by 19% in the US over the same period. Receipts from customers were $842,000 in this quarter, and net cash outflow was $3.0 million. The company's burn rate should be lower in subsequent quarters following the downsizing of the business.

Impedimed is capitalised at $25 million. It had $11.4 million in cash at the end of September.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Correction

In the last edition of Bioshares we incorrectly stated that Tissue Therapies' VitroGro was subject to a regulatory review by the MHRA that would take at least 210 days to complete. In fact the review should take no more than a maximum of 210 days to complete. Tissue Therapies understands that 'recent data on full drug reviews shows that the EMA is getting these done in 192 calendar days and the VitroGro ECM review is substantially smaller than a drug review.'

Five Stock Wrap

Company	Biotron	**Code**	BIT	**CMP**	$0.14	**Cap'n ($M)**	$30.8	**Cash ($M)**	$7.7	**SI**	**3.9**
• BIT is developing BIT-225 to treat HCV and HIV. MOA* is as a virus assembly inhibitor, offering new class-of-drug advantage											
• Share price has benefited from BIT-225 Phase IIa data which showed 100% sustained virologic response at 48 week at the 400mg dose											
• Has also benefited recently from setbacks of drugs with other MOAs, including compound BMS acquired through Inhibitex acquisition											
• A market opportunity exists because of expectations of emergence of drug resistance											
• BIT has commenced a 12 pt Phase II trial in HCV/HIV compromised patients; BIT-225 is active against both virus types											
• BIT must also complete PK and resistance studies in current Phase IIa HCV trial											
• Company must undertake 3 month animal toxicology studies to support more advanced in-human studies											
Comment: Biotron has potential to consolidate recent gains if second Phase II recruits on target in 2013 H1 and delivers positive results											
Bioshares recommendation: **Speculative Buy Class B**						Timing Considerations -					

Company	Prana Biotech	**Code**	PBT	**CMP**	$0.23	**Cap'n ($M)**	$78.4	**Cash ($M)**	$6.0	**SI**	**0.9**
• Developing PBT-2 to treat Alzheimers and Huntington Diseases, PBT-434 to treat Parkinson's Disease and PBT-519 for brain cancer											
• Recently completed $6M placement											
• Setbacks with several Big Pharma AD drug programs likely to have influenced a run on the stock recently											
• Is conducting an imaging trial at the Austin Hospital in 40 pts with mild Alzheimers Disease (enrolled first pt in March 2012)											
• In April, enrolled first patient in IND backed 100 subject Phase II trial of PBT-2 in Huntington Disease patients											
• Prana's focus has shifted from Alzheimers to the smaller and more accessible Orphan Drug indication of Huntington disease											
• While Prana has completed a Phase II AD trial, futher Phase III trials have been beyond its capabilities to effect, directly or in partnership											
Comment: Prana's commercial prospects without a primary AD focus are much more limited											
Bioshares recommendation: **Speculative Hold Class B**						Timing Considerations -					

Company	Resonance Health	**Code**	RHT	**CMP**	$0.02	**Cap'n ($M)**	$6.1	**Cash ($M)**	$1.2	**SI**	**5.1**
• RHT is marketing Ferriscan, a non-invasive test for iron overload in the liver and is an alternative to an invasive biopsy											
• Company has posted sales of $1.5M in FY2012, compared to $1.7M in 2011											
• Sales volumes were approximately 4,000 tests in FY2012, up fom 1,500 in FY2008; test is supplied at 40 MRI facilities in the US											
• Sales have begun to occur outside of clinical trial markets											
• Lack of insurance reimbursement has been a drag on broader sales											
• Has lodged an FDA submission for HepaFat Scan for diagnosis of fatty liver diseases											
• FDA recently asked RHT to submit an Expanded Indication of Use for Ferriscan so that it could be used as a companion diagnostic											
• Two US insurers (Kaiser Permanente and BCBS Mass.) have consented to coverage if clinical circumstances require it											
Comment: Several recent positive developments indicate growth curve may be about to shift for RHT											
Bioshares recommendation: **Speculative Buy Class B**						Timing Considerations -					

Company	Anteo Diagnostics	**Code**	ADO	**CMP**	$0.067	**Cap'n ($M)**	$51.6	**Cash ($M)**	$3.9	**SI**	**1.7**
• ADO is commercialising a chemistry technology which optimises the attachment of protein molecules on synthetic surfaces											
• The lead market for the technology is the *in vitro* diagnostics industry											
• Sales revenues: FY2012, $146K; FY2011, $11.8 K; FY2010, $84K; FY2009, $226 K.											
• ADO has 60 material transfer agreements in place and 69 CDAs in place											
• Conversion from MTAs into revenue has suffered for multiple reasons, often external to ADO product performance											
• Expected benefits from eBiosciences deal completed in March 2012 slowed when Affymetrix bought that company in June											
• An 'Intel inside' business model requires patience and significant sales and support resources											
• Adoption and integration by third parties of a sub-manufacturing method or componentry is not trivial											
Comment: ADO may to have to consider additional cash injections to improve sales and support capabilities											
Bioshares recommendation: **Speculative Hold Class B**						Timing Considerations -					

Company	Consegna Group	**Code**	CGP	**CMP**	$0.01	**Cap'n ($M)**	$10.4	**Cash ($M)**	$0.21	**SI**	**0.1**
• CGP was formed from the shell of Helicon Group in early 2011 and four assets acquired/optioned											
• Goal has been to build a portfolio of assets and effect a speedy return following part improvement (the 'purchase-package-profit' model)											
• A deal for its most advanced asset, BreatheAssist has still not been finalised (following a 31 October deadline)											
• Linguet drug delivery assets were assigned to Imugene, with CGP taking a 29% stake in IMU											
• CGP will not exercise its option to acquire Aspen Medisys, which has been developing a magnetic nanotherapy for treating cancer											
• CGP's fourth asset, Vibrovein, is 24 months away from achieving a commercialisation goal											
• The company's management of cash and capacity to raise further funds is a major cause of concern											
Comment: CGP has not performed to expectations with dwindling cash resources clouding prospects											
Bioshares recommendation: **Sell**						Timing Considerations -					

*Notes: SI - Survival Index - refer to Bioshares 480 for explanations * Mechanism of Action*

Bioshares Model Portfolio (11 November 2012)

Company	Price (current)	Price added to portfolio	Date added
Nanosonics	$0.560	$0.495	June 2012
Osprey Medical	$0.40	$0.40	April 2012
QRxPharma	$0.70	$1.66	October 2011
Somnomed	$0.83	$0.94	January 2011
Cogstate	$0.360	$0.13	November 2007
Sirtex Medical	$10.87	$3.90	October 2007
Clinuvel Pharmaceuticals	$1.85	$6.60	September 2007
Pharmaxis	$1.21	$3.15	August 2007
Universal Biosensors	$1.00	$1.23	June 2007
Alchemia	$0.530	$0.67	May 2004

Portfolio Changes – 9 November 2012

IN:
No changes

OUT:
No changes

Osprey Tweaks CINCOR System with 37% Reduction in Injected Dye

Osprey Medical (OSP: $0.40) is commercialising the CINCOR system, which is a catheter and vacuum system designed to capture contrast media once it has been used in angiography or stenting procedures so that the volume of media flowing through to the kidneys is significantly reduced .

Contrast media is toxic and patients with chronic kidney disease (CKD) run the risk of developing contrast induced nepthropathy (CIN), a condition which can be fatal if not a major health issue for patients and which is also a substantial burden for hospitals.

The CINCOR system was evaluated in a 41 patient trial which showed that 50% of contrast media was captured. The number of recorded CIN events was three, when an expected number (in the absence of the capture system) was eight.

The CINCOR System is CE Marked in Europe and is at an early stage of market development in that area, with the focus currently on building awareness.

The New Step Reduces Reflux

Osprey has added a new step to the CINCOR system which reduces the amount of dye injected into patients and a phenomena called 'blow-back' or reflux.

Osprey has added a capacitance chamber to the dye injection device so that the dye that is blown back is captured by the injection system.

A study of the technology in 44 patients in a pilot clinical trial at the Baker IDI Heart and Diabetes Institute demonstrated an average 37% reduction in the volume of dye that was injected in order to fulfil the required imaging performance.

The reflux reduction technology will be included in Osprey's pivotal clinical trial in the US, which is expected to start this year and conclude in 2014. The trial will enroll 600 patients with advanced chronic kidney disease. The cost of the trial is budgeted to cost between US$8-$10 million.

A very attractive feature of the trials is that the endpoint will be the level of serum creatinine, a protein which is measured within several days of the surgical procedure by in-house labs.

Summary

Osprey is a very attractive investment opportunity for two reasons. The technology is essentially directed towards patient safety which means that its regulatory oversight will be relatively more benign (as compared to many novel drug or device interventions that demand difficult risk-benefit assessments).

Secondly, the endgame for Osprey is in all likelihood a trade sale which could potentially occur before the company completes its US pivotal trial. The management challenge is for Osprey to execute its clinical, regulatory and commercial programs to the highest standard in order to optimise its future selling price and to also generate strong competition amongst prospective acquirers.

Osprey is capitalised at $40 million and retained $17 million in cash at the end of September.

Bioshares recommendation: **Speculative Buy Class A**

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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Subscription Rates (inc. GST)

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