

**COMMERCIALISING UNIVERSITY RESEARCH: THE CASE OF
KINACIA PTY LTD**

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ABSTRACT

The research presented in this paper is part of a broader study examining the development trajectories of early stage technology-based companies. The aim is to understand the contribution of various organisational and strategic factors to the success and failure of such companies. A particular focus is the role of investors in guiding the development of firms in which they invest and serve as board members, and the extent to which such guidance differs between different types of investors. A related consideration is the various institutional arrangements that may influence the interaction between such start-up companies and investor directors.

This paper presents a case history of Kinacia Pty Ltd, a company established to commercialise several scientific discoveries made at Monash University's Australian Centre for Blood Diseases. The paper examines the history of the company from its establishment in 1997 through to early 2002, at which time events took place that led to a strategic shift in the company's direction.

A separate analysis of the company's later years, leading to a merger with Cerylid Biosciences, and the eventual sale of the technology to Astra Zeneca in 2007 is currently under development.

Some of the key issues examined in this paper include:

- the impact of the organisations structure on the key relationships within the team;
- the advantages and disadvantages of outsourcing key research activities;
- the role of incentive structures;
- the way that certain government policies in the area of research commercialisation can interact in an unexpected way to produce outcomes other than those intended;
- fund raising strategy; and
- board structure and the significance of operational experience in the industry sector.

INTRODUCTION

Over the past two decades, Australia's higher education sector has undergone a dramatic transformation. Since the Dawkins reforms of the late 1980s, policy in the sector has been in an almost continuous state of flux, as have the broader policies related to funding of academic research.

Increasingly, Universities are expected to make an active contribution to the development of Australia's economic and technological base, with development and transfer of technology being seen as one of a University's key functions. (Slaughter & Rhoades, 1990; Dooris, 1989). Lockett and Wright (2005) commented on the "...increasing focus on universities' ability to become more adept at exploiting their own science base and transferring [it] to the private sector" while Hindle and Yencken (2004) posit that

It is uncontroversial that research commercialisation, entrepreneurship and technological innovation are closely linked phenomena that are vital to the creation and maintenance of national wealth.

Both the Commonwealth and state governments have made major efforts to support research commercialisation, and that Universities have endeavoured to enhance their capacities in this area with the ultimate aim of "...reaping the benefits from research by transforming knowledge and technology into commercially useable forms..." (Harman and Harman, 2004)

A key behavioural driver in this area is that commercialisation – through industry partnerships and the sale (or licensing) of intellectual property developed through academic research – holds out the promise of supplementing increasingly scarce sources of public research funding. Government efforts to grow the magnitude of industry involvement in funding of academic research are widespread (OECD, 1981). In Australia, securing such funding is an explicit policy objective, with a task force established by the Minister for Science and Technology to examine research commercialisation in Australia (Block, 1991), recommending that:

By the end of 1996, each higher education institution should be required to find an amount equivalent to 5 percent of its total Commonwealth funding for research from industry. In addition, at least 10 percent of Australian Research Council expenditure and 10 percent of National Health and Medical Research Council expenditure should be set aside for projects that have demonstrated commercial commitments by industry.

These efforts have been quite successful, with the \$280.3 million attracted by universities from industry in 1999 representing 14.5% annual growth over the 1992 figure of \$108.6 million (AVCC, 2001). Much of this funding though represents industry payments for research undertaken by Universities under contract, rather than gains from commercialisation of academic research per se. Harman (2002) found that only 20.5% of researchers reported that their research had resulted in "...a product or service that is being marketed." When only the industry-funded projects were considered, the figure rose to 36% (p.153) ... still quite low when one considers that in many such cases, a marketable product or service would have been a direct objective of the research.

Traditionally the most common technology transfer mechanism used by universities has been licensing (Siegel et al, 2003). This mechanism minimises the investment of researcher and managerial time and effort into commercialisation activities, and provides a built-in risk management mechanism. Increasingly however, licensing arrangements are seen as not allowing the University to capture the full value of their intellectual property.

Creation of spin-out companies is seen as an increasingly important mechanism of commercialising technologies emerging from academic research (Pries and Guild, 2007). There is a perception that this mechanism allows external funding to be secured at an earlier stage of the technology's development, and that equity ownership in a spin-out venture increases the potential up-side gains (Bray & Lee, 2000). Notably though, a UK Treasury review of business-university collaborations suggested that most university spin-outs do not create substantial value, and that too many such spin-outs were being created (Lambert, 2003). As well, access to sufficient capital to sustain effective operations is a key consideration, and Wright (2003) reported that lack of access to venture capital is a key constraint on the development of spin-out companies in the UK.

One key factor that may influence the success rate of spin-out ventures is the availability of relevant skills and experience – both at the University's commercialisation offices and within the new venture's management team. It is recognised that ventures seeking venture capital funding typically need to be in a suitably "pre-prepared" state, lowering the investment evaluation costs for the venture capital firm (Zacharakis et al, 1999). Packaging spin-out firms for venture capital investment

requires specialised skills, as does the subsequent management of the venture's development and growth. Lockett et al (2005) report on findings that the lack of investor readiness of spin off companies is a frequent complaint of venture capitalists, and suggest that research institutions may need to recruit commercialisation staff with direct personal experience of starting a business.

Much more research is needed to develop a better understanding of the factors that contribute to successful efforts to commercialise new technologies – whether through spin outs or other mechanisms. In particular, there is a need to examine specific commercialisation initiatives – both successful and unsuccessful. Such an analysis may help to identify systematic differences in how these initiatives were launched and pursued that could guide further research in the area.

METHODOLOGY

The research presented in this paper is part of a broader study examining the development trajectories of early stage technology-based companies. The aim is to understand the contribution of various organisational and strategic factors to the success and failure of such companies. A particular focus is the role of investors in guiding the development of firms in which they invest and serve as board members, and the extent to which such guidance differs between different types of investors. A related consideration is the various institutional arrangements that may influence the interaction between such start-up companies and investor directors.

The current stage of the research project is exploratory, and aims to produce detailed case histories of a diverse set of emerging technology companies, with the aim of identifying through observation particular regularities and patterns that may serve as the focus of later analysis.

This approach reflects Christensen (2002), as well as Yin (1994) who notes that

...case studies are the preferred strategy when 'how' or 'why' questions are being posed, when the investigator has little control over events, and when the focus is on a contemporary phenomenon within some real life context.

Though it is recognised that case study research is subject to selection and observation biases, the case study method offers an effective mechanism for detailing and highlighting influential factors in complex situations. It can thus serve as a key source of insight for the development of hypotheses, with case studies being particularly useful in the identification of issues for further investigation (Benbasat, 1987).

This paper presents in-depth case history of one particular venture: Kinacia Pty Ltd, a university spin-out company. While the authors recognise that comparison of multiple cases is needed to develop generalized results (Benbasat, 1987), in context of developing and testing a framework model, key insights can emerge from examination of a single case.

To control for recollection bias, interviews were conducted with multiple protagonists, specifically:

Name	Position/Role	Duration of Interview (hr:min) ¹
Dr. Ergad Gold	Director (representing Momentum)	1:50
Mr. Stephen Robinson	Director (representing ATG)	1:00
Prof. Shaun Jackson	Founding Scientist	1:40
Prof. Hatem Salem	Founding Scientist	1:30
Dr. Alan Robertson	Head of Chemistry	1:00
Dr. Elane Zelcer	CEO	1:30
Dr. Ross Murdoch	CSO and later CEO	0:40
Mr. Ron Finkel	Director (representing Momentum)	1:00
Mr. Robert Moses	Chairman (Independent)	0:50

All interviews were recorded. The comments made by each interviewee were contrasted with those of the others and with any available contemporaneous documents to develop a synthesis perspective on the key events in the company's history. Where, a synthesis was not possible because different recollections were irreconcilable, the case presents and highlights the different perspectives. All of the interview subjects were given the opportunity to review the draft document, and the final text reflects the various resulting comments and corrections.

¹ Approximate – to nearest 10 minutes; initial interview only – does not include time of later discussions ensuing from comments on various drafts or need for clarification.

CASE REVIEW

Kinacia was a Victorian biotechnology company, established to commercialise a set of discoveries emerging from research into blood clotting and thrombosis conducted at Monash University's Australian Centre for Blood Diseases (ACBD). The case examines the initial stages of the venture's history, from 1995 through early 2002 when a number of strategic changes in the leadership and direction of the company took place.

THE BEGINNING

In 1995 Dr. Shaun Jackson was a National Health and Medical Research Council (NHMRC) Fellow at the Australian Centre for Blood Diseases, leading ACBD's research into blood clotting. ACBD had been established at Melbourne's Box Hill Hospital by Prof. Hatem Salem, Professor of Medicine at Monash University. ACBD's research focused on blood diseases such as lymphoma, leukaemia and myeloma, and on developing a better understanding of the clotting process.

Clotting is an essential part of the wound healing process: it stops bleeding to allow damaged vessels to be repaired. Sometimes though, clots form within functioning blood vessels, blocking circulation in those vessels. On occasion, such clots (then known as "thrombi") can block blood flow to vital organs – causing heart attacks and stroke.

Jackson's research indicated that a particular molecule played a critical role in the clotting process, and if a way to "inhibit" (block the function of) that molecule was found, it could be developed into a therapeutic product – a "drug" that could prevent the formation of such clots. Jackson and Salem were endeavouring to identify and isolate the molecule, in order to develop such an inhibitor (which they designated "PCAP").

Although the research had been progressing well, and Jackson had succeeded in purifying a small quantity of the target molecule, funding was typically difficult to obtain and fundraising took up much of the team's time and efforts. Jackson recalls that in 1995, upon receiving a substantial grant from the National Heart Foundation, the team was advised that their work had progressed to the point where it would be considered commercial, and that they should thus patent their discovery and pursue industry funding. To the researchers, this represented a key opportunity to progress their research. Salem recounts his perspective

...we had our funding from the university, from NHMRC ... this was another source of funding that may allow us to realise our dreams...

Like most Australian Universities at the time, Monash University was actively seeking to build closer links to industry, and had established a subsidiary company, Montech Pty Ltd, to manage the University's commercial activities and industry relationships. Montech's commercialisation activities were led by Dr. Elane Zelcer, the acting CEO. Having been approached by Jackson and Salem for advice on accessing industry funding, Zelcer began to investigate market opportunities for the PCAP technology.

Zelcer's initial plan was to establish an R&D syndicate, taking advantage of the then prevailing taxation legislation. Promoted by the government as a way to encourage investment in R&D, such structures enabled investors in early stage technology to realise significant tax credits on their investment.

However, the market's sentiment towards such arrangements had shifted and the team was unable to find the right partners. Salem's recollection is that

...we did a lot of visits, lots of people; I think there was a couple from Korea, from Japan, from wherever. We sat down and talked to them about what we had and – we never got any money.

By 1997, the main prospect for investment in the technology was The Australian Technology Group (ATG), a government-funded venture fund focused on early stage Australian technology companies. ATG's "life-sciences" investments were led by Dr. George Jessup, a medical doctor with operational experience in the US life-sciences sector, and Steve Robinson, a chartered accountant.

Although ATG was interested in the technology, the fund's operational model was to take equity positions in independent ventures. To secure ATG's investment, Zelcer suggested establishing a spin-off company that would own the intellectual property associated with the technology. ATG would then invest in that company. Salem and Jackson agreed, taking the view that in commercial

matters they should defer to the expertise and experience of Montech and ATG. Salem recounts the team's lack of familiarity with the commercial sector

... we people in medical research ... too engrossed in what you do ... don't think about companies; don't think about the commercial world ... just focus on the medicine and treating people ... level of understanding of commercialisation and the realities thereof is very limited... "

Thrombogenix Pty Ltd commenced operations in July 1997, and Dr. David Beames, one of Australia's most experienced biotechnology executives, was recruited to serve as the founding CEO.

ATG committed to invest \$1.2 million at a \$1.5 million pre-money valuation, with the money to be paid in instalments subject to the research team meeting an agreed set of milestones. The resulting capital structure (fully diluted for the three tranches) left ATG with 40% of the equity, with Jackson and Salem holding 6.6% each² and 10% set aside for an ESOP.

The company's board comprised Beames (as CEO), Robinson (representing ATG), Zelcer (representing Monash), and Salem. Jackson, though not a director, attended most board meetings – as an observer and as Salem's alternative.

The initial plan was to have a "virtual" company – Beames would manage a research contract with Monash, whereby Jackson and Salem would conduct the research on PCAP at the ACBDs lab as Monash employees. The aim was to leverage the \$1 million investment by taking advantage of ACBD's infrastructure and the other resources.

However, there was an almost immediate diversion from this plan. Rather than a contracting with Monash for a "research project", Thrombogenix hired Jackson and Salem directly as consultants.³ The work was still to be conducted at ACBD's labs, thus maximising the amount of time Jackson and Salem could devote to the project and enabling them to draw upon the skills and expertise of other staff at the lab as necessary. Thrombogenix would meet all direct costs of the research (such as lab consumables and any consulting fees charged by the ACBD researchers).

As well, within a few months Beames resigned from the CEO position to focus on his full-time role as CEO of Virax (another early stage biotechnology company), though he remained a non-executive director. Zelcer took up the CEO role, resigning from Montech and giving up the board seat she held as Monash's representative. Unable to get an office at the ACBD, she worked from a private office she secured nearby.

These arrangements meant that the CEO (Zelcer) was effectively isolated from the venture's day-to-day operations and decision making. As new researchers joined the project, they too were based at ACBD, growing the gap between Zelcer and the rest of the team. The CEO role thus became primarily a supporting one, emphasising fund raising and financial management, as well as any other activities not directly related to research. Further, with increasing numbers of staff working for both Thrombogenix and ACBD, the distinction between ABCD and the company became blurred.

Initially, progress was good, with a good relationship developing between the ACBD team, the board, and Zelcer. Zelcer successfully applied for a \$1 million grant from AusIndustry's *R&D Start* program, which provided matching funding for commercialisation activities, validating the decision to seek industry financing. Salem recalled his surprise at the ease of obtaining funds in the commercial sector: "...put in an application as skimpy as can be and get a million dollars".

By mid -1998 however, having spent almost \$2 million (\$1 million of ATG's original investment as well as the *R&D Start* grant proceeds) the research team had been unable to isolate sufficient quantities of the PCAP molecule to determine its structure and thus develop an inhibitor. There was an emerging consensus that the prospects of achieving a successful outcome with the available funds were poor, and that the company's future was in doubt.⁴

² Monash's policy was to award researchers who create IP that becomes commercialized a share of any value realized by the University.

³ Monash's policy allowed academic staff to spend up to one day per week on private consulting work.

⁴ Jackson notes that the PCAP puzzle was finally solved in 2006 by researchers at the Cleveland Clinic, who successfully identified and described a new class of lipids in the bloodstream. These lipids, which significantly increase the risk of blood clotting, and the elusive PCAP appears to be one of these lipids. See: Jackson SP & Calkin AC (2007), *The clot thickens—oxidized lipids and thrombosis*, *Nature Medicine* 13:1015-1016.

A decision was made to refocus. Thrombogenix had a “*right of first refusal*” to invest in any other technologies that may be developed at ACBD, and a different, NHMRC funded research project at the lab appeared to have commercial potential. The key insight related the role in clotting of a particular class of molecules – the *PI3 Kinase*.

A NEW DIRECTION: THE PI3 KINASE INHIBITOR

The blood clotting process, which is an essential part of the wound healing process, functions by activating *platelets*, specialised cell fragments circulating in the blood. When activated, platelets begin to adhere to each other, forming a solid aggregate (or clot). This clot is then strengthened by the action of various complex proteins, and serves as a “plug” at the injury site, stopping blood flow to allow the damaged blood vessel to be repaired. If the blood fails to clot properly, bleeding can continue indefinitely, causing extensive blood loss or internal bleeding.

Although clotting is necessary for injury repair, it can have adverse consequences. Clots can form inside important blood vessels (a condition called *thrombosis*), and can then block blood flow to essential organs such as the heart, brain, or lungs. In some cases, such blockages cause damage to the organ – and such damage can lead to death.

Thrombosis is a significant risk for some people, particularly the growing proportion of the population suffering from high blood pressure. Anti-thrombotic drugs such as *Aspirin* or *Warfarin* reduce the risk by weakening the clotting mechanism, but have the unfortunate side effect of increasing the risk of internal bleeding.

Jackson had discovered that clotting in turbulent flow conditions – when blood is under pressure inside a constricted blood vessel – involved a different process than when clotting took place at wound sites. He also found evidence that a particular protein, the *PI3 Kinase*, was necessary for the first process *but not for the second*.

This discovery suggested the possibility of creating a drug which inhibited (blocked) the function of the *PI3 Kinase*. Such a drug would significantly reduce the risk of thrombosis without increasing the risk of uncontrolled bleeding (or haemorrhage).

The commercial potential of such a drug was clear – and substantial. Annual sales of anti-clotting drugs were in billions of dollars, and a safer drug would likely capture a substantial proportion of that market.

A new agreement was negotiated with Monash University, giving Thrombogenix the rights to develop and commercialise *PI3 Kinase* inhibitors in exchange for a royalty on final sales. Notably, the terms did not provide for any up-front payment for the IP, nor were any additional shares in the company to be issued to either Monash or the inventors. The inventors (Jackson and Salem) would however be entitled to a share of any royalty payments received by Monash (once again, in keeping with Monash’s policy in this area).

This arrangement offered certain advantages to all the parties. For Monash and the inventors, the royalty model protected their interest from dilution in the course of subsequent investments. For ATG and the other existing shareholders, it injected new value into the Thrombogenix corporate shell.

With the licensing agreement in place by early 1999 Zelcer, with the board’s support, began a new round of fund raising– seeking \$3 million to further develop the new technologies. As well as the three venture capital funds recognised as the market’s most active early-stage investors – Macquarie Bank’s Technology Fund, Rothschild Bioscience Managers (now GBS Venture Partners), and JAFCO (now Starfish Ventures) – Zelcer approached a variety of other prospects. One of these was Ron Finkel, a former Advent executive who was in the process of setting up a new AU\$30 million venture capital fund – Momentum Ventures.

Momentum liked the opportunity, but was concerned that the venture team lacked the skills needed to transform the innovative discovery into a commercially viable drug. They were willing to invest, but only on the condition that the funds be used to bolster the medicinal chemistry team, and that “...*pharmaceutical industry expertise be introduced to the board.*” This was agreed, and Mr. Bob Moses, a senior CSL executive was recruited as independent chairman.

Macquarie and Momentum jointly led a \$3 million, Series “A” investment round. ATG also participated, investing the residual of the funds they had committed in the initial round, but that had not yet been expended. The “A” round investors (including ATG) received preferred shares

representing 47.2% of the firm's equity. The ESOP was replenished to 10% (including the 4.5% that had already been issued), and Jackson and Salem were diluted to 3.2% each.

The new investors also received the right to appoint two directors, and so as well as Bob Moses, Dr. Ergad Gold (representing Momentum) and Dr. Kathy Kociuba (representing Macquarie) joined the board.

The focus now became development of lead compounds for the desired drug – a PI3 Kinase inhibitor. In keeping with the terms of the investment, the company recruited a “medicinal chemistry” team. The chemistry team was led by Dr. Alan Robertson (working part-time as a consultant), and comprised three full-time chemists and several research assistants. The research work continued to be carried on at ACBD's facilities.

The research progressed well, with a novel inhibitor for the PI3 Kinase synthesised within six months. Other compounds with enhanced properties followed in rapid succession, and the company had begun to develop a strong IP position, filing the first in a series of patents.

In partnership with Melbourne University's department of Pharmacology, one lead compound was trialled “in-vivo” (on animals), with encouraging results. Although this compound was not suitable for human use, other compounds were progressing through the research pipeline and there was an expectation of a viable product.

Yet here again, the venture's ambiguous structure was laying the seeds for a future problem. The chemistry team that develop the compounds was employed by the company – which provided their main income. However, the biology work was done by ACBD staff, who drew a University salary while providing consulting services to Thrombogenix on a part-time basis. Consequently, they were less dependent on the company's success. Further, as University staff they could participate in the royalty stream due to the University, while the chemists would not. For several members of the chemistry team, the unequal financial position was a key source of frustration.

Jackson and Salem reject the suggestion of a conflict. Jackson's perspective is that “...*Kinacia was our blood sweat and tears ... we were passionate about it...*”, and Salem likewise recalls

... we looked after this company. We treated it like our baby. Not because we were hoping we were going to make money then, but we saw this as a fantastic opportunity to fund our research.

At this time, early 2000, the capital markets were buoyant and a decision was made to proceed to a new “Series B” round of financing. The venture had made substantial progress, and the investors wanted to get a significant step-up in valuation to reflect the achievements to date. Macquarie Bank was retained to manage a \$7 million (of which the existing investors committed to take up \$1 million). The valuation for the new round was set at a \$24 million (pre-money), representing a 220% appreciation in the value of Thrombogenix in less than two years.

There was strong interest and Macquarie rapidly secured commitments of some \$3 million from “high net worth” clients and funds managed by Macquarie. There was a need for a “cornerstone” investor who would commit the remaining \$3 million, and there was a view amongst the board that an investment from Rothschild, the largest biotechnology focused investment fund in Australia, would significantly enhance the company's credibility. Rothschild agreed to invest the \$3 million, although Jackson recalls that the investment was conditioned on some additional terms “...*a whole series of conditions, anti-dilutes and the like...*”. Momentum was also able to secure an additional \$250K from various private investors, and the round closed with \$7.2 million of new capital.

FROM A RESEARCH VENTURE TO A BUSINESS ENTERPRISE

With the closing of the \$7 million Series B investment round, Zelcer and some of the directors sought to transform Thrombogenix from a “research project” into a business enterprise – putting in place formal planning and reporting mechanisms.

As a research venture oriented towards developing a credible lead compound, the scientific leadership team of Jackson, Robertson, and Salem had substantial autonomy and decision-making authority – though formally only consultants to the venture. With the focus of Thrombogenix's activities being at the ACBD labs, Zelcer's CEO role was increasingly seen as oriented towards supporting the decisions of the research team. Robertson, who was the head of medicinal chemistry, recalls that most of the critical decisions for the venture were being made in regular Thursday morning meetings held at the ACBD labs.

Now, as the company was moving towards clinical trials, there was an expectation of a shift towards a more formal operating structure. One of the directors described his expectations of the change

... until we discover a lead it's chemistry ... it's not drug development, it's not business development ... [once we had a lead] it became a drug development program, different skills involved and the company grows up, it changes.

With shift in focus from conducting research to managing a development program, Zelcer (with the support of some of the directors) sought to formalise some aspects of the venture's operations: putting in place detailed project plans and more clearly delineating the company's activities from those of ACBD. The clear objective was to enable Thrombogenix to be spun-out from ACBD's facilities.

Her efforts encountered opposition from the scientific team. One of the directors, Ergad Gold, recalls significant friction around Zelcer's efforts to impose tighter financial controls and project timelines.

To some extent there was a conflict of world views. Zelcer (with the support of some of the Directors) was sought to emphasise the "development" aspects of "R&D". In this respect she wanted to instil a "business" culture of reporting relationships and clear accountabilities, and to bring predictability to what was seen by some as a disorganised process by ensuring that detailed project plans were developed and followed.

The scientists came from an environment of significant autonomy, and believed that Zelcer's efforts to lock them into what they perceived as relatively deterministic plans were unrealistic. They believed in following their research where it takes them, making spontaneous changes to project plans with a confident expectation that value would eventually emerge. In Salem's words

... medical research is not always a straight forward game ... you really don't know what's around the corner, you are walking in the dark ... you don't really know what's going to crop up. ... this is never predictable ... there'll be bumps on the way, but at the end of the day you will come up with some goods if you have a good team. And it might well be that you start heading in this direction you find yourself actually going there...

Contributing to the conflict may have been what appears to be a difference in "preference for closure" between the business people and the scientists. The scientists, clearly saw their role as being to improve the technology, and were comfortable with open ended plans – knowing that each day could yield a valuable insight. The business people however wanted a clear point at which they could transition to the next stage of development. To them, the "moving feast" (in the words of several) of ever better options was not a positive, but rather something that interfered with reaching a tangible outcome that would be valued by the financial markets.

Further, Jackson and Salem believed that the efforts to separate Thrombogenix and ACBD were fundamentally misguided. Jackson pointed out that the company lacked the financial and personnel resources to replicate the infrastructure and expertise available at ACBD. Most of the biology team were ACBD employees, who were not willing to leave their academic posts to move to Thrombogenix.

He also noted that at ACBD the company had

...a highly focused world class medicinal chemistry team led by Alan Robertson ... these individuals had a wealth of industry and drug development experience. This contrasted with the board, whose members had limited clinical or drug development expertise in the anti-clotting area...

Jackson also noted that throughout, board members had played an active role in the venture's decision making process, with several regularly attending the research and management meetings "...keeping a very close eye on the finances and decision making". His view was that the scientific team had the board's support because they repeatedly demonstrated that they had the better understanding of the operational needs of the company.

Others have different recollections. Moses, the Chairman at the time, recalls "... the scientists ... lobbying ... to retain decision making control ..." This view is shared by another director, who believes that the company

...had a strong-willed and empowered scientific team who didn't want to let go...didn't want us to set up any operation that was Thrombogenix and not ACBD or Monash, so any attempt to spin-out, any attempt to install layers of management, any attempt to remove them from the commercial side of things ... was met with resistance.

At the heart of the disagreement was whether the company should be making a shift from a broad research program that was yielding a portfolio of valuable discoveries, towards a focused development process that would marshal the venture's resources behind *one* technology – in an effort to transform it into a commercial product. A key consequence of such a transition would be that the company's focus would shift from conducting research, to emphasise administrative and commercial activities. Zelcer recalled

... and that started to get very uncomfortable for Shaun [Jackson] and Hatem [Salem] ... they recognised that the company was going here and their research had pushed it along ... but now their research was diverting a little bit from the company and they were more interested in the research than the company...

With successful animal trials, and the medicinal chemistry team producing new and better compounds, the investors were looking for rapid results. Jackson recalls that the board “...*putting a lot of pressure on to put something into development*”, and so after some discussion a decision was thus taken to move the best available “lead candidate”, TGX155, to the next stage. Jackson recalls that it was recognised that TGX155 was not an ideal candidate: it had poor solubility, and significant work was needed to develop a formulation that could be injected. Further, the market for anti-clotting drugs was rapidly shifting towards orally administrable formulations – the commercial prospects for an intravenous product based on TGX155 were not strong.

However, although not lucrative, a credible market for a TGX155 drug did exist, and the board believed that a successful clinical trial would serve as a “proof of concept”, underpinning a new funding round, hopefully at a higher valuation. Ultimately, this view prevailed, and TGX155 was progressed to clinical trials.

With increasing resources devoted to the clinical trials process, there was an effort to strengthen the management team. According to Jackson, some of the investors felt that Zelcer lacked the experience needed to move the company to the next level and wanted “...*more industry-credible people*”. Zelcer agrees that there was a need for someone who could “...*help the company get into the expansion phase*”. A decision was taken to hire an experienced pharmaceutical industry executive to lead clinical development and an international search firm was retained to recruit such a person.

Jackson was also encouraged to leave Monash to join Thrombogenix on a full-time basis, but declined

...they put pressure on me to join and I basically said that this wasn't in the company's best interest ... my research at Monash was receiving funding of \$1 million per year from the NHMRC ... Kinacia was benefiting greatly from this research, however it would have made no sense at all for Kinacia to be picking up that bill.

The international search identified Dr. Ross Murdoch, then Head of Global Clinical Project Management for AstraZeneca, and previously AstraZeneca's Director of Cardiovascular Therapeutics. An Australian who wanted to return to Melbourne for personal reasons, he seemed a perfect fit. In Gold's view, Murdoch “... *absolutely was the right person ... everybody really felt we'd lucked out – someone with so much experience.*”

Jackson believes that the investors “... *saw [Murdoch] more as a future replacement CEO*”, as does Zelcer who notes that “...*one of the reasons for hiring Ross ... was to train him up so that he would be able to take over ... as an interim or permanent CEO*”.

Unfortunately Murdoch's appointment was not well received by the scientific team. A key friction point emerged around the fact that Murdoch was given the title of “Chief Scientific Officer” (CSO). This was done on the advice of the recruitment firm, which indicated that this was necessary in the US Market to attract the right candidates.

The scientists however saw the CSO role as a scientific (rather than managerial or clinical) one and saw that Murdoch, whose career had been in management rather than in laboratory research, as lacking the scientific depth for the role. One of the research team described it as “...*a scientific role ... you're supposed to sit down and have great thoughts and great ideas and set strategy and direction...*” and argued that Murdoch “... *wasn't capable [of that] he didn't have the background didn't have the degrees*”. Jackson's view was that “...*Ross was not really CSO material for this, he didn't know the technology well, wasn't strong on the R&D...*”. To some, having Murdoch presented as the company's senior scientist was almost a personal affront.

Some of the scientists also felt that the board, which lacked operational experience in the pharmaceutical industry, misunderstood the nature of Murdoch's expertise. Their view was that Murdoch's roles at AstraZeneca primarily involved managing project teams, and that this role had not prepared him for the "jack-of-all-trades" nature of leading a start-up company.

The board dynamics were also evolving. Brigitte Smith had joined the board as Rothschild's representative, Dan Phillips succeeded Kathy Kociuba (who had left Macquarie), and Salem now represented Monash as well as the inventors. Zelcer attended as a non-voting observer, as did Jackson, Robertson and now Murdoch. One director recalls that in board meetings "... *there were nine or ten people around the table ... it just wasn't functioning.*"

With the change in composition, the members were also less familiar with each other's personal styles, had more varied experience and differing opinions on the best way for the company to proceed. To some extent there were also different investment horizons and exit plans, with some expecting an early IPO. Gold's recollection is that

...there was a bit of a change of climate ... what had been a very harmonious company to that point, lost a bit ... there was a lot more friction ...

By June 2001 Zelcer had become increasingly frustrated with her inability to get the board's support. After almost six years and three successfully financing rounds that secured over \$10 million (as well as \$4 million of grant funding), she left the company.

At that point some of the investors also pushed for a new chairman, recruiting Ken Windle (who had earlier in his career served as Glaxo's Head of Commercialisation) as Non-Executive Chairman. Windle was known to both Rothschild and Robertson and had their confidence.

With Zelcer's departure, there was a need for a new CEO. There was a preference for an internal candidate, with the primary prospects being Murdoch and Robertson. While the scientific team, including Salem and Jackson, backed Robertson, he was strongly opposed by some of the directors and ultimately did not actively pursue the position. Murdoch was appointed as CEO to the dismay of the scientific team, who felt that their views had not been properly considered. Jackson sees Murdoch's appointment as

... a defining moment ... there was a breakdown of trust ... the company up to that point at the board level and throughout was a fairly united group but after that there was a fair bit of distrust...

Throughout this period of management reorganisation, there was significant scientific and technical progress. A paper discussing the function of the PI3 Kinase research was accepted for publication in *Nature Medicine* (the leading academic journal in the field) and formal preclinical approval for the drug had been received. The preclinical toxicology studies and animal trials on TGX155 had been conducted for \$1.2 million by *Inveresk*, a specialised Clinical Research Organisation (CRO) based in Scotland.

The results from *Inveresk* were very positive, and there was a consensus to move to Phase I clinical trials. Although some consideration was given to continuing to work with *Inveresk*, who now had some experience with TGX155, a decision was taken to contract with an Australian CRO – Adelaide based CMAX. One factor leading to the decision to choose CMAX was the belief that working with an Australian contractor may enable the company to access some government grant funding. The scientists were also pushing for a local contractor, as this enabled them to carry out some preliminary efficacy tests in conjunction with the Phase I trials.

There was also a push by some directors to bring forward the next financing round. The original plan was to seek additional funding for Phase II trials, but the failure to institute stronger financial controls had meant that the company's cash burn rate had been higher than anticipated. As well, some believed that the positive results to date justified a substantial increase in valuation ... potentially even an IPO.

In late 2001 though, events took a negative turn: the results from the Phase I clinical trials were not positive. CMAX reported that a significant proportion of the patients in the trials (some 10-20%) were developing *phlebitis* – an inflammation of the vein at the injection site.

The scientists received the news with equanimity. The effect was reported in both the test and control groups, and thus could be seen as due to the formulation rather than to the active compound itself. The formulation used was similar to that of *Dilantin* (a similarly "high pH" anti-convulsive drug that was on the market), and the incidence of phlebitis was comparable to that reported with *Dilantin*.

They also believed that the effect was not very significant for TGX155's intended application, and in any case thought that the drug could be reformulated to reduce the incidence of the phlebitis side effect.

The investors were less sanguine. They had been expecting a successful Phase I trial to burnish the valuation for the planned Series "C" financing round. They felt that for an anti-clotting drug, *phlebitis* (which in itself can lead to thrombosis) was a much greater problem than it would be for an anticonvulsive. One investor described it as a critical failure, commenting "...we had an anti-clotting drug that caused clotting." It would be very hard to convince any potential investor to take the time to understand the technicalities.

Concerned about the potential consequences of reporting a failed clinical trial, Kinacia's board decided to suspend the trials and to try to reformulate the drug. It was here that the lack of trust between the scientists and the investors that emerged over the Murdoch appointment was making itself felt, with one investor commenting

...after that trial they should have dropped it cold ..." but "...didn't have another lead ready, so ... rather than go back to nothing they kept spending resources on something they shouldn't have.

In retrospect, the decision to suspend the trials may have been an overreaction. Gold notes that it later emerged that CMAX had no experience of conducting clinical trials with intra-venous drugs, and when Inveresk later reviewed the data they indicated that the reported results were what should have been expected. In fact, in normal cases of hospital administration of intra-venous drugs, as many as 10% of patients often develop local irritation that can often be misdiagnosed as phlebitis by inexperienced staff.

By this stage, the company had expended some \$3 million of the \$7.2 million raised in 2000. The failed clinical trial alone cost almost \$2 million. Even if it TGX155 was successfully reformulated, a new clinical trial would need more money. There was also a new compound, TGX309, that had been presented by the chemistry team. It had significant advantages over TGX155 – including higher potency and solubility, as well as the prospects of being developed into an oral formulation. More money was needed for its development.

The planned funding round was now urgent and in early 2002 a decision was made to launch a new fund raising effort. Led by Ron Finkel (who succeeded had Gold as Momentum's representative), the board opted to expand the search to international investors, and Windle, whose role was expanded to Executive Chairman, was asked to lead a \$15 million fund raising.

Unfortunately, the investment climate had changed. In the aftermath of the "Tech wreck", investors had become more conservative, and the collapsing markets presented those with money to invest with a multitude of "rock-bottom" priced opportunities. As well, with the "failed" clinical trial and rumours of conflict amongst the company's management, Thrombogenix (renamed Kinacia to avoid confusion with a Nasdaq listed company found to have the same name) was seen as a much less attractive investment opportunity.

Murdoch too was increasingly frustrated in his role as the CEO. Like Zelcer before him, he was unable to get the board to support him in disagreements with Jackson and Salem, and found that his role as CEO was seen as administrative. He recalls that in early 2002 he was explicitly directed to "...no longer to attend Board meetings or act strategically for the company". In June 2002, having spent less than a year in the CEO role, Murdoch announced his resignation to take up the COO position at Prana (another early-stage Australian biotechnology company). Murdoch remarked that he saw the inability or unwillingness of Kinacia's board to control the founding scientists as a key obstacle for the company's further development, and that one of the things that attracted him to Prana was that Prana's board was much more functional in that respect.

One of the directors at the time concurs, commenting that Murdoch

...didn't get much support because people were too worried that the scientists would go ... it was a shame ... he would have done a good job.

In Murdoch's view, the core problem at Thrombogenix/Kinacia was that some of the company's directors "...lacked the vision of building a business..." and believed that "...the founders were the company's most important asset ... the commodity they had invested in ...". In his view, these directors

...had an overriding belief on how investors should act, and acted almost exclusively as investors ... looking to minimise investment and spending and make the exit ... as rapid as possible.

Windle succeeded Murdoch as the CEO, formally taking up the position in July 2002. With the company's financial position now seen as a key concern, Windle's focus became securing the necessary funding, with research operations scaled down to conserve cash.⁵

OBSERVATIONS AND INSIGHTS

This paper presents some early results from an ongoing research project, and the analysis and insights presented here are only preliminary. Nevertheless, to the extent that Kinacia can be seen as a representative example of technology commercialisation initiatives at Australian, the history of the company's establishment and development (as presented here) provides some valuable insights and raises intriguing questions.

GOVERNMENT POLICIES RELATED TO FUNDING OF RESEARCH AND COMMERCIALISATION ACTIVITIES

Perhaps of most immediate note is the extent to which the company's very existence can be seen as the outcome of the unintended interaction of a set of separate government policies related to research commercialisation.

As discussed in the case, the initial decision to pursue investment from industry was prompted by the challenges Jackson and Salem encountered in accessing the more traditional sources of public research funding to continue the PCAP project. In practice though, almost the entire \$2 million spent by Thrombogenix prior to the "A" Series investment round was public funding – specifically:

- \$1 million from ATG, a government funded investment vehicle created to support commercialisation of Australian technologies – “...provide seed and start-up capital for technology commercialisation” (Howard, 1997)
- \$1 million grant from AusIndustry's *R&D Start* program, which was established to promote private sector R&D investment by providing matching funds for such investment

The policy objective underlying the creation of these funding mechanisms was clearly to support “technology transfer” – facilitating the transition of innovative new technologies into the commercial market. In this case though, the funds were apparently deployed as an alternative source of funds for primary research. The lack of a technology that could be described as “commercial ready” is clearly evidenced in the fact that two years later, having expended the \$2 million, Thrombogenix/Kinacia was unable to demonstrate even a prototype of PCAP.

The issue that emerges is that extensive promotion by government and Universities of “commercialisation” may, by creating unrealistic expectations, leading researchers to pursue industry funding for their work before it is “commercial ready”. This in turn may be leading to adverse outcomes, by encumbering the research effort with significant costs (including the need to put in place complex legal and governance structures), and alienating any resulting IP.

The pathway from a discovery emerging from basic scientific research to a commercially viable application has a number of different stages. Basic research, oriented toward the *discovery*, typically yields new *knowledge*. For that knowledge to be deployed into the community in the form of a commercially viable, innovative application, significant applied research is necessary. In Australia, while public funding is available for basic research, and numerous individuals and organisations are actively searching for viable technologies that can be deployed into the market, a funding and capability gap lies between these two stages. This is particularly the case in the area of biotechnology, where there is broad recognition that laboratory (*in vitro*) discoveries often do not successfully translate into viable technologies.

While significant policy effort has focused on bridging this gap, there appears to be a failure to recognise that *scientific knowledge*, *technological capability*, and *innovation* are fundamentally

⁵ Ultimately, Windle was not able to secure the necessary investment for Kinacia, and in June 2004 the company merged with Cerylid Biosciences, another early stage biotechnology company. The combined entity also proved unviable, and ceased operations in 2005. A separate case study discussing the period between Windle's appointment and the eventual sale of the technology to Astra Zeneca in 2007 is currently under development.

different, and that the creation of each requires deployment of a distinct set activities, resources and capabilities (Morita 1992; Burshtein, Gillin, Kaseko 2005). The existing mechanisms, which typically aim to encourage an early transition into the commercial markets, appear to disregard this distinction, and thus may tend to encourage inappropriate structures and behaviour.

GOVERNANCE MECHANISMS

Also of note is the process that led to the company's initial creation, and the mechanisms through which it was subsequently managed and governed. Particularly notable is the role played by the venture capitalists, both as investors and in their capacities as board members.

Unlike traditional business ventures which are typically established to serve an identified market need, the key incentive behind the creation of Thrombogenix (Kinacia) was to secure funding for a scientific research project by selling the rights to any intellectual property that may result from that project. This arrangement had significant implications for the company's structure and decision making processes.

In particular:

- From the very beginning, the company was seen as simply a shell that would channel money to the research team. The planned "virtual" model with Beames as a part-time CEO, may have been efficient in the sense of minimising overhead expenses, but also downgraded the significance (and authority) of the CEO's role and blurred the distinction between the roles of the CEO that of the Board. Individual board members were actively involved in operational decisions, on occasion overruling the person in the CEO position.
- With technology development seen as the company's *raison d'être*, substantial decision authority was delegated to the senior researchers (as the people with the greatest technical expertise). No significant investment was made in building a credible management team with relevant commercial experience in the field. Over time, having led company's core activities, the research team established a high level of credibility with several of the board members, and was thus able to take on increasingly more authority within the company (leading to the departure in rapid succession of two CEOs and a Chairman).

A related issue is one of locus of activity. With the primary focus of the company's activities being the ACBD facilities (which were controlled by Salem and Jackson), Zelcer and Murdoch lacked a forum in which they could authoritatively raise issues they considered important for company's development. This too contributed to the diminution of the Zelcer's and Murdoch's authority and credibility in the company.

RELEVANT EXPERIENCE

Notably, throughout the period of Kinacia's history presented in this case, not a single member of the firm's board or senior management team had any operational management experience in an early stage pharmaceutical company. Some of the directors (Beames and Moses, and eventually Murdoch) had management experience in the life-sciences sector, such experience was mostly in large enterprises, and did not encompass the particular challenges and issues that needed to be navigated by Kinacia.

Consequently, when decisions that later turned out to be critical for the company's survival needed to be made, none of the people involved in making these decisions was able to bring directly relevant experience to the deliberation process.

Key events where this lack of experience may have played a role include:

- Appointment of Murdoch with the CSO title was made on the advice of the "recruitment firm", with no consideration given to the effect this decision may have on the morale and commitment of the research team.
- There is a broad consensus that an important contributor to success of early-stage, resource poor ventures is a "shared vision" of the company's direction and the nature of its business. Underpinning a strong culture it helps guide a cohesive effort to accomplish the desired goal by the entire organisation. Lack of such a "shared vision" can lead to dissipation of effort and conflicts over resources. No effort appears to have been made to develop such a vision within Kinacia, and consequently the company was subject to conflicts over optimal strategy and resource allocation.

- A key issue for innovative ventures is the need to manage emergence, the search for unforeseen results (Lester & Piore 2004). This contrasts with the emphasis on control and effective planning found in the more established organizations (Dougherty 2006). This distinction was not explicitly managed, leading to the conflict between the scientists, who wanted to emphasise *emergence*, and the management team.
- Another issue where lack of experience with early stage pharmaceutical companies may have played a role was in relation to risk management. Several of the difficulties ultimately faced by the company can be seen to stem from a failure to fully consider downside risk in key decisions. This includes the decision to proceed to clinical trials with TGX155 (which was known to be a high-risk candidate) and the decision to contract with CMAX in spite of Inveresk's greater expertise. Notably, in the absence of the risk actor, both of these decisions (as well as several others) can be readily justified on cost/benefit grounds. The presence of other similar decisions (which however paid off) may explain the company's reported ability to achieve dramatic progress with the relatively minimal resources expended.

CREATING VALUE AND REALISING VALUE IN COMMERCIAL MARKETS

Another conflict that appears to not have been well managed at Kinacia was between value creation and the actions that needed to be taken to realise that value in commercial markets. This is particularly clear in the conflict between how the scientists perceived their performance in delivering a stream of ever better compounds, and the way this stream was perceived by the board as a "*movable feast*" which prevented effective decision making.

The key conflict there is between the activities needed to make develop a significant insight, and the relatively prosaic activities involved in effectively "packaging" that insight for deployment into the market that does not want to invest the time and effort into understanding the esoteric technical issues.

FUTURE DIRECTIONS

The Kinacia case offers a rich source of data and insight into some of the key decisions that shaped the growth and development of an early stage biotechnology company. A key priority for the research team is to examine the later years of the company's history, to better understand how the decisions made in the initial stages of its development influenced the events that led to its eventual failure.

As well, it is important to understand to what extent the issues identified in this case may be representative of the Australian "research commercialisation" sector, and whether the lessons from the Kinacia example may serve to improve success rates in that sector.

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