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Spinning off, cashing up and branching out: Commercialisation considerations for bioentrepreneurs in Australasia

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Abstract

There are myriad issues to consider when commercialising a biotechnological innovation. In Australia, because of market structure, the tendency for biotechnology companies to list early in their life cycles has caused problems. A fledgling venture capital market in Australia has been partly to blame. The authors outline practical, strategic considerations for bioentrepreneurs in Australasia, focusing on innovations stemming from biomedical research.

INTRODUCTION

You may recall the Red Queen from Lewis Carroll's 'Through the Looking Glass'. She runs terribly fast yet goes nowhere and to get anywhere at all she has to run faster again. To some extent biotechnology companies in Australia have suffered from the Red Queen effect – putting considerable effort into expanding their businesses, only to find themselves working harder and harder to maintain the status quo.

This paper looks at some of the underlying reasons for this phenomenon and how industry and local institutions (such as the Australian Stock Exchange and the Australian Government) are working to overcome it. We will approach our subject matter by outlining the commercialisation considerations facing biotechnology companies throughout three main stages of the company life cycle, from spinning off through cashing up (including listing on a stock exchange) to the expansion phase.

SPINNING-OFF

The biotechnology sector in Australia has a reputation for generating world-class research but being 'deplorably bad' at commercialising such research.¹ Australia's poor ability to commercialise research successfully has been blamed on a combination of insufficiently developed commercialisation skills in the biotechnology sector and inadequate financial support by government and private industry.¹ For example, the premature licensing away of 'first-born' products to generate revenue is a recognised trend in the Australian biotechnology sector.²

While there have been successes, Australia has missed opportunities to capture significant value from its research findings – for example, the discovery of the cause of haemochromatosis (the most common inherited liver disease known), as well as the location of the underlying genetic defect.¹

This section examines factors in the 'spin-off' phase that affect our ability to commercialise innovations in the

biotechnology sector. We deal later with how market structure is also partly to blame, what is being done to address these problems and strategic considerations for biotechnology companies wanting to commercialise their innovations.

Institutional barriers to commercialisation

Much of our life sciences research emanates from publicly funded research organisations, including universities, medical research institutes and the Commonwealth Scientific and Industrial Research Organisation (CSIRO).³ These publicly funded bodies play a central role in developing biotechnological innovations that have medical applications. They face the additional challenge of recognising the value of an innovation and exploiting it in a manner that is consistent with their role in disseminating and sharing knowledge.⁴ A major review of health and medical research in Australia revealed that there are institutional barriers to university researchers' involvement in new business enterprises – especially in relation to holding equity, directorships and moving between academia and industry.⁵

With some exceptions, Australian universities have generally not been actively involved in the commercialisation of research until relatively recently. They have confined their role until the recent past to the pursuit and exchange of knowledge through teaching, publishing and collaboration between researchers. In the face of dwindling support from the public purse, however, universities in Australia have come under increasing pressure to attract private sector funding and to generate revenue by exploiting intellectual property (IP). Similar pressures are being experienced by universities in the UK.⁶

While Australian public research bodies today view it as an important part of their role 'to encourage and facilitate commercial development of intellectual property',⁴ they are hindered by a lack of cumulative experience in handling the

complex processes of commercialisation.⁷ This is reflected by the finding that Australian publicly funded research bodies (including 34 universities, 15 medical research institutes and 21 divisions of the CSIRO) collectively generated only AUD\$99 million from licences in the year 2000.³

While this represented a greater licence income per US\$1bn spent on research than either the USA or Canada, two-thirds of this income was derived from only 9 (13 per cent) of the 70 bodies surveyed and one-quarter of Australian research bodies failed to execute a single licence or to generate any income from licences in the year 2000.³ These findings indicate that a only a small proportion of Australian research bodies is commercialising research in a successful manner. For the majority, improvements can be made and there is a general need among publicly funded research institutions for better performance and outcomes when commercialising research.

Broadening the portfolio of commercialisation activities

Another relatively recent development in both UK⁶ and Australian⁷ university systems is the use of spin-off enterprises to commercialise IP. Up to 2000, Australian university policies failed to specifically address the issue of start-up companies, being focused on commercialisation through the licensing of intellectual property.⁷ Yet the formation of start-up companies is one of the key factors to successful commercialisation.⁸

It has been reported that the ability to form new business enterprises is more likely to bring long-term, substantial commercial benefit than licensing (ARC,³ citing the report of the National Innovation Summit held in 2001). In turn, however, licensing is key to the ability to spin-off new commercial enterprises.

Dealing with conflicting interests and responsibilities

Researchers may find the duties they owe to any new commercial enterprise conflict

Public funded research organisations must exploit innovations consistently with their role in disseminating and sharing knowledge

The formation of start-up companies is a key factor to successful commercialisation

Educating researchers about business processes, management and responsibilities will help develop a culture that is more aware of and positive towards commercialisation

with their academic interests. The 'publish or perish' culture of most universities rewards academics who regularly and freely share their knowledge by publishing in academic journals. However (with the exception of countries that provide a 'grace period'), publication precludes the ability to obtain patents – the cornerstone of any licensing activity.

This is illustrated in the *Rescare* case, in which the inventor published an article in *The Lancet* about his invention shortly after a provisional application had been lodged with the Australian Patents Office.⁹ When Rescare tried to sue a competitor for infringement of its patent, the competitor cross-claimed that (among other things) the complete patent was not 'fairly based' on the provisional specification. The Full Federal Court agreed (and a subsequent application to appeal to the High Court was dismissed).¹⁰ The effect of this decision was that the priority date of the patent was taken to be the date of filing of the complete specification and not the date of filing of the provisional application. This meant that publication in *The Lancet* rendered the patent invalid. Australian patent laws have recently been amended to introduce a grace period so that publication in the 12 months prior to filing a patent application will not preclude the inventor from obtaining a patent.

Even in the absence of any patents, knowledge gained for the benefit of a commercial enterprise may be valuable and confidential. Disclosure of such information may have commercial consequences (and potentially be a breach of director's duties in Australia and New Zealand, where director's duties are more onerous than in the USA). The education of researchers about business processes and management, as well as business responsibilities and potential conflicts with academic duties will help develop a research culture that is more aware of and positive towards commercialisation. The transfer of researchers to industry will help build a network of role models and

mentors, and assist researchers to participate in entrepreneurial activities. The adoption by universities of commercialisation measures (eg numbers of patents) in assessing staff performance will also assist to address cultural barriers to commercialisation.⁸

Cashing up

Sources of funds available to biotechnology companies

Figure 1 shows the important sources of capital raised by Australian biotechnology companies.¹¹ In 1998, stock exchange listings (initial public offerings, IPOs) were the third largest individual source of income for biotechnology companies in Australia. By 2000, the importance of venture capital (VC) had grown significantly as the local VC market matured, and VC was a much larger contributor to income than public capital raising.¹¹

More recent statistics have shown that venture capitalist confidence in Australia and New Zealand continued to increase until the first quarter of 2002, a time when capital confidence in the USA and the UK was at its lowest levels in years.¹² While local confidence among venture capitalists waned early in 2002, 65 per cent of Australian and New Zealand venture capitalists remained confident that the financial performance of their investee companies would improve until the end of 2002, compared with 38 per cent in the UK.¹³

Government funding

In recent years, both State and Federal government funding of the biotechnology sector has been greatly increased, in recognition of the importance of the sector to the economic future of Australia. For example, in 2001, the Federal Government announced proof of concept funding grants (known as the 'Biotech Innovation Fund') as part of a wider initiative to promote research, development and innovation in Australia.¹⁴

Despite the increased availability of

Funding to the biotechnology sector by Australian governments has greatly increased in recognition of the sector's economic importance

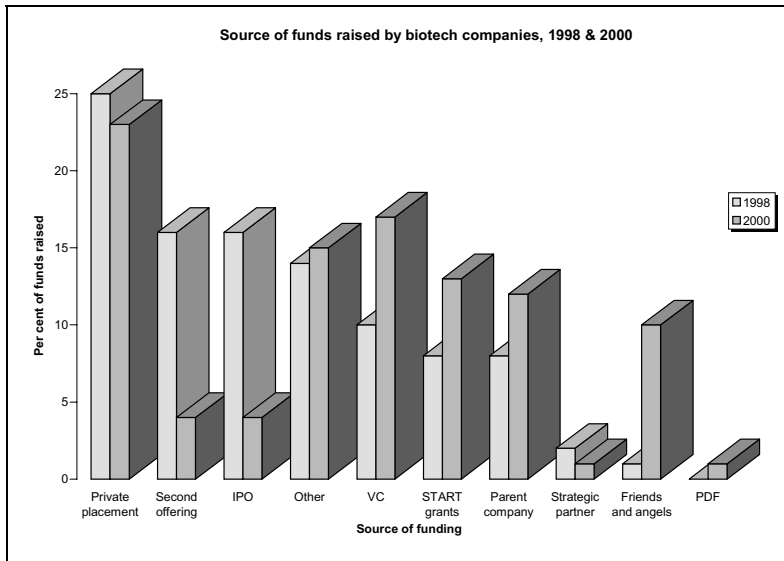


Figure 1: Source of funds raised by biotechnology companies, 1998 and 2000 (Source: Bivell and Thorburn¹¹)
 PDF = pooled development fund

The accountability which government investment brings to a biotechnology company is a major advantage in attracting private investors

funds for the biotechnology sector, demand has outstripped supply. For example, demand for one major source of government funding – the Federal Government R&D Start Grant Scheme – was so high in 2002 that it caused a \$40m blowout in the allocated budget. As a result, the body administering the grants unexpectedly halted the review of any new applications for a period of seven months.¹⁵ Nevertheless, government funding remains one of the major sources of funding for Australian biotechnology companies, most of whom are still in the research phase and therefore are unable to rely on income from sales as a revenue stream.¹⁴

Government investment will always have different benefits and disadvantages to investment from the private sector. In Australia government investors tend to be motivated by broader aims than simply a financial return on investment – therefore issues such as control of intellectual property, and the location of aspects of the business such as manufacturing may be influenced by policy imperatives as well as commercial factors. In addition government investors are often structured as grant-making bodies, with complex systems of corporate governance, leading

ASX initiatives to encourage developing industries paved the way for many biotechnology companies to list early in their life cycles

to extended time frames for decision making and uncertainty about the identity of the entity entering into the transaction.

However the accountability which government investment brings to a biotechnology company is a major advantage in attracting private investors. For overseas investors particularly, the validation of investment by Australian government bodies is necessary to confirm the credibility of the investee.¹⁶ The Australian government has recognised the importance of forging partnerships with private investors in biotechnology companies and has focused its own investment programme on initiatives which encourage the participation of private capital through co-investment.⁸

Other government initiatives to assist the biotechnology sector in Australia include tax concessions and a cash rebate scheme for small-loss companies that undertake eligible R&D.¹⁵ While these initiatives are not sources of income *per se*, they can free valuable capital for cash-strapped biotechnology companies. However, there has been criticism that the eligibility criteria for R&D tax concessions or cash rebates are too stringent to assist many biotechnology companies.

Private sector support

In the past, a paucity of private-sector support for the Australian biotechnology sector plus an overheated stock market encouraged many biotechnology companies to list on the Australian Stock Exchange (ASX) in order to generate sufficient resources to continue research and development.

The overheated stock market was the result of ASX initiatives to encourage developing industries, including lowering of the entry bar to its main board.¹⁷ This paved the way for many biotechnology companies to list on the ASX earlier in their life cycle than would previously have been possible. It is not surprising that such immature companies have small market capitalisation. The fact that one-

The large number of listed biotechnology companies in Australia sets Australia apart from its regional neighbours

third of listed Australian biotechnology companies have a market capitalisation of less than AUD\$10m¹⁴ reflects the large proportion of biotechnology companies that have adopted the strategy of listing early in their life cycle.

A recent survey published by analysts Frost & Sullivan Asia Pacific nominates Australia as the clear winner in the biotechnology race in the Asia Pacific.² One of the factors that they identified as setting Australia apart from its regional neighbours was the large number of publicly listed biotechnology companies in Australia (around 74 at the time of writing¹⁸).¹⁷ By contrast, for example, Singapore has yet to see its first biotechnology IPO. However, activity in the region is set to change, with:

- increasing awareness and interest in local biotechnology stock markets in Hong Kong and South Korea;²
- aggressive venture capital investment (up to US\$2bn) in local and foreign biotechnology companies by the Singapore Government, as part of a 15-year push to turn Singapore into a world class hub for biomedical research;¹⁹
- the establishment of a Biotechnology Strategy Council in Japan to review deregulatory and other proposals in order to expand the value of the nation's biotechnology markets 20-fold by 2010 and enhance the industry's overall competitiveness;²⁰ and
- the relaxation of listing requirements for biotechnology firms in certain countries, in order to encourage the listing of biotechnology companies. For example, the Securities and Futures Commission rules for listing on the TAISDAQ stock exchange in Taiwan have been relaxed so that the completion of a new product is no longer a prerequisite to listing. This is expected to increase the number of local biotechnology companies looking

to list rather than entering into foreign partnerships as a means of raising capital.

The authors of the survey expect to see growth in individual local biotechnology stock markets in line with growth of the industry as a whole – a trend they see as being led by Australia. However, as we discuss in the section 'Branching out' below, listing is no guarantee of liquidity and lowering the entry bar to assist biotechnology companies to list on the ASX has created problems for the sector. Biotechnology companies that list too early often end up in a cash-strapped position, unable to raise funds from the market or from private equity.^{11,14,21,22}

The ASX is now looking for new ways to assist the biotechnology sector, including the possibility of re-introducing a second board for developing industries.¹⁷ The aim would be to enable differentiated shareholder rights, so that VC providers can invest in listed securities (which their trust deeds generally prevent them from doing currently).¹⁷ This would provide listed companies with the profile of listing but still allow them to access VC capital after they have listed.

The ASX has also recently amended the escrow provisions of the ASX listing guidelines,²³ which prevented founders, promoters and directors of newly listed companies from selling their shares for two years after listing. This was an additional deterrant to VC investment in young biotechnology companies. Under the amended guidelines (effective since March 2002), an investor who meets the definition of 'genuine venture capitalist' can obtain relief from the two year escrow provision. The four criteria that must be satisfied to meet the definition are:²³

- the VC fund has a strategy of VC investment and there are no personal connections between the investor and the founders of the company;
- the fund holds no more than 30 per

Listing too early can leave a company in a cash-strapped position, unable to raise funds from the market or from private equity

cent of the company prior to the company's listing on the ASX;

- the fund has no more than one non-executive director on the company's board; and
- the fund has paid issue prices for securities comparable to the prices paid by other unrelated parties investing at or around the same time, and has not obtained any identifiable benefit beyond the opportunity to invest in the company.

Increasing VC market sentiment towards the biotechnology sector may make private equity a real alternative to listing for young biotechnology companies in Australia

Together with increasing VC market sentiment towards investing in the biotechnology sector, these reforms are aimed at lifting private equity support for biotechnology companies and making private equity a real alternative to listing for young biotechnology companies.

Encouraging further private equity investment in the biotechnology sector

In recognition of the difficulties being faced by Australian biotechnology companies, a number of reforms are being touted by ASX and the Australian Tax Office, to assist the biotechnology sector. Australian Tax Office reforms include:

- broader concessional tax treatment of venture capital funds, in particular²⁴ 'flow through' taxation treatment for Venture Capital Limited Partnerships (VCLPs) and exemption from tax on profits on the disposal of investments in eligible investee companies for foreign investors who are tax exempt residents of specific jurisdictions or partners in eligible VCLPs.
- proposed alterations to tax regulations affecting the professional managers of VC funds, lowering their taxes on what are essentially performance bonuses.²⁵

The Australian Venture Capital Association Limited (AVCAL) is also urging reform of tax laws relating to

employee share ownership plans.²⁶

Currently, employee share options are taxed when they are issued or exercised, rather than when they are sold. They are also subject to rates of tax payable on ordinary remuneration, rather than lower capital gains tax rates. AVCAL argues that the current tax structure is an impediment to Australian biotechnology companies attracting and retaining the best and brightest employees.

BRANCHING OUT: THE EXPANSION PHASE

As discussed, there is a general perception that Australian biotechnology companies generate world-class research but fail to compete internationally because of a lack of funding and/or commercial nous. In recent times, biotechnology companies have been forced to go to IPO for cash flow in order to survive, rather than using funds raised through IPO for strategic, mid- to long-term growth.²⁷

This problem is compounded by the trend in Australia for share prices to be buoyed by newsflow.²¹ Thus public companies must make frequent announcements to sustain public interest in their shares. For companies that have listed at a premature stage, this is problematic because they do not have a strong product pipeline in place and are not generating significant sales. This forces them to make announcements on trivial matters,²¹ if at all. Public interest wanes, along with the company's share price. This has been the traditional path for biotechnology companies on the ASX and has even resulted in some companies choosing not to list on the ASX because of the danger of being tarred with the same brush.

The demands of public life (listing, reporting requirements, public scrutiny) are an additional drain on resources that immature biotechnology companies can ill afford.

Dollars and sense: the value of the VC experience

Our advice to early-stage biotechnology companies is that they should look to

Public companies must make frequent announcements to sustain public interest in their share price; this is problematic for companies that do not yet have a strong product pipeline or significant sales

Early-stage biotechnology companies should look to VC as a preferable source of funding to listing on the ASX

venture capitalists as a preferable source of funding to listing on the ASX. While access to VC funds has often been difficult for Australian biotechnology companies in the past, the maturing biotechnology venture capital market in Australia may improve the availability of VC funds in the future. Venture capital investment in the Australian health/bioscience sector increased from AUD\$26.54m in 1996/1997 to AUD\$116.14m in 2000/2001.¹¹ This reflects a similar increase in VC investment in the region. Asian VC investment into the biotechnology sector has increased from US\$30m in 2000 to US\$106m in 2001. In the first quarter of 2002, US\$61.2m was invested, representing a doubling of VC investment into the biotechnology sector on the previous year's figures if investment continues at the same rate.²⁸

We note, however, that economic confidence among Australian and New Zealand venture capitalists has fallen since the first quarter of 2002, when it was relatively high compared with investor confidence in the USA and UK.¹⁴ By the third quarter of 2002, only 3 per cent of venture capitalists in Australia and New Zealand expected the economic climate to improve over the six months to March 2003. This has been reflected by transaction volumes being much lower than market expectations. In light of global market turbulence and political tensions, there is still much uncertainty among private equity investors in Australia and New Zealand, with 53 per cent expecting deal volumes to improve in the six months to March 2003 (from a very low base), and 47 per cent expecting deal volumes to decrease.²⁹ This is similar to the UK private equity market, where 55 per cent of venture capitalists expect the environment to become more challenging for raising new funds.²⁹

Despite the currently downbeat private equity market, we advocate dealing with venture capitalists as an important – even essential – pre-float step, because they bring experience,

connections and management rigour to biotechnology companies. Venture capitalists in high-technology companies are actively involved in monitoring business performance and prosperity – a role they have adopted because of the high-risk nature of such investments and the length of time before returns may be realised.³⁰

Typically, venture capitalists involved in high-technology ventures employ detailed monitoring mechanisms involving the following:³⁰

- **Extensive shareholder contracts**

Typically, venture capitalists hold a control block of shares and exercise a broad range of governance roles. A shareholders' contract sets out the relationship between the venture capitalist and the VC-backed company and may be contingent on specified financial or non-financial performance, actions, dividend payments or future security offerings. As such, shareholder contracts provide a mechanism for venture capitalist monitoring of a funded company.

- **Differentiated shareholder rights**

The ability of venture capitalists to monitor business performance will depend on specific shareholder rights. By differentiating voting rights from cash flow rights during the lifespan of venture-backed companies, venture capitalists have developed a mechanism for monitoring business performance. This difference may be achieved through unvested stock options, non-voting stock or explicit contractual rights to exercise votes depending on specific targets. The rights (voting or cash flow) may be contingent on performance-related incentives or time-based milestones. The voting rights of venture capitalists increase when a VC-backed company is underperforming or as the venture proceeds and needs additional financing. Conversely, venture capitalist control of voting rights

Dealing with venture capitalists is an important pre-float step, because they bring management rigour and experience to biotechnology companies

decreases when management performance and stock vesting milestones are met. Cash flow rights may also increase as company performance improves.

- **Board membership**

In the USA, venture capitalists hold the majority of board seats in 25 per cent of cases.³¹ In Australia, venture capitalist dominance of boards is rare, but VC representation on boards is a well-recognised means of monitoring business performance and retaining some control over investments.

- **Relationships with management**

Strong relationships and regular interaction with management are another means by which venture capitalists can monitor a business. Reports of the total number of hours (including site visits) devoted by venture capitalists to VC-backed companies range from 79 in France, through to 154 in the UK and 194 in the USA.³² The length of time increases with industry experience of the venture capitalist and the growth path of the funded companies, but is not related to the size of shares owned by the venture capitalist or underperformance by the funded company.³²

In Australia and New Zealand, venture firms may opt to co-invest with other venture firms as a means of spreading risk while maximising financial support to companies.¹¹ Dealing with private equity investors, particularly in co-investment situations, is invaluable experience for biotechnology companies in preparing for an IPO. This experience assists biotechs to come to terms with accountability regimens, public scrutiny (albeit on a smaller scale) and rigorous reporting requirements. The VC will often drive the company to IPO as a means of realising its investment and potentially receiving very high returns on its original investment.³³

Venture firms may opt to co-invest as a means of spreading risk while maximising financial support

Experience with VC firms assists biotechnology companies to come to terms with accountability regimens, public scrutiny and rigorous reporting requirements

Various incentives are being touted to increase local and international VC funding of the Australian biotechnology sector

CONCLUSIONS

There are many issues to consider when commercialising a biotechnological innovation. In Australia, because of market structure, the tendency for biotechnology companies to list early in their life cycles has caused problems. A fledgling venture capital market in Australia has been partly to blame.

In the last few years, Australia has witnessed a growing number of VC firms specialising in the bioscience/health industry (from none to nine in two years).¹¹ These firms understand the nature of investment into the biotechnology sector, including the long-term nature of investments. VC firms also indicate a willingness to 'co-invest' in biotechnology companies – this reflects the high level of risk associated with investing in the sector, but also provides biotechnology companies a valuable opportunity to learn about accountability regimens, public scrutiny, dealing with the needs of different investors and rigorous reporting requirements.

Various incentives are being touted to increase local and international venture capital funding of the Australian biotechnology sector. Coupled with maturation of the local venture capital market, these incentives should result in increased early private equity support of the biotechnology sector and, in turn, improved performance of listed Australian biotechnology companies. Industry and local institutions (such as the ASX and the Government) are also working to overcome some of the financial difficulties being faced by biotechnology companies.

The lessons for biotechnology companies is not to be lured into listing too early in their product development, but instead to focus on other sources of funding, such as private equity and government grants. While VC funding for biotechnology companies has been scarce in the past, the outlook in Australia and New Zealand is now much more favourable, even in the face of global market turbulence. Biotechnology

companies seeking private equity should approach firms specialising in the sector, and be open to the possibility of co-investment by two or more VC firms.

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