



## Australian Life Scientist Wednesday 1/06/2011

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The Australian biotechnology industry has entered a new phase, with several high profile deals demonstrating the sector can truly deliver. Now attention is turning to what comes next.

*By Tim Dean*

**WHEN MESOBLAST ANNOUNCED** in December last year that US middle-weight pharmaceutical company Cephalon was pitching to acquire a 20 per cent stake in the regenerative medicine company at an eyebrow raising 45 per cent premium, along with a cash payment of \$130 million and potential milestone payments of up to US\$1.7 billion, sentiment within the Australian biotech industry changed overnight. No longer was biotech the realm of high hopes and speculative returns, it was now yielding tangible results with real dollar figures attached.

And Mesoblast (full story, page 24) wasn't the only company to share some good news. Cephalon also took a shining to ChemGenex and its targeted treatment for chronic myeloid leukaemia, looking to acquire the company for a neat \$159 million in cash. In other acquisitions, Dutch sample and assay company Qiagen sought to pick up diagnostics specialists Cellestis for US\$355 million in April. Perth-based iCeutica was also snapped up in April by its US partner, Iroko Pharmaceuticals, for its SoluMatrix reformulation platform for an undisclosed, but apparently tidy, sum.

AcruX took its testosterone replacement therapy, Axiron, into the US market care of a partnership with Eli Lilly, fetching the Victorian biotech US\$137 million in milestone payments in the process – \$100 million of which immediately went out as a singularly magnanimous 60c-per-share dividend. Sydney-based Pharmaxis recovered from its regulatory wobbles in Europe to receive the tick of approval from the Therapeutic Goods Administration back home for its cystic fibrosis treatment Bronchitol. Living Cell Technology received regulatory approval in Russia

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for its xenotransplantation-based type 1 diabetes treatment, boding well for further regulatory hurdles here and abroad.

Sirtex saw profits from the sale of its anti-cancer treatment, SIR Spheres, rise. Biota is reaping growing royalty payments from GlaxoSmithKline for Relenza, and secured a tidy \$230m deal from the US Health Department for development of its anti-flu drug, Laninamivir. Several companies have also posted some very promising clinical trial data, including QRxPharma, Bionomics and Mesoblast – the results of which helped the latter get over the line with Cephalon. There were even a couple of IPOs, breaking the post-GFC drought.

According to PricewaterhouseCoopers numbers, the biotech ex majors (all those excluding giants CSL, Cochlear and ResMed) grew by almost 24 per cent over the past six months, with medical device ex majors nudging 16 per cent – both outperforming the wider ASX after a bumpy second half of 2010.

According to Anna Lavelle, CEO of AusBiotech, the timing of this confluence of good news is no accident. “These are some spectacular results,” she says. “What this is reflecting is the seven to 10 years of investment in the front end to deliver these outcomes.”

Unlike many other industries, biotechnology is inherently a slow-moving sector, with a regulatory framework that demands products be meticulously

trialled and tested before reaching the market. As a result it can easily take the best part of a decade for an innovation to reach the point where the market rewards it with solid returns. Given many of the companies that just cut their deals or saw regulatory approval were founded around a decade ago, it’s not unexpected to see some of them bearing fruit today.

#### CONFIDENCE

One of the impacts of this run of good news has been to change the mood in the market towards the life sciences industry at large. As PricewaterhouseCoopers analyst Craig Lawn puts it: this industry runs on confidence, and confidence is at a new high on the back of these results. While it’s been a long time coming, the recent run of deals with big dollar figures attached shows that biotechnology isn’t just talk, but can deliver the goods to investors and consumers alike.

And according to Lawn, the good news may not have finished yet. “There’s a strong sense there are a significant number of biotechs that are close to major clinical trial results or major announcements,” he says. “From the clients we speak to, I can see the next quarter having a similar amount of positive news. And momentum will continue as these announcements are made.”

David Blake from Bioshares agrees that we likely haven’t seen the last of the

good news from the biotech industry. “I think this positive sentiment has a strong chance of being sustained. We may have even turned a permanent corner,” he says. “I know that’s bold, but more good news from the likes of Acrux, Mesoblast, Biota, Pharmaxis and others will be confirmatory of that prediction.”

For many people the life sciences industry has been seen as one of big claims and tremendous potential – imagine the returns on a cure for cancer – but one that is plagued by an uncompromising regulatory landscape and a lengthy product development cycle that can suffer from any number of pitfalls. This makes it particularly hard to pick a potential winner early on, which is precisely when the startup needs an injection of funds to embark on the development process.

But the fact that some biotechs are now delivering returns to their investors not only means that some of the claims have been fulfilled, but it also means good things for the rest of the industry. In fact, it has a doubly positive effect: money flowing into biotechs not only allows them to pursue more trials and move more products down the pipeline; but money flowing back to investors also has a greater chance of being reinvested in biotech.

“Some of that money may see its way back into early stage biotechs,” says Blake. “People might reinvest it keep it in the biotech sector. When you can do that again and again, you have a



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press clip



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ANNA LAVELLE

viable sector, with companies reinvesting their earnings and investors reinvesting their gains.”

According to Lavelle, the investors are also becoming more informed about the sector, and starting to see its unique charms. “Investors now feel they understand

the sector,” she says. “They’ve become connected to the sector. They see that it is complicated but that it’s also interesting and important. A lot of people see the X factor, that extra interest level you don’t get when investing in brown coal. Of course, they want to make money, but they’re also interested in the outcome for the community and the patient cohort.”

### THE THIRD WAVE

One question the current spate of success stories raises is who’s next? Following on the heels of the first wave of Australian biotech, including veteran players like CSL and Cochlear, we have the second wave, which were established in that window around 10 years ago and are now reaching maturity. But who’s behind them? When will the third wave arrive?

Even a decade ago there was far more

support for biotech start-ups, particularly from the government with the likes of Commercial Ready and its predecessors. Now, with the double whammy of the global financial crisis squeezing private investors and the government axing Commercial Ready, there’s substantially less support for biotech in that uncomfortable pre-profit stage.

“You need an open pipe from discovery to market to get optimal outcomes,” says Lavelle. “But we have a broken pipe. By reducing funding or not supporting young companies, or not recognising the benefit of programmes like Commercial Ready, it makes the environment hostile to business.”

One policy that could change this environment to make it more conducive to biotechnology is the passing of the R&D Tax Credit through the senate.

This bill aims to help research-intensive companies which are yet to turn a profit gain a little government support for research and development via a tax credit. It offers a 45 per cent refundable tax credit (equivalent to a 150 per cent concession) for companies with a turnover of less than \$20 million per annum, and 40 per cent (equivalent to a 133 per cent concession) for companies with a greater turnover.

The bill was intended to replace the R&D Tax Concession and to fill the gap left by Commercial Ready after it was dumped by the Labor government in 2008. However, it hit a road bump in the senate in mid-2009 and then the federal election shenanigans put it on hold until this late last year. To date the coalition and Family First senator, Steve Fielding, have refused to pass it through the senate, meaning it’ll have to wait until the changing of the guard – and the balance of power – in the senate midyear for any hope to be signed into law.

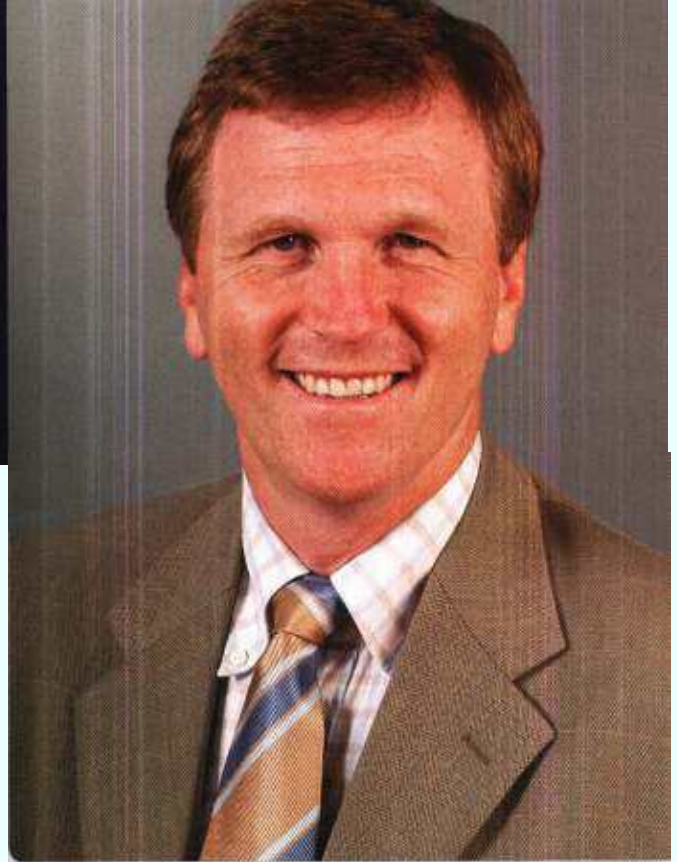
According to Lavelle, AusBiotech has had conversations with Greens senator, Christine Milne, who has vouched the support of her party to the bill, which raises hope it might be passed later this year. However, a further issue is when the credit will take effect. Innovation minister, Kim Carr, has made a commitment to have the bill apply retrospectively for the financial year 2011-2012, and is seeking treasury advice on the matter, although the later the bill is passed, the less likely this is to happen.

Another legislative issue is the Patent Amendment (Human Genes and

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CRAIG LAWN



Biological Materials) Bill 2010, which was introduced as a private member’s bill in November last year, just days before the Senate Committee Inquiry into Gene Patents was to release its findings. The new bill seeks to ban the patenting of any biological materials, even when modified from their natural form.

According to AusBiotech and the Institute of Patent and Trade Mark Attorneys of Australia (IPTA), the bill will backfire and instead of freeing up research, it will hamper research and commercialisation of any technology involving biological materials. “The language in the bill is absolutely unacceptable,” says Lavelle. “It is broad and ambiguous, and it will only lead to drawn out legal discourse about definitions. The bill has no inherent benefit for patients, clinicians, researchers of industry – except lawyers. It will be damaging to the biotechnology industry and it has to be voted down.”

AusBiotech and the IPTA argue that the existing legislation prevents the patenting of any discoveries, such as genes as they’re found in nature, but only allows the patenting of any development that involves an inventive step that covers something not in its naturally occurring state and which has a demonstrated use. The two organisations also prefer strengthening the Patents Act 1990 to include an explicit research use exemption to further ensure that patents don’t restrict further research.

The broad sentiment is that the Patent Amendment (Human Genes and Biological Materials) Bill 2010 is unlikely to pass in its existing form, but uncertainty over its existence has added unwanted jitters to investors who are wary of putting money into something that might potentially be unable to seek IP protection.

#### TWO TIERS

Add to this that venture capitalists are still coy in the wake of the GFC, especially American VCs, and early stage biotechnology companies are facing some stiff challenges in securing funding to get their technology off the ground. The risk is that this will create a two tier industry, with the existing vanguard – which benefited from a more forgiving environment and more generous government support a decade ago – starting to generate revenues while the next wave are struggling to gain the attention of investors.

While we have some truly positive news emerging at the moment, and perhaps continuing for the next year or so as more companies mature, then things might go quiet for a while as the third wave is delayed in bringing its technology to the market.

Yet overall the signs emerging from the Australian biotechnology industry are overwhelmingly positive. It really is amazing what a string of good news can do. After beavering away for around a decade or so, and weathering the storm of the global financial crisis, Australian biotechs are starting to make world class deals and be noticed on the global stage.

As Osagie Imasogie, chairman of iCeutica and Senior Managing Partner at Phoenix IP Ventures says, Australia is fertile ground for innovative life science technologies, and is sure to garner more attention from smart investors abroad.

“Australia is off the beaten path, and that is very important” he says. “There are world class scientists here working on intriguing challenges but doing it in their own unique way. There is a tendency in the US or Europe – where many people attend the same schools and work for the same companies – to think exactly the same way. But true innovation is developed out of different perspectives.” And it seems those maverick ways are truly beginning to pay off. **ALS**