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In this edition...
Pharmaxis has finally received approval from the US FDA for Aridol, its lung function test. While not expected to be a huge earner, the take-up of Aridol is likely to expose a product that is essentially the same as Bronchitol (a therapeutic) to end-users and physicians, who may prescribe Bonchitol.
At Sirtex Medical, sales of its SirSpheres treatment appear to be strengthening.
The FDA has agreed that Chemgenex can use data from two current trials in its submission for Omapro to treat CML patients who have failed treatment with two or more kinase inhibitors. Bionomics is set to commence two Phase I studies in France of BNC210, an anxiety and depression compound. And we update readers on progress at Viralytics and KarmelSonix.
The Editors
Companies Covered: BNO, CXS, KSX, PXS, SRX, VLA

	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 - May '10)	49.2%
Year 10 (May '10 - Current)	-4.0%
Cumulative Gain	**178%**
Av Annual Gain (9 yrs)	**18.5%**

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Bioshares

8 October 2010
Edition 380

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

Pharmaxis Gains FDA Approval for Aridol

Pharmaxis(PXS: $2.59) has received approval this week to market its lung function test, Aridol, in the USA. Pharmaxis expects to launch the product in the first quarter of 2011 once the final necessary documents have all been completed with respect to the product, such as packaging design. Pharmaxis will sell the product direct in the US, using its own staff and will use a team of asthma nurses to support training.

The company has just under 10 people in its US team to co-ordinate the sales, distribution, marketing and reimbursement. The test will go up against an existing test which uses nebulized methacholine chloride. That test is sold by **Methapharm** from Canada with about 150,000 such tests sold in the US each year. At around $70 a test, the existing market in the US is worth around $10 million a year.

The methacholine test is complicated to use, requiring specialised equipment and time consuming clean up. The Aridol test uses mannitol power inhaled through a simple hand held disposable device. Aridol is arguably a much safer and easier test test to use.

Pharmaxis believes its test will be very competitive against methacholine, having taken 50%-80% market share in other markets it has entered. In the US, the existing market is largely to pulmonary labs, of which there are around 3,000 in the US. The untapped market is for use by allergists who generally do not have the equipment to conduct the methacholine test.

In FY2010, Pharmaxis generated sales of Bronchitol of $828,000. The product is being sold into Australia, Europe and South Korea. Sales in South Korea are going well with 1000 packs a month being sold. Other areas such as southern Europe are very challenging due to the tough economic conditions those regions are experiencing.

Pharmaxis believes there is some low hanging fruit in the US that will allow its product to gain traction quickly (within six to nine months). Bronchitol for the treatment of cystic fibrosis and bronchiectasis is the main game for Pharmaxis. However the launch of Aridol will build the company's expertise, distribution channels and user base ahead of the Bronchitol launch.

Pharmaxis is awaiting approval for Bronchitol for the treatment of cystic fibrosis in Europe with the target date the end of 2010 for a decision. In the US, the company is expected to meet with the FDA to discuss its NDA submission.

Pharmaxis is capitalised at $585 million and retained cash assets of $86 million at June 30, 2010.

Bioshares recommendation: **Speculative Hold Class A**

Sirtex Medical – Healthy Growth Set to Resume

For Sirtex Medical (SRX: $5.08), it looks like growth is set to resume a healthy rate after unit sales of its liver cancer therapy started to plateau in FY2010. In the September quarter the company indicated that it had achieved record dose sales, for a period that normally has interruptions from the northern hemisphere vacation period.

Sales growth rates throughout FY2010 were declining, from 27% in the first quarter, down to 17% for the first half, then 15% for nine months and 14% growth for the year. Given the strong start to the year in FY2010, the last quarter was then likely to be well below 14% growth over the previous corresponding period.

In the first quarter of the new financial year, dose sales have bounced back to 16% growth over the previous corresponding period. In the US, which accounts for 60% by unit sales, unit sales increased by 12.6%, however this does not include the 7% price increase, which then translates to a 20% growth in the US in the first quarter of FY2010 over the same period in FY2009.

US Staffing

Sirtex has put a lot of effort into improving the performance of the US market, where sales increased by only 8% in FY2010. And those efforts look to be working. It has installed a new business manager in the US. A VP of Sales has been appointed in the US, also a VP of marketing, three additional sales people, who are all hitting their targets, and two re-imbursement specialists (now four). In the last 12 months staff numbers in the US have increased from 30 to 40 people.

Aiming for First-line Therapy

To date over 16,000 people have been treated with the Sir-Spheres tumour irradiation product. A year ago in the US there were 140 centres that had used the Sirtex product and there are now 220. The short-medium term growth will come from more investment in marketing and sales of the product. In the long term, and the real acceleration in growth, will come from use of the product as a first line therapy in conjunction with chemotherapy (currently it is used in third line salvage therapy), and from use of the product for the treatment of primary liver cancer (currently in the US it is approved only for use secondary cancers that have spread to the liver).

To achieve this the product is currently being assessed in four major trials around the world, which are expected to enrol 1,675 patients.

Singapore Facility

Another driver for the company will be the opening of the Singapore manufacturing facility, which is expected to occur around May next year. Currently the company manufactures product only in the US and Australia. With the product involving a decaying radioisotope, the company has only three days to ship its products. This complicates manufacture and transportation of the product. The Singapore plant will be able to service Asia and Europe and the cost of goods are expected to drop given the higher costs involved in manufacturing the product in Australia.

Europe contributes 30% of group unit sales. In FY2010 sales growth was strong, increasing at 25%. In the first quarter of that year the growth has continued with unit sales increasing by 27%. A driver for 2010 will be entry into France with the company expecting to start selling in that country for the first time from January 2011.

R&D Programs

In FY2010 the company invested $3.1 million in R&D, which is only a low R&D expenditure. The company prefers to work with third parties and in-license novel technologies. One program the company is investing in is a radioprotector technology that is being developed at the **Peter MacCallum Cancer Centre** in Melbourne. This is a small molecule drug that is in preclinical stages of developed and a program the Peter Mac group has been working on for the last 12 years. The aim of the compound is to protect healthy tissue from the effects of radiation. This has an application in oncology to protect the non-cancerous tissue of patients undergoing radiation therapy. The US Army has also shown some interest in the program.

Financials

In the last financial year the company generated product sales of $64 million with a net profit of 16.1 million. The company held $41 million in cash at June 30. Net profit decreased from $18.2 million the previous year with a net negative $2.9 million impact from foreign exchange losses and legal settlements compared to the previous year. In FY2010, the company increased clinical trial costs by just under $2.9 million to $8.9 million. The size of the clinical team has been doubled to support these trials. The company has increased overall staff numbers from 60 to 80 in the last year.

Clinical trial costs are expected to increase and peak over the next three as the major trials mentioned above are conducted. However those costs are not expected to double from FY2010. It is money very well spent for the company, helping the product get to the inflection or tipping point.

Sirtex is capitalised at $283 million. Excluding legal settlements and associated costs and foreign exchange losses, the company generated a profit before tax of $15.4 million. Assuming a 70% tax rate this places the company only a PE trading multiple of 26 times.

Summary

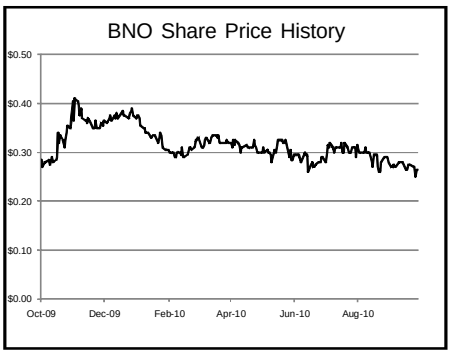
Financial year 2010 has been a year of consolidation for Sirtex Medical after a strong year's performance in 2009 (42% increase in dose sales over 2008). Performance in the US was not ideal in 2009 and this now appears to be back on track with new management, a price increase and extra staff.

The first quarter result for FY2011 indicates stronger growth is set to resume for the company. Key factors for growth are improved management in the US and a price increase (from US$14,000 to US$15,000), commencement of Singapore operations, and entry into a new market (France).

Bioshares recommendation: **Buy**

Bioshares

Stock Briefs



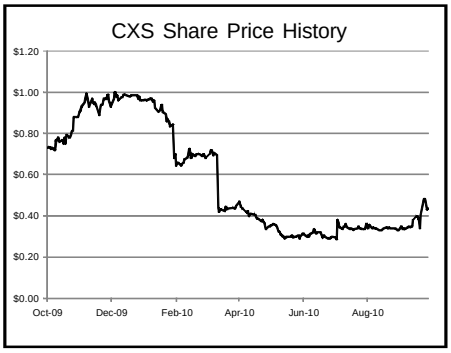
Bionomics – Gets OK for Two European Trials of BNC210

Bionomics(BNO: $0.265) has received authorisation from the French Medical Agency to conduct two Phase I trials of BNC210, a compound developed to treat anxiety and depression.

Trial **BNC210.003** will evaluate a single BNC210 administered in 24 healthy male volunteers, who will also be administered Lorazepam, a anxiolytic drug, or placebo. Attention performance will be assessed. Comparison against Lorazepam has been chosen because that drug can cause cognitive impairment in some patients over the long term. Trial **BNC210.004**, a randomised, double-blind study, will evaulate the compound in 22 healthy male patients who have been administered a peptide that induces panic-like symptoms. Data from both trials may be available in 2011 Q1.

Bionomics' stock has eased of late and is down 35% from its twelve month high in November 2009. The stock is attractive buying at current prices. Bionomics is capitalised at $84 million, with $12.6 million cash at June 30, 2010.

Bioshares recommendation: **Speculative Buy Class A**



ChemGenex Pharmaceuticals – Successful Pre-NDA Meeting

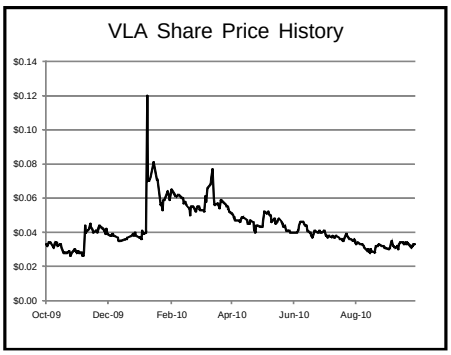
ChemGenex Pharmaceuticals (CXS: $0.435) has completed a pre-NDA meeting with the FDA. The meeting discussed the pathway for Omapro for the treatment of chronic myeloid leukemia in patients who have failed treatment with one or more tyrosine kinase inhibitors (e.g. imatinib, dasatinib) regardless of their tyrosine kinase mutation status.

The FDA agreed that ChemGenex did not need to conduct additional trials for this indication and that the company could submit combined data from two pivital studies, #202 and #203, supplying data from approximately 180 patients. The FDA did make the requirement that further data would need to be collected from sites involved in the trials.

The results of the meeting are positive for ChemGenex, clarifying the approval process for Omapro, following a setback earlier this year when the FDA asked ChemGenex to provide a validated diagnostic in support of its application for Omapro in the treatment of T315I mutation positive CML patients.

ChemGenex is capitalised at $123 million, with $12.8 million cash at June 30, 2010.

Bioshares recommendation: **Speculative Buy ClassA**



Viralytics - Moves to Next Stage of Dosing in Phase I Trial

Viralytics (VLA: $0.033) is developing a novel cancer therapy, CAVATAK, which deploys a naturally occuring strain of the *coxsackievirus* to break up and destroy tumour cells. The *cocksackievirus* is commonplace and is a cause of common cold-like infections. The company has completed a Phase I trial of CAVATAK in melanoma patients.

The company is conducting a Phase I study in patients with melanoma, breast and prostate cancer. The trial will now move to administer patients with a dose (10^9 $TCID_{50}$) that is ten times the previous dose. The first of the final cohort of four patients will be dosed shortly (total - 9 patients).

A second Phase I trial is underway in patients with head and neck cancers (9 patients), and a Phase II trial under an FDA IND is planned.

Viralytics is capitalised at $18 million, with $5.1 million cash at June 30, 2010.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares Model Portfolio (8 Oct 2010)

Company	Price (current)	Price added to portfolio	Date added
Phylogica	$0.048	$0.053	September 2010
Sunshine Heart	$0.027	$0.036	June 2010
Biota Holdings	$0.97	$1.09	May 2010
Tissue Therapies	$0.26	$0.21	January 2010
QRxPharma	$0.87	$0.25	December 2008
Hexima	$0.26	$0.60	October 2008
Atcor Medical	$0.12	$0.10	October 2008
Impedimed	$0.80	$0.70	August 2008
Mesoblast	$2.60	$1.25	August 2008
Circadian Technologies	$0.60	$1.03	February 2008
Patrys	$0.07	$0.50	December 2007
Bionomics	$0.27	$0.42	December 2007
Cogstate	$0.26	$0.13	November 2007
Sirtex Medical	$5.08	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.19	$0.66	September 2007
Starpharma Holdings	$0.55	$0.37	August 2007
Pharmaxis	$2.59	$3.15	August 2007
Universal Biosensors	$1.40	$1.23	June 2007
Acrux	$2.38	$0.83	November 2004
Alchemia	$0.52	$0.67	May 2004

Portfolio Changes – 8 October

IN:
No changes.

OUT:
No changes.

KarmelSonix Develops New Sales Model for the Wholter Device

KarmelSonix ($0.02) has developed a range of non-invasive devices that detect and monitor asthma-related wheezing. These include Wheezometers for clinical and personal use, the Wholter for ambulatory testing, and the Pulmotrack for use in hospitals. Nearly all these devices are CE marked and have received FDA approval, with the additional benefit that CPT codes are in place for devices in the US.

The company announced in early September a major board and management restructure, which would see the Israeli-based CEO, Prof. Noam Gavriely, make way for a new CEO and board members with appropriate industry experience to be appointed. A US-based venture capitalist, Ross Haghighat, was appointed to manage a review of the business and was also appointed as interim CEO.

The challenge for KarmelSonix has been to build sales of its products, which have been negligible to date (FY2010 - $348,493; FY2009 - $225,432).

What has emerged from the review by Haghighat is a plan to adopt a new sales model for the Wholter device, a device that can be used for testing in the home and away from sleep labs. The company would generate trailing revenues from each model sold or leased, collecting fees on each occasion the device is used through the provision of data analysis and interpretation.

KarmelSonix held cash of $2.3 million at June 30, 2010, after posting a loss of $5.9 million. Its net operational cash flow for the year ended June 30 was a negative $5 million, implying a Survival Index measure of 0.5, i.e holding six months cash at hand.

KarmelSonix could emerge as a stock of interest when it has strengthened its financial position. The company is capitalised at $14 million.

Bioshares recommendation: **Speculative Hold Class B**

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, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, BioMD, Tissue Therapies, Viralytics, Phosphagenics

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