In this edition...

Peptech and Evogenix look set to create a sizeable specialty antibody group, with a merger announced between the two companies this week. It's a logical fit and creates a very competitive global biotech business in the hot area of therapeutic antibodies. We report back from the BIO 2007 conference held in Boston this week. Preparing for a potential influenza pandemic is still a big issue and was the subject of a 'Super Session' at BIO. And there have been more positive developments at Phylogica, which has looks to have delivered the goods with its Opsona collaboration, and with Neuren, which will now start a 600 patient Phase III study. But it can't all be good news, with the Dendreon setback a blow to Prima Biomed.

The editors Companies covered: EGX, NEU, PTD, PRR.PYC

	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 6 (May '05 - May '06)	77.8%
Year 5 (May '06 - May '07)	17.3%
Year 7 (from 4 May '07)	2.4%
Cumulative Gain	235%
Av Annual Gain (6 yrs)	26.8%

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Bioshares

11 May 2007 Edition 215

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

Third M&A Deal In 12 Months As Peptech Moves Up The Biotech Food Chain

It should not be that much of a surprise that **Evogenix** (EGX; \$1.00) is to be acquired. Almost any company operating in the antibody space at the moment is a potential acquisition candidate following a major M&A trend in the biologics sector over the last two years. The rapidly dwindling number of companies that provide antibody optimisation and humanisation services made Evogenix even more of a likely acquisition target as suggested in Editions #191 and #210 of Bioshares. It is a clever and logical move by **Peptech** (PTD: \$1.70) to acquire Evogenix, with Peptech set be positioned as a sizeable global player in the field of antibody therapeutics.

The bid for Evogenix currently implies a price of \$1.01 per share or a capitalisation of \$140 million. Under the terms of the deal, Evogenix shareholders will receive 15 cents cash plus 0.5055 Peptech shares for each share they hold in Evogenix. At the time the bid was announced, it represented a 33% premium on the Evogenix share price prior to the announcement of the offer. It's an excellent return for Evogenix shareholders with the stock listing in August 2005 at 25 cents a share. However there is the potential that a higher bid may emerge given the interest in this field.

Deal terms

When Peptech bid for Agenix for in 2005, the proposed merger failed, for the second time. This time around with Evogenix, Peptech has sharpened its skills as an M&A player. The acquisition offer is being conducted under a Scheme of Arrangement that requires only 75% acceptance from Evogenix shareholders. There is also a break clause that compensates either company if the deal does not go ahead (\$1.5 million to Evogenix or \$1 million to Peptech depending on which party breaks the agreement to merge). Peptech will not require shareholder approval for the deal to proceed, which should be completed in August.

The combined entity will have a new name (yet to be announced) and there will be a mix of both companies' directors on the new board. Peptech's CEO, John Chiplin, will be the CEO of the merged company, Peptech's chairman, Mel Bridges, will continue as chair of the new board, with the only staff to depart being Evogenix's CEO, Merilyn Sleigh. The new company will be capitalised at \$400 million at current prices and will have \$175 million in cash assets.

The acquisition is an excellent fit for Peptech. It gives Peptech an additional antibody technology platform that is complimentary to its recently announced 'Synhumanisation' technology. The Evogenix team will continue to optimise and humanise antibody leads for third parties, however the difference now is that the large and better funded group has the capacity to potentially take compounds from smaller companies into clinical trials on its own.

The third party work that Evogenix conducts will continue as it provides future value by way of milestone payments and royalties from sales of any drugs that reach the market, which has been the Evogenix business model.

The acquisition helps fill out the Peptech pipeline, although it still has gaps in later stage clinical trials. Evogenix's lead compound, EGX-010, is an in-house program for the treatment of osteoporosis. The company was intending to out-license this program this year, but if the merger succeeds, then the program will be kept inhouse and is anticipated to be in Phase II clinical trials in 2009.

Peptech currently has its first single domain antibody drug candidate in Phase I clinical trials and by late 2009 expects this compound to move into Phase III trials. Two other compounds are also planned to move into Phase I clinical trials in 2009. One is an Evogenix antibody licensed in from the **University of Massachusetts** for the treatment of lung cancer. The second is an antibody from Peptech's **ScanCell** acquisition for the treatment of cancer.

Solid track record

Peptech is delivering on its plan to become an active international M&A player with a focus on the antibody space. It is in the process of making its third deal in 12 months following the completed acquisitions of **Promics** in May last year for \$4.5 million and ScanCell in December last year for US\$4.1 million. A private equity buyout of Peptech now seems unlikely,

The company has been built on the royalty stream from its early work on anti-TNF antibody drugs that has seen the company receive US\$110 million with a further US\$75 - \$100 million to come. It has invested early proceeds from royalties with stunning success in **Domantis**, with the \$40 million outlay returning \$178 million in December last year when Domantis was sold to **GlaxoSmithKline**. The proposed merger with Evogenix appears well priced and if successful, will move Peptech up the food chain in the global biopharmaceutical business.

Bioshares recommendations

We place a **Hold** on Peptech and a **Speculative Buy Class A** on Evogenix. Investors may consider buying shares in Evogenix that should translate to Peptech shares, unless a higher bidder emerges for Evogenix.

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Bioshares Model Portfolio (11 May 2007)		
Company	Price (current)	Price added to
		portfolio
Acrux	\$1.30	\$0.83
Alchemia	\$1.15	\$0.67
Biodiem	\$0.34	\$0.29
Biota Holdings	\$1.81	\$1.55
Cytopia	\$0.70	\$0.46
Chemgenex Pharma.	\$0.83	\$0.38
Optiscan Imaging	\$0.44	\$0.35
Neuren Pharmaceuticals	\$0.45	\$0.70
Peplin	\$0.88	\$0.83
Peptech	\$1.70	\$1.31
Phylogica	\$0.45	\$0.42
Probiotec	\$0.91	\$1.12
Sunshine Heart	\$0.20	\$0.19
Tissue Therapies	\$0.53	\$0.58



Thredbo Biotech Summit 2007

The third annual Thredbo Biotech Summit is being held on Friday 20 and Saturday 21 July, 2007. Once again, the conference aims to provide the ideal turf-neutral venue for investment and commercial biotech participants to meet and discuss key issues affecting the Australian biotech sector.

Registration is now open. Full conference details are available on our website <u>http://www.bioshares.com.au/</u> <u>thredbo2007.htm</u>

Building on the success of previous years, the aim is to provide a high quality networking opportunity with a challenging and relevant program geared to encourage lively discussion, all within the picturesque location of the Thredbo Alpine Village. If you only attend one biotech conference this year, make it the Thredbo Biotech Summit, the essential biotech investment event in Australia!

*******Please note that you need to book accommodation early******

BIO 2007 Report – Pandemic 'Super Session'

The BIO 2007 conference was held in Boston this week and was attended by Bioshares. The conference runs a very strong speaker program in addition to a vast exhibition display, with its break-out sessions attracting the very best of the industry's thought leaders, CEOs and other industry executives.

Billed as a 'Super Session' was the session titled "*The Pandemic Flu Syndrome: Are we Ready for the Big One...Or Just Crossing Our Fingers?*" Speakers included Bruce Gellin, Director of the National Vaccine Program at the US **Department of Health and Human Services**, Gary Zieziula, Vice President, Commercial Operations at **Roche**, David Ozonoff from **Boston University's School of Public Health** and James Young, President, Research and Development at **MedImmune**.

General observations

A common theme from the session was the emphasis on the need for biotech companies to be prepared for an influenza pandemic, a somewhat unexpected suggestion given that the conference had many industry participants more than likely looking to explore how to gain business in the area, not how and why they should develop a crisis plan. Nevertheless the fact that Roche has its own internal management plan is sign of how serious the issue is taken by companies in prime positions in the pharma sector.

While a number of initiatives have been undertaken by the US government and other authorities to address the threat of a flu pandemic, one issue recognised as important but still requiring much further attention and development is that of public communications, with the need for transparency emphasized.

Another clear point emanating from the session was the lack of capacity in many areas (eg vaccines manufacture) compared to national need, although these issues are beginning to be addressed at least by the US Government and others.

In summary, the session reinforced the view that there is no doubt about the reality of the threat and the potential impact of an influenza pandemic and that preparedness is entirely appropriate.

DHHS Speaker – Bruce Gellin

Judging from comments supplied by Bruce Gellin, Director of the National Vaccine Program, the US Government has made substantial inroads towards preparation of managing an influenza epidemic. This is evidenced by The National Strategy announced in 2006 as well as guidelines produced by the CDC.

The view as enunciated by Gellin was that essential approach to managing a flu pandemic is mitigation – you dampen and minimize, not conclusively defend against it.

Aware of the critical role of communications, the US government has established a single website to deal with the issue, <u>www.pandemicflu.gov</u> And the US government has also introduced new legislation to deal with pandemic issues, the 'Pandemic and All Hazards Preparation Act (2006)'. The US government is sponsoring a raft of projects, in many different areas. It is aiming to expand egg-based manufacturing systems, support the development of and diversify cell based manufacturing systems, improve methods to reduce the amount of antigen needed in vaccines; and support the development of other vaccine technologies.

Gellin also discussed manufacturing capacity concerns, listing the following global output by region. He suggested that potential capacity could reach 500 million doses per annum if three manufacturing shifts per day were adopted.

Global manufacturing for trivalent flu vaccines

Latin America	19 million doses
North America	73 million doses
Europe	223 million doses
Asia	32 million doses
Africa	0
Total	347 million doses

However, the national requirement in the US alone is for at least 300 million doses, with the lack of capacity representing a 'huge problem'.

MedImmune Speaker – James Young

MedImmune's head of research, James Young, addressed the topic of "The Role of Vaccine Technologies in Pandemics Preparedness". He argued that there is hope when considering the pandemic challenge because of the unprecedented level of development that is now occurring in the history of vaccinology.

Young set out a number of challenges facing the vaccine industry and the public health sector. A key challenge at least in the USA was the need to be able to develop capacity to deliver 600 million doses. (This equates to roughly two doses per person in the USA). Another challenge was considering what it is that is in fact being prepared for. Currently the focus is on the H5N1 influenza strain. However, there are 16 sub-types, of which 13 could cause a pandemic.

Young posed the question of how current industry capacity could transition manufacturing 600 million doses, noting the demands this would place on raw material supplies, not to mention the demand for 600 million syringes as well as fill capacity. He said such a transition would require a shift in QC testing on an unprecedented scale. Further questions requiring consideration include which vaccines specific to a particular strain would be manufactured, or whether simply a prototype vaccine should be constructed, or even whether simply bulk vaccine should be manufactured. Another issue is that vaccines must be stored cold, which generates logistical considerations. Then there are separate ethical challenges of who would get a flu pandemic vaccine and in what regions would such a vaccine be made available.

Another issue, or factual reality, is that there are only two approved vaccine technologies available, these being the Trivalent Inactivated Vaccine (TIV) and the Live Attenuated Influenza Vaccine (LAIV).

In April 2007, the first H5N1 vaccine was recently approved by the FDA for use in 18-64 year olds. This is an inactivated or 'killed' vaccine that requires two doses totalling 90 milligrams, which can be compared to the 45 milligram dose that is the basis of seasonal influenza TIV. A problem with this vaccine is that only 44% of recipients sero-convert i.e. develop the antibodies necessary to protect against the flu. In other words only 50% of the population are protected by this vaccine, and therefore much more work needs to be done.

MedImmune (being acquired by AstraZeneca for US\$15 billion) has the US license for Flumist, a LAI vaccine, that is delivered intranasally. Benefits of this vaccine include its capacity to develop 'herd' immunity, especially with younger patients. The company has developed a refrigerated version of Flumist, which was approved by the FDA in January 2007. (The initial version of Flumist is a frozen product that must be thawed, and once thawed be stored at temperatures of 2 to 8 °C for no longer than 60 hours). MedImmune's plant has the capacity to produce 45 million doses. It currently is conducting two Phase I trials for a pandemic flu vaccine and it has received \$170 million in funding to develop a cell culture manufacturing process. The company's ambition is that by 2009, it will be able to manufacture 40-80 million doses using cell culture manufacturing methods. MedImmune is also working on alternative delivery devices, and improved filling technology.

Young said that the although the US government had taken leadership role with the flu pandemic issue, there was still a need for industry and government to collaborate on creative regulatory approaches, capacity commitments, raw material stockpiling contracts and product indemnification. And within industry there was a need for capacity and technology sharing.

Implications

The conference session confirmed that flu pandemic preparedness is an issue taken very seriously by the US government and public health officials. The issue of manufacturing capacity is an issue and companies such as Biodiem with an interest in an underutilised flu technology (similar to MedImmune's Flumist) and manufacturing links are positioned very well in a very topical biotech sub-sector.

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Phylogica Passes Major Milestone

Phylogica (PYC: 45 cents) has seen a strong interest in its stock in the last week. The reason is twofold. Firstly, the company completed its first major milestone with its Partner, **Opsona Therapeutics**. It developed a suite of 37 peptides as potential drug candidates for treating inflammation, targeting Toll-like Receptors. Modulating this pathway has the potential to treat diseases such as asthma, rheumatoid arthritis and psoriasis.

Of the compounds supplied to Opsona, more than half could be developed as drug candidates. It supports the Phylogica approach of developing novel peptide drug candidates using its ancient bacterial genomes to build seven peptide libraries with about 260 million of its diverse 'Phylomer' peptides.

The other reason for an increased interest in Phylogica is the proposed acquisition of Evogenix. The bid by Peptech for Evogenix reinforces the interest in companies that can provide novel protein or protein fragment drug candidates.

Opsona and Phylogica will now seek to expand their collaboration, further narrowing down the pool of potential drug leads and presumably look to form a collaboration with a major biotech or pharmaceutical group.

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Neuren Recieves All Clear for Phase III Trial

Neuren (NEU: 45 cents) will start its Phase III trial in the next two weeks with its lead compound, Glypromate, for the prevention of cognitive decline in patients undergoing heart surgery. A total of 24 sites have been set up to conduct the trial, including seven in the US, with 600 patients to be enrolled over the next 18 months.

Developing drugs to prevent cognitive decline, either in patients who have undergone a stroke, or dementia, has proven to be very difficult. Neuren has designed a well though out approach to testing its market, where patients undergoing surgery will not only be compared against a placebo, but also against their own cognitive function prior to the operation. Cognitive function has been shown to fall off significantly in patients undergoing coronary artery bypass graft surgery (CABG). Remarkably, the company will conduct this large Phase III trial for an estimated \$10 million.

After 300 patients have been treated, an independent board will review the data and suggest whether further patients need to be added to the trial to support the generation of a statistically significant result. The trial is expected to finish at the end of 2008 with trial results in early 2009.

Neuren is also conducting two trials in conjunction with the US Army for the treatment of traumatic brain injury (TBI), both mildto-moderate and severe, with its compound NNZ-2566. NNZ-2566 is a synthetic analogue of its lead compound Glypromate. A Phase

Cont'd over

Neuren - from previous page

II trial in mild-to-moderate TBI is scheduled to start in the second half of 2007 in about 70 patients. Results from this trial are expected about the same time as the Phase III trial results in early 2009.

A Phase II trial in people with severe TBI will start in early 2008, will run for one year and will involve up to 50 patients. The US Army is funding both trials with Neuren maintaining commercialisation rights to the compound.

Neuren is capitalised at \$59 million and remains significantly undervalued. The drawback with this stock is that clinical outcomes from its trials assessing efficacy of its compounds are not expected until early 2009, although out-licensing events for its earlier stage programs can be expected this year.

Bioshares recommendation: Speculative Buy Class A

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Bad News for Prima Biomed

It seemed that Prima Biomed was thrown a commercial lifeline last month when Dendreon looked like it would receive approval for its cancer vaccine, helping pave the way for Prima Biomed's ovarian cancer vaccine that has completed a Phase II clinical trial. Dendreon's market value skyrocketed to almost US\$2 billion last month but this week plunged by 60% when the FDA requested further information from the company regarding its trial and the manufacture of the product.

The news makes Prima's urgent capital raising all the more difficult.

Bioshares recommendation: Sell

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tages of comm ially speculativ	rm positive cash flows, history of losses, or at early nercialisation. In this second group, which are essen- ve propositions, <i>Bioshares</i> grades them according to thin that group, to better reflect the very large spread hose stocks.	<i>Speculative Buy</i> – <i>Class A</i> 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. <i>Speculative Buy</i> – <i>Class B</i>
	ting positive cash flows or close to producing positive cash	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
Buy Accumulate Iold Jighten Sell CMP–Current	CMP is 20% < Fair Value CMP is 10% < Fair Value Value = CMP CMP is 10% > Fair Value CMP is 20% > Fair Value Market Price)	 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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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 st ti re 0

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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

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