Risk management for the biotechnology industry: A Canadian perspective

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Abstract

In order to break down industry barriers and decrease failure rates, biotechnology companies require a sophisticated risk management plan. Biotechnology is an industry sector where a high failure rate for companies is considered the norm. The opportunity for high-profit levels is what currently drives the industry and sustains investment even in the backdrop of the elevated risk. A recent survey of senior management of Canadian biotechnology companies identified the industry's key risk and growth factors and allowed for the development of models of the changing profiles over the product lifecycle. The model for company growth reinforces that a company's dependence on funding decreases during product development as product distribution and generated profits support company growth. The model for company risk exemplifies that risk is higher earlier in development and decreases with expanding market exposure. These models provide a framework to build an infrastructure to position companies in the knowledge-based economy. In order for biotechnology companies to mitigate risk, they need solid corporate governance with adequate resources to develop a risk management plan. Making the risk management plan part of the strategic plan and the strategic planning process improves a company's ability to manage growth and to compete in the local and global economy. This paper investigates what the industry growth and factors are from a Canadian perspective, how risk factors can be managed by developing a risk mitigation plan and how risk impacts the industry's success as a whole.

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CANADA'S CRITICAL SUCCESS FACTORS AND RISK OF DOING BUSINESS

Canada is seen as a leader in the biotechnology sector and has a competitive advantage maintained by high levels of

Research & Development (R&D) expenditures and revenue generation. Canada, however, will quickly lose its competitive advantage in the market if it does not position itself by building an infrastructure with a global approach that defines its competitive advantage. Biotechnology is being utilised for effective and affordable solutions to deal with prevention in healthcare and agricultural problems.[1] Increased costs, limited resources, disjoint resources/services and a changing consumer view of their role and access to information, however, has been increasing the risks in this already high-risk sector.

In 2001, PricewaterhouseCoopers (PWC) did one of the first studies to look at the scope and framework of risk management in 72 leading Canadian organisations that included global and national corporations, government and not for profit organisations. The survey addressed the business risk management practices in Canada in terms of commitment versus the development of risk management framework. Key findings were that only 40 per cent of senior management are committed to risk management and only 28 per cent have risk controls and processes.[2] In comparison, a 2003 survey of the biotechnology industry found that 63 per cent of senior management felt a risk management programme was critical for success but only 27 per cent actually had a risk management plan.[3] The PWC study found that, though it is not unusual for business practice to lag behind business theory, the urgency with which companies move to close the gap is a measure of management effectiveness.[3]

There are two main reasons for company failure in any industry: insufficient cash flow and management team failures, with additional risks in the biotechnology sector resulting from technology failure at any point in the development phase. Both of these areas are critical in the biotechnology industry that has a wide range of companies who are at risk and have on average cash flow of only 12–15 months and the management skills required at the various development stages lacking in training or tools to move the company forward. The Ernst and Young risk report for 2008 states that the top ten risks that will affect the biotechnology industry include regulatory and compliance issues, global financial shocks, emerging markets, strategic transactions, cost inflation and the impacts of our aging population.[4] In order for biotechnology companies to mitigate risk they need solid corporate governance with the resources to develop a viable risk management plan. Making the risk management plan part of the strategic plan and the strategic planning process would facilitate companies' ability to manage changing growth and risk profiles and prepare companies to compete in the local and global economy. A risk management plan protects the shareholder's value and reputation, creates awareness of risks, mitigates losses and ultimately improves a company's competitive advantage.

In 2007, the authors identified some critical success factors for the Canadian biotechnology industry.[5] The industry's dependence on intellectual property (IP) protection and strategic product development were significant survey findings with the top five critical factors being entrepreneurial environment, product distribution to target market, product focus, policies to protect IP and value of the firm's knowledge assets. This study ranked the key elements but did not define how they could be leveraged in order to reduce failure rates and manage risks. The purpose of this paper is to identify some of the key risk factors and to make recommendations on how they might be managed in order to mitigate company and industry risk.

In order to manage risks, the risk factors cannot be static, but must be fluid and change with company development and market pressures. When the data set from our 2007 survey of the industry was segregated based on stage of company development there was a shift in what was considered a priority for success in the industry.[5] High priority for earlier stage companies, not yet self-sustaining,

is to secure funding with more dependence on external factors such as government support. The later stage companies, having access to product-derived funds, are more able to build internal resources and expand into global markets.

Understanding how success factors transition through product development can be used to devise effective strategies to manage risk. The survey data set collected in 2007 was reanalysed in order to address the Canadian industry's perspective on risk.[5] A further analysis of the quantitative survey of primary data and incorporation of the qualitative data derived from survey respondent comments allowed for the generation of industry profiles that compared the key elements of company growth and risk using the product lifecycle as a time scale. This 'accumulation' of the impact of the key elements over time rather than overall ranking allowed for the generation of models of the risk and growth profiles of the biotechnology industry.

Our model for biotechnology company development is depicted in Figure 1. In order to model company growth in the industry, the original elements that defined success in the survey data set were graded on a relative scale (number of positive scores cumulated based on rank assigned by survey responders and then normalised to a maximum value of ten). The changing priorities when data set was stratified between early and late stage companies were used to model trends of the elements over a product lifecycle. The model highlights how companies' dependence on funding decreases during product development as product distribution and generated profits support company growth. The greater demand for resources is evident as the company moves into the global market, with IP protection shown to be critical early in development.

A resource constrained, technology-based start up company in Canada, that has limited records of achievement needs to strategically map how it will introduce its product into

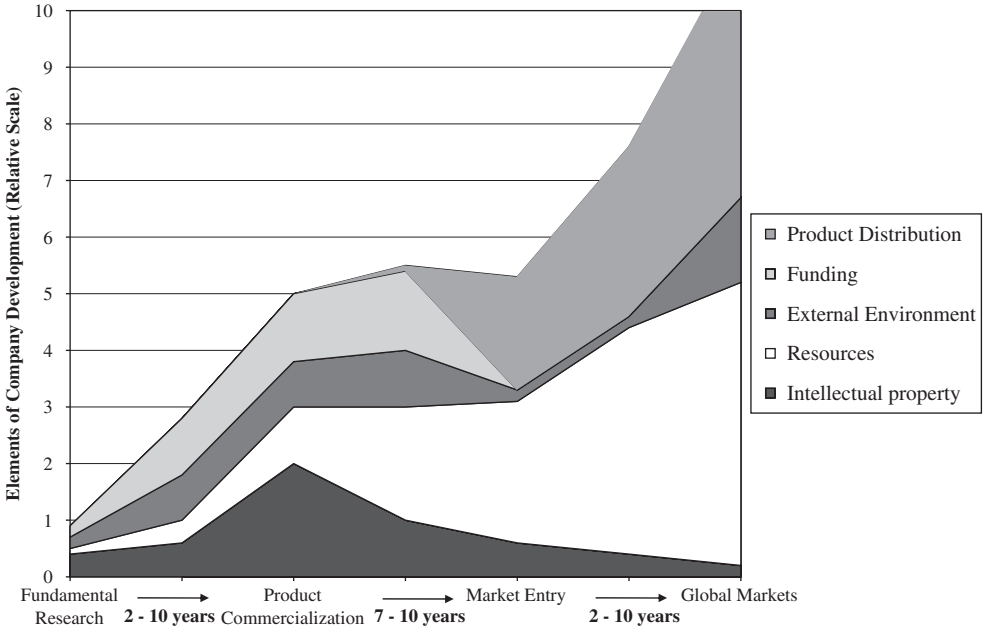

Figure 1: Model development profile of biotechnology companies. Factors that affect company growth shown on a relative scale with 'area under the curve' shaded regions used to represent the changing focus of the critical elements as they accumulate over the product lifecycle time scale (*x*-axis)

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the market. In order to introduce a new biotechnology product in the market, several phases need to be accomplished. The time-frame will depend on the biotechnology area (ie, whether health, agriculture, environment, forestry or chemicals) and will also vary by product and how well the company manages its growth and thus the overall time-frame. The growth follows a series of product development relevant intervals that includes the stages of research, patenting, approval and development of the innovation and finally commercialisation of the new product. Financing in the form of venture capital and other private placement and public capital markets, all play critical roles in this industry due to the average 15-year development periods typically required for the commercialisation of a product.

In the start-up phase, the management teams are looking at entering the market and need to address product focus and adequate funding. Once management has built strategies around securing a solid biotechnology product portfolio then they will look to implementation strategies such as collaborating for the purpose of technology sharing, cost-effectiveness and less risk. In the early stages, innovation grants are used to fund the technology proofing stage that leads to start up commitment. Specialised industry focused venture capital pooled with different investment criteria are required to support the start up phase of the new biotechnology firms. A mature or proven biotechnology company, even post-IPO, may be four to five years away from self-sustaining revenue streams. The working capital supplied by the public market and private funding is just as important as the early venture capital.[6]

The survey of the Canadian biotechnology industry highlighted that securing knowledge assets and attracting skilled employees was critical for company success.[5] According to the Canadian Council of Chief Executives, Canada must ensure strong patent protection for high-risk and high-cost inventions or it will lose investment in the R&D in biotechnology.[7] The United States will introduce changes in patent regulations as of 1st November, 2007 generating concern that IP protection will be costlier, more time-consuming, take more funds away from research and delay the patent process from one year to two years.[8]

The model of company growth highlights the dependence on securing funding decreases in the later stages of product development as the distribution of the product and product-derived profits supports company growth. When the company's stage of growth is at the commercial sales phase it may have products that will impact Canadian & global markets but the impact is not automatic, so as the companies move to market entry and to expand globally they lack the ability to commercialise the product. Some of the barriers for commercialisation of products, identified in our survey of the Canadian industry, were the gap between R&D to first commercialisation needs government support and increased collaboration between industry and government, there is not enough time from incubating technology before licensing and there is a lack of investment capital to take the product from the lab bench to market entry.[5]

There are two dimensions of commercialisation that require investments by government. The first is taking university-based research closer to the market so that theoretical-based IP is not sold at a discount to the US but made into job creation in Canada. It is also important to understand the incentives and disincentives that affect Canadian entrepreneurship and find ways to facilitate seed stage investments that can develop into new knowledge-based initiatives.[9] Further to that approach, because government funding cannot distinguish between viable and non-viable projects, it perpetuates funding of more opportunities at lower than preferred levels and jeopardises adequate funding of the strong initiatives. In 1998, the US National Science Policy discussed the need to ensure that funding is

driven by science and not funding driving the science.[10] There must be a focus on setting national strategic directions to leverage Canada's strengths in biotechnology and to provide adequate support. Risk-mitigation strategies for companies will help to improve the success rate for companies, provide greater opportunity for the viable projects to move forward to commercialisation and thus improve Canada's reputation for success overall.

MODEL OF RISK PROFILE FOR THE BIOTECHNOLOGY INDUSTRY

Defining the critical elements for success over stages of company growth allows for the management of risk at each specific phase. Making sure that policies and business plans are in line with these identified key growth elements is an obvious way of mitigating risk. Associated risk factors, however, must also be considered. Expertise of management and the ability to market and communicate complex technology were identified as key barriers by Canadian senior management in the biotechnology sector.[5] Analysing these industry risk factors against the backdrop of the Canadian economic profile, and investigating the impact on the structure/product profile of the company are necessary in order to formulate a risk management company portfolio.

The risk management profile depicted in Figure 2 is modelled based on the perceptions of senior management from our survey of the biotechnology industry.[5] The risk model highlights the landscape of risk management for the industry. The level of risk is higher because strategic plans to mitigate risk are not normally part of the planning process or are inadequate, at least in the early stages of the company lifecycle. For example, most of the risk is early in the product's development before it enters the market, which is on par with the large failure rate of this industry. The major risks early in the company lifecycle are proving the technology feasibility, securing

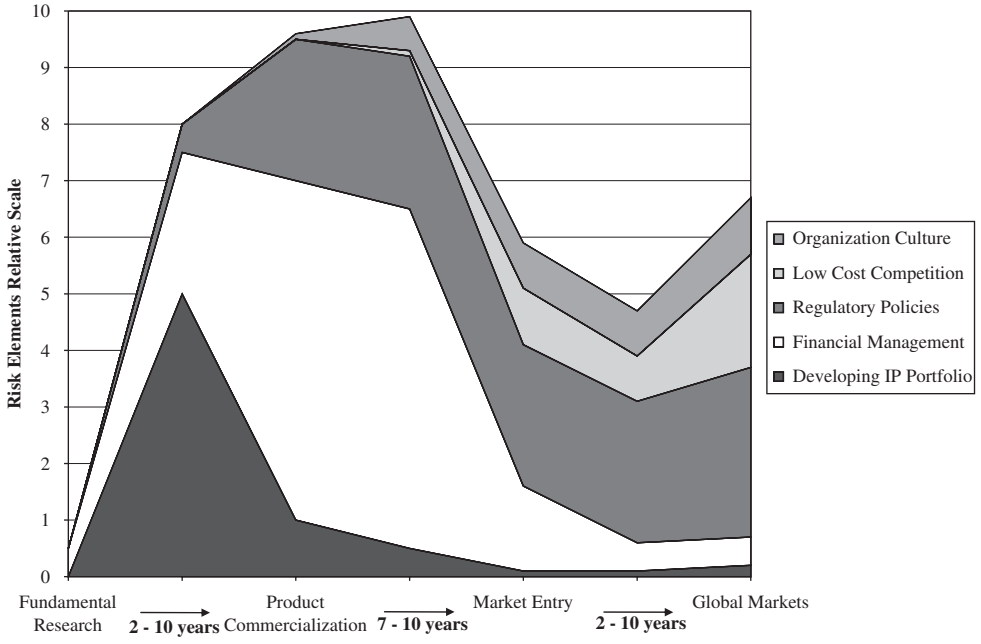

Figure 2: Model risk profile of biotechnology companies. Examples of elements that affect the risk profile on a relative scale with 'area under the curve' shaded regions used to represent the changing focus of some of the critical elements as they accumulate over the product lifecycle time scale (*x*-axis)

IP or the knowledge assets of the company and financial management of the resources. As the company continues to grow, the overall risk profiles decrease but market risk becomes more prominent as shown by an increase in the influence of regulatory polices and the threat of low cost competition. The overall risk profiles increase slightly as the company moves into global markets due to increasing threat of low-cost competition and the addition of culture influences of doing business in a global environment.

Identification of these barriers and management of them is important in an industry with a 90 per cent failure rate.[11] The surviving companies that continue to grow recognise the risks and adapt to focus on new risk priorities; these include threat of low-cost competition, over-regulation and access to skilled resources. This result is supported by the 2007 PWC survey where emerging economy CEOs expressed concern with over-regulation, availability of key skills, low-cost competition and raw material costs.[12] Macro external issues such as terrorism, global warming and pandemics risks were lower on the scale and it was suggested that the issues are too big or too improbable to warrant attention.

DEVELOPING THE RISK MITIGATION PLAN

Understanding how the industry risk profile impacts at the company level is critical. An outline of some of the key points to be considered when developing a risk mitigation plan is shown in Figure 3. A company's risk tolerance and survival is dependent on whether it is producing the technology only for spin-off or if the product itself will be competitive in the marketplace. If a company sells technology it benefits operationally from an infusion of funds and mitigates some of the risks associated with the huge costs of product development but this has to be balanced with the impact of loss of profits from product commercialisation and less opportunity for development of a product pipeline. The company in terms of its values and milestones must define the term 'impact'. To measure impact over time, a risk assessment highlights on how an occurrence might cause company performance to vary from its business plans,

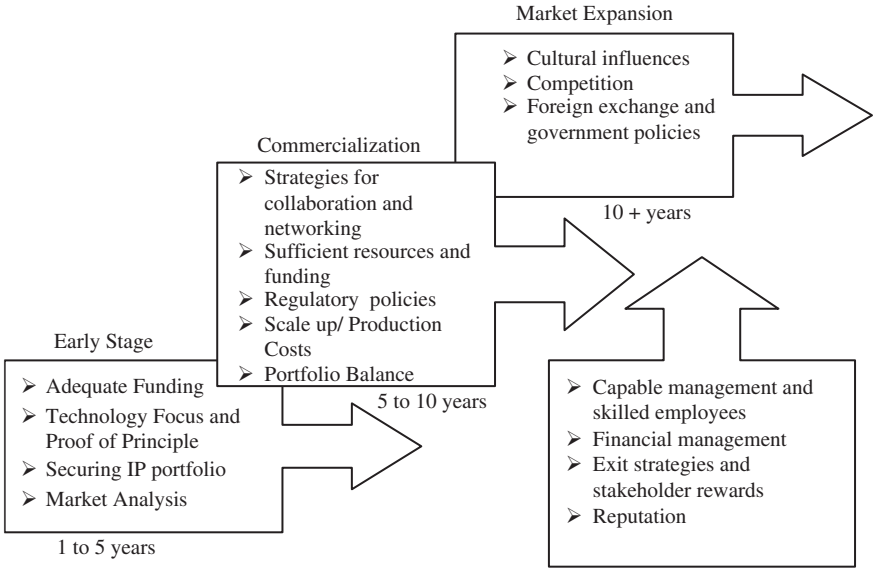

Figure 3: Outline of a risk mitigation plan. Examples of key elements that change priority over the product lifecycle are shown in horizontal arrow text boxes from one to five, five to ten and ten + years. The vertical arrow text box depicts examples of key elements that should be assessed over the entire lifecycle

identifies the external risks that affect the viability of the business model and addresses the internal risks that can affect the execution of the business model.

How the business environment influences relationships is also important. Over the past decade in modern business management there has been increasing awareness that culture influences the business relationship. In a global environment companies are recognising how culture provides the context for business relationships and plays a key role in business success. As discussed in a 2007 PWC CEO survey, cultural barriers are identified as the main hindrance to achieving access to new markets and in order to deal with this respondents consider proximity of the deal to overcome the cultural barrier.[12]

A risk management plan provides a company with the following: a confident and effective basis for decision making, allows them to gain value from uncertainty and to better identify opportunities and threats. In addition, it promotes proactive versus reactive management, allows for more effective allocation of resources, improved incident management, reduction in loss and cost of risk including insurance premiums, improves stakeholder confidence and trust, increases compliance with legislation and ultimately will allow for better corporate governance.

BIOTECHNOLOGY AND THE IMPACT OF RISK IN THE BIOTECHNOLOGY SECTOR

Risk occurs at all levels in organisations, encompassing business, market and financial aspects. In business, risk is often defined in terms of hazards or negative impacts, whereas risk for the biotechnology industry is further defined as the exposure to uncertainty or potential deviation from what is planned or expected.[13] Biotechnology is an industry where a high failure rate is considered *status quo*.[11] A major difference in making investments in the biotechnology versus other industry sectors is in the risk profile.

In the past, the high biotechnology risk warranted high profits, but this is shifting as the industry responds to pressure to lower costs, increased competition for markets and funding from investors. These trends increase the need for the industry to define risk as part of the strategic plan, develop a risk profile and a risk management plan that aligns the organisation to meet its goals.

How risk impacts a company overall begins with the company and how it governs. A company with solid corporate governance where the board sets the standards allows for identification of the risks they will and will not tolerate. As part of the strategic plan a solid risk management plan requires the board to ask some tough questions such as:

- Is there enough support and funding to launch and be sustained in the initial stages?
- Are the market conditions adequate?
- Who are our customers and what are their needs?
- What strategies exist for potential collaboration and networking?
- Is the innovation following an appropriate path for the business?
- Is the existing management team capable?
- What training needs do we have? What exit strategies or exit pathway should we create to have a successful risk and reward system for our investors and stakeholders?

The decision to invest in biotechnology requires looking at risk in terms of people, technology and the market. Morgenthaler Ventures' partner Ralph Cristofferson estimates that only 10 per cent of the overall risk levels are tied to the market.[14] This is attributed to the fact that research is generally conducted on unmet medical needs so the only risk is threat of competition of another company working on the same disease. Approximately 40 per cent of the risks are attributed to the technology, since biotechnology products are inherently biologically unpredictable. Fully half of the risk lies in the expertise of the biotechnology management team.[14] The credibility of the

CEO and CFO is reflected on the company as the whole, and impacts the investor's confidence that the business plan will be successful.

The biotechnology risk based on the people, technology and market is in contrast to most industries where risk is based solely on the return on investment (ROI) in the market. Most venture capitals (VCs) target at least a 30 per cent ROI as an attractive investment in biotechnology in order to compensate for the high technological failure rate. While Canada is a low risk country for investment, biotechnology in Canada as is highlighted above is considered a 'risky' sector and is financed accordingly. A perspective of this is exemplified by comparing industry ROIs with ROIs of various country risks for product entrants. For example, in low risk countries, a 15 per cent ROI is defined as a new product utilising excess capacity, moderate risk of 20 per cent ROI is defined as a new product confronting competition and high risk is considered at 25 per cent ROI when a new product is brought in to establish a foothold in the market.[15] There has traditionally been an expected 30 per cent ROI in the technology sector, in which biotechnology falls, which makes the biotechnology industry high in comparison to most other industry standards.

Risks in the industry, outside of technology failure, can range from lack of expertise or experience in companies to overselling, to controversial research, to lack of preparedness for ordinary dangers such as business interruption with flood or fire. According to Chubb[3] in a survey of 100 biotechnology executives, 63 per cent believed a risk management programme is critical to their organisation's success and 50 per cent think it is critical to their VC partners but few have programmes for disaster readiness. While 66 per cent were very satisfied with their risk management programmes one-third noted that their companies lack a strong disaster recovery programme. Seventy-nine per cent were not prepared for a product recall and 73 per cent do not have a risk management plan.[3] From a Canadian perspective these risks are not as high a priority as most companies in Canada are in the development stage and thus have less product-related risks. The real risks in the early stage are obtaining funding and completing trials in a timely and 'on budget' (or 'just in time' funding) manner. Companies that have a solid risk management programme have a competitive edge when it comes to attracting capital, as investors have the comfort that their investment is protected from unexpected disasters. Many biotechnology companies understand this and have designed risk management and insurance programmes, but as the survey results highlight, others have a significant amount of work ahead in this area.

The risk profile as shown in Figure 2 was generated based on primary survey data from the perspective of senior of management. The risk profile highlights the key elements but cannot be assumed to be the only elements that warrant consideration and discussion by senior management. This is exemplified by secondary sources that identified additional critical elements with varying degrees of priority. Comparison of these diverse survey pools, as shown in Table 1, provide a broader

Table 1: Surveys of the industry: Comparison of risk focus in order of priority

Source: Global CEO survey[7]	Source: Canadian market survey[12]	Source: Industry – technology survey[3]
Over regulation	Culture	International
Key skills	Low-cost competition	Professional liability
		D and O
Low cost competition	Regulatory policies	Financial – increased competition, rising fuel costs and devaluation of dollar
Raw material costs	Financial management	Terrorism and natural disaster
External factors	Securing IP	
Terrorism		
Global warming		
Pandemics		
	Technological disruption	

perspective on risk. This allows for consideration of other areas of risk not included in the current model. Ultimately, it is important that the biotechnology industry recognises the diverse risk indicators and how identification of critical success factors can help companies to manage risk and make effective decisions in growing and competing both locally and globally.

MITIGATING RISK THROUGH RISK MITIGATION PLANNING

The unique biotechnology risk profile must include uncertainties that arise from an industry heavily reliant on research, the specialised environment required to produce scientific breakthroughs, and its tangible and intangible costs.[13] The risk profile must be further expanded to include business reputation as well as environmental, ethical, cultural and even religious concerns.[16] The complexity of risk management for the biotechnology industry is compounded by the reality that costs accumulate over long time intervals before returns can be realised. The costs to produce a new drug can be upward of, or over $800m to $1.7bn from start up and take more than ten years.[17,18] This range includes the cost of failures averaged over the entire industry. The actual cost of drug development is approximately $403m with opportunity costs of approximately $399m.[17] In comparison, a food/animal product development can cost upwards of $250m and take 20 years.[19]

Risk management achieves an appropriate balance between realising the opportunities for gains while minimising losses. With growth in biotechnology comes risk. A company mitigates this risk with a high standard of corporate governance and develops a risk management plan as part of its strategic plan. The company then aligns its goals with its risk profile and the industry in general.

At a strategic planning level, a risk management plan needs to create a culture of best practices that manages intangible and tangible assets with a focus on creating a good and protecting the company's reputation. Primarily biotechnology requires an enterprise wide business risk management plan, which is a process that is structured and aligns strategy, processes, people, technology and knowledge in order to evaluate and manage uncertainties. This approach divides risk into two categories, one, environmental, which are external risks such as market and economic conditions, political, social, new regulatory requirements and technology. Once a strategic course is designed then focus can be directed at the second category, process risks, which are the internal risks including the threats and opportunities that arise out of operating a business such as operations, credit and business. Some examples include the ability to secure funding, the ability to manufacture sufficient product, the ability to recruit and retain employees, and uncertainties affecting execution of the business model. The last class of risk is the risk that the information or data used to make strategic decisions are inaccurate, incomplete or irrelevant.

A synopsis of some risk indicators and how they can be applied using a risk management tool is shown in Table 2.

Diversity between industry sectors, whether it is health, agriculture/food, environment, chemicals or forestry translates into changing risk profiles and varying degrees of risk. Each company needs to rank the importance of a risk source in order to have relevant information for decision making. For example, in the pharmaceutical industry drugs are religiously regulated, involve extensive testing, involve strict labelling and involve choice by the consumer. In comparison agriculture products have less complex regulatory processes. Traditional risk involves product liability and product recall and the result can often be uncontrollable and irreversible. Risk is greater if there are ethnical issues that must be addressed in achieving the end goal. An example is the direct adverse effect on human life and ethical concerns of human genetic manipulation. In parallel is the criticism of genetically modified crops, with recognised potential to fight

Table 2: Risk mitigation tool example

Discovery – Pre-clinical phase **Discovery of new drug or medical device**			
Timeframe	One to two years initial phases of the estimated 15 years to develop product		
Probability of success	1%. Model of company development (Figure 1) at relative scale of less than one unit out of maximum of ten.		
Risk level	Low – risk due to developmental stage and no infrastructure and no compound discovered. Model of company risk (Figure 2) at relative scale of less than two units out of maximum of ten.		
Risk focus	Technology failure		
Developing plan and identifying risks	**Risks**	**Risk mitigation questions**	**Strategies**
	Strategic – focus and product	What research activities already exist? What has been working and what has not? Who is your customer? What business is the company in and what should it be in? Discuss the length of research time to validate targets and associated costs. What is the reputation of the scientists and/or are collaborations with respected research institutions? How difficult is the disease target/segment selected? Can it/should it be tested across the disease spectrum? Does the compound have the potential for repositioning?	Explore the organisation's strategic focus in terms of its vision, mission and business relevant to the diseases targeted and disease segmentation. Establish a strategic plan that can be operationalised. Explore new treatment modalities and build portfolio. Consider the costs and probability of risks. Formulate decisions based on probability of risks, costs and supply chain synchronisation considerations. Consider collaborations (ie other partnerships or to transfer, trash or reposition the compound). Establish principles of quality management such as considering each phase a project and using project teams to monitor results and regularly assess for deliverables.
	Safety (toxicity) – pre-clinical and clinical trial data	What hazards exist that could disrupt or fail the compound/product? What hazards exist because the product could be used, misused or potentially defective? What is the cost analysis and scientific relevance of pre-clinical testing? Are similar products on the market or that have failed in clinical trial that can be predictive of outcome?	Incorporate new scientific information from external sources into a database to be used as a resource for available toxicology data from comparable products. Keep informed of existing or new regulatory standards and policies by incorporating new scientific information as required. Build in best techniques of risk assessment and risk management to address regulatory practices and industry standards.
	Efficiency – future clinical trials on time and on budget	Who is monitoring clinical trial and do they have the expertise? If compound has value to move to the next phase need to establish funding and discuss potential partnerships. If compound has value but requires further investment that can establish targets for development.	Ongoing monitoring ensuring human resource and financial management in place in advance of company development phase. Increase productivity and decrease costs by employing innovative cutting edge science and engineering knowledge, ensuring best practices in quality management to challenge new discoveries. Quality management will focus on improving quality on every aspect of projects using well-trained teams and tools to measure and report results. Meet investors' short-term expectations with targets in development and motivate the organisation.

Table 2: Continued

Developing plan and identifying risks	Risks	Risk mitigation questions	Strategies
	Funding (cash flow on hand only 12–15 months)	What critical business conditions/elements exist that the organisation faces in investing? What funding is in place? What hazard could prove costly as a result of the investor, that is, government, grant or private? What is the relationship with the investor? What point will cost outdo the opportunity cost?	Brainstorm potential partnerships and develop the networks for creative collaborations. Develop a network of venture capitalists and angel networks. Develop partnerships with universities and other companies to share knowledge and technology. Increase transparency. Consider vertical partnering and regionalisation. Develop a solid business plan with contingency for cash flow targets in the strategic plan. Outline decisions triggers for halting research, transferring technology, partnering and when to attempt repositioning the compound with targets and costs established.
Risk mitigation plan follow-up	*Identify the loss impact* Can the risk be eliminated before they affect the company? If not then what needs to be done to minimise the impact on the company and limit the effect? What is the probability of loss for the risks identified? Should the compound be further tested in disease segments and if so at what cost/loss? *Identify solutions* What are the solutions identified? This includes risk avoidance, technology transfer, partnerships and loss reduction. *Decisions and Implementation* What go/no go decisions trigger implementation? that is, to reposition the compound, purchase loss insurance, halt product development, segment it or investigate risk financing. *Monitoring the results, post marketing and any changes in risks* Who is monitoring the results of the decisions made? Are all the key stakeholders involved? What changes in risks are occurring? How is the strategy being adjusted and the projects being altered to ensure targets are being met based on this new information?		

Risk inherent to an organisation will originate from three sources: (1) the mission, structure and culture, (2) the assets and resources owned or controlled by a company and (3) the organisation's partnerships. To give an example of the process of risk mitigation and its impact, consider early phase (initial one to two years) in a drug development company whereby future costs and number of compounds being developed are high compared to the one compound that will make it to the consumer.

world hunger yet criticised for being produced with technology that poor countries cannot afford.[20]

Further to this, the political and social unrest, terrorism and the challenges in the global economy are creating new sources of risk for biotechnology organisations. Mitigating these sources of risk is critical to biotechnology firms, especially when it comes to securing venture capital funding, successfully completing a clinical trial or profitably manufacturing a drug.

Once the risk profile is established it needs ongoing monitoring and clear processes that rectify or minimise any risk at any time. It also must have enough flexibility to respond to the changing landscape of doing business in Canada and staying competitive, as a company can still fail due to the external factors such as new regulatory requirements. For example, among major industrialised countries Canada has one of the slowest drug approval records averaging approximately 550 days well behind the 300-day track record of other industrialised countries. Canada, Australia and Japan are the slowest (518 days, 526 days and 17.7, months respectively) behind the UK, US and Sweden (308, 369 and 371 days, respectively).[21–23] Addressing Canada's slow performance in the regulatory processes that tend to be costly, too complex, and too lengthy and subject to political decision

making would lead to improvements in the Canadian sector, but in reality the fact that the Canadian market is so small most companies are focused on the larger European and US markets and their regulatory requirements. The risk mitigation plan must take into account not only the ramifications of doing business from a Canadian perspective but also how those impact and can be leveraged to take advantage of global competitiveness. Risk mitigation strategies by increasing the performance of companies also improve Canada's reputation overall.

CONCLUSIONS

Management of risk is an integral part of having a strong company and must be an interactive process of continuous improvement in a company or organisation. Organisations that understand their risk profile will be able to manage their risks more effectively and efficiently, have a greater chance of success and lower cost of doing business as compared to top tier competitors. Using models of growth and risk profiles provides a basis for management teams to prioritise risk at various stages of development. By implementing risk mitigation plans as part of the strategic planning process, rather than reacting to risk, management can now respond and prepare for changing risk profiles.

Models of risk and growth profiles encourages further dialogue of all stakeholders, whether it be the government, the industry or companies themselves, as to where they are, where they need to be and where they need to go in order to be proactive at managing and mitigating the risks that are inherent in the industry today. Implementing management training programmes to align company goals with industry risk profiles while finding solutions to complex problems is crucial to the industry and to improving company survival rates in Canada.

Recognising the risk areas that impact the industry both locally and globally will provide Canada with a competitive position to be a leader in the global knowledge economy of the 21st century. In order to see Canada continue to develop and grow as a leader in the global biotechnology field, we must find ways to lower the risk of cultivating innovation, attracting foreign direct investment, improving R&D results and bridging the current gap between discovery and commercialisation of our biotechnology products. Canada must keep pace with the world market that is continuously improving and becoming more competitive around us. Complacency and our past track record are not going to keep us competitive as a nation and unfortunately companies are only as good as their last success.

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