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Biosharses

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Edition 346

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

In this edition...
In a first for Bioshares, we have tallied discussion entries on biotech stocks on a popular chatroom to gauge day trader interest. The results are surprising in a number of ways.
Bionomics has now begun enrolling patients in its Phase II kidney cancer trial for its cancer compound BNC105 and expects to see patients enrolled in a mesothelioma trial soon. The prospects of interim data from both these trials emerging in later in 2010 and 2011 may pave the way for BNC105 to be partnered in 2011.
We also update readers on developments at Alchemia, Avexa and Benitec and provide readers with our regular Survival Index analysis of companies that report cash positions each quarter.

The Editors
Companies Covered: ACL, AVX, BLT, BNO, Cash Analysis

	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)	63.1%
Cumulative Gain	**217%**
Av Annual Gain (9 yrs)	**20.1%**

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Extract from Bioshares –

Succesful Completion of Current Business Plan Will Set Up More Ambitious Phase for Bionomics

Bionomics (BNO: $0.30) has started recruiting patients into its 152 person Phase II renal cancer study with its lead compound, BNC105. Outcome of the study should generate considerable interest from potential partners, with at least 17 companies having registered an interest in the program.

The Phase II trial is expected to be fully enrolled by the end of 2011, although interim data is expected to be available by the end of this year. BNC105 is termed a vascular disrupting agent (VDA), meaning it specifically destroys the vasculature in solid cancers. The leading VDA in development was licensed by **Novartis** from **Antisoma** in 2007, paying Antisoma US$75 million in upfront payment and a further US$25 million when it entered Phase III trials. The total deal value was worth up to US$890 million.

The first Phase III trial results with this Antisoma/Novartis drug candidate (in non small cell lung cancer) are expected to be released by mid year. This compound is also being tested in breast and ovarian cancer.

Bionomics arguably has the second leading VDA in development. To not compete with Novartis/Antisoma, Bionomics has selected renal cancer and mesothelioma. In a Phase I study completed last year, the Bionomics drug candidate was shown to stop cancer progression in two patients with renal cancer (at 12mg/m2 dose) and one patient with mesothelioma (at 8mg/m2 dose). Importantly this trial showed no negative impact on cardiac function at higher doses unlike other VDAs (as measured by QTC prolongation).

Interim data from the mesothelioma trial (in 67 patients) is expected in early 2011. This trial is due to commence shortly. Perhaps not by coincidence, Bionomics will be at the same stage of development when it seeks to partner BNC105 that Antisoma was when it partnered with Novartis.

Mesothelioma a Potential First Indication

Mesothelioma may be the first indication for Bionomics' BNC105. With no second line treatments available, patient recruitment will be easier and a primary endpoint of progression free survival (rather than overall survival) should be acceptable to regulators. There will also be no existing drug to compare treatment with, with patients being those that have failed first line therapy. This means a registration trial could be started in 2011 and the drug filed for approval in late 2012 if everything goes to plan.

It appears that an objective for Bionomics is to have its first three programs partnered with larger biotech or pharmaceutical groups by the end of next year. In 2008 Bionomics licensed one of its earlier drug candidates for multiple sclerosis with **Merck Serono**. The other partnering objective is with BNC210, a compound for the potential treatment of anxiety and depression.

Cont'd over

A Phase Ia was successfully completed with BNC210 last year. A Phase Ib trial will start in the next two months and should be completed by the end of September this year. At that stage Bionomics will seek to partner the program.

This drug candidate is much further away from market than the lead cancer drug candidate, with far larger trials to bring the drug to market. However the market is larger, with antidepressant drugs generating sales of around US$11 billion in 2008.

Potential Deal Sizes

A very good licensing deal for BNC105 would include at least a US$50 million upfront payment with a 15-20% royalty rate from sales. For BNC210, a very good deal would include a US$20 million upfront payment from a potential partner with a 10-12% royalty entitlement.

Summary

Bionomics is on track to complete its current commercialisation plan, that of three partnered R&D programs representing a full clinical pipeline by the end of 2011. If it can achieve the clinical and commercial goals over the next two years, then the next phase of its commercial life will allow the company to more aggressively progress its programs, which may see in-house development up to registration trials of the next round of compounds and even manufacture of final products in Adelaide.

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

Corporate Subscribers: Pharmaxis, Cytopia, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx, BioMd, Tissue Therapies (commencing February 2010)

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