





AusBiotech

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The Australian biotechnology industry has had a challenging six months, with funding drying up, an ambivalent policy environment and several high profile stumbles. But where the science is strong and management is smart, Aussie biotechs continue to blossom. AusBiotech 2010, held in Melbourne, will bring the industry together and look at future opportunities.

GLASS HALF EMPTY

After a promising start to the year, economic instability and political uncertainties, along with stumbles by key companies, have put a dent in confidence amongst biotechs, but it's not all bad news.

By Tim Dean

THE GLASS, YOU MIGHT SAY, appears half empty. This is a subtle change from six months ago, when the glass appeared half full. In the March/April 2010 edition of *Australian Life Scientist*, released shortly before the international BIO conference, the general sentiment was one of optimism and an expectation that we were through the worst of the global financial crisis (GFC).

This sentiment was echoed at BIO, the largest international gathering of biotechnology companies in the world. "It was interesting comparing BIO this year to BIO last year," says Ian Nisbet, Partner at life science consultancy, Afandin. "This year the mood was reasonably optimistic, whereas last year it was still very pessimistic. There were expectations that the US economy would pull out of recession, and that things were on the upswing."

Yet in the months since BIO, that light at the end of the tunnel has, if anything, dimmed slightly. The post-GFC recovery, particularly in the US and Europe, has proven to be more bumpy than hoped, with lingering sovereign and private debt concerns, continued high unemployment, and governments running out of tricks to stimulate their economies – even the euphemistically-named 'quantitative easing' (i.e. printing

money), normally a gambit of last resort, is becoming disconcertingly popular with many governments. These international economic perturbations, along with some more parochial factors, have put a dent in confidence in the Australian biotechnology sector.

"Bleak is too strong a word. But things have certainly been patchy," says Anna Lavelle, CEO of AusBiotech, which is hosting its annual conference in Melbourne in October. One of the main issues facing biotechs has been attracting fresh funds, particularly from a dwindling pool of venture capital. "According to Ernst & Young, there's 50 per cent as much venture capital available around the world as there was in 2007. That's got to hurt."

Adding to this has been some high profile setbacks that have put a damper on sentiment amongst biotechs and investors, says Nisbet. "Particularly amongst Australian biotechs, the mood is more pessimistic than optimistic at the moment. There were a lot of big expectations early in the year, and unfortunately they have not been met, or have been met in a negative sense rather than a positive sense. In the general climate of the market going sideways, this negative news has hit biotech hard."

BUMPS IN THE ROAD

That said, all sectors have been hit hard and, relatively speaking, the life sciences sector has fared better than the broader market. The second quarter this year saw the ASX as a whole shed 11.6 per cent, and it has remained wobbly, hovering around the 4500 mark ever since. Biotechs followed the market down, although to a softer landing, says PricewaterhouseCoopers' Life Science Partner, Craig Lawn.

"The Life Science Index dropped 9.4 per cent," says Lawn, with a sigh. "But there's a positive in that – a strange positive – which is that the Life Science Index outperformed the ASX. It's down, but not down as much. So it's a half-negative."

According to the PricewaterhouseCoopers Life Science Index, the 9.4 per cent decline largely reflects the 11 per cent fall of that 800lb gorilla of the Australian life sciences, CSL. This dragged down the PwC Biotech Index, which dropped 22.7 per cent. However, interestingly enough, this was almost offset by a perky rise in the medical device index of 21.5 per cent, primarily driven by Heartware International's 78 per cent gain over the quarter.

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David Blake

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Australian biotechs did hold up well compared to the US market, with the NASDAQ shedding 12 per cent in the quarter, and the US biotech index declining nearly 15 per cent. So, while things weren't rosy, Australian biotechs have been weathering the rumbly economic climate better than most.

But it's not just the broader economic conditions that have impacted biotechs, says David Blake, who produces the weekly Bioshares stock report. There were high expectations held of several biotechs that were on the cusp of significant deals or approvals – some of which failed to manifest.

While Acrux's licensing deal with Eli Lilly was positive news, there were several stumbles that put a dent in confidence. One is the continuing saga of ChemGenex versus the FDA over its chronic myeloid leukaemia treatment, Omapro. Another was Pharmaxis' unspectacular results from a phase III clinical trial of its flagship cystic fibrosis drug, Bronchitol, in May. Then there's Avexa, which abandoned its anti-HIV programme, also in May, much to the chagrin of its shareholders. All of these setbacks have introduced greater "doubt and uncertainty" in the market, says Blake.

That's not to say the occasional setback should be a surprise in an industry with regulatory bodies that can make or break a product in the drop of a hat. "You've got to expect the occasional stumble," says Blake. "Everybody's up against the same thing, even the likes of CSL, Pfizer and Eli Lilly."

According to Blake, the big issue is the inherent lack of predictability and certainty that comes part and parcel with the life sciences industry, but that's just how the industry is. As such, it's more about how a company manages a stumble rather than expecting it to have the divine foresight to avoid it altogether.

SHOW US THE MONEY

The major legacy of the GFC has been the dearth of funds floating around in the market that are available for biotechs. And not only do VCs have less money to throw around, but the stark lack of IPOs this year – and the relatively bleak outlook for IPOs in the near future – makes their exit strategy less clear. The combination of greater risk aversion and the prospect of a delayed return means VCs are shying away from biotech firms. In fact, says Nisbet, some even wonder whether the traditional VC model of the past can work in the current and future climate.

Lavelle agrees that the current climate doesn't make biotechs look like an attractive prospect to many investors, particularly ones looking for a quick win. "What's up against biotech companies are the facts, and the facts are that they're probably going to be operating at a loss for a decade. And that's not attractive to certain investors who are looking for quick returns."

However, that's not to say that there isn't money to be found, only that it's harder to find, says Lawn. "Wallets in the US will be tighter, but there are still some

big deals being done," he says. "Even though there's been a drop in the market, it's trending in the right direction."

Funding has been a big focus for AusBiotech, particularly since the GFC, says Lavelle. "We've been focusing for the last two years on money, which has been a serious problem for the Australian sector. We're doing that by conducting investment summits at J.P. Morgan in San Francisco each January, and we're doing it again next January, which will be the fourth year in a row.

"This year we also did an investment summit before the BIO meeting in Chicago. We had 15 companies present, and around 60 people involved for a full day. Last year, we also held the Australasian Investment Summit before the AusBiotech conference in Melbourne. We had more than 100 investors and over 30 per cent of those were international. An exit interview with investors by an independent group suggests that \$22 million was pledged on the day, and we know that other companies followed up afterwards and did invest.

"We're going to do a similar Summit again this year, and we already have 75 companies who want to present, so clearly there's a need for capital. But, most importantly, we have more interest from investors internationally. In fact, I predict that more than 30 per cent of the investors will be international. There is an interest in Australia because Australia is very well priced on the global scene. Also Australians are seen as good managers and as doing good science."

And, as Lawn points out, the companies that have made it this far through the GFC are likely to be the ones with the best prospects for the future, both in terms of management and technology, making them attractive prospects for investment. "The GFC has taken its toll," says Lawn. "The companies that are left are likely to be the ones on the right track. So the cream is rising to the top."

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SWINGS AND ROUNDABOUTS

As this issue of *Australian Life Scientist* goes to press, we finally have a new Labor government, of sorts. Although the uncertainty surrounding the election result is matched only by the uncertainty over the future of the much-debated R&D Tax Credit. The Tax Credit was intended to be the replacement for Commercial Ready, which the Rudd government turfed not long after it took office – a move that dealt a stunning blow to the growing but vulnerable biotech industry.

“Axing Commercial Ready was dismal, stupid, short sighted and dumb,” says Blake, echoing the sentiment expressed by all the commentators your correspondent has spoken to. The cost of pulling Commercial Ready and not providing a replacement has been significant, says Blake. Not only because much needed funds suddenly vanished, but because the industry has lost momentum without a replacement – such as the R&D Tax Credit – being put in place. Along with the GFC, it has significantly reduced investment in biotechnology, which not only hurts the biotech sector, but the wider community. Less funding today means it takes longer for new therapeutics to reach the public – therapeutics that might ultimately save billions in treatment and lost productivity due to diseases like cancer and diabetes.

“Smart companies don’t have a holiday on investing in research and development,” says Blake. “That’s an important message for investors and governments. But this government wanted to have a holiday on life sciences R&D.”

Yet the election campaign held little promise for the life sciences sector. The R&D Tax Credit – arguably the policy with the single greatest significance for biotechs – barely rated a mention. Even with a Labor minority government, there’s no telling when the Tax Credit might be reintroduced into the senate, and even if it does pass, whether it’ll be made to retrospectively apply to this financial year.

And it’s not only the absence of a funding aid that hurts the sector, says Nisbet, it’s the uncertainty it introduces into forward planning. A company that



Anna Lavelle

invested heavily in R&D under the expectation that the Tax Credit would apply this financial year is going to find itself in a hole should the legislation not pass. With some clarity over the matter, at least biotechs can plan to spend or not, but when it’s in doubt, more biotechs will likely refrain from investing in order to play it safe.

HALF FULL

Despite the bumps, the Australian life sciences industry still has plenty of fight left in it. One of the surprise results of the last several months has been the strong performance of medical device companies, led by Heartware, ResMed and Cochlear. “There’s definitely an emerging gap between medical devices and biotech,” says Lawn. “This was exacerbated by Heartware, but there’s a clear trend developing.”

According to Lavelle, it may be that investors are attracted to the lower risk and faster potential exit for medical devices. However, Blake suggests it’s too soon to know whether this is a lasting trend or just a short term reaction of a risk-averse market steering away from biopharma companies, which are perceived to be less reliable earners. “There’s still interest in small molecule drugs for chronic disease,” he says.

One of the things to look forward to, says Lavelle, is the phase III trial results that are expected to emerge over the next 12 months. “We’ve currently got a lot of companies that are in phase III,” she says. “And it’s those phase III results that will



Craig Lawn

really make or will bruise the industry in Australia over the next 12 months.”

There are also several companies that have been consistently performing well, and look to continue rising in prominence, including Prima BioMed, Mesoblast, Patrys and Starpharma (see “Rising star”, page 74), amongst others.

And if the US economy continues to wobble, it’ll only encourage biotechs to diversify internationally – as Lawn points out, one cause of the discrepancy in results between CSL and ResMed or Cochlear is that the former is more closely wedded to the US market, while the latter are more internationally diversified.

There are also opportunities to be had in Asia, says Blake. “There are 50 to 60 million people in the Asia-New Zealand-Singapore-Malaysia block, and they’re all within striking distance of each other,” he says. “If you can do it, why not develop a product opportunity for those territories, and work to be successful but on a smaller scale. That’s achievable, and can be the basis of building a business that can emerge on a larger global scale in six or seven years time.”

A lot can change in just a few months, and the next 12 to 18 months are sure to be dynamic for the life sciences industry. A new government, with the prospect of new legislation, a recovering (or stagnant) world economy, a blooming Asian market and the ever-evolving challenges presented by the regulators, are all set to keep the industry on its toes. But while the glass might appear half empty at the moment, it could equally be seen as half full. And it’s certainly far from empty. **ALS**



INCUBATING SUCCESS By Tim Dean

There are benefits, tangible and intangible, to clustering life science companies together. The Thebarton Bioscience Precinct in South Australia shows how it can lend a boost not only to the companies involved, but to the entire biotech industry.

IT WAS THE END of a tough year, and Dr Meera Verma, Director of Site Operations at Hospira Adelaide, was feeling weary. Still, she reluctantly picked herself up and attended the end-of-year networking function at the Thebarton Bioscience Precinct, located in Adelaide's western suburbs. And her experience that night saw her leave energised and optimistic about the future of the biotechnology industry in South Australia.

"I can still remember how great it made me feel when I walked into that Christmas function" says Verma. "It made me feel like I was part of an industry. It helped me realise that it wasn't just us at BresaGen trying to make something happen. There were other people who had similar challenges and were finding similar solutions. That was the moment I realised the biotech industry in South Australia had actually got to a point where you could feel like you were part of an industry. It was a really energising moment for me."

Fostering that feeling of collegiality is one of the main goals of the Thebarton Bioscience Precinct, and promoting such a community atmosphere is not only paying off in terms of bringing people together, but it also has more tangible economic benefits.

According to a 2009 Access Economics report on the performance of South Australia's government biotechnology development agency, BioInnovationSA, the state has been punching above its weight when compared to the two perceived accepted leaders in biotech: Victoria and Queensland.

While South Australia issued fewer grant dollars to the bioscience sector per capita than the Victorian Government, the bioscience sector in South Australia outperformed Victoria and Queensland in six out of 10 key indicators: new company formations; biotechnology patents; clinical trials; Biotechnology

Innovation Fund (BIF) grants; Commercialising Emerging Technologies (COMET) funding; and Cooperative Research Centres (CRCs). BioInnovationSA also returned nearly \$4 for \$1 invested – an impressive achievement.

Part of this success has come from taking a long-term view towards cultivating a thriving biotechnology industry in the southern-central state, says Jurgen Michaelis, Chief Executive Officer of BioInnovationSA. And one key element of this strategy is the Thebarton Bioscience Precinct, which Michaelis has championed ever since he took his position at BioInnovationSA in 2001.

INCUBATING INDUSTRY

When Michaelis came on board, there were already a handful of biotech companies that had set up shop in the old industrial area in Thebarton, near the University of Adelaide Research Park, capitalising on the proximity to the expertise and facilities nearby, and aided by the South Australian government's efforts to foster the local biotech industry.

"In the late 1990s, the state government had bought up several blocks of land in a government initiative to help companies construct biotech buildings on deferred purchase. The founding companies were BresaGen [now Hospira], GroPep [now Novozymes], Bionomics and TGR Biosciences. It turned out that the land the government had was fully occupied in very short time."

Michaelis saw an opportunity to build upon this foundation and grow the area into a bioscience cluster. When a large block of land – around 50,000 square metres – adjacent to the existing

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block came on to the market, he encouraged the state government to acquire it, although there was a lot of work to be done to make the land suitable for new high-tech biotech facilities. “It was an old tannery, with very old buildings and contaminated soil. We got to work and cleaned it up with government money and turned it into a prime industrial area.”

Cleaning up the land wasn't the end of his efforts, though. Michaelis also had aspirations to build a business incubator to attract early-stage biotechs to the area. Michaelis had seen – and worked in – such incubators in his native Germany, and could see the benefit they lent to fledgling biotech outfits. “We convinced the government to provide the funding to build a dedicated biotech incubator building. Not mixed industry, but office and laboratory space specifically for life sciences companies.”

The BioSA Incubator was to be the hub for the growing Thebarton Bioscience Precinct, providing not only office and lab space for early-stage biotechs, but conference facilities and a café – a vital focal point for informal interaction and community building between people at the Precinct.

The Incubator is currently fully occupied, with six early-stage companies taking residence: Each one has a three-year lease with an option to extend. Michaelis expects the current occupants to stay on, although not indefinitely. Hopefully they'll see success and outgrow the Incubator and move on to bigger facilities elsewhere – ideally within the Bioscience Precinct.

In fact, Michaelis would like to see the Incubator have some turnover to open up some vacant space rather than have it be fully occupied all the time. “Good incubators are not always 100 per cent occupied,” he says. “As an incubator you always need an office or lab vacant, so if someone knocks at the door looking for space, or one of the companies in the building needs extra space, you don't want to prevent that from happening. Turnover is important, and 90 per cent occupancy or so is a good rule of thumb.”

With several established companies based at Stage 1, and the BioSA Incubator forming the hub of Stage 2, the entire Bioscience Precinct now covers 70,000 square metres and hosts over 25 bioscience outfits, which is one-third of the total in South Australia. Plenty of land is still available within the Precinct for future developments, including a large 10,000 square metre tract that Michaelis suggests would be well suited to a larger manufacturing facility.

WE'RE ALL IN THIS TOGETHER

Clustering biotechnology companies together in one area has manifold benefits, says Michaelis, such as when it comes to attracting staff. “Companies find it easier to attract high calibre staff into a cluster. This is because if an employee moves into a company located in a cluster and the job doesn't last, or they want to move on up the career ladder, they can move out into the next company, which might only be next door. And they can do this without changing where they're living and without moving their kids to a different school. So it provides job security and stability.”

Being a part of the cluster also allows a biotech company to brand themselves a part of a high-tech industry, rather than being in isolation in a generic business park, says Michaelis. However, possibly the most important benefit is the community building.

“Our industry relies heavily on tacit information – information that hasn't been written down but is shared between people. And being in an environment amongst like-minded industries where people can exchange information is a key advantage.”

Verma entirely agrees. “Having a critical mass of like-minded people works to give you cross-communication,” she says. “It also gives you access to technical know-how and fosters interaction across the groups. Like, we may not be the people who develop a particular technology, but a company down the road does. If you have a question you can easily set up a meeting and go over and talk with them about how they tackled a particular problem.”

Competition also isn't necessarily a problem, says Verma. “Most of us don't directly compete in the same space. So you can talk to people about an issue or an idea, and how they dealt with it. It certainly facilitates interaction between executives. We'll go down and have a coffee locally and catch up on what's happening.”

There's also the practical benefit of having neighbours who are likely using similar specialised equipment as you – something you're unlikely to experience in a common business park, where the most sophisticated piece of equipment nearby is likely to be a photocopier. “Occasionally, there's been a crisis situation, and we've called on each other to see if the other person has equipment that can support what we're doing,” says Verma. “That's been one very tangible benefit.”

ACCELERATING ADVANCES

The next step in the development of the Bioscience Precinct is to build a larger incubator facility for biotechs at a more advanced stage in their development. This BioSA Accelerator building has been designed and fully costed, and BioInnovationSA is currently seeking to raise the \$31 million required to have the facility built. However, Michaelis is realistic that this won't happen overnight. “It's not a fabulous economic environment out there for raising money,” he says.

He also stresses that business incubators like this don't usually make a profit. “To run them at break-even is hard enough, so from private investor point of view, it is not best return on investment story. So there's always a role for government to either underwrite or to provide some of the funding. It's just the nature of business incubators in our space. Worldwide experience has shown that.”

But Michaelis takes a long-term view of industry development in the biotech space. “There are no short-term fixes that will give immediate results. It requires 10 to 20 years of dedicated government support. That's the model that has worked in South Australia. We have a small team at BioInnovationSA that has industry knowledge, so we understand what the industry needs. And then we have the means to find land, clear the site, zone it, build an incubator and attract companies to the site. It just takes time. But the benefits long term are there.” **ALS**

Rising star

By David Binning

In an industry obsessed with finding the next big blockbuster, Melbourne-based Starpharma is using its technology platform to steadily accumulate wins in a broad range of markets.

ORIGINALLY DEVELOPED by the CSIRO's molecular research institute, Starpharma's dendrimer nanotechnology platform has seen the company sign licensing and co-development agreements with some of the world's largest pharmaceutical and medical technology companies, including Eli Lilly, Elanco and GlaxoSmithKline (GSK). In addition to developing new product pipelines, many of these companies are now applying Starpharma's technology towards improving the efficacy of existing products.

"We are looking at using the dendrimer as a scaffold to which we attach someone else's drug to improve its performance," says Starpharma CEO, Dr Jackie Fairley. "This is something that is a very important value driver for the company moving forward."

Starpharma's dendrimer platform was recently applied to increase the solubility of cancer drug paclitaxel, while another leading cancer drug, doxorubicin, has seen its toxicity levels reduced and its efficacy increased. It is envisaged that the technology could be applied to improve a wide range of current and future drugs in numerous ways, including making them persist longer in the body.

In addition to its dendrimer technology products, Starpharma also derives revenues from its Stratus CS cardiac marker diagnostic, licensed to Siemens Healthcare, its gene transfection technology, SuperFect, licensed to Qiagen, while its siRNA and DNA transfection reagents are licensed to EMA Merck.

Ironically, for a company that eschews the blockbuster business model, Starpharma is itself close to possessing that most cherished prize. The company's lead product, a microbicide called VivaGel,

is garnering serious attention globally for its potential to affect a major reduction in the incidences of sexually transmitted infections (STIs), in particular HIV AIDS and genital herpes. The product is currently advancing through clinical development with the FDA recently granting the product 'fast-track' status.

While the social and economic costs of the global HIV pandemic are well known, genital herpes is less understood. In the US, around 26 per cent of all women are infected with genital herpes, while for African American women the figure is an alarming 50 per cent.



The disease is an enormous drain on health systems throughout the developed world, both in terms of the life-long costs of medications and professional attention required to treat it, as well as its contribution to a range of other health problems. For instance, genital herpes is one of the main reasons for women being forced to give birth via caesarean. Fairley notes that genital herpes was estimated to be costing around US\$1.6 billion a year in the US several years ago, and that the figure is likely to be considerably higher now.

Starpharma recently received a grant of US\$26 million from the US National Institutes of Health (NIH) to progress the development of VivaGel to combat HIV, in addition to separate funding to develop VivaGel against genital herpes.

Starpharma is eyeing a number of additional markets for VivaGel. Recently it commenced a Phase II study to examine its effectiveness in both the prevention and treatment of bacterial vaginosis (BV), a market currently estimated to be worth around \$US350 million. BV is the most common cause of vaginal infection, and Fairley says that the market is severely underserved with current treatments creating a number of undesirable side effects.

Starpharma is also working with Durex to deliver VivaGel as a coating for condoms, in a deal which could be worth as much as \$US100 million. The company notes that this provides a fairly clear path to market with the first royalties expected to be generated some time next year. All up, Fairley says that VivaGel is targeting a market potentially worth \$US6 billion a year. "There's no question that a topical microbicide cover for HIV and genital herpes is a huge commercial opportunity."

Fairley stresses, however, that human life sciences represents just one of several markets where the company is hoping to sell its technology. Others include animal health, water purification, inks and coatings as well as agricultural chemicals. Late last year, Starpharma signed a large deal with a leading US agricultural chemicals company, and expects to sign further deals in this space, a market currently estimated to be worth around \$US35.8 billion.

The US is a key market for Starpharma, and it is working closely with its fully-owned subsidiary, Dendritic Nanotechnologies Inc, towards expanding its potential products across the life sciences and industrial markets, with the company noting that several of these products have near-term cash-flow opportunities. **ALS**

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