
Papers

Critical success factors for biotechnology industry in Canada

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Abstract

Critical success factors and performance indicators provide the biotechnology industry with a foundation on which to grow and manage risks. In a recent survey of 247 biotechnology companies across Canada, elements critical for sustainability in the industry were investigated. The industry's dependence on intellectual property (IP) protection and strategic product development were significant 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. When the data set was segregated based on stage of company development, there was a shift in what was considered a priority. Earlier stage companies, not yet self-sustaining, are more focused on funding with a 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 with programmes directed at retaining and educating employees. Even with divergent interests, regardless of stage of company, IP and knowledge assets are key elements for success in this research and development rich industry. By understanding critical factors and changing priorities during business development, the industry will service an unmet need, facilitating modification of current marketing and business structure models. The results will promote sustainability in the industry as a whole.

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INTRODUCTION

The majority of biotechnology companies in Canada are at the development stage, in a climate with minimal resources but requiring huge investments to develop technology and

secure intellectual property (IP) rights. It is the norm to face a decade of product development before becoming sustainable operating companies.¹

There is a huge demand in the industry to define the success factors that dictate what makes a company successful. This need is driven by the reality that in order to attract capital to promote industry growth, investors require predictable indices. It is further supported by the fact that risk assessment to

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improve failure rates by only 10 per cent can save approximately a \$100m in development costs per drug.²

Research on the critical success factors for product development has been largely centred on the larger American markets, and there is an implicit assumption that the Canadian markets will be guided by the same indices. There are numerous studies directed at strategies to secure funding to cover the huge research and development (R&D) costs that are the hallmark of the industry.³⁻⁶ It is widely accepted that funding is a critical element for success. This has been validated in a recent report, 'Canadian Life Sciences Industry Forecast 2006'.⁷ Other critical elements reported in the literature include human resources and competence of key personnel, networking, industry clustering, infrastructure, national policies, quality of products and strategies, risk management of drug development and commercialisation.^{3,8,9} These papers present guidelines for the building of a successful biotechnology company, but they do not specifically address the challenges of the Canadian industry and what the key players are focusing in on as key issues in the Canadian business climate. To address these issues, a survey of the biotechnology industry in Canada was undertaken in the last quarter of 2005, targeting those companies in Canada with a proven track record.

SURVEY METHODS AND DEMOGRAPHY

The survey was delivered at the end of September 2005 by Canada Post to senior management contacts at 247 Canadian biotechnology companies. Sixty-nine surveys were returned, representing a response rate of 28 per cent of which 4 per cent were excluded from the study. This exclusion was due to fact that data from 12 companies did not meet the study requirement of having a proven industry performance track record. Reasons ranged from companies moving from Canada or closing biotechnology operations to survey respondents questioning their eligibility. Over 97 per cent of the 53 responding companies selected for analysis met 'at least one' of the industry performance

benchmarks of Greetham (1998), which include receiving venture capital (VC) funding, collaborations, conducting successful initial public offering (IPO), entering or completing a clinical trial or doing a product launch.¹⁰ Of the remaining 3 per cent that did not, the senior management responder met selection criteria based on expertise in the field. The basis for selection criterion was to ensure that the survey responders had insight into what was required to make a biotechnology company successful in Canada.

The landscape of the biotechnology industry in Canada is represented by diversity in sector, geographical location and stage of product development. Distribution of biotechnology products in the companies surveyed is in a variety of areas of interest from agricultural based to diagnostics and health, to waste and environmental management. The survey data were collated and stratified based on the stage of the company product development. Late-stage companies, defined as having one or more products on the market, represented 54 per cent of the companies surveyed. Mid-stage companies with clinical/field trial initiated but no products on the market were represented by 32 per cent of the respondents, and early R&D stage represented 14 per cent of the respondents.

The geographical landscape of the industry is reflected by provincial distribution, with three concentrations of the industry in British Columbia, Quebec and Ontario (Figure 1). The survey distribution mirrored closely the Canada distribution of biotechnology companies, with only the province of Quebec being slightly underrepresented (30 per cent of biotechnology companies are located in Quebec represented by a survey response of 20 per cent).¹¹

Key points investigated in the survey that had high rating (high score on questionnaire scale of 1-5) and response consensus (low standard deviation of less than 1) were deemed as a factor critical for success in the industry. In order to be classified as a significant success factor, the average score (scale of 1-5, with 5 being very important) on the survey must be equal to or greater than 3 taking into account

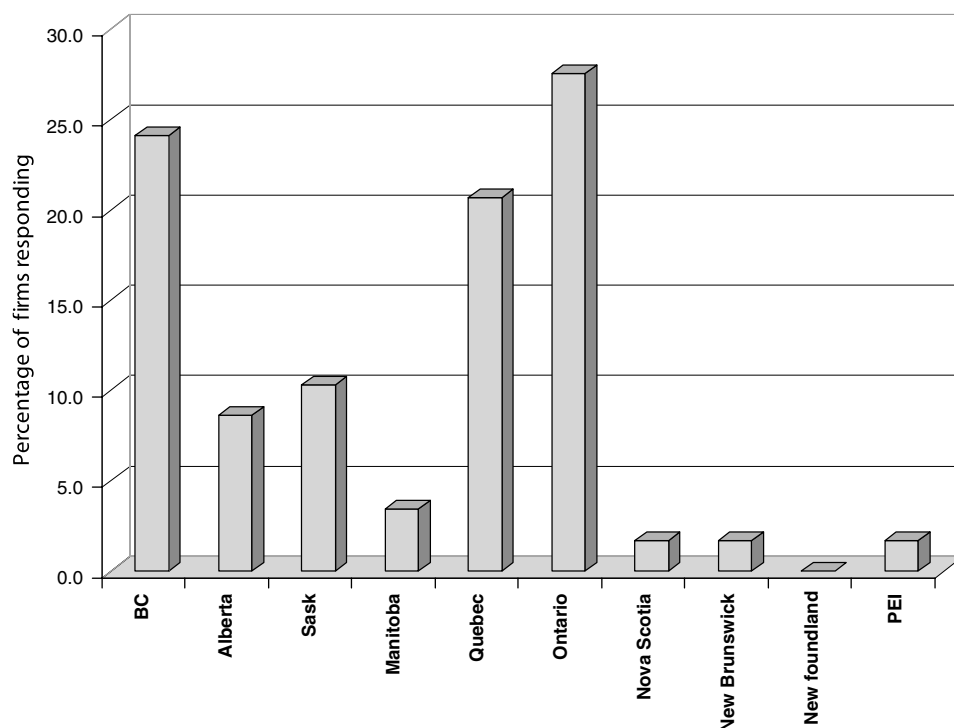


Figure 1: Geographical distribution

standard deviation of responses. Questions that were ranked on a scale of 1–5 were normalised against those that were scored based on percentage (for questions in which more than one option could be selected). This was achieved by assuming that the highest percentage was equivalent to the highest rank score, and expressing both as a fraction. In addition, this score was weighted based on the priority assigned to the broad category it fell under, the category ranking derived from a survey question where responders prioritised each category on basis of relevance for success. This allowed for a stratification of all elements investigated using normalised and weighted rankings such that factors could be compared between categories. A normalised value of greater than or equal to 0.4 represented what the survey responders deemed to be an issue, with a value of greater than or equal to 0.5 deemed a significant issue. Any factors having values of less than 0.4 are considered as not being critical elements for success, even though they might be considered important and should certainly be considered by management for solution/resolution.

SURVEY RESULTS

Ranking of business development critical success factors

The critical elements defined by the biotechnology companies in Canada are placed into five categories, prioritised based on ranking score. These categories and rank are:

1. Knowledge assets including the IP and internal and external company databases.
2. Use of resources from internal R&D products to entering of foreign markets.
3. External environment ranging from government support, industry clusters to resources networking.
4. Funding focusing on marketing conditions, management expertise and development of products.
5. Recruitment investigating the human resource issues in the nation, from lack of qualified candidates to available resources to compete for these candidates.

Under each of these broad categories, specific characteristics that would define this broad

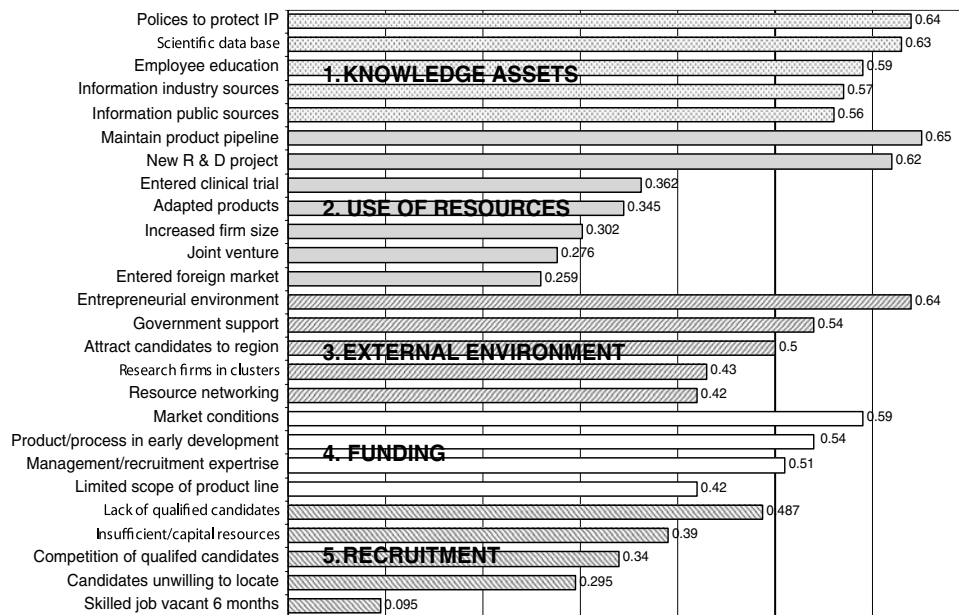


Figure 2: Ranking of critical success factors. Overall categories are defined by rank 1, knowledge assets; 2, use of resources; 3, external environment; 4, funding; and 5, recruitment. Under each of these broad categories, specific underlying issues that define these categories are listed on the left-hand column. The bar graph shows the normalised value of where issue ranked against all other issues tested. A value of greater than 0.5 is marked by a thick line across bar graphs. This line highlights characteristics with bars that extend over this line as being critical elements for success

issue were ranked and normalised such that each category can be compared to the integral issues in a lower ranking category (Figure 2). In other words, a specific issue in the broad category ‘use of resources’ may have a high score that would reflect that the industry deems this specific issue critical, although other elements in this category could be deemed as not significant. What this has allowed is the determination of not only the key elements, but also underlying issues that are the critical for success in the Canadian industry.

Differences in priority based on stage of company product development

When the data set was segregated based on stage of company, there were variations found in the priority of critical success elements, with early–mid-stage companies giving the external environment top priority and late-stage companies focusing more on the use of resources (Figure 3). Earlier stage companies do not have clearly defined revenue product streams so it is not

surprising that they are more dependent on the external factors, which would include entrepreneurial environment and economic climate. Later stage companies tend to have more internal resources so they have greater potential to offset external environment risks.

Funding risk factors

Biotechnology is well-known as a high-risk industry but having potential for large rewards. In the companies surveyed, funding ranked number four as a critical success factor (Figure 2) even though this is an assumed top priority in the industry. This is an interesting study finding, as what are the other factors that successful companies would focus on with higher priority than funding, which is considered one of the foundations of the industry. The low ranking assigned to funding in our survey pool may be a reflection of the fact that respondents were selected from those companies that have established some benchmarks for success. As these companies are well on their way in a development path to become self-sustaining, it drives funding to a lower priority. Nevertheless, funding was still

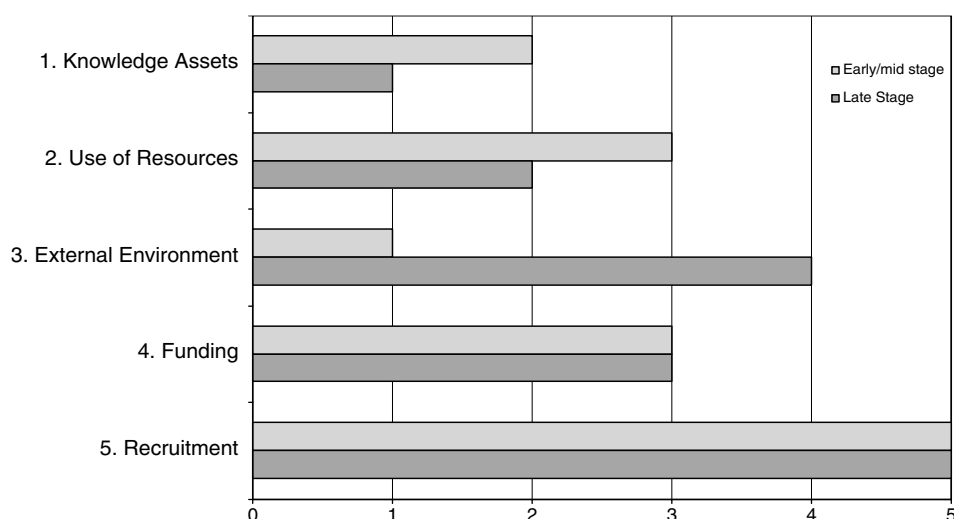


Figure 3: Ranking based on stage of product development. The priority given to critical success factors varied when looking at the stage of product development, in how early and late companies defined the top three ranks. The most divergence in rank is shown by the external environment ranking overall as number 3, but late-stage companies ranking it lower as number 4, and early-/mid-stage companies defining it as the highest priority

recognised as a critical success factor and so warrants discussion.

In order to secure the funding required for development of a product, there are some key areas that must be addressed. To be successful, firms must have a clear business plan and product development model, management with a proven track record and a well-defined exit plan for the investors.⁴ Early-stage companies are often dependent on angel funding in order to get off the ground before they can attract a broader investment base. The industry is further hindered by the fact that biotechnology is a diverse field. A result of this is that it is often a challenge for financing agencies and venture capitalists to understand the technology or its applications. The lack of experts or knowledgeable investors capable of assessing risks in an increasingly complex technological world is cited as a major impediment to the growth of Canada's biotechnology industry.¹²

The underlying issues related to funding are defined in Figure 2. How the investment community feels about the risk of biotechnology investments will drive the market. They take into consideration mediating factors, such as having a product early in development means a longer gestation

period until the product is proven marketable. Expertise of management is a documented critical factor, and having a differentiated product pipeline to compensate for the high product failure rate of this industry are baseline indices of success. When the Canadian firms surveyed ranked these elements, market conditions, and hence investor and customer perceptions were at the pinnacle, the next barrier was early-stage development and third ranking was the management (Figure 2).

Knowledge assets given top priority in industry

A high priority given to knowledge assets is not surprising when you take into account that biotechnology is one of the most R&D intensive industry sectors in the world.¹³⁻¹⁵ The survey examined this critical element further by investigating how biotechnology companies in Canada placed value on knowledge sources that supported R&D. These included elements such as the existence of scientific database, the policies to protect IP, employee education and information that are derived from industry and public sources (Figure 2). Information from industry and public sources was deemed not important

for sustainability in the industry. The reasoning may be that they are easily accessible in Canada and so do not represent a barrier.

Top priority was given to protection of IP followed by high value placed on the firm's scientific database. Why these two elements? First, the database is the concrete representation of the companies innovation, and the policies for IP is how the company assigns value to the research and protects it from imitation in the market. There is a strong correlation between amount of resources invested in R&D and the opportunity for bringing a product to market, and compensating for high product to market risk by having other products in the pipeline.³ In order to be awarded patent status the product is deemed novel, which increases company valuation. The patented product is protected from competitors over the term of the patent, allowing for a marketing monopoly to recoup product development costs and make a profit. This justifies the resources spent to maintain a

patent portfolio early in the company's life cycle.

Employee education was ranked third of the knowledge assets (Figure 2). The training of personnel is a recognised avenue for company growth, and therefore has value. It is of note that there was wide variation in the assignment of importance on employee education compared with stage of company (Figure 4). The early–mid-stage companies gave education the lowest ranking; later stage companies consider it very important. Explanation for this variation is supported by survey data on stage of product development, where it was shown (Figure 3) that earlier stage companies place more importance on external environment factors for success. It is likely that early-stage companies have not met required critical skill mass and are contracting or recruiting rather than educating in-house personnel.

Another factor may be available funds in which to support employee education. Since early–mid-stage companies are focusing much of their available resources towards product

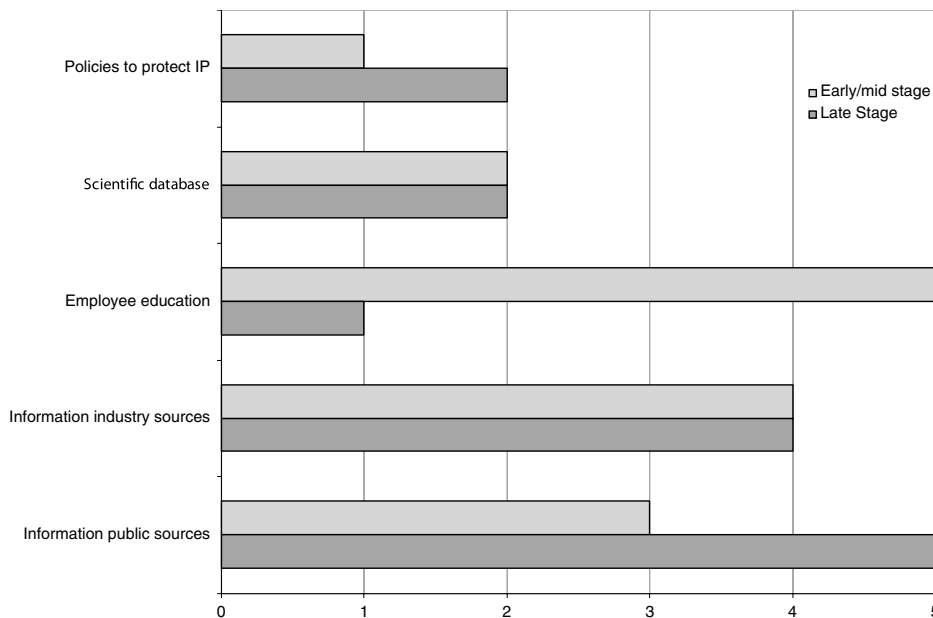


Figure 4: Knowledge assets ranked based on stage of product development. The priority given to critical success factors varied when looking at the stage of product development. This was based on how early/mid and late companies defined the top priority on a rank of 1–5 from survey scores. The most divergence in rank is shown by the employee education ranking overall as number 3, with late-stage companies ranking it first priority and early-/mid-stage companies assigning it the lowest priority of the five elements ranked

development, professional development becomes an opportunity cost. What was interesting was the high priority score given to employee education, and reflects the dependence of this industry on qualified personnel. It also raises the issue that it is important to develop employees within the industry – which is in contradiction to the fact that recruitment was deemed as not significant to the Canadian industry. Regardless of this, it still reflects an environment where firms feel it is a priority to develop their current staff rather than drawing from external sources.

Use of resources

Use of resources ranked second as a critical success factor for business development. The survey results presented a snapshot of where firms were focusing internal resources in 2005 (Figure 5). This served two purposes, first it allowed verification that the companies had

performance indicators to justify inclusion in the survey sample, and secondly allowed a profile of where mid–late-stage biotechnology companies in Canada are focusing resources. The importance of the product pipeline is shown clearly in Figure 2, where maintaining product pipeline and having new R&D projects were key priorities for the industry. It cannot be ignored that entering foreign markets and joint ventures were not deemed critical for success; however, Figure 5 shows clearly that the later stage companies are involved more in these types of activities. So it might not be critical for success but increasing firm size and entering foreign markets is part of the natural progression for market expansion.

It is not surprising that more than 50 per cent of companies surveyed are involved in new R&D projects and maintaining market share of an existing product, as this is one of the hallmarks of the industry (Figure 5). It is

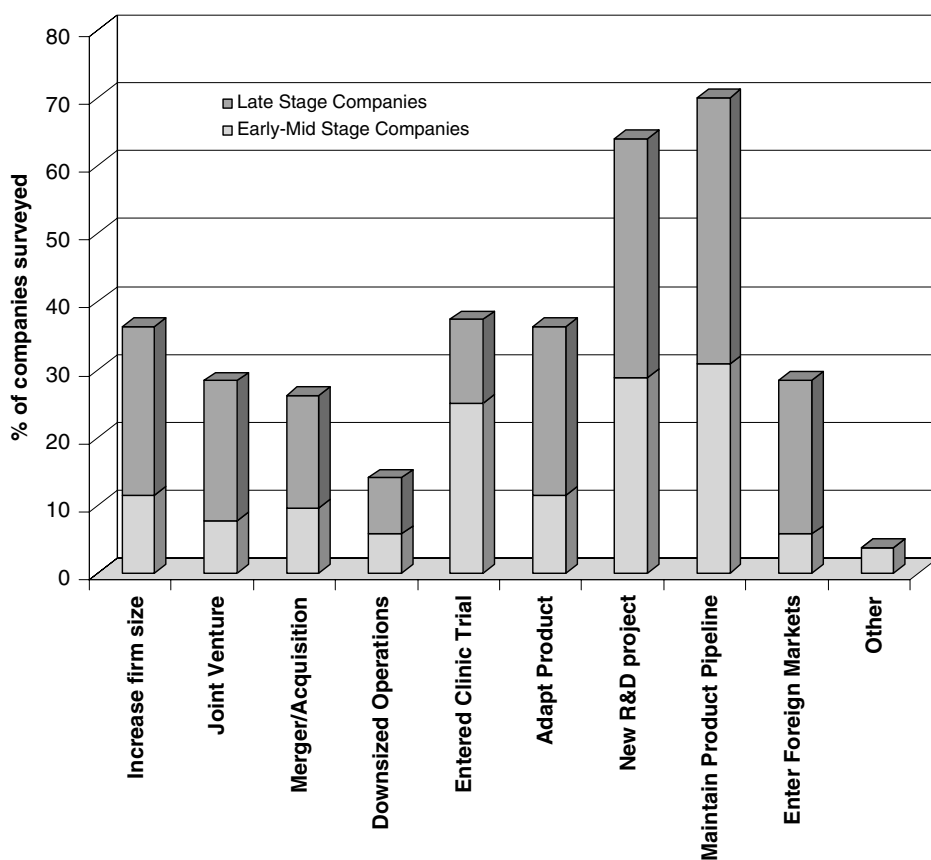


Figure 5: Current focus on resources in biotechnology industry in Canada with bar graph showing composition of response based on stage of company, with light defining early-/mid-stage company and dark defining late-stage companies

important to have lead products, but also necessary to continuously support those lead products with other supporting products in the pipeline.^{14,15} This is a well-known strategy for sustainability and this survey confirms that this strategy is not changing.

More than 20 per cent of the companies surveyed were investing internal resources into clinical trials, joint ventures, merger and acquisitions, adapting products for further market penetration and entering foreign markets. These are all indicators of industry growth.

To get a more in-depth view on the progression of the industry, the focus of internal resources was analysed based on stage of company. Contrasting areas on the bar graph (Figure 5) represent the contribution of early—mid-stage *v* late-stage companies. This visually maps the activities of companies in the industry. The early—mid-stage companies were three times more likely to be involved in a clinical trial. These companies had less diversity and the majority of their resources were focused on product maintenance, R&D and clinical trials. Later stage companies have a more diverse profile. They are 1.5–3 times more likely to be involved in adapting a product for better market penetration, moving into foreign markets or taking part in a merger or acquisition (Figure 5). These data support the current business model for the industry where biotechnology companies are improving product pipelines and finding that in order to compete they have to merge resources. The implication for the industry is that biotechnology will be feeding its own pipelines (not going to pharmaceuticals).

External environment

The external environment influences strategic decisions, and an unfavourable environment within Canada will motivate Canadian companies to move into global markets for opportunities to expand product sales, or to find alternate funding sources.¹⁶ The analysis of results found a significant difference in perception, between early—mid-stage *v* late-stage companies, with respect to importance of the external environment on performance. The late-stage companies place

minimal importance on the external environment compared to the early—mid-stage companies which gave this factor the top rank for business development in Canada (Figure 3).

The reasoning for the wide disparity based on stage of the company and how significant the external environment is for success is a consequence of how these two stages of development differ with respect to availability of internal resources. The previous section allowed a comprehensive snapshot of the use of resources in Canada (Figure 5). The later stage companies have more diversity with respect to the allocation of resources so are more able to mitigate the risk related to the influences and fluctuations of the external environment. In contrast, the early—mid-stage companies are generating no or minimal product-related revenues and are more than likely confined to the Canadian market, so consequently are more affected by external environment factors such as the financial and economic climate. With this viewpoint, it is not surprising then that the external environment for early—mid-stage companies is the most crucial success factor with respect to overall business development indices (Figure 3).

The effects of the external environment were further examined by looking at related elements, and these were ranked according to the order of importance: entrepreneurial environment, government support, ability to attract candidates to region, formation of research firms in clusters and finally resource networking. The entrepreneurial environment is a reflection of the economic climate in Canada and in some respects a measure of the risk willingness within the financial community. Strong government leadership promotes biotechnology to grow. The national healthcare system in Canada is a strong foundation for support of pharmaceutical drug development. There are multiple ways in which federal and provincial governments can aid the growth of the industry by supporting venture capital, increasing allowance to carry forward tax losses and capital gain exemptions, R&D tax credits and drug reimbursement policies. Governments can also play a role in helping the companies deal with new regulatory

and market situations. This can be through education or supporting agencies whose role is to educate the industry in these areas.

Clusters and networking not critical for success

Both research firms in clusters and resource networking were scored as not important to success (Figure 2). One of the models for biotechnology growth is that industry niches are necessary to support growth. Clusters form in which academic groups and universities are sources of technology and research support, grouped closely with alliance partners and suppliers. A similar reasoning is the close association of networking resources, with ready availability of key professional groups such as patent lawyers and funding agencies. Rautiainen⁹ determined clustering and networking in the US to be high priority as external success factors. This is in contrast to our results, where neither of these areas was given high ranking, and in fact the average ranking of two elements was deemed to be not important at all to performance.

Future improvements

The companies surveyed highlighted a wide gap between the biotechnology companies and the venture capitalist groups. There is a perception in the industry, and supported in the general comment section of the survey, that the Canadian VC market is not experienced in this field, and that Canada must look towards the US to validate its technology and support the industry.¹⁷ It would seem that there is a need to educate the VC community, and perhaps the industry as whole should investigate means in which complex technology can be communicated. The other issue is that the cash flows of biotechnology are often after a long gestation period and the investors have to look at the valuation in the backdrop of the high risk. In other words it makes the investing community leery unless they have a proven product plan. Education and closer interaction with the investment community would be means to support what has been identified in this survey as critical success factors.

An ongoing concern in the industry is the low valuation that VC firms assign to biotech

companies. A long product development timeframe and the resultant higher risks are key factors that suppress company valuations. In return for the capital investment, the VC secures more equity. This is counterintuitive. The lower valued biotechnology companies receives less funds at a critical stage in its development and is faced with continual limited resources that results in slowed development.¹⁸

The proposed strategies for business development must centre on improving communication with the investment community to promote funding in this potentially lucrative, important and growing yet, high-risk industry. Improving industry management skill sets was recognised as a requirement to move the industry forward, which would be facilitated by government support for education and corporate support of professional development.

CONCLUSION

Defining Canada's critical success factors and performance indicators provides the biotechnology industry with a basis on which to build a development path towards sustainability. Later stage companies with access to product-derived funding are more able to build internal resources. They can focus on providing the company with necessary skill sets by professionally developing and retaining employees. Earlier stage companies are more dependent on external factors such as government support. The study highlights the industries' dependence on building knowledge assets as a critical success factor, which then supports the maintenance of product pipelines, which in turn promotes better valuation by the VC community. Understanding the progression of a companies' focus as it changes during development, and the relationships between critical elements, is a map for companies to develop their business models, business and marketing plans.

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