ISSN 1443-850X

Extract from Bioshares –

In this edition...
We look at the good progress that Australian biotechs developing cancer therapeutics are making. Investors have the full spectrum of development stage companies to invest in, from very profitable and high growth businesses such as Sirtex Medical, to companies that will shortly embark on clinical evaluation such as Patrys.

We also provide an update on Avita Medical and it looks like Biota Holdings is set to accelerate in-licensing or acquisition activities.

The Editors

Companies Covered: AVH, BTA, BNO, CIR, CYT, CXS, PAB, SRX

	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 - May '09)	-7.3%
Year 9 (May '09 - Current)	45.5%
Cumulative Gain	**182%**
Av Annual Gain (9 yrs)	**18.1%**

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

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) 9329 3350
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

Individual Subscriptions (48 issues/year)
$320 (Inc.GST)
Edition Number 329 (18 September 2009)
ISSN 1443-850X

Bioshares

18 September 2009
Edition 329 (Extract)

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

Australian Cancer Stocks Review

The full spectrum of cancer therapy development companies trade on the ASX. From **Sirtex Medical**, which has become a very profitable business that is now attracting wider institutional investor support, to companies that have just filed their drug for approval such as **Chemgenex Pharmaceuticals**, to companies that are conducting clinical trials (Bionomics and Cytopia). These two companies should hit major inflexion points over the next 18 months. And to companies moving into the clinic (Patrys). What is striking is the quality of these businesses and why Australia can expect to see more Sirtex-type commercial successes.

Sirtex Medical – Profitable, With Strong Growth Prospects

Sirtex Medical (SRX: $4.98) has become a very successful liver cancer therapy company. In the last financial year, the company generated a net profit $18.2 million, compared to a net profit of $1.2 million in FY2008. The company has well and truly reached the value infection point, where sales and sales growth is increasingly falling through to the bottom line.

The stock has had few institutional shareholders aside from **Hunter Hall International** which owns 29.5% of the company. That is now changing with 4.6 million shares this week being sold on to institutional investors from the **Cancer Research Fund** at $4.50 a share through **Taylor Collison** stockbroking house. Institutional interest is expected to continue to increase.

What is stimulating that interest is the company's steady, strong growth potential. Unit sales of its short-acting, radiation emitting silicon spheres are growing at around 1,000 treatments a year, to 3,500 treatments last year. This corresponds to a 30% ongoing growth in revenue and a higher growth in net profit. Sales in FY2009 were $65 million.

A huge unmet need continues for patients with secondary and primary liver cancer which will keep demand high. The company continues to support ongoing clinical programs, investigating other combination uses of the product for the treatment of liver cancer, for use in treating primary liver cancer, and for higher treatment order as a first or second line therapy. However for oncologists to prescribe the product for other treatment regimes, clinical data is required. The market limit for the product at this stage appears to be in training of sufficient interventional radiologists to perform the procedure and other clinical center support staff.

There are currently 15 clinical underway or in the planning. The trials registered in the US are listed in the table on the next page. Of interest in these trials is use of the drug for treatment of primary liver cancer (currently the product is only approved for patients who have colon cancer that has spread to the liver), and where the drug is being trialed as a first line therapy. Currently it is used a third line salvage therapy.

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Sirtex SirSpheres Clinical Studies Underway or in Planning in USA

	Study	Status
1	Sir-Spheres + Systemic Chemotherapy (FOLFOX)	Recruiting
2	Sir-Spheres + Sorafenib, 1st line therapy, primary liver cancer	Active, not recruiting
3	Sir-Spheres + Cetuximab and Irinotecan	Not yet recruiting
4	Sir-Spheres + Capecitabine	Recruiting
5	In primary liver cancer	Recruiting
6	In primary liver cancer versus transarterial chemoembolisation	Recruiting
7	In patients having failed intra-arterial pump chemotherapy	Recruiting

Sirtex is capitalized at $277 million with $26.5 million in cash. Although net profit growth we expect will stay strong, the appreciating Australian dollar will have a negative impact on the top and bottom line this financial year. Most of the sales are gained outside of Australia and most costs are generated within Australia. The company has no debt and franking credits of $9.2 million.

Over the next four years we estimate sales can reach around $200 million a year, based on sales growth of 30% per annum, assuming growth continues in Germany and the US, expansion into other countries occurs and the Sir-Sphere's treatment is taken up for liver cancers where the primary cancer is not in the colon. The company currently generates a gross margin in excess of 80%. Based on a 5.0 times sales multiple, the company we would argue would potentially be valued at approximately $1 billion, which would equate to a 40% annual investment return on this stock over that four year period. This is the long term appeal of this investment opportunity.

Bioshares recommendation: **Buy**

Chemgenex Pharmaceuticals – Through The Clinic and Over To Regulators

Chemgenex Pharmaceuticals (CXS: $0.765) this month filed its lead oncology drug candidate for approval with the FDA. The compound, which has been renamed OMAPRO, has been found to be very effective at treating patients with chronic myeloid leukemia (CML). Not quite as effective as Gleevec, the drug however will find a use for patients who have failed Gleevec treatment and have a particular type of genetic mutation.

The next 12 months will be busy for the company, with a European regulatory submission also to be filed this calendar year, a corporate partnership to be negotiated this calendar year for Europe, and expected approval in the US in the first half of next year and approval in Europe in the second half of 2010.

The aim for Chemgenex is to complete a marketing deal for Europe and use funds from a marketing deal to help finance rollout of the product in the US. As with almost all cancer drugs, Chemgenex will seek to show efficacy in other cancer applications or drug combinations. The first additional application, for which a 100 patient trial is continuing, is for patients who have chronic myeloid leukemia and have failed more than one tyrosine kinase inhibitor (TKI) drug treatments (there are currently three TKIs on the market: Gleevec, Sprycel and Tasigna).

Next is to trial OMAPRO in combination with other drugs, presumably Gleevec. An appeal of OMAPRO is that it is effective in not only killing leukemic cells in the blood stream, but it is effective at killing the stem cells in the bone marrow responsible for generating the circulating leukemic cells. As such it could further improve the first line therapy for CML.

Other future indications for OMAPRO could include the treatment of acute myeloid leukemia and myelodysplastic syndrome.

The current annual drug costs for treatment with existing TKIs ranges from US$50,000 - US$100,000. We estimate that OMAPRO could generate revenues in excess of US$200 million a year. At June 30 Chemgenex had $17 million in cash and is now capitalized at $216 million.

Bioshares recommendation: **Speculative Buy Class A**

Bionomics – Moving Through The Clinic

Bionomics' (BNO: $0.26) lead drug candidate, BNC105, a vascular disrupting agent (VDA) for the treatment of solid cancers, is at the Phase II stage of development. Interim results from its Phase II trial in patients with renal cancer are expected to be available at the end of 2010, with final trial data out at the end of 2011. Another Phase II trial in patients with mesothelioma has a similar timeline although is still in the planning, with trial details to be released in the next two months.

Bionomics will conduct a Phase II trial in kidney cancer using BNC105 in combination with Afinitor, a new 2nd line treatment for kidney cancer approved only in March 2009. Its drug candidate has a synergistic pathway with Affinitor and an open competitive path relating to other VDAs. In mesothelioma the company needs only to conduct a single arm trial (not blinded and no control) with no other drugs given the lack of existing drugs for this disease. The path to market is potentially more straightforward.

Bionomics is also conducting a Phase I trial with its drug candidate BNC210 for the treatment of depression/anxiety. This is a very large market and the aim is for this compound to have improved drug properties to existing blockbuster drugs such as Valium or Prozac. Results from this Phase I trial should be out at the end of the year. This will be a major derisking for that program, with the side effect profile, including changes in liver enzyme levels, and the sedative effects being closely monitored. Being a drug candidate that will be potentially taken by millions of people, safety profile of the compound is the leading issue.

Once the data is available, Bionomics will be in a position to negotiate a licensing deal , which could be significant. The company is very optimistic at this stage.

Bionomics has recently announced an impressive $15 million capital

Cont'd over

raising which is underwritten by Linwar Securities. This will give the company $19 million in cash at June 30 this year. Of interest and significance is that venture capital group Start-Up Australia will top up its investment by $7 million, moving from 23.3% ownership to a 27%-28% holding. It's an intelligent capital raising as it gives the company sufficient cash to partner out BNC210, and to pass the interim data milestones for BNC105 in both cancer trials and to approach the stage where final data from these trials can be achieved. It will also allow the company to fund a Phase I/II trial with BNC210 if required.

Bionomics is capitalized at $82 million (including capital raising).

Bioshares recommendation: **Speculative Buy Class A**

Cytopia – Second Compound into Clinic

Cytopia's second drug development program has received the all clear from the FDA to commence trials in the US. (See table on page 4).

The CYT387 compound will be evaluated in 30 patients with myelofibrosis at the **Mayo Clinic**. The trial is expected to start in October/November this year. Data is expected to emerge from this trial in the first half of 2010. CYT387 has the potential to treat a range of myeloproliferative disorders and as a cancer therapy through the JAK2 cellular pathway.

A Phase II trial with CYT997, the company's lead oncology drug candidate, is progressing in patients with glioma. Results from this trial are expected also in the first half of 2010.

While the company continues to make good progress in moving compounds into the clinic using its internal drug discovery platform, the company needs to address its funding requirements. At June 30 the company had only $4 million in cash. The company is capitalised at $11 million.

Bioshares recommendation: **Speculative Hold Class B**

Patrys – Moving Into The Clinic

Patrys (PAB: 13.5 cents) has released some more positive preclinical data on its lead human antibody compound, PAT-SM6. In the fourth type of animal model study, the drug candidate showed a reduction in the spread of colon cancer to the liver by 50% over the control group.

What is particularly appealing about this program is that if successful, the compound could be used to prevent the occurrence of secondary cancers. There are no specific drugs on the market that have been designed to mop up the cancer metastases. Given that the Patrys platform is derived from existing human immune system function, the use for such an application appears ideal.

The drug candidate has previously shown to prevent secondary cancer formation from gastric cancer, and in two other preclinical trials the compound has shown to have a positive effect in treating primary pancreatic and gastric cancers. The compound has been tested against over 200 different tumours in various cancers and shown specific binding to over 90% of those tumours.

The Phase I trial with PAT-SM6 is expected to start by year's end, about nine months later that what was expected last year. It will be primarily a safety study conducted in Australia, including Melbourne, but the trial will be designed to capture some measure of efficacy. Results should be out by mid 2010, although some interim results may be available sooner.

The trial will involve patients with solid tumours. Although the initial aim will be to see what effect the drug has on the primary tumour, perhaps the most appeal with this drug is for it to be used to prevent secondary cancers.

Over the last 12 months the company has made good progress in getting its candidates PAT-SM6 and PAT-LM1 ready for clinical evaluation. The company has become the first group to show that human antibody drug candidates can be manufactured on scaled-up quantities. The drug has also passed critical preclinical toxicology tests, which have showed the drug candidates do not illicit an immune response and that the drug's safety profile was very good at high doses in larger animal studies.

Patrys had $13 million in cash at mid August and is capitalized at $25 million. The company is continuing partnering discussions for one or more of its suit of human antibody drug compounds.

With the company having addressed its medium term funding requirements and with the clinical stage of development approaching, the stock is in a position to generate positive investor interest in coming months after being heavily sold down last year and in the early part of 2009.

Bioshares recommendation: **Speculative Buy Class B**

Circadian – Aiming for the Clinic in 2011

Circadian (CIR: $0.75) is developing antibodies that inhibit or modulate the VEGF-C and VECF-D growth factors, which are implicated in a range of disorders, including cancers. Circadian will initiate toxicology studies on a lead from its VGX-100 series in 2010 and will submit an IND filing in 2011 with trials to commence shortly after. The company expects to have a clearer idea of which cancers it should target in three-to-four months time.

Over the next twelve months Circadian will aim to select a lead candidate from its VGX-200 series and demonstrate manufacturing capability of its VGX-300 series.

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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