

Media Coverage

Company: AusBiotech
Date: 19 October 2010
Publication: Australian Life Scientist
Page: Online

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AusBiotech 2010 Special Feature: State of biotechnology in Australia

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.

Tim Dean (Australian Life Scientist)

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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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.

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“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.”

Swings and roundabouts

As the September/October edition of *Australian Life Scientist* went to press, we finally had 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 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

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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 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.