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Risk management: ADAM STEEN FCPA AND ASSOCIATES LOOK AT MODELS TO ADEQUATELY MANAGE RISK IN ORGANISATIONS WHERE UNCERTAIN RESEARCH AND DEVELOPMENT ACTIVITIES ARE CORE PARTS OF THE BUSINESS.

Managing high-tech risks

THE TRADITIONAL AUDIT COMMITTEE risk management model may provide inadequate risk management in today's complex business environment for many public companies. This is particularly true for research-intensive industries such as biotechnology, where innovation and the associated research and development activities bring additional layers of risk, increasing the complexity of risk management.

Corporate collapses such as Enron and high-profile legal actions in the US and elsewhere in the late 1990s and early 2000s, plus the recent global financial crisis, have highlighted the need to make management and directors of public companies more cognisant of risk management. These events have also led governments to actively promote higher standards of corporate governance. In Australia, the government's *Corporate Law Economic Reform Program*, CLERP 9 (2002) requirements include increased levels of disclosure on corporate governance. Similarly, securities regulators such as the Australian Securities and Investments Commission and the Australian Securities Exchange (ASX) have increased their focus on governance and risk management.

In 2006 the ASX Corporate Governance Council released its principles and recommendations, which emphasise group-wide approaches to risk management. Not only are finan-

cial risks highlighted, but principle seven explicitly states "material business risks" can include: "... risks, such as operational, environmental, sustainability, compliance, strategic or external, ethical conduct, reputation or brand, technological, product or service quality and human capital which if not properly managed will impact on the company". It also states that: "companies are encouraged to adopt appropriate risk oversight, management policies and internal control systems rather than disclosing specific material business risks." Following a revision in 2007, recommendation 7.1 now specifically requires company boards to establish and regularly review a risk profile for the company, including their definitions of material business risks and the company's appetite for risk.

While identification of potential risks is one thing, risk management is another. In practice this can be achieved by the adoption of a risk management framework such as enterprise risk management (ERM) or business continuity planning (BCP), also known as contingency planning or disaster recovery planning.

ERM is one method used by organisations to manage risks and seize opportunities related to the achievement of objectives. The aim is to assist the board and company to ensure management officials actively work through a process of identifying and analysing risks in order to make



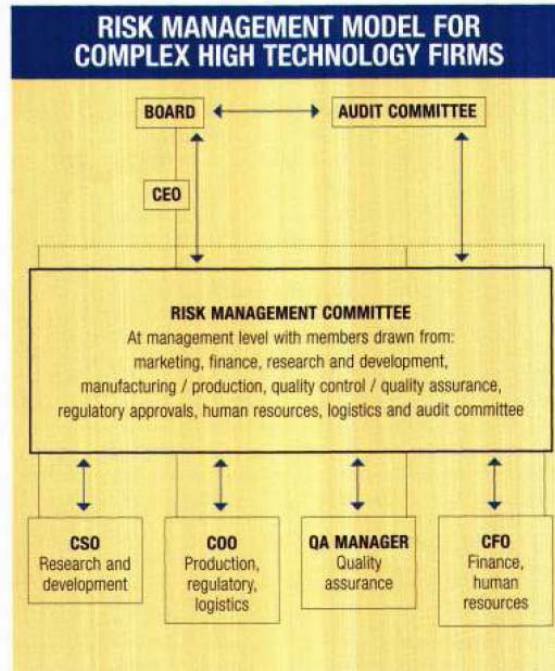
informed decisions regarding their mitigation and management. BCP on the other hand is a formal plan established to manage the business in, and recover the business from, any potential disasters or disruptions. Overall, risk management is focused on enabling companies to achieve objectives through performing activities cognisant of risks.

In some industries there are additional reporting and risk management requirements in addition to the ASX principles and recommendations. For firms operating in the biotechnology industry, for instance, the ASX and AusBiotech – the Australian life sciences and biotechnology industry representative body – published a *Code of Best Practice for Reporting by Life Science Companies*. While the code is not yet mandatory, it provides a framework for life sciences and biotechnology companies to use when reporting,

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and notes that public biotechnology companies face unique risks that need to be reported and managed. It cites a range of risks such as patent application risk, patent freedom to operate risk, patent challenge risk, research and development risk, co-development risk, production risk, licensing risk, partnering risk, joint venture risk, other commercial arrangement risk, regulatory risk, clinical trial risk, patient



Another structure that could be appropriate for many high-technology firms, such as those engaged in the biotechnology industry, could be a separate risk management committee. The composition may vary from industry to industry, depending on industry and organisational complexity, and may comprise additional people of various levels, experience and qualifications, not just board members. The risk management committee could include representatives from the audit committee and operational management (marketing, finance, research, development, production, quality assurance, regulatory, human resources and logistics).

When these companies engage the appropriate ERM culture and use the appropriate risk management and risk mitigation tools, they can build very successful businesses. There are many good examples of successful biotechnology companies such as US companies Genentech and Genzyme, and the Australian company CSL have been built on technology innovation in highly complex and dynamic risk environments utilising an ERM culture and appropriate governance model. Boards of biotechnology companies and other high-technology companies should make sure an ERM culture and an appropriate model is established in their company for optimal outcomes. ■

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safety risk, drug tolerability risk, drug efficacy risk and approval classification risk. Given their potential to retard the development of a biotechnology company by a number of years and cost many millions of dollars, these risks are significant.

With the number and complexity of risks involved and legislative requirements for a biotechnology company involved in the full gambit of operations, from theoretical research to product development and joint ventures, it is clear that a risk management framework such as an ERM system should be established and regularly reviewed and that the scope of the framework should include financial and non-financial business risk. In addition, the entire organisation can be engaged in risk management.

The issue then becomes: what is the appropriate governance mechanism by

which to oversee the risk management framework. Our recent article on risk management in *Corporate Governance: An International Review* examined various governance structures that could be employed to manage the numerous risks, both financial and non-financial, that companies face. It could be argued that risk management oversight has not been considered as a traditional role of the board. While the board sets policy, the responsibility for managing risk rests with management. The board, however, provides direction, authority and oversight across the company while external auditors provide independent assurance regarding the appropriateness and effectiveness of financial risk management, controls and processes from an accounting standards perspective. In practice this has meant that for most companies the audit committee has been entrusted

with the risk management policy and oversight.

But as the business environment has become increasingly more complex, as in the case of high-technology companies, it has become ever more obvious that risk management is beyond the scope and capabilities of the audit committee alone.

As a general rule, the level and complexity of risk management should be commensurate with the degree, cost and complexity of potential risk. In practice a number of alternative governance structures could be adopted starting with the common audit committee, which incorporates the management of financial and non-financial risks. An alternative structure could involve the creation of a risk management subcommittee of the audit committee, charged with oversight of risk management.