

**In this edition...**

Biotechs have been heavily sold down over the last 18 months in stark contrast to the solid progress being made in the sector. Some of the sell down looks to have been accentuated by tax loss selling in recent weeks. But if these prices continue, it may be inevitable that we will see several acquisitions in the year ahead. We look at what might be on the shopping list for international pharmaceutical businesses.

We also provide two interesting private company profiles, of Verva Pharmaceuticals and Haplomic Technologies.

The editors

**Companies covered: Verva Pharmaceuticals, Haplomic Technologies**

	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 - current)	-8.2%
<b>Cumulative Gain</b>	<b>91%</b>
<b>Av Annual Gain (7 yrs)</b>	<b>17.8%</b>

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# Bioshares

27 June 2008  
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*Delivering independent investment research to investors on Australian biotech, pharma and healthcare companies.*

## 2009 Takeover Targets

At some point in the near future the bargain-basement values of several Australian biotech companies, which have fallen around 50% on average since the start of last year, will become a little too attractive for global life science companies to pass up. In recent editions we highlighted the growing appetite of Japanese pharma for international biotechs, both large and small. As the list of Australian biotechs with products on or near the market continues to build, we expect more acquisitions to occur in the sector over the next 12 months.

Global businesses with established sales and distribution teams in place are well placed to leverage off the successfully completed development work of smaller companies. The leveraging is often achieved through the acquisition of the firm that developed the product or products. With the strong progress made in the Australian sector over the last two years being largely unrecognized by investors, it is difficult to see several bids not being made for Australian biotechs. Below is a list of companies that might be catching the eye of international suitors.

### Chemgenex Pharmaceuticals (Acquisition target rating: High)

Over the last twelve months, Chemgenex Pharmaceuticals has been cleaning up its portfolio asset structure. The company has divested its non-oncology development assets into a private company (Verva Pharmaceuticals, see coverage on page 4) and more recently has acquired the remaining rights for Europe from **Stragen** for its lead drug candidate, omacetaxine.

Omacetaxine is completing pivotal studies for the treatment of chronic myeloid leukemia and the company is expecting to start filing a rolling NDA (New Drug Application) with the FDA for approval of the drug in the next two months.

Omacetaxine is being trialed in patients who are resistant to Gleevec treatment with a particular genetic mutation (T315I). Potential acquirers of the company included Novartis, which sells the highly successful Gleevec, and Merck. Both companies have had programs to develop drugs for patients with the T315I mutation although Merck stopped its program in November last year. The drug showed a low response and poor duration with a poor side effect profile.

The appeal of Chemgenex is not just that the drug appears to work particularly well in the lead application, but that there may be several other indications where the drug may prove to be effective.

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**Avexa (Acquisition target rating: High)**

Avexa is conducting Phase III trials for its HIV drug, apricitabine. The company has achieved excellent Phase II data for this drug candidate for second line treatment of drug resistant strains of HIV (M184V). The drug candidate has a high probability of reaching the market.

There are several companies with established HIV franchises. These include **Gilead Sciences**, **Bristol-Myers Squibb** and **BlaxoSmithKline**. The combination of therapies in HIV, generally three types of drugs, has resulted in combination drugs into the one tablet to improve patient compliance. An example of this is the HIV drug Truvada sold by Gilead, which combines two HIV drugs in the once a day tablet of Emtriva and Viread.

Avexa's drug is being trialed for patients who fail treatment on GSK's Lamivudine or Gilead's Emtriva, making either company a logical suitor for Avexa or more likely its leading technology asset, apricitabine.

**Arana Therapeutics (Acquisition target rating: High)**

Arana Therapeutics is cashed up and is building an international antibody drug development business, both very attractive qualities. That the company has a cash backing of 77 cents a share, with further royalties expected until 2011 for its TNF patents, adds further appeal.

The company is developing the most clinically advanced domain-based antibody drug candidate, ART621, for the treatment of psoriasis and rheumatoid arthritis. Psoriasis Phase II trials (as a systemic treatment) are underway with results expected by year's end. If the drug shows signs of efficacy in psoriasis, then that will be enough to get several groups excited about the drug candidate's potential as a treatment for the massive rheumatoid arthritis market. Expect interest from Japanese pharma here, with **Kyowa Hakka** and **Takeda Pharmaceuticals** high on the list.

**Universal Biosensors (Acquisition target rating: High)**

Universal Biosensors (UBI) has developed an improved, point-of-care, diagnostic platform. The first biosensor for the measurement of blood glucose levels has largely completed development with release onto the market expected in 2009. The meter and test strips will be sold by UBI's partner, **LifeScan (Johnson & Johnson)**, which has about 30% of the global market. We estimate the global market for electronic test strips to be around US\$5 billion a year. That UBI can manufacture these strips *much* more cheaply than anyone else makes the company very attractive.

LifeScan has rights to the application for glucose only. It may seek to acquire UBI to secure the manufacturing capabilities, even though there is a manufacturing contract in place. However, a more likely group would be the highly acquisitive **Inverness Medical Innovations**, to apply the technology, including the manufacturing systems, to other tests. Inverness has made a string of acquisitions over the last 18 months, all in the diagnostic space, including **Panbio** last year.

**Optiscan Imaging (Acquisition target rating: Medium)**

Optiscan Imaging's share price has fallen hard over the last year.

Delay in building sales of its endomicroscope by Japanese partner **Hoya (Pentax)** has been the major contributor. Our expectation is that the Optiscan/Hoya endomicroscope will eventually receive global adoption by medical practitioners. In the meantime the company is accelerating other applications of its miniature confocal imaging technology.

That Hoya has built up a substantial war chest for acquisitions makes it an obvious acquirer of Optiscan. Hoya will also know well before other groups when demand for the product starts to accelerate.

**Cogstate (Acquisition target rating: Medium)**

Cogstate is a small life science company that provides cognitive testing services to pharmaceutical and biotech companies. The company has delivered strong sales growth over three years, albeit from a low base, and is expecting revenue for this financial year of around \$3.5 million. The company should move into profitability next year with demand for its product/service accelerating. It would make a handy add-on business to other companies with the same customers servicing the pharmaceutical development industry. An acquisition is unlikely to get through unless there was a substantial premium bid to the current share price.

**Acrux (Acquisition target rating: Medium)**

Acrux has one product on the market, Evamist, in the US and has just started Phase III trials in the US for its male testosterone product. It is expected the company will file this product for approval in the US in the fourth quarter of 2009. The global market for this product is valued at \$US800 million a year.

We believe the company is significantly undervalued. However, a bid for the company around \$5.00 a share might be considered although it would need the backing of the largest shareholder in the company, **Orbis Global Equity Fund**, which owns 17% of Acrux.

**Solvay Pharmaceuticals**, which controls around 80% of the US male testosterone market with its Androgel product might be an interested buyer if it sees the Acrux product as a serious threat to its franchise. The annual market in the US for male testosterone gels is valued at US\$570 million and is growing at 23% per year. Two thirds of users have indicated they preferred the Acrux lotion to existing gels!

Other potential acquirers might include **Procter and Gamble** and **Watson Pharmaceuticals**.

**Cytopia (Acquisition target rating: Low)**

Cytopia's share price has fallen 70% in the last 12 months. It has a capitalisation of only \$18 million with \$14.4 million in cash at the end of December last year. Our view is that all is progressing well at Cytopia, aside from the share price.

The company is conducting a Phase II trial in multiple myeloma with its lead candidate CYT997. Further Phase II studies with this compound are expected to begin in solid tumours later this year. The company has a development collaboration with **Novartis** and

*Cont'd over*

has one of the country's best drug discovery engine rooms.

While the company is ridiculously undervalued at current prices, a bid for the company is unlikely to get past major shareholders, who own 26% of the company, at anywhere near these low current prices.

If anyone were to bid for the company, local oncology group **Progen Pharmaceuticals** might have an interest as well as Cytopia's development partner **Novartis**, if it likes the quality of the technology emerging from Cytopia. Novartis has a strong interest in oncology and auto-immune disorders, both areas of work for Cytopia.

#### Pharmaxis (Acquisition target rating: Low)

Pharmaxis is another stock that has fallen hard this year, down 67% from its 12 month high of \$4.53. The company is now capitalized at \$293 million with \$116 million in cash at the end of March.

Being on the cusp of commercialising its product Bronchitol for the treatment of cystic fibrosis and bronchiectasis, it is unlikely a bid would get approval from Orbis Global Capital Group, which owns 18.9% of the company, in the vicinity of the current price. Orbis recently topped up its stake, acquiring \$3.2 million of Pharmaxis stock at around \$1.60 a share.

The field is open for potential acquirers.

#### Biota Holdings (Acquisition target rating: Low)

Biota Holdings has several attractive assets worth bidding for. The company had \$80 million in cash and receivables (at the end of last year), a healthy ongoing revenue stream from Relenza royalties, and a suite of clinical programs. This includes: a long acting neuraminidase inhibitor (a longer acting version of Relenza) currently in Phase II studies and being jointly developed with **Daiichi Sankyo**; a respiratory syncytial virus program that has been licensed to **MedImmune** and is currently in Phase I trials; an unpartnered rhinovirus program (treatment for the common cold) that has completed a Phase I clinical study; and a hepatitis C program that has been licensed to Boehringer Ingelheim.

Biota's LANI partner Daiichi Sankyo recent acquired **Ranbaxy Laboratories** and it could be an interested party in acquiring Biota down the track to gain full access to the LANI program and Biota's expertise in antiviral drug discovery and development.

Any bid however would be unlikely until a resolution of the litigation against **GlaxoSmithKline** has been reached.

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#### Bioshares Model Portfolio (27 June 2008)

Company	Price (current)	Price added to portfolio	Date added
Avexa	\$0.32	\$0.32	Jun-08
Cellestis	\$2.50	\$2.27	April 2008
IDT	\$1.86	\$1.90	March 2008
Circadian Technologies	\$0.88	\$1.03	February 2008
Patrys	\$0.30	\$0.50	December 2007
NeuroDiscovery	\$0.09	\$0.16	December 2007
Bionomics	\$0.37	\$0.42	December 2007
Cogstate	\$0.13	\$0.13	November 2007
Sirtex Medical	\$3.00	\$3.90	October 2007
Clinuvel Pharmaceuticals	\$0.33	\$0.66	September 2007
Starpharma Holdings	\$0.28	\$0.37	August 2007
Pharmaxis	\$1.51	\$3.15	August 2007
Universal Biosensors	\$0.90	\$1.23	June 2007
Biota Holdings	\$0.79	\$1.55	March 2007
Probiotec	\$1.30	\$1.12	February 2007
Peplin Inc	\$0.41	\$0.83	January 2007
Arana Therapeutics	\$1.13	\$1.31	October 2006
Chemgenex Pharma.	\$1.11	\$0.38	June 2006
Cytopia	\$0.21	\$0.46	June 2005
Optiscan Imaging	\$0.22	\$0.35	March 2005
AcruX	\$1.17	\$0.83	November 2004
Alchemia	\$0.30	\$0.67	May 2004

#### Portfolio Changes – 27 June 2008

##### IN:

Avexa has been added to the portfolio. Avexa's share price has fallen to 32 cents and represents a more attractive purchase point.

##### OUT:

No changes.

## Private Company Profiles

### Verva Pharmaceuticals

Focus is an established rule for biotech companies looking to maximize returns for shareholders. **Chemgenex Pharmaceuticals** has undergone a number of transformations over the year such that it is now structured as a pure-play cancer drug developer.

A by-product of its drive to focus was the spin-out of ChemGenex's metabolic diseases unit into Verva Pharmaceuticals, which was merged with the privately held obesity drug developer **Adipogen** in December 2007. The company is an unlisted public company with a large share register courtesy of an *in specie* distribution of shares to ChemGenex shareholders into the Verva Pharmaceuticals vehicle, on a one-for-five basis.

Verva is located in Geelong, Victoria, with research facilities located at the Metabolic Research Unit at Deakin University. However, the CEO of the company, Australian Vince Wachter, is based in San Francisco. Ian Nisbet, the CEO of **Xenome** is the non-executive chairman. Other non-executive board members include Andrew Baker (**GBS Venture Partners**), Greg Collier (CEO – ChemGenex Pharmaceuticals) and Andrew Macdonald, (CEO – **Cytopia**). The board is good example of how Australian biotech boards are likely to be structured in future, with members being sourced from the management ranks of existing biotech firms, where substantial commercialisation experience has been established.

#### VVP-808

Verva's lead program is an insulin sensitising drug candidate, VVP-808, for administration in diabetic patients. This compound is interesting because it has a 40 year history of pharmaceutical use in the USA in an undisclosed indication. This fact of extensive use, coupled with a well understood safety profile, significantly reduces the development risk associated with the compound. This 'established use' feature balances the risk associated with diabetes drug candidates, which is that the sector is highly contested, both with existing drugs and new drugs in development. Commercial advantages can come from improvements to delivery systems, as well as drugs that improve uptake of insulin. However, VVP-808 will be evaluated in conjunction with metformin, a drug that works by limiting the liver's capacity to make sugar.

VP-808 is attractive for another reason, because it works through a different mechanism of action compared to other insulin medicines and insulin sensitizing agents. VVP-808 was discovered through an in-house screening program. Manufacturing is relatively straight and offers a low 'cost of goods' feature that should make partnering a more successful outcome.

The company expects to commence a 60 patient Phase IIa trial of VVP-808 in Q4 2008, with safety and efficacy data available in H1 2009. Verva will conduct the trial in Geelong, with patients recruited from the area. Animal studies show VVP-808, in conjunction with metformin, significantly reduces blood glucose and HbA1c levels.

*Cont'd over*

### Haplomic Technologies

Haplomic Technologies is a Melbourne-based company that was founded in 2004 by Malcolm Simons and Geoff Swanson. Swanson and Simons are the major owners of the firm. Simons was one of the founders of **GeneType Ag**, the company that is owned by Genetic Technologies (GTG). Simons is also the inventor named on the so called 'junk DNA' patents that have been the source of an important licensing income stream for Genetic Technologies.

Simon's history, through the commercial benefits that have accrued to Genetic Technologies, means that his current corporate and business interest warrants global investor attention. There is some irony that the nomenclature for the company follows the name for Genetic Technologies, with the 'haplome' or haplomics emerging as field of therapeutic and scientific enquiry in the way that the genome and genomics had done.

Haplomics as defined by Simons refers to the collection of more accurate information from genes through the separate analysis of genes from single as opposed to paired chromosomes.

Haplomics describes itself as an Australian research and development company that specializes in haploid genetic, epigenetic and genomic diagnostic technologies and genetic-based technologies.

#### GenFusAb

However, Haplomic Technologies' chief attraction now looks to be emerging from a new therapeutic approach it has developed for the treatment of a number of cancers. The company has developed a technology for the treatment of gene fusion cancers, called GenFusAb. An example of a gene-fusion cancer is the bcr-abl mutation which sees a gene fused with another gene. Haplomics has identified many gene-fusions associated with both blood-based cancers as well as solid tumours. (See table on following page.)

The GenFusAb approach involves the targeting of 'chimaeric' or fused cancer proteins using single stranded antibodies (ssAb). At half the size of double stranded or two arm antibodies, the payload is significantly reduced.

#### Vector delivery system

The therapeutic strategy is based on a vector delivery system into cells. The vector delivers the DNA code for the single stranded antibody. The DNA construct also incorporates code for peptides that help the ssAb to signal and effect movement within the cell to the correct region of activity. The binding of the ssAb to the fusion oncoprotein within the cell halts the development of the cell and sends it into the cell death phase.

Haplomics has developed two technologies to complement GenFusAb. The first of these is called TransCrypt, a process that enables the detection of any gene fusion cancer. TransCrypt uses micro-array technology to identify patient specific gene fusion

*Cont'd over*

– *Verva cont'd*

At its inception, Verva raised \$2.75 million from Uniseed, GBS Ventures and QBF through a convertible note round, but has been seeking to raise an additional \$5 million. It has also flagged that it will make a compliance listing in H2 2008, depending on market conditions.

### Bioshares

– *Haplomic Technologies cont'd*

cancers. DNA micro-array technology is now very established in research but still in development as an industrial tool for therapeutic applications. However, it is well within the bounds a company today to design a therapeutic system utilizing the utilizing microarray systems.

The second complementing technology is termed Tri Print, which bar codes the vectors and provides a means to establish ownership of the 'manufacturing' of the vectors.

Haplomic Technologies is looking for funding to support working capital and research requirements, including contract laboratory work and patent costs. The company has filed a number of patents that cover its inventions, with two patents reaching the national stage of prosecution. The company would be amenable to the inclusion of additional directors as part of the introduction of new investors coming into the company.

Although the company utilises both DNA vector technologies and antibodies, it does not believe it would need to license intellectual property from other firms or inventors to exploit its inventions. Haplomics would be seeking to eventually sell its technologies but would also consider partnering opportunities.

### An interesting technology

The GenFusAb therapeutic approach is genuinely interesting because it addresses the challenge of delivery of antibodies into the cell and looks to be a novel way of treating a wide range of both blood-based and solid tumours that takes advantage of the patient specificity of tumour types. It may be also be a well-timed approach as the tools and systems in hospitals to deliver personalized therapies are more common than they used to be. The clinical evaluation of the GenFusAb approach is certainly warranted.

It would be fair to say there are still a number of unknowns with personalised cancer therapies. Determining the capital requirements for the development and the large scale roll out of the technology will still be a demanding exercise because of still to be characterised scale-up requirements of a new approach to cancer therapy into a market that is still dominated by surgery, radiotherapy and chemo-therapy. These challenges would then also impact on the pricing of any products that emanate from the technology.

Bioshares



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### Tax Loss Selling

Several biotechs have been sold down heavily over the last three months with much of those falls possibly attributed to tax loss selling. These include Alchemia, Biota Holdings, Cytobia, NeuroDiscovery, Optiscan Imaging, Pharmaxis and Peplin. Expect a strong start to the new financial year for many of these and other biotechs in July.

**Examples of Gene-Fusion Pairs**

<b>Gene</b>	<b>Fusion Pairs</b>
<b>Haematological Cancers</b>	
AF10	(AF10-CALM)
ALK	(ALK-ALO17; ALK-MSN; ALK-ATIC; ALK-NPM; ALK-CLTC;ALK-TFG; ALK-TPM3; ALK-TPM4; ALK-MYH9)
AML1	(AML1-ETO; AML1-ETV6; AML1-CBFA2T3; AML1-EVI/EAP; AML1-FOG2)
BCM	(BCM-IL2)
BCR	(BCR-ABL; BCR-FGFR1; BCR-JAK2; BCR-PDGFR-alpha)
CBF-beta	(CBF-beta-MYH11)
DEK	(DEK-CAN; DEK-NUP214)
E2A	(E2A-PBX1; E2A-HLF)
ETO	(ETO-AML1)
ETV6	(ETV6-ABL; ETV6-JAK2; ETV6-PDGFR; ETV6-SYK; ETV6-ARG; ETV6-TRKC;ETV6-FGFR3; ETV6-CDX2; ETV6-AML1; ETV6-MN1)
FGFR1	(FGFR1-FIM (ZNF198 or RAMP); FGFR1-FOP; FGFR1-CEP110; FGFR1-
FUS	(FUS-ERG)
HOXA9	(HOXA9-NUP98)
IG	(IG-BCL6)
MLL	(MLL-AF4; MLL-AF9; MLL-AF10; MLL-ENL; MLL-AFX1; MLL-AF1P; MLL-AF6; MLL-AF17)
MOZ	(MOZ-CBP; MOZ-TIF2; MOZ-p300)
OTT	(OTT-MAL)
PDGFR-beta	(PDGFR-beta-ETV6; PDGFR-beta-HIP1; PDGFR-beta-RABEP1 (Rabaptin);PDGFR-beta-(H4)-CCDC6; PDGFR-beta-TPM3; PDGFR-beta-PDE4DIP;PDGFR-beta-PRKG2; PDGFR-beta-GPIAP1; PDGFR-beta-GIT2;PDGFR-beta-NIN; PDGFR-beta-KIAA1509; PDGFR-beta-TP53BP1;PDGFR-beta-NDE1; PDGFR-beta-SPECC1 (HCMOGT-1)
RAR-alpha	(RAR-alpha-PML; RAR-alpha-NPM; RAR-alpha-NuMA; RAR-alpha-PLZ;FRAR-alpha-STAT5b)
REL	(REL-NRG)
SET	(SET-CAN)
<b>Solid Tumour Cancers</b>	
ALK	(ALK-CLTC; ALK-TFG; ALK-TPM3; ALK-TPM4; ALK-RANBP2; ALK-CARS; ALK-SEC31L1)
ASPL	(ASPL-TFE3)
CHOP	(CHOP=TLS/FUS)
CRTC1	(CRTC1-MAML2)
EWS	(EWS-ATF1; EWS-FLI-1; EWS-ERG; EWS-ETV1; EWS-ATF1; EWS-CHN;EWS-WT1)
JAZF1	(JAZF1-JJAZ1)
MECT1	(MECT1-MAML2)
PAX	(PAX3-FKHR; PAX7-FKHR)
RET	(RET-PTC1/PTC3; RET-PTC2)
SSX	(SSX1/SSX2-SYT)
SYT	(SYT-SSX1 or SSX2 )
TFE3	(PRCC-TFE3; PSF-TFE3; NONO-TFE3; ASPL-TFE3; CLTC-TFE3)
TRKA	(TRKA-TPM3; TRKA-TPR)

Source: HaploMic Technologies



**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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