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In this edition...
Portfolio composition has driven investment fund Biotech Capital to look for later stage companies with cash imminent from product sales. In what looks to be an astute investment, Biotech Capital has secured a stake in Sensear, a hearing technology company. This company's technology has significant potential in industrial settings where hearing damage from noise is a problem. More upside could eventuate from the assisted hearing market.

The rest of this week's edition discusses progress at Circadian's Vegenics, Incitive and Optiscan Imaging.

The editors
Companies covered: BTC, CIR, HGN, ICV, MBP, OIL

	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 (from 4 May '07)	1.5%
Cumulative Gain	**231%**
Av Annual Gain (6 yrs)	**26.8%**

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Blake Industry & Market Analysis Pty Ltd
ACN 085 334 292
PO Box 193
Richmond Vic 3121
AFS Licence
No. 258032

Enquiries for *Bioshares*
Ph: (03) 9326 5382
Fax: (03) 9671 3633
Email: info@bioshares.com.au
David Blake
Ph: (03) 9326 5382
Email: blake@bioshares.com.au
Mark Pachacz
Ph: (03) 9671 3222
Email: pachacz@bioshares.com.au

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Bioshares

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

Biotech Capital Invests $2 million in Sensear

Biotech Capital (BTC: 35 cents) has made a $2 million investment in an innovative hearing technology company, called Sensear as part of a $3 million capital raising. Sensear has combined microphone technology with hearing protection, neither of which are new but when combined deliver a novel technology application that will be released to the market in September this year.

Development of the first product range has been largely completed and initially there will be two devices; one that looks very similar to standard industrial hearing muffs, and the second, a more slim-lined version that looks more like an I-Pod.

What does the technology do?

The Sensear devices filter out loud background noises while allowing the wearer to clearly hear a conversation in a noisy environment. *Bioshares* has road-tested the device and can say it's impressive! By understanding speech patterns, the device selectively filters noise to allow close conversation to be effectively quarantined and played into the head-set, less the continuous noisy background sound. Local conversation is detected with microphones and amplified as necessary with the speech delivered to the earplug or earmuff.

For the retail consumer product, the microphones are located on the earplugs, which look like standard music player ear inserts. With the industrial earmuffs, the microphone and controls are located on the head set. The retail product control can be worn around the neck, or incorporated into a baseball cap, ideal for bar staff. The device will also have a blue-tooth capability for mobile phones and have a facility for two-way radio communication.

What are its applications?

Immediate applications of the technology are for use in noisy industrial settings, with companies such as **Alcoa**, **Rio Tinto** and **Qantas** having trialed the product and may be first customers for the company. This is not an insignificant market.

Cont'd over

Sensear Industrial Earmuff

Sensear Earplug

Another large potential market for the technology is as an assisted listening device for people who suffer from frequency loss. There are an estimated two million Australians with this condition. Hearing aids simply amplify sound and are of limited use in noisy environments. The Sensear technology uses mathematical algorithms to filter out unnecessary noise.

A third application is for more general use for people frequently in noisy environments, including pubs and music concerts. Bar staff at noisy hotels would benefit from this device as would any patrons with 'cocktail party deafness' or potentially for any other patrons tired of labouring to conduct conversations at such venues. The device has been designed to have the appearance of a fashionable accessory that should not warrant any stigma of hearing impairment.

Sales strategy

The retail product is expected to sell for around $400 and will be sold over the internet from the company's base in Perth. The company will also work through distributors throughout the world to sell large consignments to industrial firms. The distribution agreements are currently being negotiated.

Competition

There are currently no such products available for the retail market other than hearing aids. For the industrial setting, there are industrial earmuffs that include a microphone and two-way radio communication but these do not have intelligent design that recognises speech and filters sound accordingly.

Safety

The device has a built in sound limit restriction of 85 dB which can not be exceeded. There are volume controls on the devices and the products have been designed to provide situation awareness, an important consideration for industrial settings. There have not been any long term safety studies conducted with the device however with the inlet sound restricted to safe levels, if should be no more detrimental and probably less than listening to a standard MP3 player through earphones.

Risks

The main risks with Sensear are market related with most of the design completed for the first products. There will be additional variations of the product developed for specific applications. The assignment of distributors and selection of the distribution plan will be crucial to the success of the company.

Summary

Biotech Capital is continuing with its strategy of investing in companies with products in later stages of development. It has taken a sizeable stake in Sensear (details not released) which comes with a board position, allowing the fund to assist in the development of the technology. If the technology is commercialised well, there should be an opportunity for multiple-fold gains to be made with this investment. Sensear may also list on the ASX in the next two years which will allow other investors to gain direct investment exposure to this company.

Bioshares recommendation: **Speculative Buy Class A**

Pentax Confirms Commitment to Optiscan Imaging

Optiscan Imaging's (OIL: 47 cents) endomicroscope received a glowing assessment recently in an industry magazine, *Healthcare Equipment and Supplies* (HES). The technology also helped a gastroenterologist, Dr Paul Hurlstone, win the *Best Diagnostic in Cancer Innovation Award* in the UK last week. These are all crucial stepping stones for the Optiscan technology to eventually become commonplace item for use by endoscopists and colonoscopists worldwide.

It may seem like a slow road for Optiscan shareholders as they wait for sales traction to occur with this product, called the ISC1000. However, the product's widespread utility in *in vivo* medical diagnosis is certain to see this technology deliver a step change in medical imaging modalities. The question is not if this will occur but rather when.

Optiscan's partner, **Pentax**, which sells and markets the device, has recently confirmed its commitment to the product by agreeing to invest a further $4.8 million in conducting clinical trials in the US and Europe through an independent clinical research organization to achieve improved reimbursement for procedures using the device. The aim is for the procedure to be reimbursed for not only the imaging procedure under current codes, but also for *in vivo* histopathology conducted during the procedure. Pentax has also committed to contribute funding to development of future models of the device ($2.2 million).

Currently, gastroenterologists use endoscopes to image internal tissues and then take biopsies for analysis by pathologists. The Optiscan/Pentax confocal endomcriscope allows targeted biopsies to taken, accelerating diagnosis, reducing biopsies and with the potential to eventually replace biopsies completely.

There are currently five formal teaching centers worldwide that have adopted or about to adopt the technology and run training programs. These include **Mainz Hospital** in Germany and **Johns Hopkins Hospital** in Baltimore. More recently it was announced that **Pentax Life Care** has formed a joint venture with the **Royal Hallamshire Hospital** and the **Sheffield Children's Hospital** to form the **Sheffield Academy of Endomicroscopy**, which will be running training courses for physicians starting in September this year. Another major US teaching hospital is expected to be added to this list shortly.

The article in HES is available on line and is well worth reading (http://www.hesmagazine.com/story.asp?sectioncode=28&storyCode=2044514)
The article describes pediatrician Dr Mike Thompson's experience with the confocal endomicroscope and highlights the usefulness of the technology in the pediatric setting. Thomson indicates that the device is highly effective in diagnosing disorders such as Coeliac disease, ulcerative colitis and Barrett's oesophagus, and remarkably, he found there to be virtually 100% correlation that pathology seen under a microscope with

Cont'd over

histopathologists. He believes that endoscopists and colonoscopists can handle the scope with virtually no additional training. The benefits of the device include a more immediate diagnosis, a safer procedure with less biopsies, more targeted/better biopsies, a cost reduction due to the lower biopsies and immediate treatment of disease.

The gradual take-up of the technology can be attributed to a lack of reimbursement for the additional histology that can be conducted with the device, and also the time it will take to have endoscopists and colonoscopists to become more comfortable in conducting histological assessment that would normally be conducted by pathologists.

Drivers for this stock in the short term may be the announcement of a collaboration for the rigid endomicroscope that Optiscan has developed. This device could be used during surgery such as pancreatic cancer resection, to establish that all of the tumour has been removed, or for liver disease diagnosis.

While it may be another two years before the Optiscan/Pentax product gets sales traction – with sales orders in the second half of this year from Pentax likely to be affected by inventory build up by Pentax – the long term investment attraction with this company continues.

Optiscan is capitalised at $50 million with an estimated $6 million in cash reserves.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Metabolic Pharmaceuticals Approaches Another Crucial Milestone

Metabolic Pharmaceuticals (MBP: 13 cents) is about to move through a pivotal milestone again, with the results from its Phase IIa neuropathic pain trial expected to be available shortly. The trial has been completed and the data is currently being evaluated.

The drug candidate, ACV1, is a 16 amino acid peptide derived from the venom of an Australian marine cone snail. These cone snails prey on shellfish and immobilize them almost immediately with the powerful venom that uses a potent combination of peptides. ACV1 is delivered via a subcutaneous injection.

ACV1 is believed to block a broad class of receptors called neuronal nicotinic acetylcholine receptors. Preclinical models have shown the drug candidate to be very effective and the drug has shown to be safe in Phase I safety studies in 45 people.

Sciatic neuropathic pain

The current Phase II study in 40 people should give a good hint as to whether it works in sciatic neuropathic pain. Phase II trial results from patients with neuropathic pain as a result of herpes infection (shingles) and diabetes (diabetic neuropathy) are expected early next year. If it does have a broad utility in neuropathic pain, then it is potentially very valuable with the current market for this affliction estimated at US$2.5 billion. This market is being poorly served with the lead product, pregabalin, being effective in only as many as 30% of sufferers.

Oral peptide drug delivery platform

Metabolic's other core asset is its potential oral peptide drug delivery platform. When working previously with the obesity treatment compound, that earlier this year failed in the clinic, the company discovered that there were inherent characteristics within the compound that made it orally available. The company has used that finding to make an oral version of ACV1 that has successfully achieved good efficacy results in preclinical studies. Over the next six months, Metabolic will complete studies with other peptide drugs to establish how broadly this technology can be applied as a peptide drug delivery tool.

The market is currently factoring in marginal value to the company's neuropathic pain program. It's difficult to predict the outcome of this trial and this is the first of three shots on goal with this compound, with shingles and diabetic neuropathy trial results still to come. The take home messages at a neuoropathic pain conference held in Edinburgh last year and attended by *Bioshares* is that neuropathic pain is a difficult therapeutic sector with few successes to date although the rewards for success should be very high. And companies need to move their products into the clinic as quickly as possible to establish efficacy was another message, which is exactly what Metabolic has achieved. Although this trial is not powered to achieve statistical significance, any hint of efficacy should be very postively received by the market.

Metabolic Pharmaceuticals is capitalised at $39 million and had cash of $25.7 million at the end of last year.

Bioshares recommendation: **Speculative Buy Class B**
Note: We expect this to be a volatile stock over the next month, due the pending release of clinical studies with ACV1.

Bioshares

Halcygen Pharmaceuticals Lists On ASX

Halcygen Pharmaceuticals (HGN) made a solid share market debut this week finishing 20% above its 50 cent offer price. Halcygen is developing two products licensed from **Mayne Pharma** that are termed super-generics. The products are improvements on existing pharmaceuticals. The company raised $12.5 million upon listing. It joins other **QRxPharma**, **Stem Cell Sciences, NuSep** and **CycloPharm** which have also listed this year.

Bioshares recommendation: **Under Review**

Incitive's ICV0019 Delivers Positive Results in Preclinical Study

Incitive (ICV: 10.5 cents) is an early stage drug discovery company based in Brisbane. The company has two development programs. The most advanced of these is the bromelain enzyme program. This object of this program is the development of two different active chemical elements, ICV0019 and ICV0025, that are found in the stems of the pineapple plant.

The company is making solid progress towards the selection of a compound that can undergo human clinical trials. It may be in a position to select such a compound within six months. However, to properly support such a decision, the company has been performing studies in different preclinical models of inflammatory diseases.

This week, Incitive released results of a study conducted in mice with induced intestinal inflammation, a proxy for irritable bowel diseases in humans. This was a study in which nine mice were treated intravenously with three different doses of ICV0019 (5, 10 and 20 mg/kg) and six animals were administered with two different doses (5 and 50 mg/kg). Six control animals were included in the study.

Study results

The study reported that all doses of ICV0019 limited colitis induced by the administration of dextran sodium sulphate (DSS) [The DSS model]. Efficacy was evaluated through a number of factors including degree of body weight loss and degree of colon inflammation which was analysed through histological grading of colon.

The study is the first data that shows the efficacy of ICV0019 in an animal model and is hence a pointer to its potential as a treatment in humans. The study is also useful in showing that ICV0019 works both systemically (because of the IV administration) and locally (because of the oral administration). Achieving similar outcomes with different routes of administration may mean the company has more options in developing future products. The company is also undertaking additional studies in animal models, with a view to understanding further the mode of action of ICV0019.

A clinical trial candidate?

The company's next key decision point for ICV0019 will be its selection as a clinical trial candidate, although this not guaranteed. And the actual commencement of a clinical trial would not follow immediately. Among other issues, the company will need to decide an 'indication' pathway, and weigh up the costs and benefits of attacking a large market indication (eg rheumatoid arthritis), or addressing a smaller niche indication in the first instance (eg Crohns disease), or even smaller markets, such as graft versus host disease. Competition considerations will come to bear on this decision, as will the entrenchment of existing therapies.

Does Incitive warrant investment at its current price?

Investment assessment of early stage companies, that is companies that have yet to commence clinical trials, can be conducted in several ways. One approach is to evaluate the company according to its ability to develop its assets appropriately. How well a company can develop a product development program, not just a research program, build IP assets of substance, address manufacturing issues, commence relationship building exercises with potential partners or even launch partnerships, and manage relationships with collaborators and contractors are all tests that can point to value creation within a small early stage biotech firm. If these questions can be answered positively than prospects for entering higher order phases of value creation increase.

In the case of Incitive, the company looks to be tracking well, although the company is studying a potentially superior manufacturing process for ICV0019 and this has caused a moderate lag in meeting milestones. The company's concern is to be able to supply sufficient quantities for its R&D. An alternative approach would offer increased yields at lower cost and may allow the company to bypass manufacturing through extraction and purification from crude plant extract (similar to **Peplin's** GMP process for PEP005), or manufacture using recombinant engineering. In fact a useful benchmark company for Incitive is Peplin, with both companies exploiting plant-derived compounds for human therapeutics. In both cases, the use of the natural crude product by humans as a complementary medicine has been used to guide development of the active compound in discovery and development and give early insights into the safety profile of the potential medicines. Peplin was founded in 1997, and listed in 2000 with an indicative capitalisation of $21 million. Clinical trials of PEP005 did not commence until August 2004. Incitive listed in 2006, with an indicative capitalisation of $8 million.

Incitive is capitalised at $4.3 million and held cash assets of $1.7 million at the close of the March quarter, 2007.

Bioshares recommendation: **Speculative Buy Class C**

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Bioshares Model Portfolio (29 June 2007)

Company	Price (current)	Price added to portfolio
Acrux	$1.54	$0.83
Alchemia	$0.86	$0.67
Biodiem	$0.26	$0.29
Biota Holdings	$1.86	$1.55
Circadian Technologies	$1.28	$1.45
Cytopia	$0.65	$0.46
Chemgenex Pharma.	$1.10	$0.38
Optiscan Imaging	$0.47	$0.35
Peplin	$0.86	$0.83
Peptech	$1.44	$1.31
Phylogica	$0.35	$0.42
Probiotec	$1.20	$1.12
Starpharma Holdings	$0.38	$0.37
Sunshine Heart	$0.17	$0.19
Tissue Therapies	$0.55	$0.58
Universal Biosensors	$1.45	$1.23

More IP Consolidation at Circadian's Vegenics

In Bioshares #218 we looked at Vegenics, a company that Circadian Technologies (CIR: $1.29) has a 67% interest in. We argued that Vegenic's is now very much the 'main game' at Circadian, with a significant portion of Circadian's cash assets invested to achieve that holding ($21.5 million).

Vegenics, in simple terms, is a vehicle that holds rights to various genes or proteins relating to the growth factors VEGF-C and VEGF-D. These circulating molecules from the VEGF family are involved in the process of angiogenesis (the growth of blood vessels).

Vegenics has consolidated IP from the **Ludwig Institute of Cancer Research** and **Licentia Ltd**, the commercial arm of the **University of Helsinki**. It has recently converted an option over VEGF-C antibodies from **CoGenesys** into a licence.
Vegenics announced this week that it would create a new US company, **Kappa Life Sciences Inc,** to develop orthopedic applications of VEGF-D, following the 100% acquisition of Italian company **SienaGen**. SienaGen and Vegenics have cross licensed their respective IP portfolios, allowing Venegics to focus on oncology applications and Kappa to focus on orthopedic applications. Vegenics will retain a 25% stake in Kappa.

Until now Vegenics and SienaGen's VEGF-D was in a state of opposition in Europe (however, SienaGen did not have an IP position in the USA). Circadian's Vegenics is being strategically managed and run with a clear focus on building IP and freedom to operate in oncology applications of VEGF-C and VEGF-D.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

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

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