ISSN 1443-850X

In this edition...
One long held view on capital sourcing has been a perceived requirement that to successfully raise funds from US investors, a company must set up a Nasdaq listing. With two Australian biotechs, Pharmaxis and Chemgenex now set to de-list from the Nasdaq, it appears that requirement is no longer the case, with US institutional investors now comfortable with direct investment in ASX listed biotechs. Diagnostic company Genera Biosystems is facing a crucial period as it completes four studies of its PapType HPV test and then seeks to have the product registered in Australia and Europe. Acrux and BioMD have passed significant clinical milestones, with the Axiron and Cardiocel products respectively, and Cogstate has flagged it will post a $1.4 million profit for the full year.
The Editors
Companies Covered: ACR, BOD, CGS, GBI

	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)	12.5%
Cumulative Gain	**119%**
Av Annual Gain (8 yrs)	**14.7%**

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 320 (17 July 2009)
ISSN 1443-850X

Bioshares

17 July 2009
Edition 320

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

Pharmaxis And ChemGenex De-list From Nasdaq

The largest, by capitalisation, of ASX development stage biotechs, **Pharmaxis** ($543 million), has announced that it will voluntarily de-list from the US Nasdaq exchange and terminate its registration with the US Securities and Exchange Commission. Pharmaxis is following in the footsteps of **Chemgenex Pharmaceuticals**, which announced its intention to voluntarily de-list on June 29, 2009. Since its founding as the US's first electronically traded stock exchange in 1971, the Nasdaq has carved out a role as an exchange catering to technology, retail, communications, financial services, transportation, media and biotech stocks. The Nasdaq is home to more companies than other any other exchange, trading the shares of approximately 3,800 companies. The Nasdaq Biotech Index is arguably the world's premier stock market index for assessing the biotech investment sentiment.

The de-listings will leave four Australian biotechs listed on the Nasdaq; **Genetic Technologies**, **Novogen**, **Prana Biotech** and **Progen Pharmaceuticals**. Both Progen and Novogen have been listed on the Nasdaq for ten years or more, with Progen listing in October 1997 and Novogen listing in July 1999. **Psvida** (ASX: PVA; Nasdaq: PSDV) was formerly an Australian entity, but re-domiciled to the USA. Only one other Australian entity, the energy company **Santos,** retains a Nasdaq listing in addition to its primary ASX listing.

On the London Stock Exchange's Alternative Investment Market, three Australian biotech and chemical technology companies, out of a total of 26 companies, remain listed – **Medic Vision, Norwood Immunology** and **Plantic Technologies**. However, only one of these, Medic Vision, also maintains an ASX listing. Other ASX primary listed biotechs that have held AIM listings in the past include **Arana Therapeutics**, **Phosphagenics** and **Clover Corporation**.

Cost has been cited as a factor in the decision by both companies to de-list, with Chemgenex stating that it would save an estimated US$350,000 per year in compliance costs. A further consideration was at play for Pharmaxis. After Pharmaxis' most recent capital raising, in which it raised $47 million through placements, the company came to the conclusion that its Nasdaq listing was not necessary to source US capital, discerning that sophisticated non-resident investors were comfortable in investing in ASX listed ordinary shares. 'Sophisticated' non-resident investors main concern would be appear to be a desire to invest in the market where most liquidity is to be found, which for Pharmaxis stock is on the ASX. In line with its soon-to-be rescinded

Australian Nasdaq-listed Companies*

Name	Code	Listing Date
Genetic Technologies	GENE	9/02/2005
Novogen Limited	NVGN	1/07/1999
Prana Biotechnology	PRAN	9/05/2002
Progen Pharmaceuticals	PGLA	10/07/1997
Santos	STOSY	3/12/1981

*following de-listings by Chemgenex and Pharmaxis

Cont'd on page 4

Genera Biosystems Approaching Crucial Phase

Genera Biosystems is approaching a crucial phase in the commercialisation of its genetic HPV test, to be used to aid in the detection of cervical cancer. In the remaining part of 2009, the company expects to complete four studies with its PapType HPV test, have the product registered for use in Australia and Europe, and if all goes well, secure a commercial partner for the test. In anticipation of positive news and the progress being made, the company's share price has more than doubled since February this year.

The PapType HPV test will compete with around eight other HPV tests on the market. The two key products on the market are **Digene**'s HC2 test, and **Third Wave Technologies**' Cervista HPV test. Both are approved for use in the US and Europe.

Advantages of the PapType Test

Multi-plexing

The Genera test uses a bead-based technology, called AmpaSand. This testing system is incorporated with existing pathology hardware and allows multiple genetic tests to be conducted simultaneously. The first genetic test is the PapType test for HPV, which tests for 14 different types of the human papillomavirus known to cause cervical cancer. This test is superior to the Cervista HPV test which only tests for the two main HPV genotypes, HPV 14 and 16.

Multiple geno-types

Another advantage of the Genera test is that it identifies the virus genotypes present. This is important as it is persistent HPV infection of a strain that causes disease. The Digene HC2 test measures for 13 different HPV genotypes but only delivers an overall positive or negative result without identifying specific genotype infection. The HC2 test does not include the HPV 66 genotype, which has now shown to also cause disease (cervical cancer).

Reduced sample volume

The Genera test requires less sample volume, 0.8ml, compared to 4ml for the Digene HC2 test and 2ml for the Cervista test. This is an important factor, as some samples in practice can not be processed due to insufficient sample volumes. A difference to the Digene test, which requires specific Digene hardware, is that the Genera test uses existing pathology hardware. The Digene HC2 test is also more labour intensive and time consuming than the Genera test.

Indeterminate result feature

Genera has also added an internal control to its diagnostic test, that will deliver an indeterminate result if there is no human DNA detected in the test (i.e. no DNA actual sample captured). The Digene test does not have this feature. In a 100 sample trial of abnormal Pap smear samples, this added feature found six indeterminate results that the HC2 test found negative. Of those six samples, four were found to correlate to precancerous cervical lesions. Under the Genera testing protocol, these six women would be retested after an indeterminate result.

Risks and Challenges

A challenge for Genera is that it must compete against products that have developed entrenched positions in the HPV testing market, and in the case of Digene (acquired by **Qiagen** for US$1.6 billion in 2007) having created the HPV testing market. Genera's success will depend on its ability to form key commercial partnerships. And the data from the forthcoming trial results over the next six months will be pivotal milestones for the company.

Trials underway

In October last year, Genera released results from a 100 sample study of abnormal Pap smear samples. The trial compared the Genera bead test to the Digene HC2 test. It found that the HC2 test returned as false negative (missed positive samples) of 27% versus only 7% for the Genera test. Both tests returned a 24% false positive result. That trial was conducted with 100 samples and has now been expanded to 900 samples from the **Royal Women's Hospital**, which is a WHO reference laboratory for HPV testing. This trial will start next week with results from the expanded study due to be released in late August or early September.

A second study is investigating the reproducibility of the Genera platform across different operators and laboratories. The trial is using an artificial sample of known infection and is being conducted by **Sonic Healthcare**. Results from this trial are expected to be released by October this year.

Two further trials expected to be completed this year, although not required for product registration, are a 3,000 sample trial in general screening for HPV. Samples are being supplied by the Royal Women's Hospital. A second trial will be conducted this year on 2,000 abnormal Pap smear samples that have been assessed using the Digene HC2 test in the US.

Registration and Commercialisation

Positive results from these trials will allow the company to gain regulatory certification to market the tests in Europe and Australia. The CE Mark certification in Europe will also position the company to form a commercial partnering deal with either a regional diagnostic/pathology group in Europe, or a global diagnostic deal. (The test is currently being used by **Gribbles** in Australia, which has conducted over 8,000 tests since 2006, but the test does not include the human DNA internal control capability. Gribbles which helped develop the test, gains access to the test at a reduced price.) Genera's new manufacturing facility in Scoresby, Victoria, is currently being audited by the TGA and we anticipate the company will be granted a license to manufacture the test at this facility in the next four weeks.

In May this year Genera raised a further $3 million, after is cash balance fell to $1.2 million at the end of March. The company expects that following that capital raising the company will be self-funded, with future funds to come from product sales and a partnership deal. The plan for the company is that a commercial partner will also help the company introduce the product into the US, where the regulatory pathway is more involved and more costly.

Commercial Application

The company is aiming to be best-in-class test in assessing abnormal Pap smear results, having incorporated new features into

Cont'd on page 4

Maiden Full Year Profit For Cogstate

Cogstate (CGS: 27.5 cents) provides cognitive testing services to pharmaceutical companies conducting clinical trials, which use its proprietary software program. The company released unaudited results for FY2009. The company will record a net profit of $1.38 million. This is a very good result for the company, although it falls slightly short of the profit guidance figure ($1.5-$1.75 million) due to the strengthening of the Australian dollar. Most of Cogstate's sales are transacted in US dollars.

Including cash to be received from debtors (all of which is expected to be received under its standard trading terms), the company now has a very healthy cash position, with over $5 million at June 30 and no external debt. The company has a market capitalisation of $18 million. The company is trading at a PE ratio of 13.

Sales for the last financial year were $8.3 million (up from $3.8 million), with sales contracts signed during FY2009 totalling $9.2 million. The company has not experienced any softening in its market as a result of the global financial crisis, with strong sales growth continuing. In the second quarter just passed, the company recorded its strongest quarterly sales to date, of $2.8 million.

Cogstate now employs 30 staff, with 10 in the US, 19 in Australia and one in Europe. The company is well managed, with a clear commercial strategy that has been well executed over the last four years. The company has delivered is maiden profit result and we anticipate growth in sales and net profit will be solid over the next three years. With a further $5 million in unrecouped tax losses, the company will be able to build its cash balance to $10 million before taxes on earnings are payable.

The next 12 months will see the company concentrate oo delivering on improved efficiencies in its business. We anticipate demand for the company's product/service will continue to grow as a result of improved branding and awareness. The move to increased computerised testing in pharmaceutical trials in the Alzheimer's and schizophrenia fields will also see a natural enlargement of the market for Cogstate and its competitors' services.
Cogstate is capitalised at $18 million

Bioshares recommendation: **Buy**

Bioshares

BioMD – Hits the 6 Month Mark

BioMD (BOD: 8 cents) has reached the six-month point in the trials of its Cardio-cel biomaterial patch used to treat pediatric patients with heart defects. The company reported that no patch related clinical adverse events, blood clots were observed, nor were dehisence (bursting open) events. The company also announced that it would conclude its South African based study at 30 patients (instead of 50), citing funding cutbacks to South African hospitals as a factor. However, the company is satisfied that the trial has delivered sufficient diversity of anatomical locations and surgical challenges to support its data package that would be submitted for EU and Australian approval in 5-6 months time.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Acrux – Phase III Completed

Acrux (ACR: $1.12) has announced the completion of the dosing phase of its Phase III trial of its Axiron product. Axiron is a formulation of testosterone that is administered by a proprietary transdermal delivery system. An extension study is continuing for another two months with four patients being evaluated for any possible skin safety issues over a six month period of continuous use.

Testosterone may be administered to males who are found to have lower than normal levels of this hormone. The symptoms from low testosterone levels include lethargy, reduced libido (sexual function), depression, and decrease in muscle mass and bone density.

The open label trial enrolled 155 patients, of whom 105 were treated for four months and 50 patients for six months. The trial is essentially a pharmacokinetic study in which the proportion of patients with testosterone in the normal range after treatment is calculated or assessed. Results of the trial are expected to be announced in September. Acrux intends to file Axiron with the FDA for regulatory approval in December 2009, with a marketing launch anticipated in 2011.

Opportunity

Testosterone replacement products, such as gels, have been on the market for some time, and annual sales of testosterone gels amount to US$750 million. However, the FDA has placed warnings on testosterone gel products, which include advice on how to limit the secondary transmission of testosterone, e.g. to children.

Axiron is a quick drying solution that is applied in small volumes to the armpit region of the body using an applicator similar to an underarm deodorant applicator, which very importantly limits transmission to third parties, such as partners and children. Therefore, it is possible that the Axiron product may be judged to be safer than current gel products and gain a commercial advantage.

Summary

Acrux has worked purposefully in developing Axiron to be a 'patient preferred' product. Although sales of Evamist in the US have been hampered by major compliance issues (not related to Evamist) with its marketing partner, **KV Pharmaceuticals**, the company has remained a very durable investment proposition courtesy of its drug delivery platform technology and evolved knowledge of drug delivery challenges at the point of patient use and application.

Acrux is capitalised at $179 million.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Genera cont'd

its HPV test that are not available with existing market products. This is a more straightforward market entry point for the company. The company will also seek to have the test used for broader screening, however larger trial results would be required to support clinical use as a screening tool. The 100 sample trial completed last year suggests the Genera trial is more accurate than the HC2 test in assessing abnormal Pap smear results, and the larger 900 sample trial will be a major event for the company. There will also be a commercial application, although smaller, in genotyping positive HPV results.

Summary

Genera Biosystems is capitalised at $32 million and holds an estimated $3 million in cash. The next six months will be a pivotal period for the company in commercialising the first of what may be several products from the company's multiplexing diagnostic platform for genetic tests. The global market for HPV testing is currently valued at around US$300 million and is expected to grow significantly beyond that.

If Genera can get it right, then its platform could become a very valuable asset for the company and shareholders. However to achieve that, the company needs to show its tests are reliable, reproducible, user friendly and accurate. This is information that should be forthcoming in the next sixth months.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Nasdaq De-listings cont'd

US reporting requirements Pharmaxis will continue to report on a quarterly basis, which is to be welcomed and is a practise that could be adopted more widely by ASX-listed companies.

Analysis

The decision to de-list by Pharmaxis and ChemGenex Pharmaceuticals sets a new mark of progress in the maturation of the Australian biotech sector. Australian companies now do not need to establish a US listing to attract North American-based institutional investors (although the need to attract international capital remains just as strong as ever). While this may have been the case in the past, dating back to the days when **Resmed** incorporated in the US and first listed on the Nasdaq (1995), then New York Stock Exchange (Sept 1999) and then the ASX (Nov 1999), the growth and maturation of a number of quality local biotech firms, in conjunction with the growth and development of local investment banking and 'sell side' research capabilities, has contributed to an improvement in capital markets access for local biotechs.

Bioshares

Bioshares Model Portfolio (17 July 2009)

Company	Price (current)	Price added to portfolio	Date added
ASDM	$0.28	$0.30	December 2008
QRxPharma	$0.46	$0.25	December 2008
Hexima	$0.45	$0.60	October 2008
Atcor Medical	$0.16	$0.10	October 2008
CathRx	$0.35	$0.70	October 2008
Impedimed	$0.60	$0.70	August 2008
Mesoblast	$0.83	$1.25	August 2008
Cellestis	$3.55	$2.27	April 2008
IDT	$1.60	$1.90	March 2008
Circadian Technologies	$0.70	$1.03	February 2008
Patrys	$0.13	$0.50	December 2007
Bionomics	$0.23	$0.42	December 2007
Cogstate	$0.28	$0.13	November 2007
Sirtex Medical	$4.08	$3.90	October 2007
Clinuvel Pharmaceuticals	$0.32	$0.66	September 2007
Starpharma Holdings	$0.32	$0.37	August 2007
Pharmaxis	$2.49	$3.15	August 2007
Universal Biosensors	$1.00	$1.23	June 2007
Biota Holdings	$1.55	$1.55	March 2007
Probiotec	$2.10	$1.12	February 2007
Peplin Inc	$0.59	$0.83	January 2007
Chemgenex Pharma.	$0.55	$0.38	June 2006
Cytopia	$0.07	$0.46	June 2005
Acrux	$1.12	$0.83	November 2004
Alchemia	$0.34	$0.67	May 2004

Portfolio Changes – 17 July 2009

IN:
No changes

OUT:
No changes

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, Pharmaxis, Cytopia, Arana Therapeutics, Starpharma Holdings, Cogstate, Bionomics, ChemGenex Pharmaceuticals, Circadian Technologies, Biota Holdings, Halcygen Pharmaceuticals, Peplin, BioMD, Impedimed, QRxPharma, Patrys, Labtech Systems, Hexima, Tyrian Diagnostics, Mesoblast, Atcor Medical, CathRx

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **$320**

For multiple email distributions within the same business cost centre, our pricing structure is as follows:	$550	2-3 email addresses
	$750	4-5 email addresses
	$950	6-10 email addresses

To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
Fax: +61 3 9671 3633

I enclose a cheque for **$** made payable to **Blake Industry & Market Analysis Pty Ltd**, or

Please charge my credit card **$** MasterCard ☐ Visa ☐

Card Number ☐☐☐☐ ☐☐☐☐ ☐☐☐☐ ☐☐☐☐

Signature _____ Expiry date _____

Subscriber details

Name _____

Organisation _____

Ph ( ) _____

Emails _____

_____

_____