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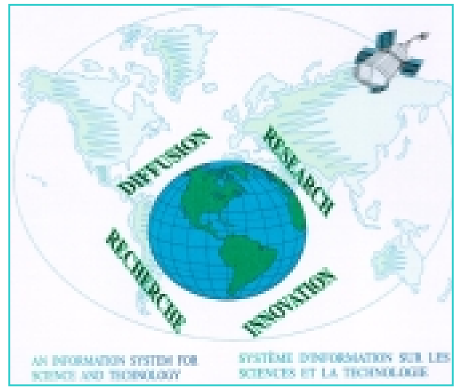

Profile of Spin-off Firms in the Biotechnology Sector: Results from the Biotechnology Use and Development Survey - 1999

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Results from the
Biotechnology Use and Development Survey - 1999

Profile of Spin-off Firms in the Biotechnology Sector

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The Science and Innovation Information Program

The purpose of this program is to develop **useful indicators of science and technology activity** in Canada based on a framework that ties them together into a coherent picture. To achieve the purpose, statistical indicators are being developed in five key entities:

- **Actors**: are persons and institutions engaged in S&T activities. Measures include distinguishing R&D performers, identifying universities that license their technologies, and determining the field of study of graduates.
- **Activities**: include the creation, transmission or use of S&T knowledge including research and development, innovation, and use of technologies.
- **Linkages**: are the means by which S&T knowledge is transferred among actors. Measures include the flow of graduates to industries, the licensing of a university's technology to a company, co-authorship of scientific papers, the source of ideas for innovation in industry.
- **Outcomes**: are the medium-term consequences of activities. An outcome of an innovation in a firm may be more highly skilled jobs. An outcome of a firm adopting a new technology may be a greater market share for that firm.
- **Impacts**: are the longer-term consequences of activities, linkages and outcomes. Wireless telephony is the result of many activities, linkages and outcomes. It has wide-ranging economic and social impacts such as increased connectedness.

The development of these indicators and their further elaboration is being done at Statistics Canada, in collaboration with other government departments and agencies, and a network of contractors.

Prior to the start of this work, the ongoing measurements of S&T activities were limited to the investment of money and human resources in research and development (R&D). For governments, there were also measures of related scientific activity (RSA) such as surveys and routine testing. These measures presented a limited picture of science and technology in Canada. More measures were needed to improve the picture.

Innovation makes firms competitive and we are continuing with our efforts to understand the characteristics of innovative and non-innovative firms, especially in the service sector that dominates the Canadian Economy. The capacity to innovate resides in people and measures are being developed of the characteristics of people in those industries that lead science and technology activity. In these same industries, measures are being made of the creation and the loss of jobs as part of understanding the impact of technological change.

The federal government is a principal player in science and technology in which it invests over five billion dollars each year. In the past, it has been possible to say only *how much* the federal government spends and *where* it spends it. Our report **Federal Scientific Activities, 1998 (Cat. No. 88-204)** first published socio-economic objectives indicators to show *what* the S&T money is spent on. As well as offering a basis for a public debate on the priorities of government spending, all of this information has been used to provide a context for performance reports of individual departments and agencies.

As of April 1999, the Program has been established as a part of Statistics Canada's Science, Innovation and Electronic Information Division.

The final version of the framework that guides the future elaboration of indicators was published in December, 1998 (**Science and Technology Activities and Impacts: A Framework for a Statistical Information System,** Cat. No. 88-522). The framework has given rise to **A Five-Year Strategic Plan for the Development of an Information System for Science and Technology** (Cat. No. 88-523).

It is now possible to report on the Canadian system on science and technology and show the role of the federal government in that system.

Our working papers and research papers are available at no cost on the Statistics Canada Internet site at http://www.statcan.ca/cgi-bin/downpub/research.cgi?subject=193.

Table of Contents

Acknowledgements

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The survey also owes a debt of gratitude to the firms, that must remain anonymous, who gave their time and ideas in development and testing of the survey and as well as those firms that responded to the survey.

At Statistics Canada numerous people contributed to the survey, among those are Fred Gault, Antoine Rose, Claire Racine-Lebel, methodologist Nicolas Lavigne, Michael Bordt, Namatié Traoré, Francois Gendron and my colleagues in the Sept. 2001 Data interpretation course, and the exceptional editorial work of Chuck McNiven.

On a personal note, thanks to my wife Angèle for her learned observations and support.

Background

The purpose of this paper is to present data from the *Biotechnology Use and Development Survey – 1999*, its focus is on spin-off firms. The survey was carried out as part of the Canadian Biotechnology Strategy to provide Canadians with information about biotechnology firms in Canada. This survey continues to gather data relating to the emerging area of biotechnology begun with the first survey of biotechnology conducted in 1996. This paper is organized under the following key topics: background information, data variables, other inquiries into spin-offs, the need to commercialize, sector/size and location, employment, revenue, R&D, benefits/obstacles, financing, strategies, patents collaborations benefits, obstacles and the product pipeline.

Biotechnology has the potential to affect almost every aspect of our day-to-day lives. Everything from human health and the environment to mining and agriculture are influenced by advancements in biotechnology. Of the 358 core biotech firms found in the manufacturing sector, 123 were spin-off firms. Created principally by universities and operating in the area of human health, spin-offs are, generally, at the early stages of development and their progress will mirror that of the sector as a whole.

> This survey used a list-based definition of biotechnology. For the full list of biotechnologies see Appendix 2. A statistical definition, recently adopted by the OECD, is included below for the purpose of simplifying the reader's understanding of biotechnology
>
> Biotechnology is; *"The application of science and technology to living organisms as well as parts, products and models thereof to alter living or non-living materials for the production of knowledge, goods or services."*

> The *Biotechnology Use and Development Survey* described a spin- off as; "… a new firm created to transfer and commercialize inventions and technology developed in universities, firms or laboratories."[1] See Appendix 1.

It is crucial to be able to measure the financial characteristics of biotechnology-related firms in order to better evaluate the future growth of the sector. The biotechnology firms are progressing towards increased commercialization, a necessary step for the sector to capitalize on its extensive research and development (R&D).

The biotechnology core group of companies are those firms that, in 1999, were developing a product or process that required the use of

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[1] 1999 *Biotechnology Use and Development Survey*. 2001: Statistics Canada.

biotechnology, or that felt that biotechnology was central to their activities. In 1999, this core group had total R&D expenditures of over $820 million and revenues of over $1.9 billion[2]. All this sectoral activity, involving over 17,000 products at all stages of development[3], includes more than 8,000 products/processes at pre-market stages. This is no doubt fertile ground for the increased commercialization of the intellectual property (IP). Spin-offs represent one way in which these firms capitalize on their IP and their R&D investments. The *Biotechnology Use and Development Survey* provided the first opportunity to study, in depth, biotechnology spin-offs. The earlier *1997 Biotechnology Survey* did not collect any information on spin-off firms[4].

Biotechnology Scorecard

	1997	**1998**	**1999**	**1999 Spin-off**	**% of Total**
Number of Firms	282	..	358	123	34%
Biotech Revenues*	$813	$1,554	$1,948	$571	29%
Biotech R&D Spending*	$494	$695	$827	$244	30%
Biotech Employees	9,019	..	7,748	2,227	29%

.. Data not collected
** Dollar figures are in $000,000*
Source: Statistics Canada Biotech Use & Development Survey 1996 & 1999

Niosi (2000) explains rapid growth in Canadian biotechnology firms, concluding that there are six criteria to explain rapid growth in the Canadian biotechnology firms. These are;

1. Companies should patent their inventions as a way to signal the financial community of the novelty of their future products, thus their exclusivity. Venture capital is much easier to obtain when the companies possess patents, and venture capital is a major growth factor in biotechnology.
2. Avoiding major delays by conducting R&D on several products, not simply one, and eventually abandoning dead ends. One-product firms are usually too risky for venture capital. Mergers with other small biotechnology firms working in compatible areas can help to increase the chances of having patents, thus venture capital, augment visibility and critical mass, and obtain larger IPOs (initial public offering).
3. Targeting export markets: the Canadian market is too small to support any biotechnology product. These are knowledge-intensive products subject to economies of scale (it pays to produce the knowledge once and to

[2] McNiven, Chuck, March 2001. Working Paper, *Biotechnology Use & Development Survey-, 1999.* Catalogue #. 88F006XIE, Statistics Canada.
[3] Ibid.
[4] Traoré, Namatié, July 2001. *The Canadian Biotechnology Sector: Features from the 1997 Biotechnology Survey*. Catalogue # 88F006XIE. Statistics Canada.

sell it embodied as many times as possible). Going for export markets seems unavoidable.
4. Looking for venture capital: Venture capital provides not only cash to firms but also management and financial services, as well as credibility to the emerging firm.
5. Conducting alliances, but timing them. Alliances may procure substantial resources to emerging biotechnology companies. However, alliances are not always successful. Too early an alliance can lead to contracts were the biotechnology firms loses most of the benefits of its innovation but conversely it can help a cash-strapped firm. If the alliance comes too late the biotechnology firm may already find itself in a weak position due to cash flow problems. The best option for the biotechnology firm is to obtain venture capital, access to the capital market, and organize partnerships at the end of Phase III[5] clinical trials or field tests, when their products are already tested and approved.
6. Planning the IPO; Going public was not a condition of rapid growth. Some of the companies that had obtained access to the stock market had only collected a few million dollars through their IPOs, while others had known major delays and product retargeting after raising substantial amounts from the financial market.[6]

The factors enumerated by Niosi provide a reference for assessing spin-off firms' characteristics and to shed light on their growth potential.

Spin-off firms are important as they made up over 34% of the core group of firms from the 1999 biotechnology survey. They also made up over 112 of the 270 small (under 50 employees) size firms, by far the largest group of core biotechnology firms, and half of the human health related firms, the largest sector of biotechnology firms. Central to this paper is the question: What are the general characteristics of this sub-group of core biotechnology firms?

The number of companies is quite small, as the biotechnology sector is still in its infancy, and thus some detail is lost due to confidentiality restrictions. Also, biotechnology is best referred to as an activity performed across a wide range of industries, rather than an industry in itself. Therefore, no data breakdown by sector is possible, with the exception of the product development pipeline, again due to confidentiality requirements. A secondary issue is comparisons of spin-off firms to non-spin-off firms in the core group for R&D expenditures, revenue and location of patents. The results from the *Biotechnology Use and Development Survey - 1999* include revenue and R&D expenditure figures for both 1998 and 1999 and, therefore, some growth comparisons are made.

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[5] For additional information on the various clinical phases, see Appendix 4.
[6] Niosi, Jorge, Research paper, *Explaining Rapid Growth in Canadian Biotechnology Firms.* Catalogue # *88F0017MIB.* 2000: Statistics Canada.

Data Variables

Variables used from the 1999 *Biotechnology Use and Development Survey* include: company size, province/region and sector of spin-off (in order to provide some basic reference statistics), human resources data and income/expenditure data (to allow an evaluation of the fiscal health of the group), intellectual property, patents biotechnologies used, collaboration data, obstacles and strategies used in 1999. This paper constitutes snapshot of spin-offs in the core group of companies as no previous data were collected. The survey is now being repeated in its current format and this will provide an opportunity for a comparison over time of biotechnology spin-offs.

Other Inquires into Spin-offs

There is a limited amount of literature directly relating to the topic of biotechnology spin-offs. Statistics Canada conducted the *1999 Commercialization of Intellectual Property in Higher Education*, which collected some detail on spin-offs from universities and research hospitals in 1999. This work reported 215 spin-offs related to biotechnology created by Canadian universities and research hospitals. Of the spin-offs reported, 101 spin-offs were classified in the "biotechnology" field and 114 in the "health sciences" field[7]. The survey defined anything related to human health, as "health sciences" and anything not related to human health as "biotechnology". While the survey used a much more narrow definition of "spin-off" it also included inactive firms as well as firms at the conceptual stage only. As a result, the numbers differ significantly from the results of the *Biotechnology Use and Development Survey*. In the 1999 *Biotechnology Use and Development Survey*, the agriculture sector, natural resources sector and all other sectors not classified as human health fell under the "Biotechnology" category in the *Survey of Commercialization of Intellectual Property*. This is the only biotechnology-specific information included and, based on the more broad definition of spin-off it, may be expected to result in a higher number of firms.

The reasons behind the decision to proceed to spin-off can vary by type of institution. Government agencies and labs, universities, research hospitals and private corporations all have different mandates and thus, different reasons to create spin-off companies.

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[7] Read, Cathy, May 2000. Working Paper*; Survey of Intellectual Property Commercialization in the Higher Education Sector, 1999.* Catalogue # 88F0006XIB, Statistics Canada.

Once the R&D has produced some form of intellectual property (IP) with commercial potential, at least three options are available to exploit it. The IP can be licensed to another company so that they can exploit it and the originating entity can reap some reward from royalties. They can also continue the development of the IP, through to the production and market stages, themselves. Another option is to create, or spin-off, another firm to do the necessary work to exploit the discovery.

Reasons behind private corporations deciding to spin-off a company are generally related to long-term benefits. Spinning off can create an entity to which the corporation can then give research funds that can then be written off as expenses. As well, they typically form alliances that allow the parent company licensing of any current or future products. The result is a benefit of access to knowledgeable management for the spin-off and increased revenue for the parent company. With corporate spin-offs, the result is often a technology transfer back to the original company. The innovation may also be in an area that is not directly related to the company's core business. In this case it would be easier to simply spin-off the new product/process than to alter the core business of the parent firm.

Universities, on the other hand, may have different reasons behind their decisions to spin-off IP. On a basic level, universities are simply not equipped to take new discoveries through to the production phase. They are in the business of producing knowledge, not biotechnology products. Their decision will not involve as many possible outcomes as for private firms. Universities may use spin-off firms as a vehicle, not just to commercialize a development, but also to give them greater access to R&D investments. It may also be a more effective way to maximize the return on their investment while, at the same time, increasing the university's academic and research profile.

The reasons behind the creation of spin-offs at universities are similar to those of government agencies and labs. These institutions can make better use of different pools of R&D capital by creating private entities to commercialize new developments. They can also streamline the commercialization of the new products/processes by removing them from bureaucratic entanglements. The proliferation of firms increases a sector's ability to grow and attract attention of policy makers and capital markets. Public sector spin-offs, that is, those from universities, hospitals and government labs, are also seen as a bridge between the realm of academic research and industry. They facilitate the exploitation of academic research by allowing a specialized firm to move it into the industrial sector[8].

[8] U.B.C. *Report on UBC Spin-off Company Formation & Growth*. http://www.uilo.ubc.ca UBC :2001.

Survey Methodology

The survey was mailed to 3377 firms in selected NAICS codes in May 2000. The sample drawn from the Business Register of Statistics Canada was supplemented by a list of firms prepared by industry experts. Biotechnology does not fit into a single NAICS code so the need to sample based on the possibility of biotechnology use is required. Selected NAICS codes, mainly in the manufacturing sector, were identified as sectors of the economy where there was the possibility of firms using biotechnologies. Firms were selected to provide a representative sample based on size, industry, and province. Overall response rate was 66%. Results from this survey were weighted to reflect the entire count of firms in the selected industry sectors.

Excluded from the sample and from the estimates are the very small biotechnology firms. These firms had less than 5 employees and less than $100,000 in research and development expenditures. The impact on the results was minimal, for example, these firms conduct less than 1% of biotechnology research and development expenditures and introduce new products and processes.

The questionnaire was compiled and written with the active input of a consultation group of biotechnology experts from a variety of areas of expertise and interest. Following its initial design, the questionnaire was field tested with potential respondents, whose comments on the design and content were then incorporated into the questionnaire. [9]

The Need to Commercialize

The biotechnology sector is moving at such a rapid pace that commercialization has become a necessary tool to capitalize on the extensive research and development currently occurring. In fact, the biotechnology core group of companies is expecting to increase its biotech R&D expenditures by 79%, from the 1999 level, by the year 2002 and revenue is expected to jump by 157% in the same time frame[10].

All of this research activity will no doubt create fertile ground for the increased commercialization of the intellectual property and a parallel increase in the number of spin-offs.

Thus, a good way to substantiate the optimistic projections for future growth of biotechnology activity as a whole would be to profile the current crop of spin-offs. Their size, location, financial position relative to other comparable firms and even the source of the spin-off are presented in the following sections.

Spin-offs: Small firms Concentrated in Human Health

Overall, the spin-off sub-group of core biotechnology firms seems to mirror those of the core group as a whole. The *Biotechnology Use and Development Survey* indicated that 123 of the core biotechnology firms were, in fact, spin-offs. These spin-offs were heavily concentrated in the

[9] McNiven, Chuck, March 2001. *Biotechnology Use & Development Survey - 1999*. Working Paper 1.
[10] Ibid.

small size category (firms with under 50 employees) and the Human Health sector. The distribution of firms by size and sector is similar to those for the entire group of core biotechnology companies.

The human health sector accounted for 75 of the total spin-offs reported, with Agriculture coming in a distant second with 21. Firms defined as small in the survey account for 112 of the total spin-offs. Large firms, (over 150 employees), made up 5 of the total and medium sized, (50-150 employees), accounted for 6 firms. See Table 1.

Provincially, Québec (33 firms), British Columbia (31 firms) and Ontario (30 firms) led the way in the number of reported of spin-offs. These provincial results also match those results found in the core group as a whole. The current results seem to reinforce earlier studies that found that universities and associated research hospitals are the main source of spin-offs in the economy as a whole[11]. The survey found that 106, or 86%, of the core biotechnology spin-offs were formed, at least in part, from university/hospital research centers. In addition, spin-offs formed by other firms or government labs/agencies each accounted for 6 of the total spin-offs. Since firms could list more than one source of their spin-off, these totals do not add to 100%. These results are in contrast to a recent Eurostat report that found that the number of spin-offs formed from public entities was only 10% of those from private firms[12].

Table 1

Distribution of Firms by Sector	**Spin-off Firms**	**Total Core Group Firms**
Sector		
Agriculture	21	90
Aquaculture	5	14
Bioinformatics	5	18
Environment	..	35
Food Processing/Production	7	29
Human Health	75	150
Natural Resources	6	18
Other	..	4
Total	**123**	**358**

Source: Biotech Use & Development Survey -1999.
.. N/A
For a full description of sectors see Appendix 3

[11] Read, Cathy , *Survey of Intellectual Property Commercialization in the Higher Education Sector, 1999.*
[12] Eurostat, June 2001. *Task Force: Benchmarking of National Research Policies.* ESTAT/A4/REDIS/Bench/TF/ .Eurostat.

Employment

Total employment for the spin-off group was 4,089 and of these, 2,227 were classified as biotechnology employees. When compared to the rest of the core group, (57,921 total employees and 5,468 biotech employees), we see a much more biotech-intensive focus. The spin-off sub-group has 54% of its employees involved directly in biotechnology. The rest of the core group has a much smaller percentage of it's total employees, (9%), involved in biotechnology. The breakdown by category of employee further reflected the research-intensive nature of the biotechnology sector. The R&D activity field was by far the larger of the two biotechnology employee categories. There were 1,699 full-time and 136 part-time employees in the R&D-related activity fields. They were evenly split between "Science/Research Direction" (802 total) and "Technicians/Engineering" (799 total) with a much smaller number reported for "Regulatory/Clinical Affairs" (237). In the Biotechnology Administration and Production Category two categories held most of the employees. "Production" led the way with 413 total employees and was followed closely by "Management/Licensing/Administration" with 391 total employees. "Finance/Marketing accounted for only 240 total employees.

Employment in the spin-off group of firms is far more R&D intensive than the rest of the group when compared to the rest of the core group of firms. The spin-off group had almost twice as many full-time R&D/scientific employees as full-time administration/production employees. The rest of the core group had only 31% more R&D employees than they did administration/production. See Table 2. This may lend some credibility to the suggestion that the spin-off firms tend to be at an earlier stage of development. We would not expect to see a significant number of employees with administrative or production related duties unless the firm was developed enough to be at the production stage.

Table 2

Biotechnology Employees

	Spin-offs	Non-Spin-offs
Total R&D Scientific	1699	2849
Total Administration, Production, Finance	936	2167

Source: 1999 Biotech Use & Development Survey

Revenues

The spin-off group of core biotechnology firms was quite healthy in 1999. The group had a high number of firms reporting revenues. A total of 81 firms, or 66% of all spin-off firms, reported revenues from biotechnology in 1999. This is an indication that the firms had a product or service already on the market. Reporting firms also expected this good health to lead to substantial future growth. When surveyed in 1999, the spin-off firms were optimistic in their projections for revenue growth for the 2002 fiscal year. Firms projected revenue from biotechnology to almost triple by 2002. A total of 69 spin-off firms reported revenue from biotechnology-related activities in 1998. For the year 1999 the number grew to 81 firms recording revenue from their biotechnology activities. This represents a 17% increase in the number of firms reporting biotechnology-related revenues.

The amount of revenue generated by these firms' biotechnology activities also substantially increased. The spin-off group of firms increased its biotechnology revenues from $374 million in 1998 to over $570 million in 1999. This represents a 52% increase. By contrast, the remainder of the core group of biotechnology firms reported a 17.8% increase in biotechnology revenues over the same period.

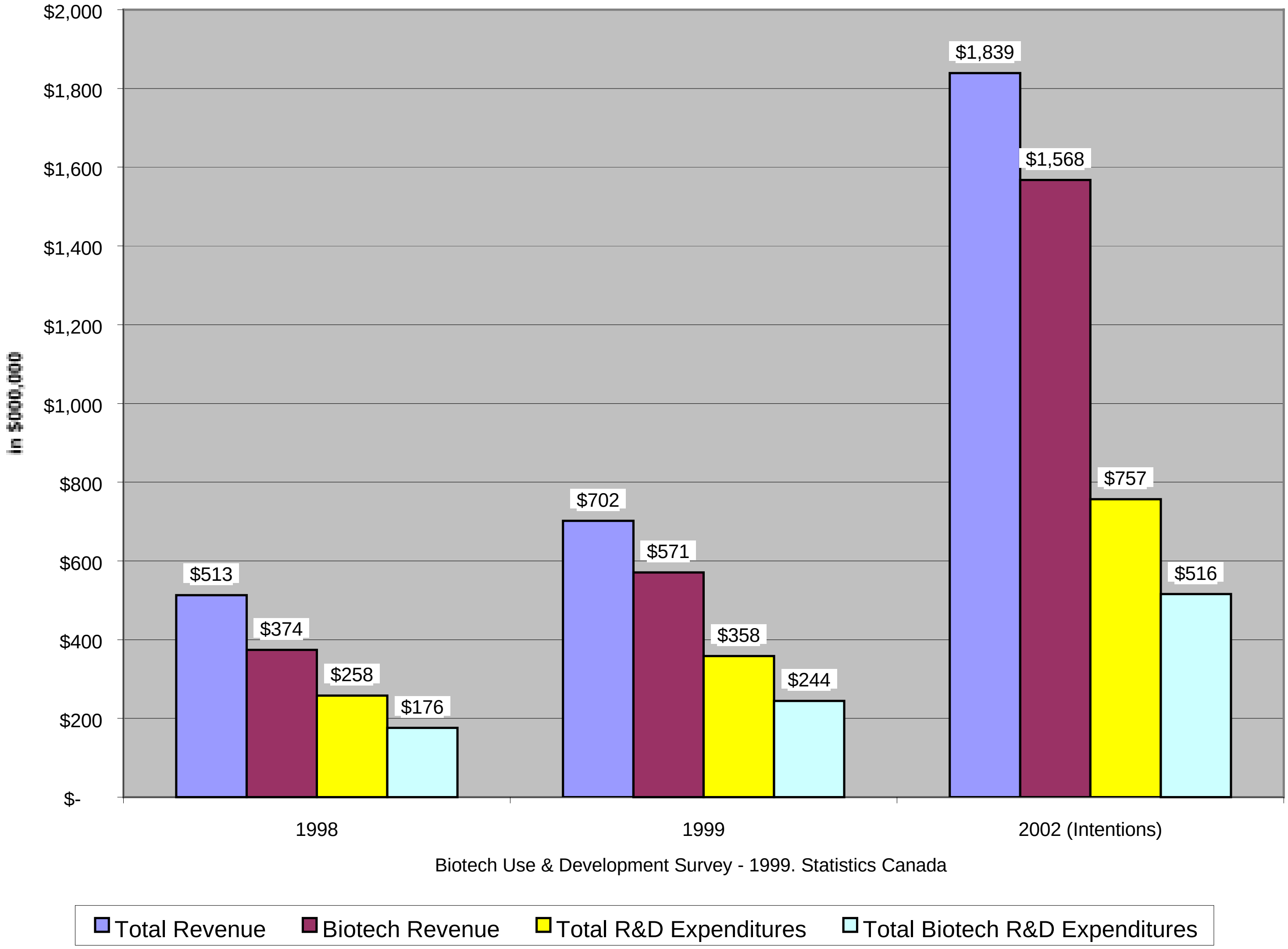
When the comparison is narrowed to the small spin-off firms and non-spin-off firms the difference becomes more marked. The small spin-off firms had a recorded revenue increase of 43% from 1998 to 1999. Conversely the non-spin-off firms of the same size recorded a drop in income of 12% over the same time period. For biotech income per firm, the 112 small spin-off firms recorded almost twice as much biotech income on a per firm basis, as well as, more total biotech income.

Research & Development

R&D expenditures are undertaken in anticipation of future growth in revenues. Firms in the biotechnology field must spend capital resources on R&D in order to be able to generate revenues later on. Biotechnology R&D expenditures for the spin-off group rose from just over $200 million in 1998 to just under $289 million in 1999, a 39% increase. Again, this is more than double the 16% increase reported for the remainder of the core group. On a per firm basis, the spin-off group spent $1.4 million on R&D in 1998 and increased this by 34% in 1999. This is significantly higher than the 0.3% increase reported by the rest of the core group for the 1998 to 1999 period. Reasons for this difference may include the later stage of development of the firm, increase in revenues and the change in the number of firms raising capital in 1999. See Table 3.

The differences between the same sub-group of small firms are less pronounced. Small spin-offs spent more, in total and per firm, than the rest of the small sized firms in both 1998 and 1999. This, in spite of the fact that non spin-offs recorded a higher year over year increase in total biotech R&D, +26% for small spin-offs to +34% for non spin-offs.

Spin-offs Expect Strong Growth to Continue Into 2002



Financing

Supporting firms' projections for revenue and R&D are the capital financing projections. Over 71% of spin-off firms attempted to raise capital in 1999 and, of these, approximately 84% were successful. These firms raised a total of $683.9 million. This success rate means that 73 firms were able to raise some form of capital in 1999. Most of these firms, 35 (48%), reported that their total capital raised was in the $500,000 to $5 million stratum. There were 14 firms reporting their total capital raised was under $500,000 and 24 reported that they were able to raise over $5 million in capital. The number of firms raising capital is expected increase in 2002 when 95, (76%), firms plan to raise capital. See table 4. The amount of capital raised is also expected to increase. Looking at the same stratums we see that 55, (59%), of spin-offs plan to raise more than $5 million in capital in 2002. This represents an increase of 31 firms from the 1999 year. The $500,000 to $5 million stratum is the level 30 firms expect to attain in 1999. The lowest stratum is also expected to shrink in 2002. Only ten firms expect to raise less than $500,000 in capital in 2002. The primary source of the capital raised was through venture capital funds accounting for over $360 million in financing. The number of firms attempting to raise capital seems to reinforce what these firms felt was the biggest obstacle to biotechnology commercialization, "access to capital".

Table 4

Spin-offs	**Number Of Firms**			
	Under $500k	$500k – $5 million	Over $5 million	Total
Capital Raised in 1999	14	35	24	73
Plan To Raise in 2002	10	30	55	95
Non-Spin-off Firms				
	Under $500k	$500k – $5 million	Over $5 million	
Capital Raised in 1999	12	33	20	65
Plan To Raise in 2002	22	45	45	112

Source:
Biotech Use & Development Survey 1999

The results from the financing question meet the factor for venture capital as outlined by Niosi. The spin-off firms are actively seeking out financing. The results indicate that the largest source of financing is, in fact, venture capital. However, conventional sources (banks etc...), as a category, is a close second in amount of funding in 1999. This suggests that sources other than venture capital should be given more consideration.

Strategies Used in 1999

The strength and projected growth of the biotechnology-related spin-offs are also evident in the development strategies used by these companies in 1999. The most popular strategy employed by these firms was to increase size. Seventy-five firms, or 61% of the total spin-off group, increased their size in 1999. This strategy was followed by the strategy category "refocused product development". Fifty-nine, or 48%, used this strategy during the year. An excellent sign for future growth is the fact that 48 firms, or 39% of all spin-offs, reported "entered new product trials" as a strategy used during 1999. This indicates that these firms have what they feel are viable products and will be moving them beyond the research phase. Related to this is the "launched new product" and it represents the end of the development cycle. This strategy was used by 34 firms in 1999. The third and fourth most widely used strategies both hint at an increase in the rate of growth for the biotechnology sector.

On the other end of the scale we find only 16 firms, or 13%, reported "Downsizing" as a strategy used in 1999. The results from this question support the optimistic projections for the increased number of firms reporting income from biotechnology activities by 2002, as well as, the projected doubling of overall biotechnology-related income for the entire spin-off sub-group.

Patents

One of the most important indicators for the knowledge-intensive group of core biotechnology firms is the number of patents it creates. Patents are often used as a barometer for the potential of a firm to capitalize on it's R&D. Once patented, it is expected that the firm will be able to develop the IP into a commercially viable product or be used in an existing one. Patents are also seen as a tangible asset, something the firm may point to as proof that they are able capitalize on their R&D. Canadian biotechnology spin-offs possess a total of 1029 existing patents. They also hold 2229 pending patents. These existing patents are concentrated in the two main geographic regions, the United States and Europe, while the pending patents are significantly more dispersed. The

U.S accounts for 40% of existing patents, Europe has 33% and Canada only 16%. The pending patents are distributed almost evenly among the U.S (28%), Canada (23%), Europe (23%) and Asia (20%). See Table 5. There was a 2:1 ratio of pending to existing patents observed for the spin-off group, compared to a 0.8:1 for the rest of the core group of firms. Patents are the main source of income for biotechnology firms.

Table 5
Patents

Existing	**Canada**	**U.S**	**Europe**	**Latin America**	**Asia**	**Total**
Non-Spin-off Firms	489	597	997	194	398	**2673**
Spin-off Firms	160	414	335	32	88	**1029**
Total						**3702**

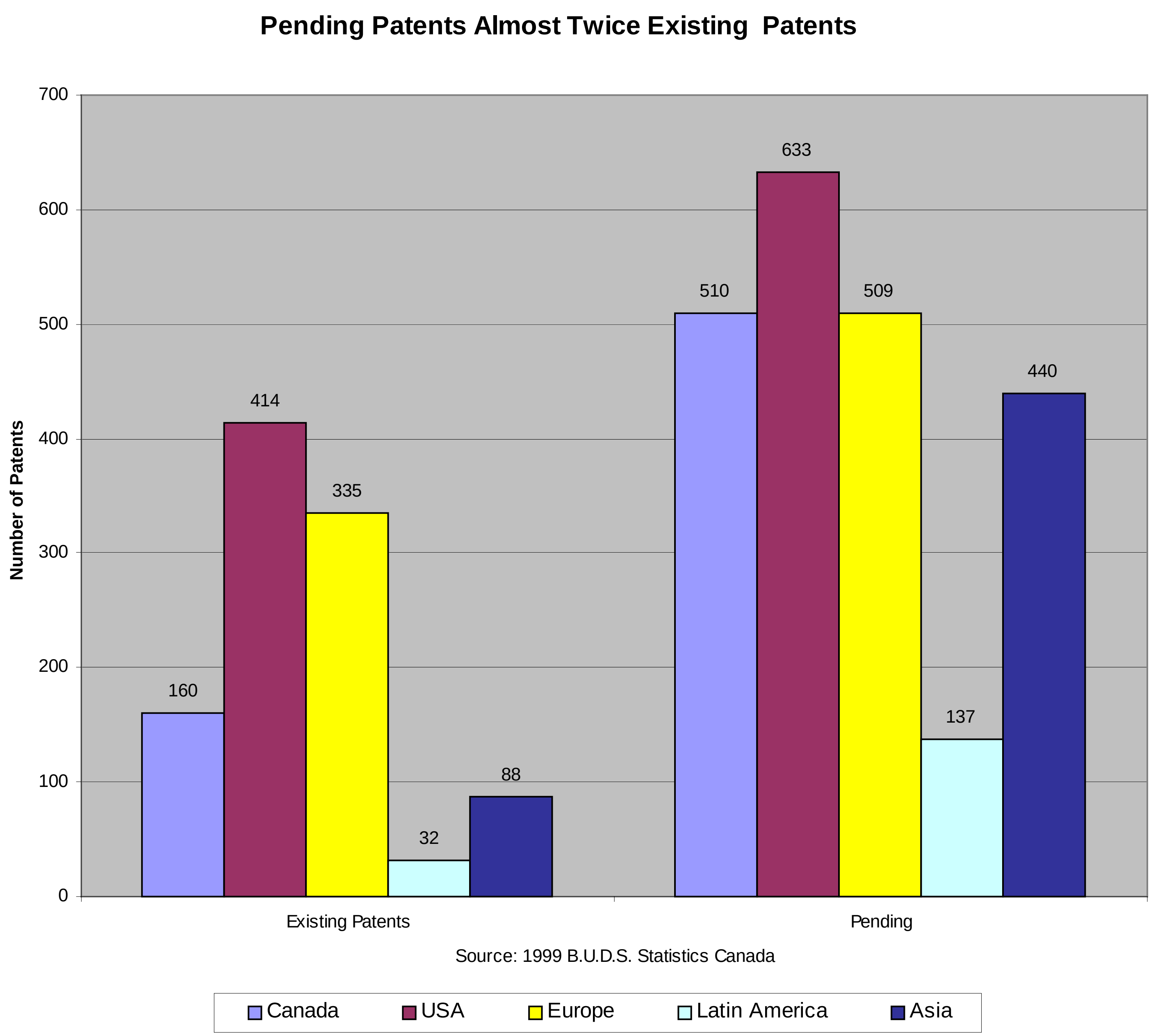
Pending	**Canada**	**U.S**	**Europe**	**Latin America**	**Asia**	
Non-Spin-off Firms	466	524	454	194	391	**2029**
Spin-off Firms	510	633	509	137	440	**2229**
Total						**4259**

Source: Biotechnology Use & Development Survey –1999
Totals may not add due to rounding

Provincially there is an interesting difference in the distribution of patents. British Columbia, while possessing 25% of the total spin-off firms, has 46% of all the patents held by spin-off firms. It has 44 % of existing and 47% of pending patents.

The number of pending and existing patents for spin-off firms meets the Niosi factor that firms patents their developments. The results indicate that the firms are actively involved in patenting their work. The volume of the patent activity may suggest a modification of the factor. Including the breadth of patenting activities may further refine the Niosi factor. This would require biotech firms to patent their work throughout the R&D process. The volume of pending patents is also an excellent indication of accelerated growth and may be incorporated into an assessment.

Significant differences are observed when the size distinction is applied. Small spin-off firms possessed more than twice the number of total existing patents than the same size firms that were not spin-offs. On a per firm basis the difference is even greater. Spin-offs possessed nearly 7 existing patents per firm, compared to 2 for the non spin-off firms. The difference is narrower, however, when the pending patents are compared. Spin-offs had 800 existing patents compared to 641 for non spin-offs.



Collaboration

The exchange of information is of the utmost importance in knowledge-intensive sectors. For biotechnology firms, the highly specialized nature of the work means that cooperation is a necessity. These firms do not normally possess all of the necessary elements to capitalize on new developments at the pace biotechnology demands. For example, a firm may have adequate funding but lack the ideas and expert knowledge another firm possesses. Almost 66%, or 81 firms, had at least one of the 261 total co-operative/collaborative arrangements. By far, the most cited reason for the arrangement was for "research and development/specialized inputs". This reason was cited by 72 of the firms reporting a co-operative/collaborative arrangement. A distant second was "access knowledge/skills/critical expertise" with 39 agreements and in third place was "prototype development/production/manufacturing" with 34.

Most of these arrangements, 77 total agreements, were with university/hospital/research network, 77 agreements. Second highest was "agreements with a larger firm" (69) followed by a "firm of smaller or equal size" at 44 agreements. These arrangements were based primarily in Canada, 103 arrangements. There was a good geographic distribution outside Canada. The U.S. 65 agreements, Europe had thirty-five, and Asia eleven. The results for the rest of the core group seem to reinforce the academic nature of biotechnology. Half of the non spin-off firms in the core group had collaborative arrangements with university/hospital/research network. This was more than any other partner category.

This factor is somewhat difficult to evaluate, according to Niosi's criteria, the crucial point in the timing of the agreement and not simply the existence of one. The spin-off firms have strong connections to universities, as Niosi has suggested, this connection is a factor to accelerated growth. It is, however, impossible to evaluate at what stage the agreements occurred and to then evaluate the timing of the agreements using the data from the 1999 *Biotech Use & Development Survey* alone.

Benefits of Biotechnology Use

The survey asked respondents to classify the importance of a number of factors to development along a rating scale. The scale ran from a "lowest" importance of 1, to "highest" importance of 5. "Product improvement” and “market performance” were, by a wide margin, the most important categories of benefits to using biotechnology. The benefit listed in “market performance” that was rated of highest importance was “improve market position”. For the “product improvement category the most important benefit was “develop new product or processes”. All of the reasons in these two categories had over 60% of respondents opting for high importance. The interesting revelation in responses to this question is the low number of firms using biotechnology in their production or processing operations. Only about 52% of firms use biotechnology in these operations. This may be attributable to the simple fact that the nature of spin-offs is such that they have a period of initial growth where production and processing operations have not yet begun. The data for contracting out tend to support a further argument that these operations are being carried out by other firms. This would seem to indicate that the spin-offs in the core group of biotechnology firms are more R&D intensive, contracting out the production of their research successes.

Obstacles to Biotechnology Commercialization

Access to capital is the single biggest barrier to the commercialization of biotechnology according to spin-offs. Over 65% of firms ranked “access to capital” as the highest importance and 88% gave it high importance. At the other end of the scale, “public perception and acceptance” was seen as the least important barrier to the commercialization of biotechnology. Just over half of the spin-off firms felt it was of little or no importance as a barrier to commercialization. This may be attributable to the fact that only half of spin-off firms have products on the market.

Product Development Pipeline

The size and characteristics of the product pipeline, which encompasses all products currently under development to those already on the market, are key indicators of future growth in the biotechnology sector. The spin-off group of firms reported on products at three developmental stages:

1. R&D phase.
2. Pre-Clinical Trials/Confined Field Trials.
3. Regulatory phase/ Unconfined release assessment.

With the results, we see clear evidence that these firms have been created with more than just one possible product. Spin-off firms have a total of 636 products/processes at the R&D phase of development. That works out to an average of 5 products/processes per spin-off firm. As expected the numbers significantly decline for the next two stages of development. The numbers decline by 75% to 161 for the Pre-clinical trials phase of development. This rate levels out to a 58% drop to 68 products at the regulatory phase. While this attrition rate is substantial, the spin-off firms seem, proportionally, to have a smaller drop than the rest of the core group. This indicates that the spin-off firms are creating a more even flow of products through the pipeline. This reinforces the desirability of spin-offs as a method of commercialization. The firms are not being created as one-off product developers, rather, they appear to be created to carry out continuing research on a strong commercial footing.

The product development pipeline serves as a proxy for Niosi's factor of delay avoidance. The fact that the pipeline shows that spin-off firms suffer less attrition in the number of products from stage to stage indicates that the spin-off firms are successfully avoiding delays. Delays would inevitably mean that the spin-off firms would not be able to move products to the next phase of development. As a result the firms would have a much higher rate of attrition than currently exists. As well, they appear to have enough products at each level of development to ensure that a delay with one product/process wouldn't cause the firm to cease operations.

Summary

The group of core biotechnology firm is characterised by the presence of a substantial group of emerging spin-off firms. Most of these firms are still at an early stage of development, only 66% reported revenues from biotech activities in 1999, and concentrating their efforts on R&D. They have protected their IP by patenting, strengthened their positions through collaborations and alliances and plan to continue to seek out increasing amounts of capital financing.

The spin-off group of firms appears to be a research-intensive sub-group of firms in the emerging Canadian biotechnology sector. As evidenced by the type of employees, the spin-off firms appear far more research intensive than the rest of the core group. This may be related to the stage of their product development pipeline. The spin-off sub-group also appears to be well positioned to capitalize on their extensive R&D, as evidenced by the characteristics and shape of their product development pipeline. These firms are formed, primarily, from universities/research hospitals and are active in the area of human health.

When the Niosi factors for accelerated growth are adapted and applied to the spin-off group of firms there is evidence of significant potential for future, rapid growth. The spin-off firms are patenting their developments and, as indicated in the pending patents, will have a significant growth in number of patents held in coming years. The firms are also seeking out financing. A significant number of firms received some form of financing in 199 and an even greater number plan to seek funding in 2002. This is a major factor identified by Niosi and something the spin-off group of firms is taking measures to address. The timing of collaborative arrangements is impossible to gauge, given the data available. However, the connection to universities is quite clear. Almost all of the firms were created by universities/research hospitals and the most popular source of collaboration was universities/research hospitals.

Appendix 1 - Definitions

Biotechnology:

For the purposes of this survey, a list-based definition was used. For the full list of biotechnologies see Appendix 2. A tentative list-based definition has been proposed to the OECD as well.

Core, User and Non-user Firms:

The survey also had respondents answer questions to filter them into "Non-Users", "Users" and "Core" firms. The "Core" group of firms were those firms that were engaged in activities directly involved the creation of a product or process that required the use of biotechnology. The survey also allowed firms to classify biotechnology as central to their activities. Users were those firms who used biotechnology only in their day–to-day operations. Non-users, obviously, were those firms who did not use biotechnology.

Spin-offs:

The 1999 Biotechnology Use and Development Survey included a question asking respondents to identify themselves as a spin-off based on the following definition; " *A Spin-off is described as a new firm created to transfer and commercialize inventions and technology developed in universities, firms or laboratories*." It went on to ask those who were spin-offs to identify the type of institution they were spun-off from. The options were university/research hospital, government lab/agency, another firm, or other. The question was included after the filter to core/non-core so the firms could all be classified as "Core biotech spin-offs".

Appendix 2 - List of Biotechnologies

List of Biotechnologies From the 1999 Biotechnology Use and Development Survey.

DNA Based

1. Gene Probes / DNA Markers
2. Bio-informatics
3. Genomics / Pharmacogenetics
4. Genetic Engineering / DNA Sequencing / Synthesis / Amplification

Biochemistry / Immunochemistry

1. Vaccines / Immune Stimulants
2. Drug Design / Delivery
3. Diagnostic Tests / Antibodies
4. Peptide / Protein Sequencing / Synthesis
5. Cell Receptors / Signaling / Pheromones / Structural Biology
6. Combinatorial Chemistry / 3D Molecular Modeling
7. Biomaterials
8. Microbiology / Virology / Microbial Ecology

Bioprocessing Based

1. Cell / Tissue / Embryo Culture
2. Extraction / Purification / Separation
3. Fermentation / Bioprocessing / Biotransformation / Natural Products Chemistry

Environment

1. Bioleaching / Biopulping / Biobleaching / Biodesulphurization
2. Bioremediation / Biofiltration / Phytoremediation

Appendix 3 - Biotechnology Sectors

Sectors:

Human Health

Diagnostics: biosensors, immunodiagnostics, gene probes.

Theraputics: Vaccines, immune stimulants, biopharmaceuticals etc...

Agriculture

Plant Biotech: tissue culture, embryogenisis, etc.

Animal Biotech: diagnostics, theraputics embryo implantation, etc.

Non-Food Agriculture: Fuels, lubricants, cosmetics, etc.

Natural Resources

Energy: industrial bioprocessing, biodesulphurization, etc

Mining: microbiologically enhanced mineral recovery, bioprocessing, etc.

Forest Products: biopulping, biobleaching, biopesticides, etc.

Environment

Air: bioremediation, diagnostics, biofiltration, etc.

Water: diagnostics, biofiltration, phytoremediation, etc

Soil: bioremediation, diagnostics, biofiltration, etc.

Aquaculture fish health, broodstock genetics, bioextraction.

Bioinformatics

Genomics & Molecular Modeling: DNA/RNA/protein synthesis & databases.

Gene Therapy: gene identification, gene constructs, gene delivery.

Food Processing

Bioprocessing: enzymes & bacteria culture.

Functional Foods/Nutraceutical: probiotics, unsaturated fatty acids.

Other

Appendix 4 - Typical Stages

Typical stages of clinical development for biotechnology firms in Canada.

	Duration	Purpose
Phase 1	Up to 1 Year	Safety
Phase 2	1 to 2 Years	Safety & Efficacy
Phase 3	2 to 4 Years	Efficacy & Cost Benefits
Phase 4	2 to 10 Years	Cost Benefits & Outcomes

Source: FDA 1997; Centerwatch: Industry in Evolution for Clinical Development Cycle. 2nd Ed. FDA;1997

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