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Biotechs ready themselves for

RECOVERY

With the worst of the GFC behind us, 2010 will be a year of consolidation growth and maximising opportunities for the biotech industry.

By Tim Dean

IF YOU EXCUSE THE MIXED metaphor, there is light at the end of the tunnel, but we're not out of the woods yet. That appears to be the sentiment amongst the Australian biotechnology community in the opening months of 2010.

2009 was a year of downs and ups, punctuated by the downs early in the year but then followed by a promising trend of ups. As of December 2009, the All Ordinaries had recovered much of its losses experienced since the dive of September 2008, although it's still well below its peak in October 2007.

By comparison, biotechnology stocks have fared remarkably well. Through to the end of 2009, biotechs clawed back the ground lost in 2008 as some colour returned to the cheeks of the market. In fact, the life sciences index has consistently outperformed the All Ordinaries over the past 12 months. Interestingly, much of this rebound was fuelled not by the titans of the life sciences industry – CSL, Cochlear and ResMed – but by the 'ex-majors', i.e. everybody else.

"The life sciences ex-majors' continued positive growth across the last four quarters was a stellar result outperforming the All Ordinaries Index for the same period by 85 per cent," says Craig Lawn, Life Sciences partner at PricewaterhouseCoopers.



PricewaterhouseCoopers
life sciences partner, Craig Lawn.

"This performance resulted in a return, for the past two years, of close to pre-GFC levels of late 2007."

However, the market has been a little less ebullient since the back end of 2009. The life sciences index was only up 1.6 per cent in the last quarter of '09, mainly due to CSL's relatively limp showing – and as we all know, when CSL catches a cold, the rest of the market wonders who to turn to for a vaccine.

This was a little surprising, says Lawn, as one would expect the larger and more established companies – those with more advanced products, more funding opportunities and more cash in the bank – to outperform the smaller more speculative biotechs. Yet the opposite was the case. Many smaller firms put in stellar performances; Biota gained a stunning 665 per cent, and Prima BioMed a breathtaking 3,650 per cent in the calendar year of 2009, while many posted gains of 100 per cent or more. But not every ex-major had it so good.

"There was a bit of a two speed thing happening there for the ex-majors," says Lawn. "There was growth in 2009, but half of small market cap companies lost value in that time as well. The clear implication is that there is a return of confidence, and people are returning to the market, but it might be smarter and less patient money."

There were also some fatalities, most notably Ventracor, which closed its doors in February 2009, although, arguably, the GFC was the catalyst rather than the cause of Ventracor's woes. Other firms went in to hibernation, pausing

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AusBiotech CEO Anna Lavelle

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non-core programmes and delaying new trials. Yet it was this prudent behaviour and the foresight of many management teams in Australian biotechs that might have staved off the mass closures predicted in this magazine only 12 months ago.

CEO of AusBiotech, Anna Lavelle, is generous in her praise directed towards the management of beleaguered Australian biotechs during this challenging period. "The CEOs were under pressure but they conducted themselves very professionally," she says. "They went off shore and raised

capital, and they did all the things that a mature sector should do. We've now moved from an emerging industry to more mature industry, with a number of CEOs with more than 10 years experience demonstrating that in the last 18 months with their steady hand. That augurs well for future."

THE ROAD AHEAD

Since we collectively escorted 2009 from the premises and welcomed in 2010, things have been a little more bumpy. The consistent gains in the life sciences index from April to October 2009 have tapered out leaving the future somewhat less clear. Compounding this are concerns over the health of the US economy.

"The US is the epicentre of the life sciences," says Lawn. And if there's a prolonged slowdown in the US, dragged back by flagging employment figures and a truly epic budget deficit, that could yet dampen the spirits in the Australian biotech market. "The US sets the standard, and because of that, if there is a US slowdown, there will be a direct impact and softening of the market," he says.

Will it happen? "Who knows?" says Lawn, sagely. And given the accuracy of market predictions made over the last couple of years, that seems a reasonable answer.

What we do know is that money is starting to find its way back to starved biotechs, eager to advance their product development. In fact, at AusBiotech's Life Sciences Investment Summit, held in October last year, there was a cockle-warming show of enthusiasm from investors towards Australian biotechs. "As it was on the back of the GFC, we had some nervousness about making it a success," says Lavelle. "But we were more than pleasantly surprised."

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R&D Tax Incentive

One beacon on the hill for many biotechnology companies is the Federal Government's proposed research and development tax credit. Under this scheme, a biotech with a turnover of less than \$20 million can claim a tax credit of 45 per cent on expenditure on research and development activities. Companies with a turnover of over \$20 million can claim 40 per cent.

The legislation was released as an exposure draft for comment just before Christmas last year and the government is currently mulling over the 131 submissions it has received since.

While the industry has generally looked favourably on the R&D Tax Incentive, particularly because it seeks to benefit vulnerable small biotechs that have yet to turn a profit, the draft legislation has suffered some criticism.

AusBiotech's main concern is that the draft legislation threatens to narrow the application of the tax credit so many deserving biotechs might miss out. "We feel that some of the clauses are very rigid and will not deliver what the minister announced was his intention on budget night, which

was to support SMEs more proactively and to support innovative companies," says Lavelle.

"There are two main things we're concerned about. The first is the number of hoops companies have to jump through to be eligible. The second is the feed stock provision, which means that once you have sales over a certain value, like a licensing deal or a product, then the government can claw back some of the money given to you to support the R&D."

Senator Carr has given an initial response to the submissions saying his department is taking them on board but he remains committed to keeping the tax credit revenue neutral, targeted towards "genuine" R&D (however that's defined) and its intention to support smaller firms.

The next hurdle for the legislation is getting the Governor General's signature on it before July 1 so it can kick in to gear in time for the next financial year. Even if it does pass into law, it'll still take 18 months or more before biotechs see the fruits of the tax credit, so a delay of another year would be most unfortunate.

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According to the Victorian Tourism Bureau, \$22 million changed hands during the day, with more being invested since. "That tells me that investments are alive and well," says Lavelle.

AusBiotech is planning to run a similar investment summit on the Monday before the world's biggest biotechnology business gathering at BIO. Lavelle is upbeat about the prospects of that dig as well. "We should get a very good turn up at that meeting."

According to Lawn, there are already signs the US venture capital market is starting to stir once again. "Into 2010, signs point towards the market continuing to respond positively to biotechs making good progress with early indications of funds being injected into life sciences from US VCs in recent quarters. This has been followed up by substantial secondary raisings both in the US and locally."

Even if secondary financing appears to be on the up, IPOs are still proving to be an endangered species with several being delayed or canned outright. "In the life sciences sector market weakness has been reflected through the postponement of PolyNovo's IPO and the numerous delays and the reduction in

minimum capital raising for CBio," says Lawn.

No IPOs took place in 2009, and while there are a couple in the pipeline for 2010, the only one that kicked off to date – CBio's – could serve to frighten off hopeful public listers. After extending the IPO period, and falling short of the hoped-for 30 million shares at an issue price of \$1, it ended up with a share price hovering around \$0.40 and a 'meagre' \$7.1 million. Ouch.

NOT JUST SURVIVING, THRIVING

How about the rest of the year? Despite the ongoing uncertainty, this is a time of opportunities, says Lawn. Just because funds are tight and programmes might be sitting dormant doesn't mean biotechs should be complacent. Eventually the market is going to pick up again, and when it does, it'll be the biotechs that have placed themselves in the position to take advantage of it that will rise to the top.

It is the companies that are talking to potential partners, building relationships, cutting deals now that will be positioned to capitalise on the times ahead. "Companies will all of a sudden wake up and say 'right, it's time.' If biotechs don't have a relationship, because they haven't been to BIO, or haven't spent time in their offices, that's the danger signal," he says.

Lavelle agrees that the Australian life sciences sector is poised for a big decade. Over the last 10 years many players in the industry have moved from pre-clinical development and are now in the final stages of clinical trials and seeking regulatory approval.

"I'm really looking forward to the phase III trials that are in the pipeline at the moment. It will be extremely exciting to watch over next year or so to see how they mature," she says. "Statistically we would think that a proportion of those trials will yield very positive news. It will be great to see how that is translated into company development, wealth creation or growth of the company in another way. That's very exciting times for us."

So it looks like the worst has past, and most of the industry has made it through the GFC intact – not through luck, but through skilful management and a strong product offering that appeals to investors. And it remains a simple truth that biotechnology – particularly involving health – is not a discretionary spend. With an aging population and greater concern over the health and wellbeing of our population, biotechnology will continue to be a foundation stone of 21st Century economy. It'll take more than a global financial crisis to stop biotech. **ALS**

