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In this edition...
Unlike the Murray River, which is suffering the effects of a drought, there is no drought affecting the line up of investment opportunities amongst Australia's biotech stocks.

The three stocks we look this week (Bionomics, Biodiem and Cytopia) each have solid reasons for investors to add them to their watch lists, if not looking to add them to their portfolios sooner rather than later. What is common to Biodiem, Bionomics and Cytopia is that they are not single product companies, but instead each has a range of assets that bolster their investment profile.

The editors
Companies covered: BDM,BNO,CYT

	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 (from 5 May '06)	12.9%
Cumulative Gain	**214%**
Average Annual Gain	**26.0%**

Bioshares is published by Blake Industry & Market Analysis Pty Ltd. The company also provides market and company analysis of the Australian pharmaceutical and biotech industries for local and international funds management institutions, venture capital funds and other related industry groups. For further details contact David Blake (see details below).

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Bioshares

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

Antisoma-Novartis Deal Validates Programs at Bionomics and Cytopia

Two Australian listed drug developers, **Bionomics** (BNO: 30 cents) and **Cytopia** (CYT: 68.5 cents), received a very strong endorsement this week for their respective cancer drug programs following the announcement of a licensing deal between **Antisoma** (UK) and **Novartis**.

Novartis licensed Antisoma's small molecule vascular disruption agent (VDA), AS1404 (DMXAA) on an exclusive global basis for an all up potential payment of US$890 million, in addition to royalties. Novartis paid Antisoma an immediate upfront payment of US$75 million, with another US$25 million to follow when AS1404 enters a Phase III trial in lung cancer. An important aspect of the deal is that Antisoma has an option to co-commercialise the product in the US market.

As far as we can discern, AS1404 is administered through intravenous infusion. AS1404 (DMXAA) is an analogue of mitoflaxone, or flavone acetic acid, and falls in the broad class of compounds known as flavanoids.

As matter of minor interest to Australian investors, Antisoma also has a research collaboration with the privately held North Queensland natural product drug discovery company, **Ecobiotics**.

Why has Novartis licensed AS1404?
Sales of Novartis' oncology products were US$5.9 billion in 2006, an increase of 15%. However, these sales dominated by revenues from Glivec, which contributed US$2.5 billion, representing 42% of oncology product sales, followed by Femara, a breast cancer treatment, which clocked up US$720 million in sales (up 33%). In otherwords, Novartis is highly dependent on the sales of one drug in its oncology franchise, which also biases its portfolio to blood-based cancers such as acute myeloid leukemia. Although it has several compounds in development that target solid tumours, the weakness of its current marketed products portfolio can be seen as a driver for Novartis's deal with Antisoma.

Compounds Novartis has in development for cancer include PTK787 (valanitib) for colorectal cancer and solid tumours, LBH589 (also for solid tumours), RAD001 (everolimus) for renal cancer and EPO 9606 (patupilone) a tubulin inhibitor and therefore a solid tumour drug candidate.

Novartis looks also to have licensed AS1404 because of its stage of development. AS1404 has completed, or is completing three Phase II studies, each with about 70 patients enrolled, that compare AS1404 and selected cytotoxic drugs with a cytotoxic treatment alone. These Phase II studies have been conducted in lung, prostate and ovarian cancer.

The Phase II lung cancer trial reported a median survival of 14.0 months with AS1404 plus carboplatin and paclitaxel versus 8.8 months with carboplatin and paclitaxel alone.

Cont'd over

Lung cancer represents a major cancer market, and the evidence gained in this study alone could have played a major role in Novartis' interest in licensing AS1404, as well as the fact that the Phase II lung cancer study has been fully completed and is ready for Phase III.

Response rates have varied across the three different Phase II trials. In the lung cancer trial, AS1404 in combination with chemotherapy achieved a response rate of 31% versus 22% for chemotherapy alone. In the ovarian cancer trial, AS1404 in combination with chemotherapy achieved a response rate of 75% versus 63% for chemotherapy alone. In the prostate cancer trial, AS1404 in combination with chemotherapy achieved a response rate of 57% against 35% for chemotherapy alone.

The mode of action of AS1404 may also have been attractive to Novartis. While the mode of action of AS1404 is not fully understood (it may target the TIE2 receptor kinase), it appears to have a three fold effect on destabilising tumours and also operates as a 'biological response modifier' (BRM). AS1404 appears to have a direct effect on causing tumour cell death, by interacting with the cells that line tumour capillaries. However, it also activates TNF-alpha, which in turn causes the release of scavenging cells called macrophages and a clotting factor (von Willebrand factor) which leads to blood clotting and the blocking of blood vessels.

New vascular disruption approaches are sought because of the issue of drug resistance that has emerged with the taxane class of drugs.

History of AS1404 (DMXAA)

AS1404 or DMXAA (5,6-Dimethylxanthenone-4-acetic acid) was discovered at the **Auckland Cancer Society Research Centre** (ACSRC), **University of Auckland**, by Bruce Baguley and Bill Denny and others. Bill Denny is also a co-founder of **Proacta**, a privately held New Zealand-based company developing therapies based on the oxygen starvation of tumours based on technology developed at the University of Auckland and **Stanford University**. **GBS Ventures**, **Alta Partners** and **Genentech** have invested in Proacta.

The first clinical trial of DMXAA was undertaken in 1996. Antisoma licensed DMXAA from the ACSRC in August 2001 for an upfront fee of £700,000 in addition to other milestones and royalties.

Antisoma then licensed AS1404 and another compound, pemtumomab (R1549), to **Roche** in 2002, in a deal valued at US$500 million. Pemtumomab was at that stage in a Phase III trial for ovarian cancer. Antisoma received an upfront payment of US$43 million in cash and stock. In April 2004, Roche announced that Pemtumomab did not meet the endpoint for the Phase III trial.

In June 2006 Roche handed back the rights for AS1404 to Antisoma. A press report cited speculation that the patent for AS1404, which expires in 2012, was a reason for the handback. However, Antisoma stated at that time that it had a combination patent that extended patent coverage until 2021.

Implications of the Novartis-Antisoma deal for Bionomics and Cytopia

Validation of the VDA approach

At a minimum, the Novartis-Antisoma deal provides very timely and worthy validation of the approach by these Bionomics and Cytopia to develop compounds that disrupt tumour vasculature. This is in spite of the dominance and reach of the tubulin class drug leaders Taxol (and its generic equivalents) and Taxotere. It is also in spite of the emergence of anti-angiogenesis drugs such as Avastin and very strong interest in developing this class of drugs.

Deal term guidance and stage of development

The deal terms reached between Novartis and Antisoma give important guidance to what Bionomics and Cytopia might achieve with a potential partner should they advance their compounds to a similar stage of development and also create convincing high quality data that is indicative of improved patient outcomes.

Cytopia's VDA compound **CYT997** has been progressing through a Phase I dose-escalation study, with CYT997 given as a 24-hour intravenous infusion every three weeks in patients with advanced solid tumours. Results are expected this quarter. A second Phase I accelerated dose-escalation study with CYT997 administered as an oral capsule every three weeks to patients with advanced solid tumours is also underway, and results are expected in the September quarter. However, there is a risk that this second trial may not be completed in time so that reporting guidance is met. An IND has been filed and accepted with the FDA for CYT997.

Bionomic' VDA, **BNC105P** is currently undergoing pre-clinical assessment. Bionomics has developed BNC105 as a pro-drug hence the change in name to BNC105P. The company stated recently that BNC105 is not sufficiently soluble to allow intravenous administration for future clinical use. It is expected at this stage the BNC105P would be administered as an infusion over several minutes. Bionomics expects to file an IND submission with FDA in September. Recent data from pre-clinical studies of BNC105 showed that two cycles of BNC105P cleared tumours in 14% of treated mice (of a total of 64 with grafted breast cancer tumours), slowed growth in 34%, 47% showed no growth and 6% regressed. These data are encouraging.

Demand from Big Pharma

The deal between Novartis and Antisoma also demonstrates the demand that exists for novel approaches to treating cancer, and the demand exists because of the weakness in large drug company pipelines.

Combination therapy likely to be necessary

What can also be learnt from the development of AS1404 is that it is essentially a synergistic medicine, the benefits of which occur when it is used in combination therapy. The implication for Bionomics and Cytopia is that their respective compounds will more than likely need to be trialed in combination with other cancer drugs, for example paclitaxel and carboplatin, or even more recently developed compounds such as Erbitux and Avastin.

Cont'd on page 5

The Potential of Biodiem's LAIV Asset

Biodiem (BDM: 32 cents) has a number of biotech assets it is commercialising that originate from several research institutes in Russia. In edition #209 of Bioshares, we looked at one of the company's assets, a compound that has shown very encouraging results in treating retinal eye diseases. Below we will look at the company's other core asset, its live attenuated influenza vaccine (LAIV), that is currently in preclinical development.

Influenza vaccine program

Biodiem partnered its influenza program with **Nobilon (Akzo Nobel)** in 2004. The vaccine is different from all other influenza vaccines bar one (Flumist from **MedImmune**) as it uses a live attenuated version of virus as a vaccine, that is inhaled through the nose rather than a killed and injected vaccine form.

Although live attenuated vaccines are not a recent novelty, they do offer certain advantages. A version of this vaccine has been used in Russia in over 100 million people to date, so its safety profile is well established. There is also a competing version of the vaccine (Flumist) now in use in western markets. In 2006 Flumist generated sales of only US$36 million, although its poor commercial performance is due to a number of factors that the Biodiem/Nobilon vaccine is aiming to counter.

Advantages of LAIV

The apparent advantages of an LAIV over a standard killed influenza vaccine have now become an important consideration with the threat of a flu pandemic. This is because of evidence of broader protection offered by the LAIV. So much so that the **World Health Organisation** has made specific reference to the development of LAIVs in September last year in its Global Vaccine Action Plan to increase supply of pandemic flu vaccine. Specifically, the report states:

"*There is preliminary evidence that LAIVs might be more effective that inactivated vaccines. A full review of data should be undertaken to evaluate (a) the safety - especially in patients with asthma, the immunocompromised, the very young and the elderly; (b) protection against homologous virus and minor variants; and (C) evidence of herd immunity through vaccination of children.*

"*LAIVs may require less complex downstream processing so would be more appropriate for technology transfer. In addition, cell-culture derived production technology for LAIV is under development. LAIVs have a lower unit cost, and higher production yield, estimated at 10 times higher than for inactivated vaccines.*"

The safety issue largely relates to delivery of the vaccine as an inhaled product. The second point refers to possible protection against minor variants of influenza strains, from antigenic drift, offering potentially broader protection. LAIVs provide not just an antibody response, but induce a mucosal, antibody and cellular immune response. A traditional killed vaccine produces a strong antibody response but a weaker mucosal and cellular response.

The third point relates to 'herd immunity' which may be provided by LAIVs but does not occur with traditional killed vaccines. Trials of the Biodiem LAIV in Russia showed that when half the children in a school were vaccinated with the LAIV, the infection rate of influenza was substantially lower in the unvaccinated group, suggesting a herd immunity effect. The live vaccine produces antibodies in the upper respiratory tract which stops the virus from replicating and spreading. The killed vaccines do not produce antibodies in the upper respiratory tract and so does not generate a herd immunity response. MedImmune has shown that its vaccine Flumist decreases flu rates in schools and families where children are vaccinated although this was not compared with a standard killed flu vaccine.

History of development

Biodiem's and MedImmune's LAIV are both vaccines developed from the master strain of a flu virus that was isolated around 1960. This strain, the H2N2 (or more specifically A/Leningrad/134/17/57) is the core asset for both Biodiem and MedImmune as no other groups in the world possess this master strain from which these LAIVs are made. There is no patent protection applied to this master strain and these are the only known LAIVs in development or on the market.

Unique attenuation

What makes this strain suitable for an LAIV is the unique attenuation it offers that subsequent influenza strains do not provide. To make the Biodiem or MedImmune vaccine, six genes from this H2N2 master strain from the 1960s are incorporated with two genes from the current circulating wild type virus that codes for the two antigens hemagglutinin (H) and neuraminidase (N).

Another advantage?

There may also be an added benefit from using this H2N2 master strain as it may have some efficacy against the current H5N1 avian influenza strain. In studies in mice, the H2N2 master strain provided 80% protection against a lethal dose of the H5N1 avian flu strain.

Commercialisation of LAIV

Biodiem had previously licensed its LAIV vaccine to **Merck**. Merck added considerable value to the program, developing a cell fermentation method for production, although in 2003 handed the program back, apparently after losing an internal product champion within the company. In 2004, Biodiem licensed the program to Nobilon. To date Biodiem has received US$4 million in up front and milestone payments with a further US$4 million remaining.

Nobilon has European marketing rights excluding Russia and the CIS, and shared rights with Biodiem to Japan. Biodiem currently has rights to market the vaccine in the US although this is subject to an option Nobilon has over this territory which it may exercise within two years after the start of a Phase III trial. Biodiem will receive royalties from sales, estimated to be standard industry royalties of about 7%.

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Nobilon to be acquired by Schering-Plough

Last month it was announced that **Schering-Plough** would be acquiring Organon for US$14.5 billion, which includes Organon's subsidiary Nobilon. Through its Nobilon subsidiary, Organon had sought to enter the biopharmaceutical and vaccine development business, leveraging from its animal vaccine business **Intervet**. The LAIV program with Biodiem was one of its first vaccine programs. It started building its production plant in 2002 and has now received GMP accreditation. Although changes of ownership can be a risk for individual development programs within the acquired company, the press release announcing the takeover specifically indicated one of the attractions to Organon was to develop a human vaccines business.

Clinical trials expected to begin in 2008

While it may take as long as six years to bring the LAIV product to market, there is considerable long-term value that could accrue to Biodiem. The LAIV program is expected to move into the clinic in the fourth quarter of 2008. Biodiem is not expected to contribute to development costs.

Although at preclinical stages of development, the delay in commercialisation is in building a cell fermentation manufacturing process that will bring considerable advantages. It has the potential to become one of the most effective influenza vaccines (in line with Flumist) produced with the most economical production method (note that other companies are developing cell fermentation based processes for influenza vaccines, including MedImmune for its next generation Flumist). There is also a significantly lower development risk with this vaccine, given it has been safely administered to approximately 100 million people in Russia.

Avian vaccine program

In August 2006, Nobilon and Biodiem signed an R&D agreement with the US Centers for Disease Control and Prevention (CDC) to develop a cell culture LAIV against the avian flu strain (H5N1). The cooperative research program will evaluate in preclinical models the effectiveness of LAIV candidates against the avian strain.

Market size

The flu vaccine market is currently valued at in excess of US$2 billion a year and this is expected to increase to US$4 billion a year by 2009. Current manufacturers include **CSL**, **Chiron**, **GlaxoSmithKline**, **Baxter**, **Berna Biotech**, **Novartis**, **Sanofi Pasteur** and **Solvay Pharmaceuticals**. It is possible that an inhaled LAIV manufactured in cell culture may represent the future gold standard in influenza vaccines. These products could realistically achieve 50% market share if they can be produced to price competitively against an injectible vaccine.

There are several factors that make LAIVs appealing over the standard injectible vaccine. These include delivery (inhaled rather than injected), potentially some broader protection against variant strains, herd immunity reducing infection in non vaccinated population, and long term asset protection. (There is no patent protection for the LAIVs in general. Protection from competitors comes from access to and possession of the H2N2 1960s master strain which provides the unique attenuated properties of these vaccines.)

Commercial market for Biodiem's LAIV

In early 2002, MedImmune completed its acquisition of Aviron for US$1.5 billion, primarily for access to the company's Flumist LAIV program. The company received FDA approval for Flumist the following year. Flumist was expected to generate sales in the order of US$1 billion a year, however due to high pricing (previously US$45 per vaccine), approval for use only in 15-49 year olds and its necessity to be transported frozen, the product has been disappointing (sales of US$21 million in 2005 and US$36 million in 2007) although remains one of the three top programs for MedImmune.

Flumist sales slow to take off

In January this year MedImmune received FDA approval to market its refrigerated version of Flumist. It is expected this 'improved' product will sell for between US$20-US$25 per dose, bridging the gap on the standard killed flu vaccine, which sells for between US$10-US$15 per dose.

MedImmune's US$170 million contract

MedImmune is also developing a cell culture-based manufacturing process to produce both seasonal and pandemic versions of its Flumist product. Last year the company received a US$170 million cost reimbursable contract from the **US Human and Health Services Department** to develop the vaccine for seasonal and pandemic flu strains in a cell culture method using its LAIV. In November last year it filed an IND for its cell culture-based LAIV, making it at least two years ahead of the Biodiem/Nobilon program.

Solvay Pharmaceuticals, another flu vaccine manufacturer, has also been awarded a US HHS grant to develop a cell culture-based influenza vaccine for seasonal and pandemic influenza worth US$298 million. Cell culture-based manufacturing of flu vaccines is likely to become the standard of choice moving forward.

Conversely, the Biodiem/Nobilon vaccine is being developed as a cell culture manufactured product rather than being manufactured in chicken eggs (as with most influenza vaccines). The reduces the cost significantly, reduces manufacturing time, which can be vital in response to a flu pandemic outbreak, and the process can be scaled up more quickly, once again a very important consideration if a flu pandemic breaks out. The Nobilion program will also trial a refrigerated form of its LAIV.

Features of LAIVs

The appeal of LAIVs is that they may offer broader immunity, potentially even some protection against a pandemic strain, if mouse studies give any indication. Also they have shown to be more efficacious in protecting against influenza infection than killed vaccines, although Flumist does carry a slight chance of

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Biodiem - from previous page

causing flu like symptoms. Also, LAIVs are delivered in a more (arguably) patient-friendly manner, via inhalation rather than injection, and LAIVs may also provide herd immunity to the unvaccinated.

Move to cell culture manufacturing

There is overwhelming interest in influenza vaccine technology at present as a result of the potential threat of an influenza pandemic. The interest is directed at developing capabilities to increase vaccine production responsiveness, largely through the development of cell culture-based methods which are likely to become the commercial standard of choice moving forward for not only pandemic vaccines but also seasonal flu vaccines.

Improved version of Flumist

Biodiem's vaccine program with Nobilon has yet to enter the clinic and is approximately two years behind MedImmune. Live attenuated influenza vaccines have yet to become a commercial success. However, a more commercially competitive Flumist product will be sold at the end of this year in the US for the northern hemisphere winter which could see sales accelerate. However approval of the product in the very young and the elderly has still not been received and this will continue to limit sales until those approvals are received.

Summary

When MedImmune acquired Aviron for US$1.5 billion five years ago, there was an obvious excitement about live attenuated influenza vaccines. This interest has since been tempered. However if MedImmune can get its Flumist product right, then interest may return and with the World Health Organisation recognising the potential role of this vaccine approach in preparing for a possible pandemic, it helps pave the way for Biodiem's product, which looks to be put in the hands of a US$50 billion partner in the form of Schering-Plough.

Biodiem is capitalised at $17 million with $5.6 million in cash at the beginning of this year. It remains considerably undervalued given the commercial relevance and progress of its core programs.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

The Bioshares 20 Index

Change from June 30, 2006	**75.9%**
Change from Dec 31, 2006	**39.3%**
Change - week ago	**-2.9%**

Nasdaq Biotech Index

Change from June 30, 2006	**12.6%**
Change from Dec 31, 2006	**4.8%**
Change - week ago	**1.6%**

Bionomics, Cytopia - from page 3

Summary

Cytopia's VDA program is more advanced than Bionomics, with BNC105P yet to enter the clinic. The Novartis-Antisoma deal gives guidance as to the value Cytopia could be hoping to achieve, with simply one compound (CYT997) over the next eighteen months, should it complete at least one Phase II study in solid tumours with a strong result. The entry of Bionomic's BNC105P into a clinical trial will warrant a positive re-rating of the stock

An aspect of the Novartis-Antisoma deal of specific relevance to Novartis is that Cytopia has an existing collaboration with Novartis, in the area of transplantation medicine. The value of such a relationship is not to be underestimated, as Cypotia has now developed contacts within Novartis, and has learnt much from the lengthy and necessarily tedious process of initiating and commencing a collaboration. To have a foot in the door of a Big Pharma company may prove to be hugely advantageous should Cytopia be in a position to partner CYT997 in 18 months time. Together with the recent selection of a lead candidate, CYT645, for the company's FMS cancer drug program, its existing partnership with Novartis, Cytopia is currently one of the most attractive biotech investment propositions, from a valuation perspective, on the ASX.

Bionomics is capitalised at $57 million, and held $7 in cash at December 31, 2006. Cytopia is capitalised at $50 million, and held $18 million in cash December 31, 2006.

Bioshares recommendation:
Bionomics - **Speculative Buy Class A**
Cytopia - **Strong Buy/Speculative Buy Class A**

Bioshares

Bioshares Model Portfolio (20 April 2007)

Company	Price (current)	Price added to portfolio
Acrux	$1.40	$0.83
Alchemia	$1.07	$0.67
Biodiem	$0.32	$0.29
Biota Holdings	$1.60	$1.55
Cytopia	$0.69	$0.46
Chemgenex Pharma.	$0.83	$0.38
Optiscan Imaging	$0.46	$0.35
Neuren Pharmaceuticals	$0.43	$0.70
Peplin	$0.81	$0.83
Peptech	$1.95	$1.31
Phylogica	$0.32	$0.42
Probiotec	$0.90	$1.12
Sunshine Heart	$0.16	$0.19
Tissue Therapies	$0.51	$0.58

Portfolio Changes

Progen Pharmaceuticals has had a very strong run since it was added to the Bioshares Model Portfolio. We will take profits and remove it from the portfolio.

How Bioshares Rates Stocks

For the purpose of valuation, *Bioshares* divides biotech stocks into two categories. The first group are stocks with existing positive cash flows or close to producing positive cash flows. The second group are stocks without near term positive cash flows, history of losses, or at early stages of commercialisation. In this second group, which are essentially speculative propositions, *Bioshares* grades them according to relative risk within that group, to better reflect the very large spread of risk within those stocks.

Group A

Stocks with existing positive cash flows or close to producing positive cash flows.

Buy	CMP is 20% < Fair Value
Accumulate	CMP is 10% < Fair Value
Hold	Value = CMP
Lighten	CMP is 10% > Fair Value
Sell	CMP is 20% > Fair Value

(CMP–Current Market Price)

Group B

Stocks without near term positive cash flows, history of losses, or at early stages commercialisation.

Speculative Buy – Class A
These stocks will have more than one technology, product or investment in development, with perhaps those same technologies offering multiple opportunities. These features, coupled to the presence of alliances, partnerships and scientific advisory boards, indicate the stock is relative less risky than other biotech stocks.

Speculative Buy – Class B
These stocks may have more than one product or opportunity, and may even be close to market. However, they are likely to be lacking in several key areas. For example, their cash position is weak, or management or board may need strengthening.

Speculative Buy – Class C
These stocks generally have one product in development and lack many external validation features.

Speculative Hold – Class A or B or C

Sell

Corporate Subscribers: Phylogica, Neuren Pharmaceuticals, Pharmaxis, NeuroDiscovery, Prima Biomed, Biotech Capital, Cygenics, Cytopia, Biodiem, Peptech, Starpharma Holdings, Cogstate, Xceed Biotechnology, Incitive, Optiscan Imaging, Bionomics, ChemGenex Pharmaceuticals, Medical Therapies

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