

In this edition...

Somnomed continues to perform well, expecting to maintain 25% growth in sales in this current year. With a huge market potential and a leading global position in oral devices to treat snoring and mild-to-moderate sleep apnea, it is a quality stock well worth considering.

Cogstate is positioning its cognitive test as a global dementia screening tool ahead of disease modifying Alzheimer's disease drugs expected to reach the market in the next three to five years.

Avita Medical is tracking well. And with news that Tyrian Diagnostics is closing up shop, we have invited Michael Johnson from Cogentum to comment on market risk, an issue that still appears to be poorly addressed by parts of the sector.

The Editors

Companies Covered: AVH, CGS, SOM

Bioshares

2 September 2011
Edition 423

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

Somnomed Posts Healthy Growth in Unit Sales; Next Gen Product in the Wings

Somnomed (\$1.19) sells a range of sleep related products, including the Somnodent device, a dental appliance used to treat mild-to-moderate obstructive sleep apnea.

Somnomed reported a small net profit of \$0.739 million for FY2011, which was a decrease of 6% from the \$0.786 reported for the previous financial year.

Top line revenue growth of 15% delivered revenues of \$12.3 million, compared to \$10.7 million for FY2010. On a volume basis, sales of Somnomed devices increased 28% for FY2011, with 25,100 units sold in the period compared to 19,500 in the previous period.

The company's operating profit before corporate, research and development overheads stood at \$3 million for FY2011, a significant improvement from the \$1.9 million in the previous year.

Somnomed's gross margins improved from 57% in FY2010 to 66% in FY2011. Improvements to margins were a consequence of production occurring in larger volumes and efficiencies gained from basing some manufacturing in the Philippines.

The US accounted for 63% of unit sales, followed by Europe with 25% and the Asia Pacific region with the balance of 12%. Somnomed sells in twenty countries, preferring to focus on more profitable territories.

Development of Diagnostic and Placement Tool

Somnomed has developed a mandibular positioning device, termed the MATRx, which it anticipates selling from October this year, once it has received FDA approval. This device allows sleep technicians to vary the settings to determine optimal performance. CEO Ralf Barschow describes this technology as a "breakthrough" because it can show if patients are responding to the device.

Although Somnomed reports that 15 clinical studies on use of the Somnodent have been completed, it recognises that sleep physicians will be more comfortable with the product if they can objectively determine which patients are likely to benefit from its device.

Next Generation Device – Somnomed G2

Somnomed has developed a new Somnodent model, labelled the G2. This device is lighter than the first generation model and contains no metal parts, which is a positive selling point in Scandinavian countries. The company expects this model to be semi-fabricated ahead of customisation, and this is a step that will enable the company to shift to even larger production volumes.

The company's product development strategy is to introduce new products which expands the product line-up with devices that offer improvements. Earlier generation product will continue to be sold. This strategy means that new products can be sold for higher

| | 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 - May '11) | 45.4% |
| Year 11 now commenced | -18.2% |
| Cumulative Gain | 244% |
| Av Annual Gain (10 yrs) | 21.2% |

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 9348 9317
Email: pachacz@bioshares.com.au

Individual Subscriptions (48 issues/year)
\$375 (Inc.GST)
Edition Number 423 (2 September 2011)
ISSN 1443-850X

Copyright 2011 Blake Industry and Market Analysis Pty Ltd. ALL RIGHTS RESERVED.
Secondary electronic transmission, photocopying, reproduction or quotation is strictly prohibited without written consent of the publisher.

– *Somnomed cont'd*

prices and presumably deliver even healthier margins.

Drivers for a Dental OSA Appliance

According to Somnomed there are 100 million OSA patients worldwide, however only 20 million receive any form of treatment. An issue with continuous air pressure (CPAP) devices such as those sold by Resmed and Philips Respironics is that an estimated 60%-80% of CPAP users stop using the device, either completely or partially.

This is where potentially a very large opportunity lies for Somnomed, which is an alternative that is now increasingly available to OSA patients and their physicians in major markets around the world.

Somnomed's US growth prospects received a major boost in the US in January when Medicare ruled that oral devices such as Somnomed's Somnodent were eligible for reimbursement if a patient was unsuitable for CPAP treatment, and were classified in the mild-to-moderate category. The coverage only applies to customised appliances as opposed to off-the-shelf products.

Summary

Somnomed, in common with other globally positioned companies which report in Aussie dollars, has seen a bottom line weakening courtesy of a higher Australian dollar exchange rate with the US dollar. The company expects sales to grow at 25% for the next financial year. While this is healthy, it shows a slowing on a previous very high rate of compound growth in revenue of ~50%. With more than 70,000 Somnodent products sold to date, one new source of revenue that can be expected to emerge in the next few years is the replacement market, with current users replacing their device after three to five years of use.

Somnomed is positioning itself as the leading oral appliance company developing products for OSA, where the company has command of a global manufacturing and sales infrastructure and products that integrate sleep medicine practise and dental practise.

Somnomed is capitalised at \$48 million.

Bioshares recommendation: **Buy**

Bioshares

Avita Medical – Recent Funding Used to Build Sales Force in Europe

Avita Medical (AVH: \$0.11) markets ReCell, a skin regeneration kit that is used to grow skin cells (harvested from a donor site on the patient) to treat wounds, burns and also has application in the areas of cosmetic and aesthetic surgery. The product is approved in Europe, Australia and China, but not the USA.

Avita Medical reported revenues of \$4.5 million for the year ending June 30, 2011, an increase of 17% from the previous year. Adjusted loss after tax improved from \$5.9 million in FY2010 to \$1.9 million in FY2011, brought about from an adjustment for the fair value of a convertible note which it retired.

Sales for FY2011 were \$3.1 million, an increase of 16% from the previous period. Cost of sales increased by roughly the same rate. The majority of ReCell sales were in the Asia Pacific region (\$2.5 million), with Europe accounting for \$0.5 million.

Administrative costs increased by 27% for the year (\$5 million) and sales and marketing expenses rose by 48% (\$2 million).

In the June quarter the company raised \$9 million from a placement and \$2.8 million placement which was heavily over-subscribed.

Increases European Sales Force

The increase to Avita's cost base is due in part to setting up a direct sales force in the UK, France and Germany. Current numbers of four sales staff are in the process of being doubled, now that the company has received a capital injection.

Another application of the company's recently obtained funding has been the employment Dr Michael Mendicino as head of the R&D program. Mendicino was formerly the Lead Scientist at Athersys, a company developing stem cell products to treat a wide range of diseases and medical conditions.

Clinical Trials

Burns Study

Recruitment for the company's US Defense Department funded burns trial is running behind schedule. This trial is looking to recruit 106 patients. The company had anticipated fully recruiting the trial by December, but has now set a revised date of March.

Scarring Study (Cosmetic Application)

The company's 20 patient feasibility study in subjects requiring treatment for scarring has received FDA clearance which means that patient enrolment may commence.

ReCell will be used to remodel pre-existing scars. Half of each scar will be treated with ReCell produced skin cells and the other half will be treated with dermabrasion and pressure bandages.

If successful, the trial is expected to be followed by a 70-90 patient pivotal trial.

The primary endpoint is healing at 6 weeks. The secondary endpoint is aesthetic outcome at 12 and 24 weeks and safety at 24 weeks. The trial is expected to be completed by mid-2012.

Summary

Avita Medical is hoping to gain approval for ReCell in the US to treat burns and scarring by 2013. With cash at hand to grow sales in Europe, and with the burns trial backed by US Army funding, the company looks set to achieve this goal. Avita is capitalised at \$26 million and retained cash of \$12.6 million at June 30, 2011.

Bioshares recommendation: **Speculative Buy Class B**

Bioshares

Cogstate Acquires Remaining Interest in JV

Cogstate (CGS: 20 cents) recently announced that it had acquired the remaining 50% of its Axon Sports joint venture. This is a positive step for the company that has positioned itself extremely well although its progress remains completely obscure to the market.

Cogstate has developed a cognitive testing platform which is being commercialised into three markets. The first is in clinical trials, the second is in cognition testing in contact sports, and the third is in broader population dementia screening.

The first reason to acquire the remaining 50% of Axon Sports, according to CEO Brad O'Connor, was because of the good upside in this business. The second reason is that both the sports market and the dementia screening markets could potentially start to crossover and the company wants the ability to deliver one suite of products that can cover both applications; healthcare practitioners can potentially use the same CogState technology (although different tests) for athletes as well as a screening tool for aging patients that may have early signs of dementia or memory loss.

But there are other benefits as well. Bringing the JV in house will make it a less complicated business to operate as it progresses. Decisions about whether funding of the sports cognition product should be increased or not will be more straightforward. And the addition of Rudy Chapa, part owner of the other side of the JV, to the board will be a very beneficial asset for the company. Chapa was formerly global head of marketing for Nike. His experience in deal making will be very valuable in structuring deals, not just in the sports cognition market, but also in dementia screening arrangements with major pharmaceutical companies.

The acquisition also clears up geographic rights to the technology - previously the JV had North American rights (USA, Canada, Mexico) as well as an option over other regions such as Australia and Europe. In terms of the operation of Axon Sports, not much will change from a day-to-day basis according to O'Connor. On the plus side for investors, they will now be able to monitor sales performance of the sports cognition testing market.

Chapa's company, Quixote Investment, sold its 50% stake in the JV for 7.5 million Cogstate shares (10%), valuing the stake at \$1.27 million. Quixote Investment also acquired an additional 5.5 million shares (7.3%) from founding CogState shareholder, GBS Venture Partners to give Quixote a 17.37% stake in Cogstate. Both transactions were conducted at 17 cents a share.

Cogstate now has very good Board, with Chapa, Richard van den Broek (formerly a US healthcare analyst - featured in edition #1 of Bioshares - and now an US institutional investor in Cogstate and also a director of Pharmaxis), David Simpson, and Martyn Myer as Chairman. In June Richard Morgan and Michael Wooldridge resigned from the board.

Underlying Business Products Best Six month Result on Record.

Over the last two years Cogstate has experienced difficult trading conditions as a result of the strengthening Australian dollar. Two

years ago the Australian dollar was worth US\$0.83. That has caused Cogstate to remove costs out of its business. In the last financial year the company generated revenue of \$8.2 million with a net operating loss of \$0.1 million. It's net loss after tax was \$0.8 million taking into account foreign exchange losses as well as its investment in Axon Sports.

Of interest also is that the company's test is now being used in clinical trials for depression, with the company signing a Phase II study in May for US\$1.55 million (with 800 patients in 100 sites) and a Phase III study last month for US\$1.1 million (with 600 patients in over 70 sites). The company's test has not traditionally been used in depression and this represents a significant market. Around 600 clinical studies are started each year in depression with about 10% of those testing for cognition according to the company.

Its first six months of this calendar year has been the strongest on record with clinical trial sales contracts worth \$5.5 million signed. It currently has \$5.2 million of revenue secured for FY2012 from existing contracts with another 10 months remaining for the current financial year. This positions the company for a strong result in the current financial year.

Cogstate is capitalised at \$15 million with \$3.3 million in cash at the end of June.

Cogstate – Positioning Its Test for Dementia Screening

"Cogstate is beginning to publish data showing strong correlation between impairment on the CogState technology and the presence of beta amyloid plaques in the brain as detected by the new biomarkers such as GE's PET imaging agent Flutemetamol", says O'Connor. According to O'Connor, data accessed through the Australian Imaging Biomarker Lifestyle Flagship Study of Aging (AIBL) that is being conducted in conjunction with the CSIRO, Alzheimer's Australia, Melbourne University and Neurosciences Australia amongst others, is proving the use of the Cogstate test a low cost, non-invasive screening tool in the area of dementia (see box on next page).

Over the last few years there appears to have been a distinct change in thought, that now there is a need to detect cognitive decline earlier on. The lack of a disease modifying drug for Alzheimer's disease has hampered development of a cognitive screening tool. However, with an increasing belief that disease modifying drugs will reach the market in the next three to five years, that is changing.

There is a lot of attention on J&J's bapineuzumab in 12 Phase III studies, which is being jointly developed by Pfizer and Johnson & Johnson. First data from these studies is expected towards the end of 2012. This could become a massive blockbuster drug generating revenue in excess of \$10 billion a year. Given that the disease costs the US around US\$100 billion a year, it is not an unreasonable estimate. Cogstate's Chief Scientific Officer, Paul Maruff, believes this area is the last frontier of blockbuster drug development for the pharmaceutical industry.

Cont'd over

Australian Imaging Biomarker Lifestyle Flagship Study of Aging (AIBL)

In 2007, a long-term study was started in Melbourne and Perth on understanding the causes and diagnosis of Alzheimer's disease and ways in which disease progression can be prevented. It is an ongoing study which has recruited 1112 volunteers. All people in the study are over the age of 60, with some healthy, others with mild cognitive impairment, or showing early memory issues or genetic susceptibility to Alzheimer's disease.

Cogstate has been one of the supporting companies of this study from the start, contributing to the design and conduct of the study. It also supplies the use of its test at no charge. Cogstate CEO Brad O'Connor says "this is a superb long term study, one of the best in the field", the progress of which is followed around the world. Cogstate's involvement has important long term, strategic value, ensuring its technology is linked in with one of the world's leading longitudinal Alzheimer's disease studies. The study assesses volunteers every 18 months and will continue as long as there is funding for it.

In June this year Cogstate scientists and others, including Colin Masters, from Mental Health Research Institute, had its results presented in a poster at the International Conference on Alzheimer's Disease in July on a subset of the volunteers in the AIBL study. It looked at cognitive decline in volunteers with normal against those with higher levels of amyloid levels in the brain. Using the PIB imaging test (Pittsburgh compound B), which is a fluorescent marker that binds to beta-amyloid plaques and is imaged using a PET scan, the study yielded some very useful results. It showed a clear cognitive decline over only six months in volunteers with high initial cerebral amyloid levels versus no significant difference in volunteers with normal cerebral amyloid levels.

One of the important aspects of this study is that potentially cognitive decline could be measured in just over six months, rather than the 18 month studies more common in Alzheimer's disease, potentially making drug development for Alzheimer's disease cheaper, and quicker. The result also shows a clear link between amyloid deposits and cognition (as expected). And it potentially sets a path for the Cogstate test to be used as a broad based screening test.

Recent Developments in Diagnostic Tools for Alzheimer's disease

Lilly acquires Avid Radiopharmaceuticals for US\$300M plus

In December last year Eli Lilly acquired Avid Radiopharmaceuticals for US\$300 million with up to a further US\$500 million in potential milestone payments. Avid's lead program is a molecular imaging agent for detecting amyloid plaque in the brain, called Amyvid. It is used in conjunction with a PET scan. The compound was filed for approval with the FDA last year but approval was not granted until the companies to develop better training and reading protocols for users.

GE Healthcare positive results on Phase III imaging compound

In July this year at ICAD, GE Healthcare reported positive results from its imaging compound, Flutemetamol, which is currently in Phase III development. GE Healthcare licensed the rights to the first imaging agent developed for Alzheimer's disease, PIB. However PIB has limitations, in that it needs to be made in a cyclotron and has a half-life of only 20 minutes. Flutemetamol has a half-life of 110 minutes.

GE Healthcare and J&J team up for new diagnostic

Last year GE Healthcare and Johnson & Johnson teamed up to develop novel biomarkers for the early detection of Alzheimer's disease, which GE says might also speed up the development of a successful Alzheimer's disease drug.

Astrazeneca working on radioligand for amyloid plaque imaging

Astrazeneca has started a Phase I trial with its radioligand in August this year. That compound is called 18F AZD4694 and also binds to amyloid plaques.

Alzheimer's Disease Neuroimaging Initiative (ADNI)

In 2004, with funding from the NIH, the Alzheimer's Disease Neuroimaging Initiative was formed. One of the goals was to find better tools for conducting more effective clinical studies in Alzheimer's disease and discovering new biomarkers that can better predict clinical outcomes. That study involved 821 volunteers with no signs of cognitive impairment, mild cognitive impairment, and patients diagnosed with Alzheimer's disease. Partners in this study included Astrazeneca, Elan Pharmaceuticals, GE Healthcare, J&J, Eli Lilly and Pfizer.

Pharmaceutical companies are investing in the development of cognitive biomarkers and amyloid imaging tests for the brain, working on improvements to the PIB test that could be used to confirm early onset of disease. Although these improved tools will aid and shorten the drug development process, the pharmaceutical industry also appears to be setting the scene so that accurate imaging tests are available to confirm disease. That then leaves the next major goal to be that of developing an accurate population screening test.

Cogstate through its involvement with the AIBL study and its involvement in clinical trials in Alzheimer's disease trials, is very well placed to make its product one of the leading screening tests

for Alzheimer's disease. There are over 300 scientific publications supporting its use as a cognitive function diagnostic tool.

Bioshares recommendation: Speculative Buy Class A

Bioshares

The news from Tyrian Diagnostics that it will close down most of its business and lay off all of its staff is another classic example of not understanding a potential product's market and what it will take to be successful. The 'build it and they will come' philosophy certainly does not apply in biotech. In fact it's the second example from the one company of not understanding the market for a product, following on from the disaster of what was Proteome Systems.

We invited Michael Johnson, co-founder of Cogentum, to contribute an article on market risk. Cogentum is a local firm that specialises in strategic market analysis and advice in the biotech sector. This external auditing/accountability of programs using firms such as Cogentum remains under-utilised in the Australian biotech sector and is a major factor why some Australian biotechs continue to make major and basic mistakes in the commercialisation of its assets.

Contributed Discussion

Market Risk – The Cancer That's killing our Biotechs

Biotech firms are continuing to put shareholder funds at risk through a systemic failure to identify, address and mitigate market risk. It's not only causing the demise of credible and established biotechs but the loss of talented people and great technology. It doesn't have to be this way.

Failure to appreciate market risk – the likelihood that a new product, service or technology will fail to gain the required customer adoption and market share – is common place within the sector. Not only should mitigating market risk be seen as critical to new product development, it should also be seen as a core competency of biotech management.

Market risk exists in every new product development process, whether you are developing a new drug or a new breakfast cereal. In more mature sectors, a company will apply a rigorous approach to identifying market risk and respond with strategies that will strengthen the product's potential for success. In contrast, in the biotech sector, not only is market risk ignored, but many believe that they don't need to concern themselves with how their technology will be positioned and marketed.

It is quite common to hear management inform investors that their pharma licensing partner will bring this expertise to the table. As a result they trustingly hand over all control for marketing decisions, including branding, key value propositions, go-to-market strategy, and sales decisions. We firmly believe this to be a fatal mistake. Not only does it weaken a biotech's position at a licensing negotiation, it can contribute to the failure of the technology in the marketplace. It's cold comfort to shareholders, after the fact, that a marketing partner didn't position the product well or miscalculated the strength of the competition.

Ultimately if the proposition for investment in a biotech is the promise of an attractive licensing deal involving big up front payments and strong royalties, then the value proposition for a new technology must come from those who develop it. Biotechs must know how a technology adds value and whose problem it solves. In essence, a biotech company must understand how the technology will be monetised. And you can only do that if you know your markets and customers inside out.

Identify and Mitigate Market Risk Early

Biotechs should seek to evaluate market risk early, preferably prior to investment in developing the product or technology. Failure to gain an understanding of the nuances of the market, the customers' needs and a competitor's ability to satisfy them early in the development process is a recipe for disaster. In a 2010 survey of

investors in the biotech sector we clearly heard that "Many start up biotech businesses just focus on developing their science or product and assume the market will take care of itself. These companies usually just end up as a bottomless sink for money."

Far too often biotechs invest heavily in technologies for which no commercial needs exists or where a competitors' foothold is just too strong to shake. Alternatively, the company simply misses the mark in developing the right features and benefits, from dosing, to delivery, to patient experience and pricing.

In 2010, ASX listed **Avexa** summarised the reasons for the closure of their ATC programme as a result of dosage incompatibility with "certain existing approved HIV drugs, making it difficult to be combined into one pill with some other HIV drugs; and an inability to determine the level of activity of ATC when used in combination with a number of new active drugs on the market". The company went on to say "in the view of our potential global pharmaceutical partners, the value of ATC diminished." For Avexa, market risks were identified far too late and only after significant investment of shareholder funds. A devastating outcome for both the company and shareholders.

Likewise, **CathRX** discovered far too late the dangers of competing head to head with large medical device companies, "Towards the end of the December Quarter 2009, with manufacturing scale up underway, it became apparent to CathRx that sales growth was permanently falling behind published projections". As a result, in 2010 they changed tack and moved away from disposable catheters to enter the reprocessing market.

Investors and potential licensees are becoming increasingly intolerant of companies who don't have a strong understanding of their markets. One investor explained it this way. "It's very important to an investor that the company knows its market, customers and competitors, because without this information, the company is without a game plan of where it proposes to go and how it's going to get there. I see too many presentations with a huge defined market for the product, but no details on how the company will get a specific percentage of that."

Market Orientation – A Way Forward

The often used defence to a lack of market knowledge is that it is impossible to predict changes in emerging markets. This is both naïve and reflective of management lacking in market orientation. Many other sectors successfully deal with dynamic market conditions and have learnt how to make critical decisions regarding the

Cont'd over

competitiveness of their innovation. Importantly, they do so well in advance of major investment.

Once committed to a project, management reviews its assumptions and plans throughout the development process to ensure critical changes are caught early. Market orientation provides them with the opportunity to refine their strategy if needed or worst case, kill the project as cheaply and quickly as possible and before significant erosion of shareholder funds.

There are always new products entering and exiting, regulatory challenges emerging, and constant tension between payers, users and prescribers. Ensuring that your technology is developed with a clear proposition in mind that responds to this dynamic is essential, as is ensuring that the proposition straddles both technical performance and marketing value. This is what distinguishes the great licensing outcomes and royalty stream deals, such as **Acrux**, from those that fail to attract attention.

History shows that technical superiority does not always translate to market share. **Tyrian Diagnostics** commented in their recent ASX release, that despite their Alpha Amylase wheat quality test providing outcomes with a "high level of precision and accuracy in evaluation trials ... it became evident that extensive marketing effort would be needed to unseat the entrenched gold standard test". What this clearly illustrates to the sector is that in many markets technological superiority alone does not guarantee sales or market share.

Hubris could lead other biotech management teams to assume that this is an isolated incident. It is not. Nektar licensed their inhaled insulin product to **Pfizer** in what became one of the more high profile examples of the dangers inherent in market risk. The result, the Exubera inhaled insulin product, was a US\$2.8 billion write off.

Nor is this a recent phenomenon. In 2002 **Optiscan Imaging** licensed their endoscopy technology to **Pentax** (Hoya) and announced that "Optiscan will contribute its patents, engineering know how and applications knowledge. Pentax will ... provide the marketing and distribution channels for the product."

When the company announced the cessation of the agreement to the market, the annual report commented that "sales had slowed to a trickle in 2008" and that "a series of discussions and meetings failed to produce any prospect of improvement and it became apparent that we were moving toward an end game". We note that according to the Company they have invested some \$100m in R&D between 1988 and 2011.

A Risk Not Worth Taking

Put simply, no biotech should put investor funds at risk from market failure. Technology risk – that the technology may not work and fail in the clinic – is inherent to investing in the sector and we believe the market to be accepting of this. However, the investment of tens of millions of dollars in a technology that fails to sell is not only unacceptable, it is also avoidable.

Market risk can be identified and mitigated and strategies can be

put in place to optimise the investment in a technology. By showing potential licensing partners that the product has a clear and validated proposition, a biotech delivers a product that can be successfully marketed. Importantly, it also delivers a product that is less likely to sit in the bottom of the sales reps satchel and can be supported and sold as a solution to clearly defined needs and problems.

The evidence clearly indicates that better management of market risk delivers better returns. Companies that have invested in developing strong technologies and mitigating market risk alongside the development of cogent branding and marketing propositions deliver superior outcomes for shareholders.

Mitigating market risk is the responsibility of the biotech company itself. To rely on the 'best endeavours' of others is to wash your hands of any responsibility for the long term return of shareholder funds. As our sector matures this is surely no longer acceptable.

Michael Johnson is a director of Cogentum, an Australian based market strategy advisory firm that works extensively in the biotech sector assisting clients to mitigate market risk and develop cogent strategies for growth. Email: michael.johnson@cogentum.com.au

Bioshares

Bioshares Model Portfolio (2 September 2011)

| Company | Price (current) | Price added to portfolio | Date added |
|--------------------------|-----------------|--------------------------|----------------|
| Genetic Technologies | \$0.21 | \$0.18 | August 2011 |
| Acrux | \$3.78 | \$3.37 | June 2011 |
| Psivida | \$4.21 | \$3.95 | May 2011 |
| Bioniche | \$0.74 | \$1.35 | March 2011 |
| Somnomed | \$1.19 | \$0.94 | January 2011 |
| Phylogica | \$0.064 | \$0.053 | September 2010 |
| Sunshine Heart | \$0.043 | \$0.036 | June 2010 |
| Biota Holdings | \$0.95 | \$1.09 | May 2010 |
| Tissue Therapies | \$0.45 | \$0.21 | January 2010 |
| Atcor Medical | \$0.08 | \$0.10 | October 2008 |
| Impedimed | \$0.60 | \$0.70 | August 2008 |
| Bionomics | \$0.51 | \$0.42 | December 2007 |
| Cogstate | \$0.20 | \$0.13 | November 2007 |
| Sirtex Medical | \$5.06 | \$3.90 | October 2007 |
| Clinuvel Pharmaceuticals | \$1.65 | \$6.60 | September 2007 |
| Pharmaxis | \$0.92 | \$3.15 | August 2007 |
| Universal Biosensors | \$0.90 | \$1.23 | June 2007 |
| Alchemia | \$0.35 | \$0.67 | May 2004 |

Portfolio Changes – 2 September 2011**IN:**

No changes

OUT:

No changes

UBI – Minor Amendment to Lifescan License

Universal Biosensors has amended its license and development agreement with Lifescan. The amendment largely caters for subtleties around IP licensing, clarifying and improving the company's position with respect to discussions with other third parties around licensing opportunities outside of the diabetes space for the diagnostic platform.

There are no changes to the manufacturing rights and obligations of the glucose strips and no changes to the service fee that UBI receives from each glucose test strip sold by Lifescan that incorporates the UBI technology.

Bioshares recommendation: **Speculative Buy Class A**

Bioshares

Corrections and Clarifications:

In Bioshares 422 in the article “The US Invasion” it was stated that QRxPharma was an example of a company that used a ‘top hat’ arrangement in listing in Australia. This was incorrect.

QRxPharma was incorporated as an Australian private company in 2002. In 2007, QRxPharma’s US subsidiary QRxPharma, Inc merged with CNS Co, Inc, with QRxPharma, Inc continuing as the surviving entity.

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. For both groups, the rating “Take Profits” means that investors may re-weight their holding by selling between 25%-75% of a stock.

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, Circadian Technologies, Biota Holdings, Mayne Pharma Group, Impedimed, QRxPharma, Patrys, LBT Innovations, Hexima, Mesoblast, Atcor Medical, Tissue Therapies, Viralytics, Phosphagenics, Immuron, Phylogica, Bluechiip, pSivida, Antisense Therapeutics, Benitec, Allied Healthcare Group

Disclaimer:

Information contained in this newsletter is not a complete analysis of every material fact respecting any company, industry or security. The opinions and estimates herein expressed represent the current judgement of the publisher and are subject to change. Blake Industry and Market Analysis Pty Ltd (BIMA) and any of their associates, officers or staff may have interests in securities referred to herein (Corporations Law s.849). Details contained herein have been prepared for general circulation and do not have regard to any person's or company's investment objectives, financial situation and particular needs. Accordingly, no recipients should rely on any recommendation (whether express or implied) contained in this document without consulting their investment adviser (Corporations Law s.851). The persons involved in or responsible for the preparation and publication of this report believe the information herein is accurate but no warranty of accuracy is given and persons seeking to rely on information provided herein should make their own independent enquiries. Details contained herein have been issued on the basis they are only for the particular person or company to whom they have been provided by Blake Industry and Market Analysis Pty Ltd. The Directors and/or associates declare interests in the following ASX Healthcare and Biotechnology sector securities: ACL, ACR, ADO, BNO, BTA, CGS, COH, CSL, CUV, MYX, HCG, IDT, IMU, PAB, PBP, PXS, PYC, SHC, SOM, SPL, TIS, UBI. These interests can change at any time and are not additional recommendations. Holdings in stocks valued at less than \$100 are not disclosed.

Subscription Rates (inc. GST)

48 issues per year (electronic distribution): **\$375**

For multiple email distributions within \$590 2-3 email addresses
 the same business cost centre, our \$800 4-5 email addresses
 pricing structure is as follows: \$1020 6-10 email addresses

To subscribe, post/fax this subscription form to:

Bioshares
PO Box 193 Richmond VIC 3121
Fax: +61 3 9329 3350

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 _____
