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CANADIAN BIOTECHNOLOGY '98

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BIOTECanada

CANADIAN BIOTECHNOLOGY '98

Success from Excellence

BIOTECanada's First Report on the Canadian Biotechnology Industry

Joyce Groote, BIOTECanada
Paul Hough, BIOTECanada
Rick Walter, BCG Inc.

In collaboration with
Industry Canada
Statistics Canada
Agriculture and Agri-Food Canada

Contact Canada
Ernst & Young LLP
KPMG LLP

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PRESIDENT'S MESSAGE

My involvement in biotechnology extends over the past 20 years. It has been a wonder to watch the science increase in sophistication and the industry grow exponentially. As a result, Canada has become a biotechnology success story around the world. Over the years, a supportive infrastructure has been created by government, the research community and industry-related organizations.

The government has helped sustain the development of the technology and the industry by adopting a pragmatic science-based approach to regulation. Fundamental to this approach was the use of existing regulatory expertise and infrastructure as well as the use of existing legislation rather than the creation of a new regulatory regime. The federal government has also played an important role in the support of basic research, especially since 1983 under the National Biotechnology Strategy. Industry looks forward to the continued federal government activities supporting our industry under the new Canadian Biotechnology Strategy.

Canadian scientists have also contributed to our success. They have a long history of excellence in research. Building on this base, the Canadian industry has excelled and achieved world class recognition for the development of a number of important products, particularly in the health care and agricultural sectors.

However, as we enter into the year 2000, an increasing undercurrent of discomfort is building in the public arena. Many people are seeking more information about the science of biotechnology, its products and their safety, to allay the fear of the unknown that drives their concern. This is most evident in Europe where both Canadian and U.S. genetically engineered products are facing barriers to market entry. Europeans are questioning the safety of these products as well as their social and ethical implications. Compounding this problem, very well funded organizations are flooding the market with anti-biotechnology information.

Joyce Groote

For the above reasons, it will be important to find ways to increase communication to the public in a more consistent and global effort. These efforts must now extend beyond the agriculture and food sectors that have been the traditional concern. Public perceptions are spilling over into the health care sector, particularly with the application of biotechnology to areas such as reproductive technologies, xenotransplantation and gene therapy. Governments and industry around the world have a shared responsibility to meet this demand for information. Public understanding of biotechnology, and eventual acceptance that biotechnology is a vital tool for providing innovative products that benefit consumers, is essential for the success of our industry.

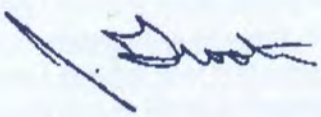
On the regulatory front, governments are facing increasing pressure to include socio-economic considerations as part of their decision making process. The most recent example of this was the Cartagena meeting of over 140 countries (February '99) to negotiate a Biosafety Protocol. There was considerable pressure on the few nations possessing the expertise and experience with genetically engineered products, to accept a Protocol that would have effectively shut down the import and export of all biotechnology products as well as living modified organisms used in research. Fortunately, for our industry, Canada held strong against those using the Protocol to address many unrelated issues ranging from socio-economics to trade strategies. Canada and a handful of other exporting nations based their negotiations on scientific principles and their experience in conducting risk assessments. The final round of negotiations will occur over the next 18 months and the industry will need to convey its requirements to government before a final Protocol is accepted.

This is only the beginning of what we can expect as new regulatory regimes are developed and existing agreements are reviewed over the next few years. Canadian government officials will face similar pressures in negotiations such as Codex Alimentarius, and review of existing international agreements which include the World Trade Organization (and its Sanitary and Phytosanitary Agreement (SPS), Technical Barriers to Trade Agreement (TBT) and the Agreement on Trade-Related Intellectual Property (TRIPs)). BIOTECanada will be working with its membership and our sister organizations to deal with these issues both domestically and internationally. We will also be working with the broader community to develop an international code of ethics with which the industry could demonstrate its sense of corporate responsibility and commitment to the highest quality products.

Domestically, despite the success of the Canadian industry, many challenges still exist. Throughout product development, companies must deal with issues related to patent and product approval as well as financing difficulties. Although the Canadian regulatory system has an excellent reputation for safety, the review process itself can take much longer than in other countries. Following approval by federal agencies, products are subject to further restrictions. As an example, health care products are subject to strict pricing controls and can face uncertainty as to whether they will be included on provincial formulary listings. BIOTECanada will be

working with both its membership and government to overcome these barriers to help the Canadian industry become more successful. It will be necessary to identify the combination of industries affected by the various issues to ensure that the relevant policy changes are carefully articulated to government. At the same time, BIOTECanada will be working to ensure that the regulatory system remains strong and that product safety for all Canadians is not compromised.

This report highlights the current state of the biotechnology industry in many of the above dimensions. It provides an important baseline for BIOTECanada to work co-operatively with all levels of government to identify important issues and to formulate coherent, supportive policies. The effort to develop this report has been a gratifying example of a smooth partnership between government and industry and I look forward to future collaborations as the industry continues to grow.



ACKNOWLEDGEMENTS

This publication is based on results from a survey conducted by Statistics Canada in partnership with Industry Canada and BIOTECanada. Industry Canada and Statistics Canada funded the survey and were instrumental in developing the list of companies to contact, in defining the sectoral classifications, and in verifying the data coding. Statistics Canada also provided invaluable assistance in ensuring a high response rate and in providing additional data verification and tabulation.

Data analysis was a team effort between BIOTECanada and our public and private sector partners (listed below). Frequent and valuable discussions were held with Industry Canada and Statistics Canada on interpretive aspects of the data. All the partners contributed significantly to the content of this report; we are grateful to them for providing information, editorial review and financial support.

The industry itself has also made a substantial contribution: 210 companies, representing 74% of the biotechnology industry, committed significant human and financial resources to providing the statistical data requested.

Government partners for this publication are:
Industry Canada
Statistics Canada
Agriculture and Agri-Food Canada

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KPMG LLP

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Ottawa Life Sciences Council
Quebec Bioindustries Association
Toronto Biotechnology Initiative

Views expressed in this report are those of BIOTECanada and do not necessarily reflect the views of Industry Canada, Statistics Canada, Agriculture and Agri-Food Canada or our other partners.

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EXECUTIVE SUMMARY

For two decades, biotechnology has been quietly growing in importance to Canada. It has application in many areas: new health care products for specific conditions; hardier crops, healthier animals, and new foods; and environmental bio-remediation, to name only a few. Biotechnology has such a broad range of uses because it is based on understanding the structure and function of the building blocks of all life forms. Characterizing this multi-faceted industry is an important way of both broadening Canadians' understanding of biotechnology, and assisting the evolution of appropriate policies.

This report describes the Canadian industrial biotechnology community. The document offers information on the size and structure of the industry, its focus and future direction, the fiscal realities, and the important business issues it faces.

Statistics Canada gathered the data for the report by means of an industry survey carried out in the summer of 1998. It gathered information from 210 firms that develop or use biotechnology to produce commercial products in the health care, agriculture, aquaculture, food processing, environment, forestry, biochemicals, bio-informatics, and mining/petroleum sectors.

In absolute numbers, Canada ranks second in the world, after the United States, in terms of the number of companies using biotechnology, employees, and revenues. This enviable position has been built through a combination of leading-edge research, determined entrepreneurial spirit, supportive government policy and increased availability of financing.

The Canadian biotechnology industry now consists of 282 companies, 72% of which are small (employing 50 people or fewer). Total employment in the industry is just under 10,000, and the firms reported having a further 1,900 unfilled positions. Biotechnology-related revenues are over $1.1 billion, and R&D spending exceeds $585 million.

The health care sector dominates activity in all aspects of biotechnology, encompassing 46% of the companies, 87% of the R&D investment, and over two thirds of the employment. Agriculture follows with 22% of the companies, 5% of the R&D and 17% of the employment. The combined sales of agricultural and food processing products derived from biotechnology almost equal the sales of biotech health care products.

Regional comparisons show that Quebec has the largest number of companies, followed by Ontario and British Columbia. Ontario has slightly more biotechnology employees than Quebec — both have over 30% of the total employment — followed by British Columbia at 13%. Both Ontario and Quebec have comparable levels of biotechnology sales — combined they account for over 70% of such sales — but companies in Ontario invest almost twice as much in R&D as those in Quebec. British Columbia, with 20% of the firms, also conducts about that level of R&D (18%). While Alberta and Saskatchewan invest 8% and 4% respectively in R&D, they enjoy twice the biotechnology sales of British Columbia. The Atlantic provinces have a growing presence in biotechnology, with 7% of the companies and 5% of the employment.

Significant growth rates (over 10% per year) are foreseen in employment to 2001. If realized, this growth would result in there being twice as many biotech employees as there were in 1995. All regions are anticipating continued growth, but British Columbia, Quebec, and Ontario expect the greatest increase.

Access to capital is a critical requirement of the industry, and one that was identified most frequently as a hurdle. Companies anticipated seeking close to $1 billion in 1998, based on responses made prior to the market fluctuations that set in during the latter half of the year. Venture capital investments rose steeply in 1997, up over 40% from 1996 and by almost a factor of three from 1995. The Scientific Research and Experimental Development (SR&ED) Tax Credit Program is very important for the industry, although a substantial number of companies have not applied for these credits during the last five years.

Financing and developing alliances of various kinds are the two top preoccupations of the industry's chief executive officers. About three quarters of both the health care and agriculture companies have created R&D partnerships. Alliances for manufacturing, marketing or distribution have been put into place by over half of all companies using biotechnology.

Regulatory issues were also identified as among the most significant hurdles facing the industry in terms of both time and cost. Rates at which products receive approval for either clinical trials or for market entry remain slow in Canada as compared with our international competitors.

Intellectual property considerations are also important. Approximately 17% of firms had to abandon projects due to blocked intellectual property rights, and an even greater percentage have been involved in patent infringement litigation.

On the scientific side, over half of the firms are using DNA-based technologies, while the high-growth technologies include biosensors, gene therapy, bioinformatics, and genomics. There are relatively few companies actively working in these high-growth fields, but a significant number of firms indicated that they would be soon developing such expertise. Virtually all areas are expected to see an increase in activity, although the more traditional areas will show by far the lowest anticipated increase.

This report presents the most comprehensive picture available to date of the Canadian biotechnology industry — those companies using biotechnology. Planning for the next industry assessment is already underway, so that we can obtain even more complete information. In the meantime, it is evident that the Canadian biotechnology industry is an important success story, with the promise of much more accomplishment in the future.

INTRODUCTION

"The extent to which Canada adopts biotechnology and pursues its development and application will significantly determine the country's future economic status and its role in world affairs."[1]

Biotechnology methods and discoveries cut across disciplines and sectors, opening up the possibility of innovation in many areas. It is therefore an enabling technology — one that creates numerous opportunities beyond the original target(s). It is a science-based technology that has elucidated the function and structure of the building blocks of living organisms. Our commercial successes over the past ten years have demonstrated the feasibility of developing products with specific characteristics and targeted applications. While the Canadian biotechnology industry is in the early stages of evolution, it has developed strengths in several sectors, using sophisticated techniques to create products, jobs and new opportunities.

This report characterizes the Canadian industrial biotechnology activity. The document offers information on the size and structure of the industry, its focus and future direction, the fiscal realities and the important business issues it faces.

The report establishes a single, credible benchmark of statistics and analyses on this important enabling technology. It provides a base for decision makers to use to ensure that biotechnology is developed and applied in Canada to the fullest extent possible.

Statistics Canada obtained the data for the report by means of an industry survey carried out in the summer of 1998. It gathered information from firms that use biotechnology to produce commercial products in human health, agriculture, aquaculture, food processing, environment, forestry, biochemicals, bio-informatics, and mining/petroleum sectors.

Canada now ranks second, only to the United States, in the absolute number of companies using biotechnology, employees, and revenues. This enviable position has been built through a combination of leading-edge research, entrepreneurial spirit, government policy and availability of financing.

Providing such an authoritative and comprehensive summary of the Canadian biotechnology industry is a key element in BIOTECanada's mandate. As a technology association that is the voice for the industry and research community in Canada, BIOTECanada strives to build a broader understanding of the industry's importance, and the many ways it already contributes to a better quality of life for all. Such understanding is essential for a supportive regulatory and policy environment to be fully realized, and for Canada to be recognized as a leader in biotechnology.

[1] *Leading in the Next Millenium*, National Biotechnology Advisory Committee, 6th Report, 1998.

METHODOLOGY

Survey Methodology

To undertake the survey, a universe of 475 firms believed to be developing or using biotechnology was identified from company listings in Contact Canada's directory *Canadian Biotechnology 1998*, Statistics Canada's Industrial R&D Survey, *Canadian Biotech News* and BIOTECanada's database. The survey excluded government laboratories, universities, hospitals, research centres, not-for-profit organizations, newly established firms, and companies using only traditional biological techniques such as dairy cultures or fermentation.

For this report, biotechnology is defined as "the application of science and engineering in the direct or indirect use of living organisms or parts of organisms, in their natural or modified forms, in an innovative manner in the production of goods and services or to improve existing processes." Various modern biotechnological tools have been included under this definition, including DNA-based technologies, biochemistry, immunochemistry and a series of advanced bioprocessing-based technologies.

Statistics Canada was commissioned to distribute the survey, collect and validate the data, and generate tables describing the survey results. Of the 475 firms contacted, 144 considered themselves to be outside the scope of the survey, had merged with another firm or were out of business. Of the remaining 331 firms, 210 (63%) provided data, 20 (6%) refused to participate and 102 (31%) did not respond to numerous requests to complete the survey. Financial data were supplied by 148 of the 210 responding firms.

To estimate the size of the industry, the 102 firms that did not respond were assumed to have the same percentage of firms outside the scope of the survey as in the universe of 475 firms. Thus, 72 firms in this group of 102 were considered to be involved in biotechnology. These 72 firms were added to the 210 that responded, providing an industry total of 282 firms. The previously determined ratio of small, medium and large firms was applied to this additional group of 72 firms.

BIOTECanada analyzed the survey results in conjunction with the private sector partners in this project, Contact Canada, Ernst & Young, and KPMG. The data provided in the report do not take into account new entrants, consolidations or bankruptcies that may have occurred after June 1998.

Unless otherwise noted, the material in this report is intended to represent the amount of biotech activity undertaken within the 282 firms considered as making up the Canadian biotechnology industry. Firms were asked to estimate the percentage of their total sales, R&D, exports and human resources that were attributed to biotechnology. This percentage was then applied to key data sets to reflect only the biotechnology activity being undertaken by each firm, keeping in mind the proportion of small, medium and large firms.

Company Size	
Small	1-50 employees
Medium	51-150 employees
Large	>151 employees

Industrial Sectors

Descriptions of industrial sectors covered in this report are provided in an Annex at the end of this section.

Financial Data and Definitions

All financial data are reported in Canadian dollars.

- *Biotech Sales:* sales of biotechnology products and services
- *Product Sales:* biotech sales plus sales of traditional products and services
- *Other Revenue:* contract revenue plus interest revenue multiplied by the percentage of biotech sales, or biotech R&D where no sales exist, declared by each firm
- *Total Biotech Revenue:* biotech sales plus other revenue
- *R&D:* biotech R&D
- *Exports:* biotech exports

Figure 1: Overview of Survey Data Sets

	Ernst & Young[1]	Contact Canada '98[2]	Statistics Canada '98[3]
Firms	224	558	282
Employees	11,000	26,800	9,823
Sales	$979M	$4.1B	$1.13B
R&D	$403M	$1.73B	$585M

[1] *Canadian Biotech '97, Coming of Age*, Ernst & Young's Fourth Report on the Canadian Biotechnology Industry, John Goudey and Deepika Nath, 1997.

[2] *Canadian Biotechnology 1998*, Contact Canada, Fred Haynes, January, 1998.

[3] Statistics Canada, *Biotechnology Firm Survey — 1997*

Comparisons with Other Canadian Reports

Data comparisons among surveys are complicated by the differences in definitions, the universe of companies surveyed and the type of questions asked. Two of the most recent and widely quoted Canadian publications are *Canadian Biotech '97 — Coming of Age* by Ernst & Young and *Canadian Biotechnology 1998*, a directory of firms published by Contact Canada. Figure 1 below provides an overview of key data sets provided in each of the documents.

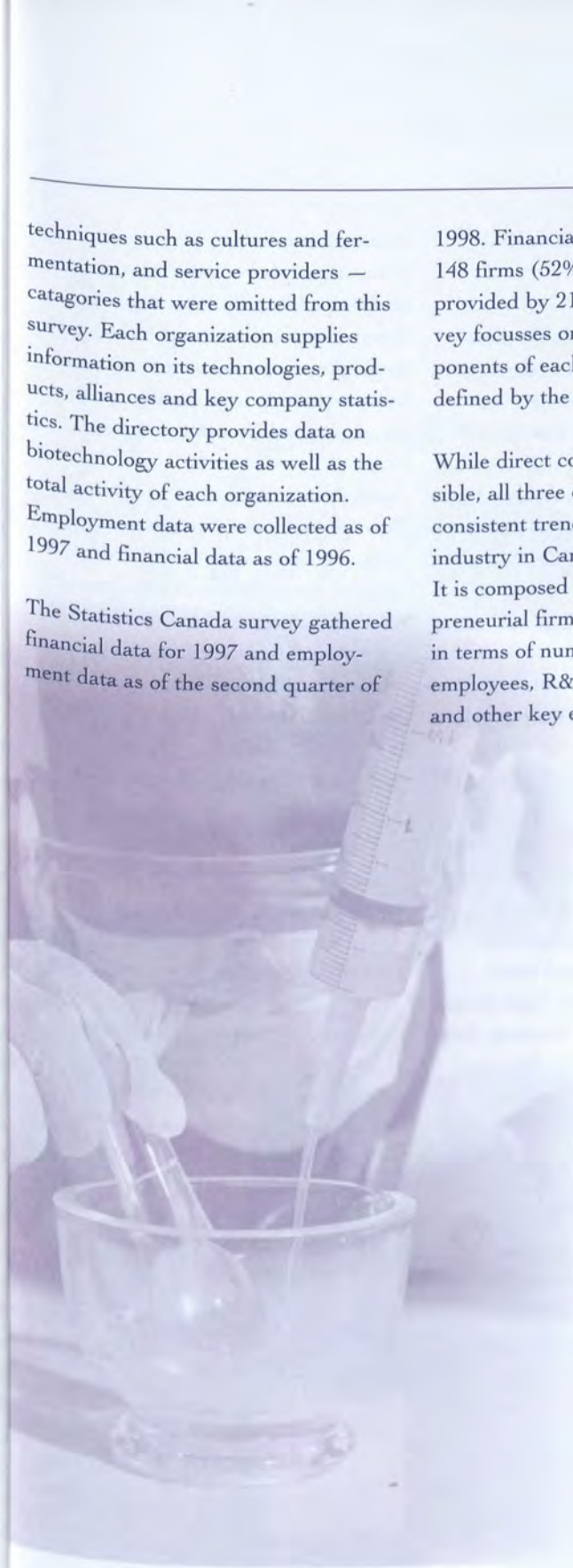
These three data sets are not directly comparable. The Ernst & Young publication reported the entire business activity of each firm, not just the biotech component of that activity. Their survey obtained responses from 71 companies (32%) and the results were extrapolated to the estimated number of biotechnology firms in Canada (224). Information extracted from the annual reports of some public companies was also included. The period covered by the survey was mid-1995 to mid-1996.

Contact Canada produces an annual directory listing companies and other organizations that consider themselves to be involved in biotechnology. The total of 558 companies listed for 1998 included newly established firms, companies using traditional biological

techniques such as cultures and fermentation, and service providers — catagories that were omitted from this survey. Each organization supplies information on its technologies, products, alliances and key company statistics. The directory provides data on biotechnology activities as well as the total activity of each organization. Employment data were collected as of 1997 and financial data as of 1996.

The Statistics Canada survey gathered financial data for 1997 and employment data as of the second quarter of 1998. Financial data were provided by 148 firms (52%) and other data were provided by 210 firms (74%). The survey focusses on the biotechnology components of each company's activities, as defined by the companies themselves.

While direct comparisons are not possible, all three data sets demonstrate consistent trends. The biotechnology industry in Canada is R&D intensive. It is composed primarily of small, entrepreneurial firms and it is expanding in terms of number of companies, employees, R&D expenditures, sales and other key economic indicators.



Annex: Sector Descriptions

Health Care
The health care sector includes therapeutics, diagnostics and gene therapy. Therapeutics includes vaccines, biopharmaceuticals, immune stimulants, rational drug design, drug delivery and combinatorial chemistry, whereas diagnostics covers immunodiagnostics, gene probes, and biosensors. Gene therapy includes gene identification, gene constructs and gene delivery.

Agriculture
Agriculture firms are involved in plant and animal biotechnology as well as agricultural inputs. Plant biotechnology includes the use of tissue culture and embryogenesis, as well as novel plant development. Animal biotechnology firms focus on terrestrial animals including diagnostics, therapeutics, embryo transplantation and other reproductive technologies. Agricultural inputs include the use of bacteria, fungi and yeast to produce feed additives, bio-fertilizers and bio-pesticides.

Environment
The environment sector is made up of bio-filtration, which includes the treatment of organic industrial emissions, as well as bio- and phyto-remediation technologies used to clean up toxic waste sites. This sector is also developing diagnostics for the detection of toxic substances using bio-indicators, biosensors and immunodiagnostics.

Aquaculture
Many aquaculture firms concentrate on fish health, including diagnostics, therapeutics and vaccines. Broodstock development and extraction of bioactive compounds from aquatic species are also included in this category.

Food Processing
Food processing companies are those which use enzymes, bacterial cultures, probiotics, and other novel food components.

Bio-informatics
The bio-informatics sector comprises those firms involved in genomics and molecular modelling. This includes DNA, RNA and protein sequencing as well as biological databases.

Other
This category encompasses all firms that fall outside the sectors described above. In general it includes firms that use biotechnology to develop nucleotides, peptides, proteins, hormones, growth factors and other biochemicals. Also within this group are firms involved in forestry, mining, energy, petroleum and chemicals, including the use of cleaner industrial bioprocessing.

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Ag-West Biotech ensures these technologies are moved forward to commercial products to improve animal production, develop new crops and to create new business. Working in alliance with the Saskatchewan biotechnology research community, it has access to the expertise of one of the top agricultural biotechnology centres in North America.

Through publications such as the monthly *AgBiotech Bulletin* and *AgBiotech Infosource*, Ag-West provides information on agricultural biotechnology to the industry and the public. It operates the Saskatchewan Agricultural Biotechnology Information Centre, featuring public tours, a demonstration laboratory and an interactive information centre. As part of its communication and public awareness role, Ag-West also operates a web site, organizes national and international conferences, carries out surveys measuring attitudes to biotechnology, holds industry seminars and supports the creation of information sources like newsletters, videos and computer-based learning modules.

Seeking strategic partners to assist in the commercialization of agricultural biotechnology projects in Saskatchewan, Ag-West Biotech services include: consulting advice; a regulatory affairs advisory service, providing expert advice and mentoring to companies wishing to move products through the regulatory process; investment funding in support of the research, development, commercialization and expansion phases of projects; facilitation of research collaborations; identification of new technologies; facilitation of intellectual property and technology transfer; professional development seminars, media information services and a small business mentorship program for the industry.

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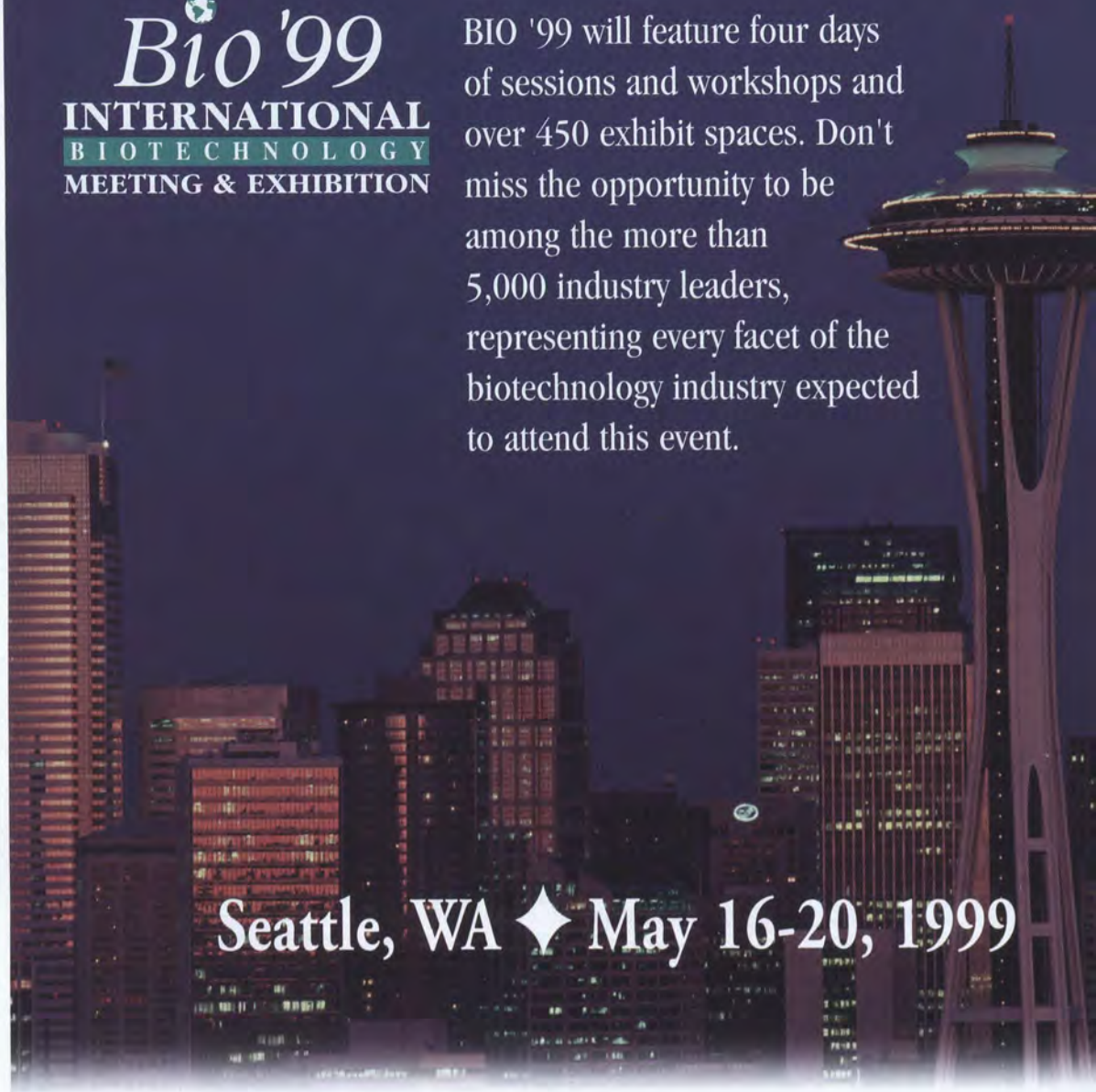

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- our new Biotechnology Secretariat which will better harness the existing biotechnology expertise in government, build awareness and help champion the industry.

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STRUCTURE OF THE INDUSTRY

SECTION HIGHLIGHTS

- The Canadian biotechnology industry now consists of 282 firms, 25% of which are publicly traded
- About 46% of the companies are in the health care sector; agriculture ranks second at 22%
- Quebec has the largest number of companies, followed by Ontario and British Columbia
- Small, entrepreneurial companies represent 72% of the total industry
- Over half the firms surveyed are using DNA-based technologies
- Employment is now just under 10,000, and an additional 1,900 positions are vacant
- Total biotechnology revenue is $1.1 billion, 90% from biotech sales
- Health care contributed to 50% of biotech sales, 58% of exports and 87% of R&D
- The combined agri-food sector is responsible for 44% of biotech sales and 7% of R&D
- R&D expenditures total $585 million

The Canadian biotechnology industry continues to grow, demonstrating international leadership as it faces several challenges, acquires people with new skills, and benefits from sales of products now reaching the market.

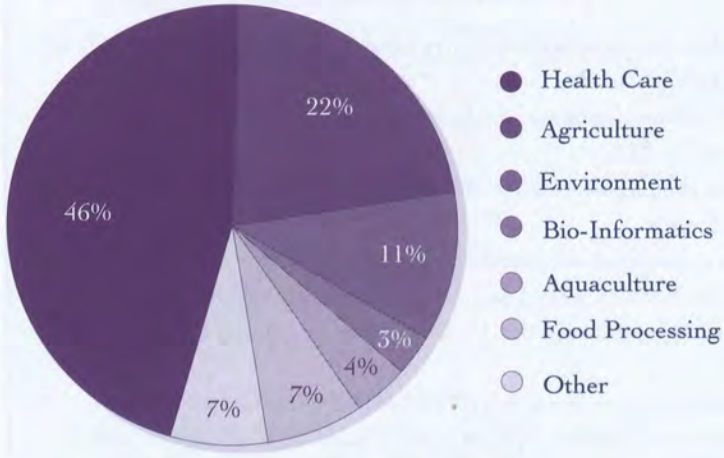
The Canadian biotechnology industry now consists of 282 firms, 25% of which are publicly traded. The industry is characterized by a mixture of firms dedicated to biotechnology, and of those using it as a tool to develop more traditional products and services. Biotechnology is the sole activity in 65% of the industry, including 27% of the large companies, 53% of the medium companies and 74% of the small companies.

The industry is defined not only by those companies developing biotechnology products but also by those using biotechnology to develop other products in addition to providing a variety of services. Notably, just over half the firms surveyed are using DNA-based technologies, with the remainder applying biochemistry-based or bioprocessing-based technologies.

Company Distribution by Sector (see Figure 2)

Health care dominates the industry, representing 46% of the total number of firms. The next largest sector is agriculture, comprising 22% of our companies. When combined with the food processing firms, the agri-food sector comprises fully 29% of the total. The environment sector comprises 11% of

Figure 2: Company Distribution by Sector (%)



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

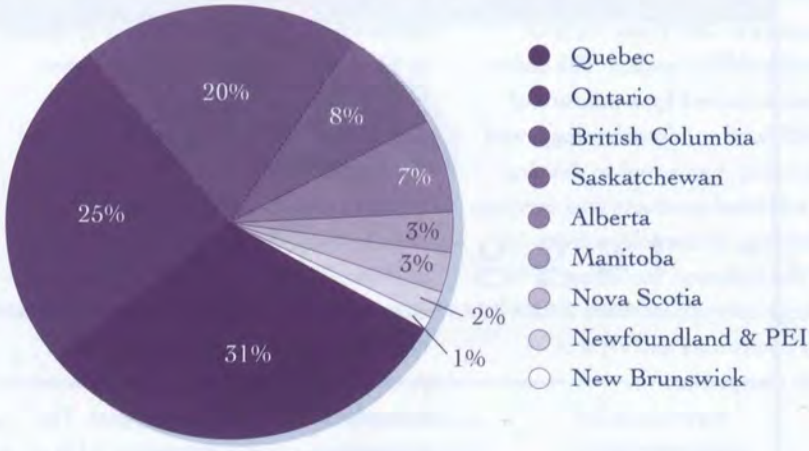
the Canadian biotech industry and the remainder is made up of a variety of industrial sectors.

Companies focussed on platform technologies such as bio-informatics, genomics and molecular modelling now make up 3% of our industry.

Company Distribution by Region (see Figure 3)

Quebec has the largest number of companies (31%) followed by Ontario (25%) and British Columbia (20%). The three Prairie provinces share 18% of the industry and the Atlantic region makes up the remaining 6%.

Figure 3: Company Distribution by Region (%)



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

Company Distribution by Size

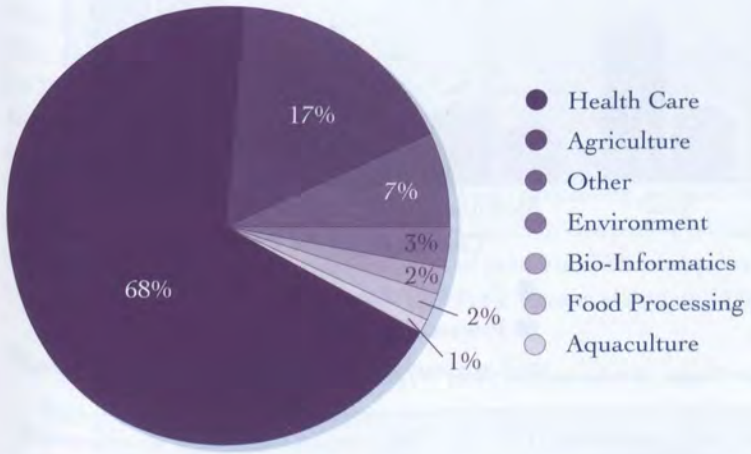
Small, entrepreneurial companies (1-50 employees) represent 72% of the industry, whereas medium firms (51-150 employees) make up 15% and large firms (151 or more employees) form 12%.

Employment (see Figures 4-6)

There are now just under 10,000 people employed in Canada on activities involving biotechnology. An additional 1,900 positions are vacant.

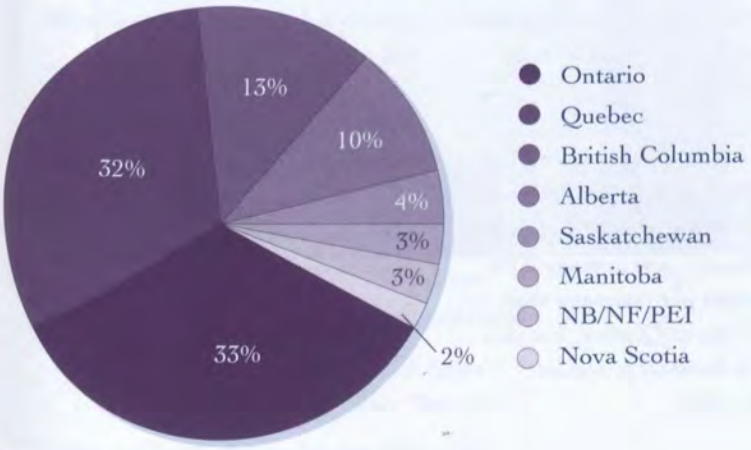
Health care leads all other sectors, with 68% of total employment. Agriculture

Figure 4: Percentage Employment by Sector



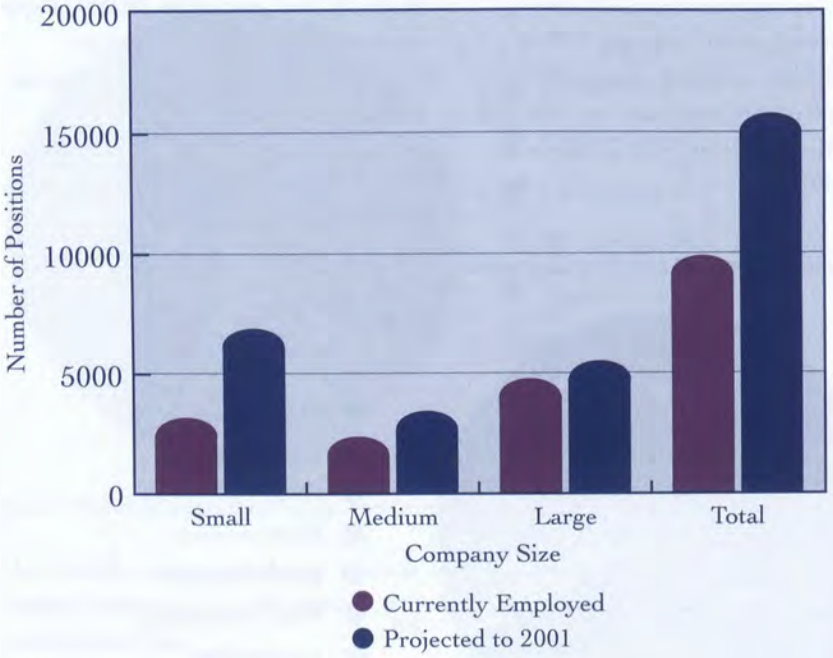
Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

Figure 5: Percentage Employment by Region



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

Figure 6: Employment by Company Size



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

is a distant second, employing 17%. Agriculture firms have an average of 29 biotech employees, significantly less than the 52 biotech employees in the average health care firm. Agriculture and health care firms expect that each of their sectors will experience an average employment growth of 55% by the year 2001.

Ontario leads the country in employment, with 33% of the total, followed closely by Quebec, with 32%. Companies in Ontario now average 23% more employees per company than their sister firms in Quebec, but this differential is forecast to almost disappear by 2001.

By company size, large firms account for 44% of all biotech employees, whereas small firms employ 32% and medium firms 24%. This is expected to change significantly by 2001, when small firms will employ 44% of all biotech employees and large firms will employ 34% .

Small companies reported that 33% of their available positions are vacant. Medium and large firms reported lower vacancy rates of 12% and 14%, respectively.

Financial Overview (See Figures 7-10)

Total Biotech Revenues

(see Methodology Section for definitions)

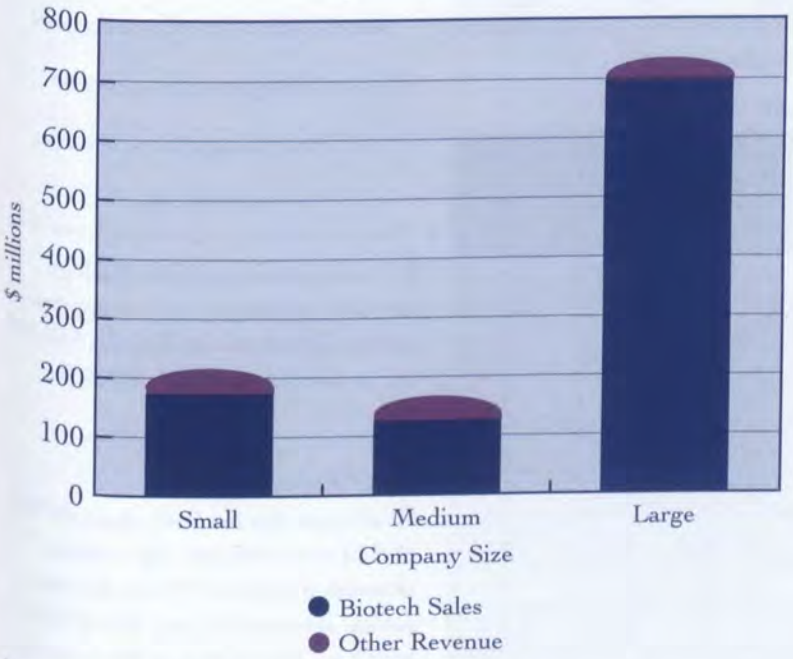
Total biotech revenues are now $1.1 billion. This comprises 90% biotech sales and 10% other revenues (contract research and income from investments). In distribution by company size, large companies account for 64% of the total, small firms account for 20% and medium firms for 16%. Total biotech revenues for large firms average $21 million. For medium firms, the average drops to about $4 million, and the average small firm has total biotech revenues just exceeding $1 million.

Small and medium firms rely more on contract research revenues: they earned 78% of such revenues.

Sales and Exports

Biotech sales now approximate $1 billion, even though 29% of the firms are not yet generating sales. Health care leads with half of all biotech sales, followed by agriculture at 23% and food processing at 21%. The combined agri-food sector has 44% of biotech sales, almost matching those from health care. Health care also accounts for the majority of exports: 58% of the total. Food processing includes only 7% of Canadian companies but achieves 21% of sales and 18% of exports. Although environment makes up 11% of the

Figure 7: Biotech Revenue by Company Size



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

companies, the sector has only 3% of sales and 1% of exports.

Ontario leads the nation with 36% of biotech sales, followed by Quebec, Saskatchewan and Alberta. Ontario also leads with 42% of exports, followed by Quebec and Alberta. Saskatchewan firms are more focussed on domestic markets: they have 9% of the biotech sales but less than 1% of the exports. The more globally oriented Alberta firms have 9% of the biotech sales but 19% of the exports.

Figure 8: Key Data by Sector

Sector	Companies %	Biotech Sales %	R&D %	Exports %
Health Care	46	50	87	58
Agriculture	22	23	5	21
Environment	11	3	1	1
Food Processing	7	21	2	18
Aquaculture	4	1	0	1
Bio-Informatics	3	0	2	0
Other	7	2	3	1
Total	**100**	**100**	**100**	**100**

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

Figure 9: Key Data by Region

Sector	Companies %	Biotech Sales %	R&D %	Exports %
Quebec	31	34	24	25
Ontario	25	36	42	42
British Columbia	20	4	18	9
Saskatchewan	8	9	4	0
Alberta	7	9	8	19
Nfld, NB, PEI	3	0	0	1
Nova Scotia	3	2	2	3
Manitoba	3	6	2	1
Total	**100**	**100**	**100**	**100**

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

Overall, exports make up a significant portion (40%) of biotechnology product sales. Small firms, in particular, depend on export markets, where over 50% of biotech sales revenue is generated. Domestic markets are more important to the large and medium firms, generating 61% and 68% of their biotech sales respectively.

Large firms reported 70% of biotech sales. Five firms account for 60% of biotech sales and 50 firms account for virtually all biotech sales.

The average sales of biotechnology products per employee were approximately $58,000 for small firms, $62,000 for medium firms and $162,000 for large firms.

R&D Expenditures

Health care has the lion's share (87%) of R&D expenditures. Agriculture, although it includes 22% of the companies, accounts for only 5% of R&D spending. The remaining 8% is widely distributed among the other sectors

(see Figure 8). While the combined agri-food sector covers 29% of the companies and 44% of biotech sales, it carries out only 7% of R&D.

Most R&D expenditures (42%) take place in Ontario; Quebec is next at 24% followed by British Columbia at 18% (see Figure 9).

Small and medium companies clearly lead the pack in terms of absolute R&D spending. Large firms report R&D expenditures of 34% of their biotech sales. In addition, the survey highlighted the fact that over half of the companies spend more than 50% of their revenues on R&D.

Figure 10: Key Data by Company Size (financials in $ millions)

	Small	Medium	Large	Total
No. of Firms	204	43	35	282
Biotech Sales	$183	$137	$698	$1,017
Other Revenue	$49	$47	$23	$119
Total Biotech Revenue	**$231**	**$183**	**$721**	**$1,135**
R&D	$192	$153	$240	$585
Exports	$95	$43	$275	$413
Employees	3,125	2,397	4,302	9,823
Unfilled Positions	1,031	281	587	1,899
Total Positions	**4,155**	**2,678**	**4,890**	**11,723**

Note: Estimations for sector totals by Industry Canada and BIOTECanada.

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

SECTION HIGHLIGHTS

- CEOs considered finance and alliances as issues of increasing importance
- Financing and regulatory issues were the most often cited hurdles to commercialization
- 73% of health care firms and 76% of agriculture firms have R&D partnerships
- Domestic partnerships were the most common
- Alliances for manufacturing, marketing or distribution were formed by over half the companies
- 17% of firms abandoned a project as a result of intellectual property rights held by other firms
- 19% of public companies were involved in patent infringement litigation

The biotechnology industry has been going through a time of rapid growth and change, especially over the past five years. This section describes some of the underlying strategies being adopted by senior management teams to deal with the constantly changing business environment.

CEO Strategic Decisions

The survey asked CEOs to identify, from a list of 19 potential choices, the important decisions that were made in 1997 and that were expected to be made in 1998. Responses were grouped into six categories to help ascertain CEOs' top priorities: product development, human resources, technology licensing, finance, alliances and other. Figure 11 identifies both finance and alliances as the issues of increasing importance.

Within each category, CEOs identified more specific concerns. For instance, from 1997 to 1998, not only has the

Figure 11: Strategic Decisions by CEOs

1997	%	1998	%
Product Development	33	Product Development	29
Human Resources	18	Finance	23
Finance	17	Alliances	20
Alliances	16	Human Resources	14
Technology Licensing	7	Technology Licensing	9
Other	9	Other	5

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

finance category become the second most important strategic issue, but also within this category alliances and sales have become more significant sources of financing. Other sources remained relatively stable. Expectations of increased financing were expressed only by small companies. Over the same period, CEOs placed increasing importance on alliances with other companies but revealed little change in their desire for alliances with either academia or government. This is particularly evident among small firms.

General Strategies

In the early 1990s, many biotechnology firms intended to become fully integrated pharmaceutical companies (FIPCOs) in an attempt to mirror the success of the pharmaceutical giants as well as a handful of flagship biotechnology firms from the US. This required developing in-house capacity for the full range of activities from early-stage research to manufacturing and even marketing services. These capabilities were expected to be acquired through in-house development, mergers or acquisitions. This model has not been achieved by any Canadian biotechnology firm.

In fact, in today's world, the FIPCO represents a bygone era. Even the largest of multi-national pharmaceutical companies now often rely on outsourcing and alliances to access the most innovative technologies, to carry out clinical trials, to provide access to smaller markets or to help them fill their product pipeline. Biotechnology firms, too, have begun to focus their efforts on core capabilities while accessing the required range of other activities through alliance formation and other corporate strategies.

This approach has helped to concentrate management focus, conserve cash positions and improve the long-term viability of many biotechnology firms. Expectations of Canadian CEOs reflect this trend toward alliance creation rather than accomplishing the same ends through mergers or acquisitions. In both 1997 and 1998 less than 4% of CEOs expected to acquire another company and less than 1% expected to be acquired.

Strategic Alliances

The survey reported on the different types of strategic alliances. Among the R&D partnerships, universities were the dominant partner, followed by research centres and other biotechnology companies. Federal laboratories and the Networks of Centres of Excellence were each cited in less than 12% of R&D partnerships, suggesting that more effort may be required to raise industry awareness of such opportunities. Considering the importance of R&D partnerships to expand the technology base and to provide access to new ideas, it is notable that 27% of health care firms and 24% of agriculture firms did not yet have a research partner.

Domestic R&D partnerships were reported most frequently (52%) among the firms surveyed. US R&D partnerships were noted by 26% of the respondents and EU links by 17%. Environment and aquaculture companies rely most heavily on Canadian R&D partners; the vast majority of their partnerships are located in Canada. Health care companies accounted for 50% of the R&D partnerships, and just over half of these partnerships were Canadian.

Increasingly, as more products reach regulatory approval, there is a tendency for Canadian firms to enter into later-stage manufacturing, marketing and distribution alliances — over half the companies surveyed already have such alliances. However, considering how important alliances are for successful business development within the industry, it is somewhat surprising that these numbers do not approach 100%. The current industry focus on research may be an important factor. Environmental firms appear to be at an even earlier phase of development than other sectors, with considerably more involvement in R&D partnerships than later-stage alliances.

These later-stage alliances enable biotechnology companies to retain their product development focus and build on existing competencies rather than vertically integrating all the functions required for successful commercialization. Canada and the US were the dominant locations for later-stage strategic alliance partners, each reported by approximately 28% of respondents. The EU and Asia were identified as other alliance partner locations by 20% and 13%, respectively.

Many firms in all sectors have more than one alliance. The vast majority of agriculture firms and health firms had at least one strategic alliance, but environment firms were less involved.

R&D partnerships were in place for 69% of firms. Marketing alliances were held by 49% of firms, followed by manufacturing at 29%, finance at 13% and regulatory at 9%. Other types of later-stage strategic alliances were reported by only 3% of firms.

Intellectual Property

Intellectual property (IP) often forms the basis for emerging companies to establish their value as market players and alliance partners. The survey showed that over the past three years 37% of respondents had assigned IP rights outside the company, with the recipients being evenly split between Canadian and foreign organizations. Private-sector firms made up 69% of the recipients. Acquisition of IP was more active: 61% of respondents were involved in such dealings over the past three years, and 60% of them acquired technologies from within Canada. Of those acquiring IP, 40% sought the technologies from universities and

a further 32% from other companies. Medium firms were the most active in both assigning and acquiring IP, with half assigning it and almost all acquiring it.

A substantial proportion (17%) of all respondents have had to abandon a project because they were blocked by IP rights held by another organization. This problem was equally cited by small, medium and large firms, whether publicly or privately held. This may suggest that an adequate level of technical due diligence, prior to the initiation of a project, had not been completed.

Within the year prior to the survey, 19% of public companies had been involved in litigation related to patent infringement. A much smaller proportion (7%) of private firms had been involved during the same period. As the industry grows and as more products enter the marketplace, we can expect these numbers to increase. Companies should consider mechanisms to deal with this potentially serious problem.

Hurdles to Commercialization

Respondents described several important barriers that must be overcome during the product development cycle. The most pressing hurdle to successful commercialization, reported by 64% of respondents, was considered to be access to capital. Small and medium firms, both public and private, were the most concerned. This issue was of greatest importance to the aquaculture and environment firms.

The cost and time required for regulatory approval was the second most often cited hurdle, reported by 56% of respondents. Aquaculture firms appear to be the most concerned with regulatory hurdles, followed by food processing and agriculture companies. The concern over the time required for approval dominated over cost, especially among the large companies. In order of priority, the other regulatory issues cited in the survey were international harmonization, IP protection and labelling. Agriculture was the sector most concerned about international harmonization and labelling, while the health care sector was the most concerned about regulatory approval. Small private companies were the most concerned group on all issues. Only 9% of survey respondents presently have alliances related to regulatory affairs, ranking last in the list of late-stage alliance types behind marketing, manufacturing and finance. Of those firms that raised capital in 1997, 7% planned to use it for regulatory approvals. The proportion increased to 12% of those companies expecting to raise capital in 1998.

Access to skilled human resources was the third most often cited problem, especially for small and medium companies.

Considering the current media interest and consumer concern over genetically engineered products, especially in Europe, it is surprising that only 25% of the responses identified public acceptance as an issue. Labelling was considered a hurdle in less than 5% of responses from food processing firms and 4% of agriculture firms.

Figure 12: Hurdles to Commercialization

Hurdles	Percentage of Responses
Access to Capital/Smart Capital	64
Cost & Time for Regulatory Approval	56
Skilled Human Resources	32
Consumer Acceptance	25
Lack of Information on Markets	21
Access to Technology	18
International Harmonization	12
IP Protection	11
Other	8
Labelling	5

Source: Statistics Canada, *Biotechnology Firm Survey — 1997*

▶ *BIOTECanada Commentary — Hurdles to Success*

Companies face a wide variety of hurdles during product development and commercialization. Canadian firms appear to recognize a number of issues that have plagued the industry since its earliest days, such as financing and alliance formation.

However, the survey was conducted prior to the sudden stock market decline and subsequent tightening of purse strings by investors in August 1998. The change in the financing environment has surely placed greater emphasis on the need for innovative mechanisms to raise and conserve cash. As well, the nature of partnering has changed due to the recent and ongoing transnational consolidation. Emphasis is now given to rationalization of both partners and product lines, more strict capital asset management, and the search for opportunities to build the late-stage development pipeline. CEOs must move quickly to consider the implications and identify both the challenges and opportunities raised by this change in circumstances. The business environment in 1999 has little in common with what existed but a few short years ago.

Canadian firms now also face a variety of other issues. Yet, according to the survey responses, CEOs appear relatively unconcerned or unaware of their potential impact. These include the Biosafety Protocol, Health Canada's legislative renewal, the socioeconomic factors creeping into the regulatory process, international regulatory harmonization, restrictions to formulary listings, public acceptance, and intellectual property protection.

Many of these issues are influenced by government policies and procedures. They have a profound impact on the success of our biotechnology industry. For example, several Canadian regulatory agencies are uncompetitive in their approval times for biotechnology products when compared to both US and Europe. To meet expectations, the regulatory agencies must become more efficient and adaptable. Whether this is achieved through increased resources for this critical function, through greater reliance on assessments in other jurisdictions (harmonization), or through a combination of measures, is not important. The determining factor will be whether or not Canada is competitive with respect to the time and cost of obtaining product assessments and decisions. At the same time, the quality of regulatory oversight in Canada must not be compromised. The reorganization of Health Canada's Health Protection Branch may help to overcome some of the expertise gaps as well as the existing management and personnel difficulties in that department. Other agencies must also move quickly to meet the rising demand for timely product review.

International intellectual property harmonization must also be achieved. Issues such as Patent Term Restoration for pharmaceutical products and patenting of higher life forms need to be revisited over the coming months.

The biotechnology business environment in Canada will require a sustained commitment to ensure that Canada remains internationally competitive and prepared to meet the global challenges we face. Greater CEO involvement will also be necessary for these pressing issues. With senior level attention to long-term structural challenges, Canadian firms can stay abreast of our forward-thinking competitors.

SECTION HIGHLIGHTS

- Access to capital is the most often cited hurdle to the development of the Canadian biotechnology industry
- Large firms generated 70% of the $1 billion in 1997 biotech sales, small firms 17% and medium firms 13%
- Biotech sales from agriculture and food processing products are now close to matching those from the health care sector
- The top five firms account for 60% of biotech product sales
- The top three public firms each have a market capitalization exceeding $1 billion
- In 1997, 37% of Canadian biotechnology companies raised capital; 56% of our companies expected to raise over $920 million in 1998
- Most firms expecting to raise new capital in 1998 intended to use it for R&D
- The average amount raised in 1997 was $3.9 million per firm; expectations have increased to an average of $5.8 million per firm in 1998
- 16% of the biotechnology industry did not apply for SR & ED tax credits in any one of the past five years
- Venture capital investment in life sciences rose steeply in 1997, with 177 deals; 62 more than in 1996 and 101 more than 1995. In all, $383 million was invested in the sector, up $113 million from 1996 and almost three times the 1995 figure

Companies involved in biotechnology have developed a number of methods for obtaining the financial resources required to meet the needs of their business. These include, but are not limited to, product sales, contract research, interest on investments, capital provided through investors and alliance partners, tax credits and government programs, issuance of debt, off balance sheet financing and other creative mechanisms. The survey results show that the most often cited hurdle to the development of the Canadian biotechnology sector, mentioned by 64% of firms, was access to capital. Regulations and human resources were also cited as challenges to development.

Sales

Sales of biotechnology products are still in their infancy but are expected to grow rapidly as products move through the research pipeline and clear the regulatory hurdles. The Canadian industry now has over $1 billion in biotech sales, with 70% accruing to large firms. Small firms account for 17% of biotech sales, followed by medium firms with 13%. Figure 13 shows that the median biotech sales per small firm are $54,000, for medium firms $2 million and for large firms $2.4 million.

Figure 13: Biotech Sales Per Company by Size ($000)

	No of companies	Average Biotech Sales	Median Biotech Sales
Small (1-50)	204	$895	$54
Medium (51-150)	43	$3,174	$2,000
Large (>150)	35	$19,950	$2,441

Note: Estimations for sector totals by Industry Canada and BIOTECanada.

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

Health care accounted for 50% of biotech sales, followed by agriculture with 23% and food processing with 21%. The combined biotech sales of ag-food products (44%) are now close to matching the health care sales. However, the survey pointed out that the distribution of biotech sales is not consistent among companies. Five firms account for 60% of biotech sales, 20 firms for 83% of biotech sales and 50 firms for 98% of biotech sales. Private firms achieved a slightly larger percentage of biotech sales than their public counterparts, although public firms hold a significant lead in total product sales of over two and half times the private firm total sales figures.

Biotech sales far exceed both contract and other revenues (often interest earned on capital from equity offerings), making up fully 90% of total biotechnology revenues. Both small and medium firms, however, rely more heavily on revenue from non-sales sources, which make up over 22% of their total biotech revenues. Health care accounts for the vast majority of both contract and other revenues.

Access to Capital

The survey showed that 37% of the respondents raised capital in 1997 (see Figure 14). In 1998, a substantial increase, to 56%, was expected in the number of firms seeking capital.

Small firms, 40% of which raised capital in 1997, were the most likely (63%) to report plans to raise new capital in 1998. An increasing number of medium firms also expected to raise more new capital; 33% were successful in 1997 and 56% reported such expectations for 1998.

Figure 14: Capital Acquisition by Company Size

	Raised capital in 1997 %	Expected to raise capital in 1998 %
Small	40	63
Medium	33	56
Large	23	20
Total Industry	**37**	**56**

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

Capital Acquisition Expectations

Among the firms that provided information on their successful search for new capital in 1997, the average amount raised was $3.9 million per firm. For 1998, the average reported intention of raising new capital was $5.8 million per firm. The industry expectation was that more than $920 million would be sought in 1998.

Figure 15 shows that all sectors anticipate substantial increases in capital raised. The biggest increase is expected in the environment sector, where more than double the number of firms that raised capital in 1997 expected similar success in 1998. In fact, the largest investment demand for capital is expected to come from smaller companies.

Sources of Capital

Private placements and venture capital were the most sought-after sources for capital in 1998; 30% and 25% of firms respectively expected to use these sources (see Figure 16). Canadian venture capital sources invested $203 million in biotechnology in 1997, equating to 11% of total venture capital disbursements.[2] The survey revealed that partnerships are also increasing in importance; 24% of firms expected to raise capital in 1998 through strategic partners, more than double the number in 1997.

Figure 15: Capital Acquisition by Sector

	Raised capital in 1997 %	Expected to raise capital in 1998 %
Agriculture	34	47
Aquaculture	43	83
Environment	23	55
Food Processing	47	47
Health Care	42	64
Other	29	50
Total	**37**	**56**

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

[2] Mary Macdonald & Associates Limited, private communication.

Figure 16: Sources of Capital Acquisition

Capital Source	Raised capital in 1997 %	Expected to raise capital in 1998 %
Private Placement	37	30
Venture Capital	24	25
Angels/Friends	13	8
Strategic Alliance Partner	11	24
Secondary Public Offering	5	3
Initial Public Offering	1	6
Other	9	4

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

Use of Capital

As shown in Figure 17, the majority of new capital continues to be used to support R&D, with 58% of firms raising new capital in 1998 expecting to use it on R&D. Process scale-up is the intended use for 24% of the total funds raised. Financing regulatory approval was identified as a goal by 7% of firms seeking capital in 1997, rising to 12% in 1998.

Federal and Provincial Tax Incentives

A variety of tax and other economic incentives are provided by governments to support the development of the biotechnology industry. Canada has

Figure 17: Capital Utilization

Purpose for Capital	Raised capital in 1997 %	Expected to raise capital in 1998 %
R&D	62	58
Process Scale-up	17	24
Regulatory Process	7	12
Other	14	6

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

one of the world's most generous tax credit systems in support of research.

One example is the federal Scientific Research and Experimental Development (SR&ED) tax credit system. It provides tax incentives to Canadian businesses conducting research in Canada. Many biotechnology firms make no profit and are therefore not in a taxable position. However, SR&ED expenditures, not deducted in the year which they are made, can be carried forward indefinitely and increase the valuation of firms that accumulate the deductions. As well, some companies are eligible for full or partial refunds of the investment tax credits that are generated from these SR&ED expenditures.

Canada's provinces also offer generous incentives that supplement the federal tax credit system. Provincial governments are increasingly competitive in offering tax incentives in their bids to attract foreign investment. Canada's two largest provinces lead in the competition, demonstrating that the after-tax costs of doing $100 of research could be as little as $32 in Quebec and $33 in Ontario.[3]

The survey showed that 94% of firms had R&D expenditures between 1995 and 1997. However, a relatively high proportion of companies are not using the SR&ED tax credit incentive program to offset these expenditures. Approximately 16% of the biotechnology industry did not apply for SR&ED tax credits in any one of the past five years. Within the bio-informatics sector, 50% of the firms did not apply, and 29% of the environment sector firms did not apply. Medium-size firms appear to be the most pervasive users of the program; all the respondents in this category had applied within the past five years.

Reasons for not using the program ranged from not meeting the eligibility requirements (or uncertainty of doing so) to the complexity of the process. Responding to calls from industry for improvements to the government's administration of the R&D tax incentive program, Revenue Canada recently released an action plan based on industry recommendations.

▶ *BIOTECanada Commentary: Sources of Financing*

Private

Public equity markets have been one of the major sources of financing for companies developing biotechnology products. The market capitalization of these companies has placed them into several tiers. The top tier, with market capitalization exceeding $1 billion, includes only three public firms (as of January 1999), one of which is the clear leader. In January 1998 there were two. Those in the next tier have a maximum market cap of just over $250 million, pointing out the great discrepancy in company valuation between the tiers. Approximately a dozen firms have a market capitalization exceeding $100 million (*Canadian Biotech News*).

Only a handful of Canadian biotechnology firms are tracked by international stock analysts who provide advice to investors, both large and small.

[3] Source: KPMG Biotechnology Report, Summer 1998

Without a significant analyst following, publicly traded stocks generally fail to reach the attention of potential investors and their visibility and valuation tend to languish.

Great strides were made in the mid '90s to gain investment community acceptance for high-risk biotechnology enterprises. Vast amounts of venture and other private capital were drawn to the industry and helped to create a variety of new biotech firms, especially in Quebec and British Columbia. As well, due to a wide-open financing window, venture capital firms were able to recoup some of their investments by taking companies into the public equity markets.

During the summer of 1998, the world stock markets declined and the biotech equity financing window closed, making new public offerings more difficult and costly. At the same time, venture capital sources and private placements also became more cautious, often limiting their exposure to new start-up ventures and focussing investments into later-stage portfolio companies with which they were familiar. Key parameters for attracting financing for these later-stage firms has been meeting milestones and demonstrating an ability to sustain steady growth.

Only a limited number of CEOs had been expecting to raise capital from public equity offerings during this volatile period, thereby minimizing the negative impact on public equity acquisition efforts. However, the volatile climate limited the number of firms able to successfully meet their capital acquisition targets even from other sources. The demand for cash in 1999 will therefore likely exceed that expected in 1998.

The trend toward the tightening of investor purse strings has occurred around the world, and Canadian biotech firms are now competing for a limited pool of global financial resources. In order to survive the existing global financial turmoil, companies must consider novel financing mechanisms, focus their existing resources on core activities and implement cash conservation or optimization measures.

Government

One of the more important assets of a small biotechnology company is the tax credits built up over the product development life cycle under the SR&ED program. However, companies have become increasingly frustrated with various aspects of the SR&ED program; complaints range from a lack of clarity about what constitutes true research to the large amounts of time spent preparing, filing and defending tax claims. Revenue Canada is now working in partnership with BIOTECanada to identify the barriers faced by the different sectors and company sizes in order to rectify this situation. BIOTECanada's goals are to ensure that this program becomes the incentive program it was initially designed to be and that the requirements are 'industry friendly' with consistent interpretation by both industry and Revenue Canada.

Government also provides support under other programs for companies in later-stage development. However, access to seed capital is limited. New federal seed financing programs need to be established for the early concept stage, so that companies may get through this difficult period. To help companies in later stages of development, existing federal initiatives such as the Technology Partnerships Canada Program (Industry Canada), the Matching Incentives Program (Agriculture and Agri-Food Canada), and the Industrial Research Assistance Program (National Research Council) should consider mechanisms to improve access for companies involved in biotechnology.

Canadian Venture Capital: A Lifeline for Life Sciences

Mary Macdonald & Associates Limited

The Canadian venture capital industry continues to experience record-setting levels of growth, attracting significant amounts of new capital each year and disbursing even greater amounts. The pool of capital being managed by the Canadian venture industry at the beginning of 1998 stood at $8.4 billion, and the capital still available for investment was holding steady at $2.4 billion despite unprecedented levels of investment in 1997. The Canadian venture community disbursed a whopping $1.8 billion over the course of 1997, up by 66% from the already record-setting level of $1.1 billion in 1996, with a growing focus on technology companies. The impetus for technology investing in Canada has clearly gathered a head of steam and is likely to be sustained in the foreseeable future.

The capital invested by the Canadian venture community in the life sciences sector (biotechnology and health combined) continued to rise steeply in 1997. A total of 177 financings were completed that altogether involved $383 million. This activity level represents more than twice the number of deals done just two years earlier and almost a threefold increase in the capital invested in these young life sciences firms.

Life Sciences Investments Continue to Rise

After a notable increase in the amount of syndication among venture investors in their life sciences deals, this collaboration is falling off somewhat, presumably because of the growing number of investors with capital available to invest. Each life sciences financing completed in 1997 involved an average of 1.7 investors, down from 1.9 in 1996.

The industry continues to strengthen its ability to satisfy the growing capital requirements of young life sciences firms over their development cycle. This is evidenced by the proliferating involvement of venture investors in life sciences deals above the $5 million level. Between 1992 and 1994, only five life sciences deals involved more than $5 million. In 1996, there were 23 deals of this size and altogether they absorbed $167 million. In 1997, the upward trend continued with 33 large deals consuming $217 million. Good young Canadian life sciences companies now appear to have access to the kind of capital they need to create and grow a world-class company.

Ontario and British Columbia Most Active Markets

Some notable shifts in the regional allocation of life sciences investment activity took place in 1997; Ontario-based firms captured 37% of the $383 million invested, up from their 24% share in 1996. Activity in British Columbia also rose sharply, with $93 million (24%) flowing into BC-based firms, up from the $48 million (17%) that went into the province in 1996. By contrast, the capital flowing into Quebec-based firms fell from $111 million to $87 million in 1997. This decline was, in our view, primarily a function of some repositioning of senior industry players in Quebec and the shift in their attentions to fund-raising for a significant part of the year. Presumably now that new funds are in place and their managers settled in, the pace of Quebec investment activity will pick up again. Medical-related biotechnology continues to be the principal focus for investment within the sector, but interest in medical devices seems to be coming on strong.

SECTION HIGHLIGHTS

- Canadian biotech firms invested $585 million in R&D in 1997
- Ontario has the highest level of biotech R&D (42%) even though it has only 25% of the firms. Quebec and British Columbia follow with 24% and 18% of the R&D investment made by 30% and 20% of the companies, respectively
- 87% of biotech R&D is devoted to the health care sector
- High-growth technologies include biosensors, gene therapy, bio-informatics, and genomics
- Rates at which products receive approval for trials or market entry remain slow

Canadian Strengths

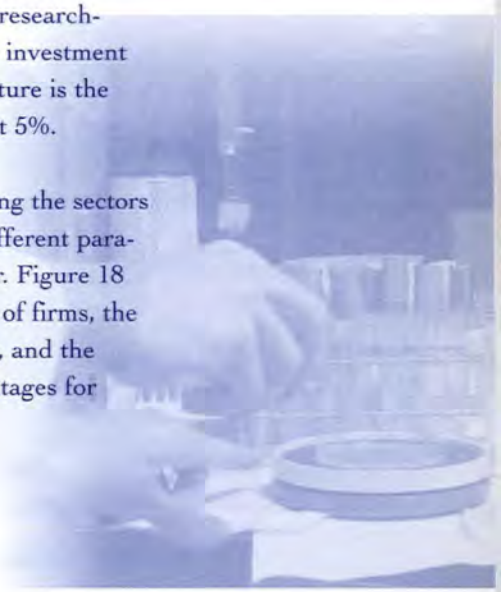
The growth and the strength in the Canadian biotechnology industry measured by this survey are, in large part, the result of a broad and productive basic research activity that has been sustained at modest levels over several decades. Canada has a long history of undertaking world-class research in numerous scientific disciplines that support the biotechnology industry. Our scientists are frequently cited and Canada ranks 6th in the world for number of publications in science, engineering and medicine (4.5% of total publications) for the period 1981-94.[4] While support for R&D in Canada continues to lag behind the rest of the developed nations, Canadian researchers are among the most cost effective in the world: Canada ranks number three in the world for the number of citations in science, engineering and medicine (non-defence) per dollar invested in R&D.[5]

This research effort is also found in industry — 94% of the companies surveyed conduct R&D related to biotechnology. In 1997, the industry invested $585 million in R&D. Publicly traded firms make up 25% of the industry, but conduct 79% of the biotech R&D in Canada.

Research Activity by Sector

The R&D activity is found in all sectors, but the health care sector predominates as the most research-intensive, with 87% of the investment being in this area. Agriculture is the second most active area, at 5%.

Interesting variations among the sectors become apparent when different parameters are shown together. Figure 18 illustrates the distribution of firms, the biotech R&D investments, and the biotech sales, all in percentages for each sector.



[4] "The Scientific Wealth of Nations", by Robert May, *Science*, Feb 7/97

[5] ibid

Figure 18: Key Data by Sector

Sector	Companies %	Biotech Sales %	R&D %	R&D/Firm ($ Millions)
Health Care	46	50	87	3.4
Agriculture	22	23	5	0.6
Environment	11	3	1	0.2
Food Processing	7	21	2	0.8
Aquaculture	4	1	0	0.1
Bio-informatics	3	0	3	1.6
Other	7	2	3	1.8

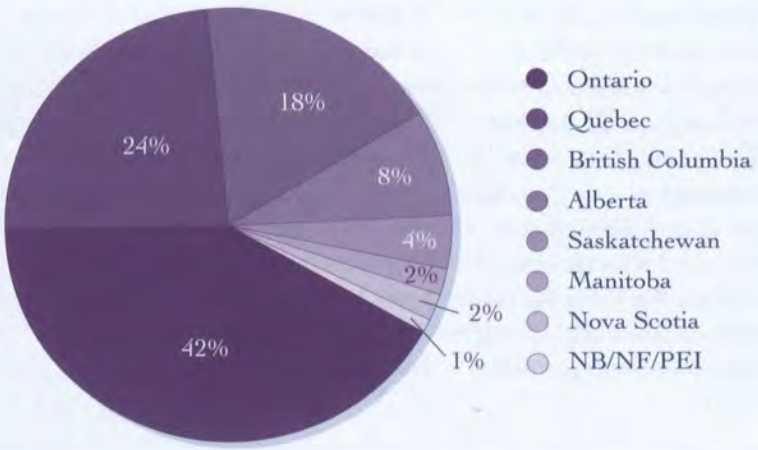
Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

The health care sector dominates in all categories. Both bio-informatics and other have only a few firms, each devoting significant dollars to R&D. In contrast, agriculture and food processing contribute substantial biotech sales from a relatively small number of firms but have a lower investment in R&D.

R&D by Region

Regional differences are apparent from the survey results (see Figure 19). Ontario firms conduct the largest portion of Canadian biotech R&D (42%), even though this province has only 25% of the total number of companies. Quebec has more companies, 31% of

Figure 19: Percentage R&D by Region



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

the total, but these firms conduct less of the total R&D (24%). British Columbia and Alberta combined conduct more R&D than Quebec (26%), with fewer companies (27%). The Atlantic provinces combined have 7% of the companies and 3% of the R&D. British Columbia, Alberta, Saskatchewan and Manitoba combined have 34% of the firms and conduct 32% of the R&D. However, British Columbia, Alberta and Manitoba focus on health care while Saskatchewan has a strong presence in agriculture.

Research Activity by Company Size

Large firms make up just over 12% of the total of 282 companies, but they make the greatest investment in R&D, as shown in Figure 20.

Figure 21 illustrates the distribution of size of firms in those provinces that have the most companies, and compares this with the R&D investment and the biotech sales.

Figure 20: R&D by Company Size

	Small	Medium	Large	Total
R&D ($ millions)	192	153	240	585
Distribution (%)	33	26	41	100

Note: Estimations for sector totals by Industry Canada and BIOTECanada.

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

Research Focus

The survey focussed on the stages of development of products, all as a function of the nature of the technology: DNA-based, biochemistry- or immunochemistry-based, and bioprocessing-based. Several technologies were listed within each group (see Figure 22), and the respondents were asked if their R&D activities, clinical trials and/or products incorporated these technologies.

Most biotechnology products, either in production or in clinical or field trials, stem from bioprocessing-based or biochemistry/immunochemistry-based technologies. Few are using DNA-based technologies. However, this

Figure 21: Key Data by Region (Size, R&D, Sales)

Province	Small %	Medium %	Large %	R&D %	Biotech Sales %
Ontario	24	25	31	42	36
Quebec	26	44	42	24	34
British Columbia	24	16	0	18	4
Saskatchewan	9	0	12	4	8
All Others	17	15	15	12	18

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

Figure 22: Specific Technologies

DNA-Based	Biochemistry- or Immunochemistry-Based	Bioprocessing-Based
• Genetic Engineering • Gene Probes • Bio-informatics/Genomics • DNA Sequencing • Gene Therapy	• Vaccines • Diagnostic Kits • Peptide/Protein Sequencing/ Synthesis • Cell Receptors/Structural Biology • Biosensors • Biomaterials • Microbiology	• Cells/Fermentation • Extraction • Bioremediation • Natural Products Chemistry

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

situation is expected to change. Survey respondents noted that they currently have as many products or processes in the development stage that are DNA-based as for each of the other technologies. This represents a significant new dimension within the industry, one that is expected to result in many more products.

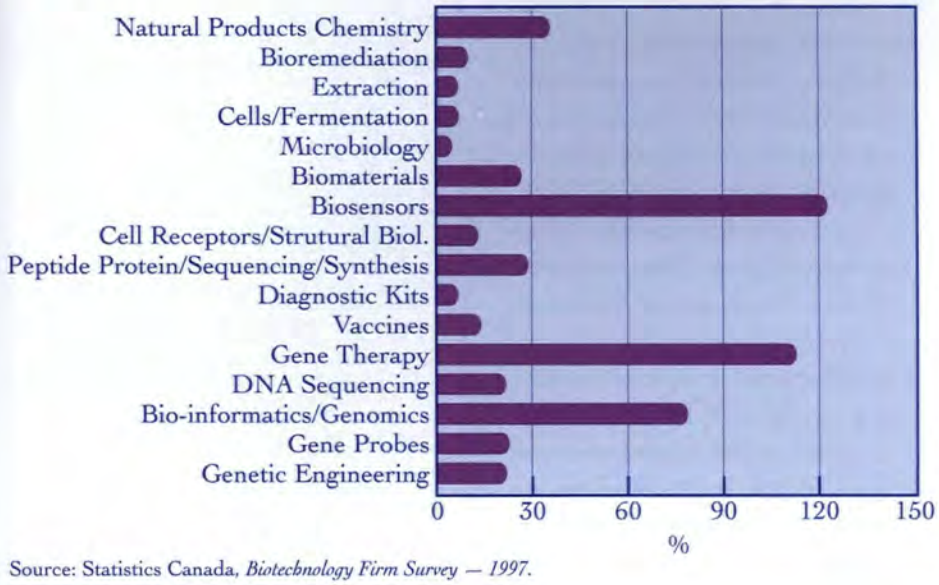
New products are being developed primarily in plant biotechnology and health care therapeutics: over 100 companies are conducting clinical or field trials. With such a significant level of products moving through the pipeline, it is essential that regulatory agencies be able to identify and track such product development, in order to plan for undertaking the necessary risk assessments. The growing use of recombinant DNA technologies to develop products, and the level of product development in general, means that the regulatory agencies in this country will be faced with a daunting work load over the next five years and beyond.

High-Growth Technologies

Figure 23 illustrates the expected increases over the next three years in the use of various technologies.

Although just a few companies are currently involved, it is evident that biosensors, gene therapy and bio-informatics/genomics will experience the most rapid percentage increase. The number of companies planning to use the first two of these technologies is expected to more than double over the next three years. As shown in the Human Resources section, the bio-informatics/genomics sector is already the third largest employer for biotech R&D in Canada, behind health care and agriculture. Figure 23 also highlights the low increase anticipated in the use of traditional technologies such as extraction, microbiology, and tissue culture. These are used more widely than the DNA-based technologies, but are not seen as areas of growing importance.

Figure 23: Anticipated Percentage Increase in Specific Technologies



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

Federal Government Initiatives

A recent study by the US National Science Foundation found that 73% of the main science papers cited in industrial patents during the 1990s were based on research financed by government or non-profit agencies. This is a strong indicator that government-financed research supports the industrial base.

For biotechnology R&D, Industry Canada estimates that in 1997 the federal government invested $160 million from federal laboratories and institutes and $144 million from the granting councils. (See the text box on p. 41 for a description of the major NRC biotechnology effort.) Of this $304 million federal investment, 15% was focussed on regulatory support for public and environmental health and safety, 75% on wealth generation and innovation, and 11% on basic research for advancing science and the quality of life. In addition to this investment, private not-for-profit organizations devoted a further $115 million to R&D, and industry allocated $585 million for a total investment of $1 billion.

Government investment in R&D has included support for the national Networks of Centres of Excellence (NCE) program. This program is considered by the international scientific community as a pragmatic and successful mechanism to

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promote multi-location, multi-disciplinary research partnerships. Its reputation is based on attracting top researchers and generating excellent research. A number of NCEs support biotechnology research: the Canadian Genetic Diseases Network, the Canadian Bacterial Diseases Network, the Canadian Arthritis Network and the Protein Engineering Network. With the additional $30 million per year announced in the 1999 federal budget, more networks will soon be established.

Provincial Government Initiatives

Support for industrial R&D activity has long been considered an important component of regional policy. R&D activities tend to provide highly skilled jobs, establish new firms, broaden the tax base and provide linkages to academic institutions. For this and many other reasons, political jurisdictions compete for private-sector R&D through policies and strategies that provide a regional competitive advantage. This competition takes the form of tax incentives, direct investment, and a variety of support systems. Quebec and Saskatchewan were among the first to implement such incentives, but all provinces recognize the benefit of a strong biotechnology industry and are putting supportive policies into place.

► *BIOTECanada Commentary: The Research Base*

Genomics, bio-informatics, pharmacogenomics and proteomics are considered upcoming growth areas, but only a handful of start-up companies are dedicated to these disciplines. This is due, in part, to lackluster research funding in Canada with little or no focus on these burgeoning areas of development. "The absence of any significant commercial presence in genomics ... is a direct consequence of our failure 10 years ago to invest appropriately in the interdisciplinary sciences needed to catalyze and support substantial genomics companies."[6] One extreme example is the Human Genome Project, where the Canadian government invested under $2 million in 1997 while the US government invested over $450 million.

Recognizing the need to enhance our capabilities in this area, the National Research Council (NRC) has recently formed the Canadian Bio-informatics Resource within the Institute for Marine Biosciences. The Medical Research Council (MRC) has also provided Genome Canada with $25 million (over five years). In addition, the Natural Sciences and Engineering Research Council (NSERC) estimates that it supports genomics research at about $19 million per year. Canadian universities have also recognized the importance of bio-informatics (as well as other areas) and are working to include them in their curricula to meet the biotechnology industry's needs. With increased support in genomics and bio-informatics, Canada has a real opportunity to make a difference in niche areas such as plant and animal research.

[6] *NBAC 6th Report*, p. 36.

The federal government has recently taken steps to improve the research funding situation in Canada in its '98 and '99 budgets. Increased support of basic research has been provided through the research granting councils. Biotechnology was allocated $55 million in the 1999 budget for genomics research in several government departments. In addition, $50 million per year has been earmarked for health-related research, with most of it ($42.5 million) to flow through the granting councils. The concept of a Canadian Institutes of Health has been accepted and is expected to receive $240 million over the next three years. All these measures are welcome and will provide essential support for the research base.

The research community has received a real boost from the recent financial support it has received from the federal government. However, it is unlikely that funding increases will be sufficient for the level of research Canadian researchers would like to conduct. Both Canadian research institutions and researchers will have to look for ways to address this funding limitation. They will have to seek both new ways to increase efficiencies and to maximize benefits from the available resources. Two possible options are increased international collaborations and closer ties to the Canadian industry.

In addition to a strong research base, technology transfer is an essential ingredient to move research results into successful commercial ventures. It will be important to increase our capability in terms of expertise and financing to improve our technology transfer capability in order to generate the social and economic benefits from Canada's increased investments in research.

National Research Council Canada

The Biotechnology Group

The National Research Council's Biotechnology Group is Canada's largest single investment in biotechnology activity. The Biotechnology Group comprises five Institutes, located across Canada, that engage in research and related activity within the realm of biotechnology — the Biotechnology Research Institute (Montreal), the Institute for Biodiagnostics (Winnipeg), the Institute for Biological Sciences (Ottawa), the Institute for Marine Biosciences (Halifax), and the Plant Biotechnology Institute (Saskatoon). Research and technology transfer programs are organized within each Institute to support biotechnology applications in agriculture and food, aquaculture, environment, pharmaceuticals and health care.

The program is complemented by support from the Industrial Research Assistance Program (IRAP) which works with small- and medium-sized enterprises (SMEs) to develop new and improved products and processes. The Biotechnology Group is also supported by the Canada Institute

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for Scientific and Technical Information (CISTI) through knowledge dissemination, and by the Steacie Institute for Molecular Sciences (SIMS) for specific basic research.

Direct returns to Canada on expenditures have included stimulating collaborative research; producing scientific, technical and commercial outputs; and providing learning opportunities for scientists, technical staff and guest workers. The activities of the Biotechnology Group have been translated over the years into enhanced industrial activity and biotechnology investments by the investment community throughout Canada. New vaccines, enzymes, value-added crops, analytical tools and methodologies, diagnostic tools and software have all emerged from the program to contribute to the establishment of a unique, viable Canadian industrial cluster.

Researchers in the Institute for Biological Sciences recently worked with a Canadian biopharmaceutical company to develop powerful vaccines for infant and adult meningitis. The deadly disease is a worldwide health problem, and the estimated market for the vaccines is between $22 million and $58 million per year.

A new Hard Red spring wheat developed by researchers at Saskatoon's Plant Biotechnology Institute is due to enter the market in 1999/2000. The strain, developed in collaboration with the Saskatchewan Wheat Pool, combines increased yield with improved disease resistance. It is expected to have a major economic impact on the Prairies.

In November 1998, the Biotechnology Group opened a new facility in Montreal's Biotechnology Research Institute (BRI). The 50,000 square-foot wing is designed to give biotech companies access to BRI's leading-edge expertise and equipment. The facility has 24 laboratories and is currently housing 14 companies. In 1997-98 the Biotechnology Group had a portfolio of 107 collaborative research agreements. Seventy-three of these agreements were with industry partners, representing around $50 million in biotechnology R&D. Expenditures for the Biotechnology Group in 1997-98 were $59.6 million, with revenues of $11.1 million.

SECTION HIGHLIGHTS

- Current biotech industry employment is approximately 10,000, with an additional 1,900 positions unfilled
- Human resource requirements are expected to increase to approximately 15,800 in 2001
- R&D staff represent the largest group (41%), followed by manufacturing (22%) and marketing/sales (14%)
- The health care sector has by far the greatest number of employees (68%). This same sector also lays claim to 48% of the firms and 87% of the biotech R&D investments
- Agriculture follows with 17% of the people, 21% of the firms and 5% of the R&D.
- Ontario and Quebec currently have 33% and 32% of the employment respectively, followed by British Columbia (13%) and Alberta (10%). Greater growth is projected for Quebec and British Columbia than for Ontario
- Employment growth rates are anticipated to be over 10% per year
- All regions foresee increases in employment to 2001: Quebec, Ontario and British Columbia project comparable numbers of new employees (approximately 2,000 in each region)
- Approximately 30% of firms are having difficulties in recruiting suitable people
- 20 companies account for over 50% of the total biotech employment

Employment Overview

Biotechnology has long been identified as a strategic technology. Measures of progress and direction are essential, and this survey sought to obtain the data on current and projected employment, vacancies, job functions and a variety of human resource issues.

Figure 24 summarizes employment data for all biotechnology firms, as a function of company size.

A few key points from Figure 24 include:

- Large firms make up 12% of the industry and employ 44% of the work force
- Small firms make up 72% of the firms and employ 32% of the work force
- Both categories of firms anticipate employment growth to 2001, by which time small firms expect to account for 44% of the workforce and large firms 34%

Figure 24: Employment by Company Size

Category	Small	Medium	Large	Total
Current Staff	3,125 32%	2,397 24%	4,302 44%	9,823
Unfilled Positions	1,031 54%	281 15%	587 31%	1,899
Employment, 2001	6,903 44%	3,461 22%	5,437 34%	15,800

Note: Estimations for sector totals by Industry Canada and BIOTECanada.

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

- Anticipated employment in 2001 indicates an overall growth rate in excess of 10% per year

An important additional fact is that the top 20 firms account for more than 50% of the total biotech employment.

Employment by Business Function

Seven distinct job functions related to biotechnology were used in the survey, and Figure 25 outlines the numbers of current employees in each function and those projected for 2001.

Figure 25: Employment by Business Function

Business Function	Current Employment %	No. of Employees	Projected Employment in 2001 %	Projected Employment in 2001	Anticipated Growth %
R&D	41	4,008	39	6,109	52
Manufacturing	21	2,108	24	3,753	78
Marketing	14	1,362	15	2,488	83
Clinical	8	777	6	987	27
Administration	7	681	6	978	44
Business Development	6	636	7	1,062	67
Regulatory	3	250	3	423	69
Totals	**100**	**9,823**	**100**	**15,800**	**61**

Note: Estimations for sector totals by Industry Canada and BIOTECanada.

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

R&D is by far the most important business function in terms of numbers of people currently employed, as well as projected employment. Both manufacturing and marketing are also functions for which considerable growth is expected. These three functions account for over 76% of both current and projected employment.

Regulatory personnel accounted for less than 3% of total employment and the unfilled positions totalled 11% of existing employees within the category, slightly greater than the average for all categories (8%). Companies expect a 69% increase in employment in the function by 2001. Recruiting regulatory personnel is a problem for 14% of firms; 79% of these are in the health care sector.

Small firms will experience much of the growth in all the business functions, except marketing/sales where the growth rate is expected to be significantly higher in large firms.

Additional aspects concerning business functions and company size can be gleaned from the survey results:

- Small firms expect to increase their R&D personnel by 115% to 2001. This represents just over 74% of the total anticipated growth in R&D employment to 2001.
- Small firms anticipate an expansion greater than 250% in their manufacturing personnel to 2001. In contrast, large firms anticipate a 10% reduction.
- Marketing appears to be a function in which all companies foresee considerable expansion, although large firms expect to increase their marketing/sales personnel by 46%, over 1.5 times the growth planned by other companies.
- Conversely, small firms anticipate growth of close to 130% in clinical affairs staff while large firms expect to reduce their personnel by almost 15%.
- Employment forecasts among small firms contribute most of the anticipated growth in the administration, business development and regulatory affairs functions. As Figure 25 shows, the numbers of people currently involved in these functions are relatively modest.

Employment by Sector

Current and anticipated employment across the different sectors of the industry is shown in Figure 26. (See the Annex: Sector Descriptions in the Methodology section for the descriptions of the industry sectors.)

Health care dominates all sectors with 68% of current employment. Projections to 2001 show that this dominance will continue. Health care also accounts for 72% of the currently unfilled positions. Employment in the other sectors will increase but the relative standing will remain consistent to 2001.

Figure 26: Employment by Sector

Business Function	Current Employment %	No. of Employees	Projected Employment in 2001 %	Projected Employment in 2001	Anticipated Growth %
Health Care	68	6,709	66	10,391	55
Agriculture	17	1,690	17	2,629	56
Environment	3	265	4	695	162
Bio-informatics	2	216	3	437	102
Food Processing	2	206	2	391	90
Aquaculture	1	98	1	152	55
Other	7	638	7	1,104	73
Totals	**100**	**9,823**	**100**	**15,800**	**61**

Note: Estimations for sector totals by Industry Canada and BIOTECanada.

Source: Statistics Canada, *Biotechnology Firm Survey* — 1997

The survey data reveal a number of other facts about sector employment levels:

- While the health care sector represents 46% of the companies, it has over two thirds of the present employment, reflecting a higher concentration of large companies in this sector. All the other sectors have a higher percentage of firms relative to their employment.
- Health care accounts for most of the current employment in each business function as well: 67% in R&D; 85% in clinical affairs; 76% in regulatory and legal; 71% in manufacturing; 53% in marketing and sales; 75% in business development; and 70% in administration.
- Within the health care sector, over 60% of the projected increase in employment is expected to occur in the combined areas of manufacturing and marketing/sales.
- On a percentage basis, the anticipated growth in non-health sectors, especially environment, bio-informatics and food processing, is much higher than in the other sectors. However, the number employed in these high-growth areas remains modest.
- Employment in agriculture is concentrated in R&D (34%), marketing/sales (32%) and manufacturing (19%). This differs somewhat from health care, where employment is concentrated in R&D (40%), manufacturing (22%), marketing/sales (11%), and clinical affairs (10%). Projections to 2001 confirm these relative distributions.

- Agriculture will remain the second most important sector in terms of employment, with almost the same level of projected employment as for all other sectors combined (excluding health care).

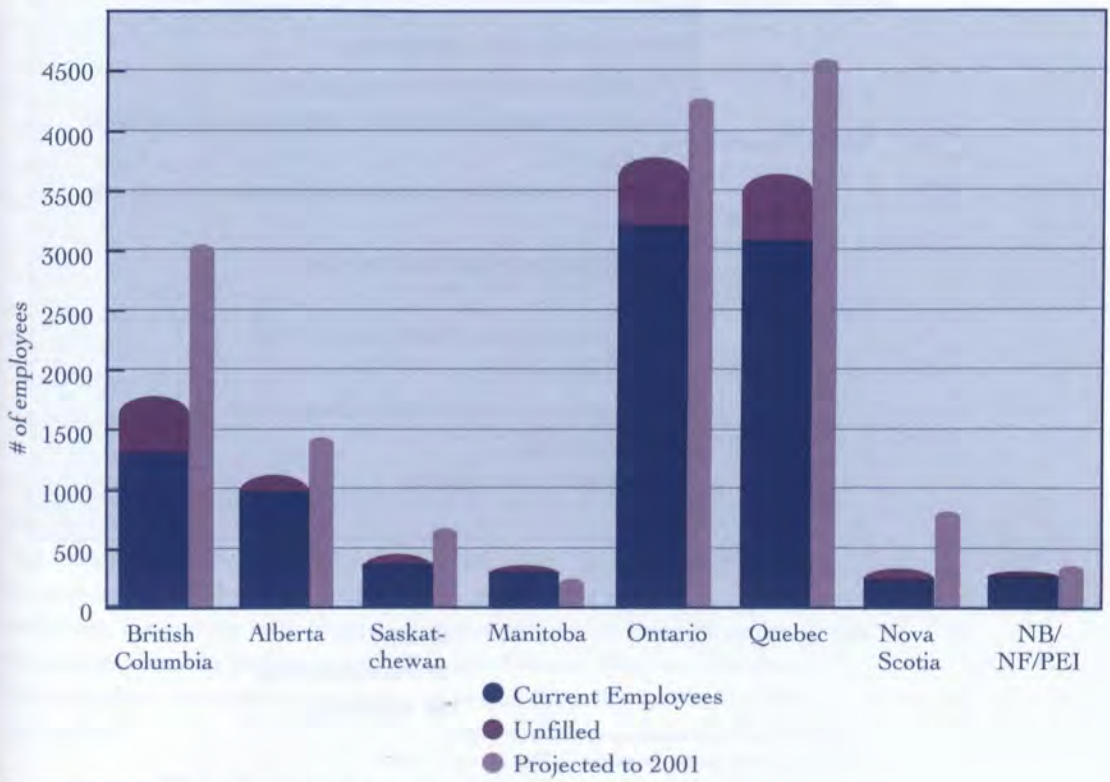
Employment by Region

Regional distribution of employment is shown in Figure 27, which describes current employment, unfilled positions and projected employment to 2001. All provinces, with the exception of Manitoba, project increases in employment through to the year 2001, with the greatest growth in numbers expected in British Columbia, Quebec and Ontario. In percentage terms, Nova Scotia shows the greatest increase.

Considering regional employment by business function, several points can be made:

- R&D represents the largest category of employment in all the provinces with the exception of Alberta, where marketing/sales has a few more people than R&D. Alberta companies' projections to 2001 maintain this focus on marketing and sales.
- Firms in British Columbia are projecting considerable employment growth in all functions, especially R&D (76%) and manufacturing (125%).
- Quebec predicts major expansion in manufacturing (58%) and some growth in business

Figure 27: Employment by Region



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

development (23%), marketing (21%) and R&D (8%).

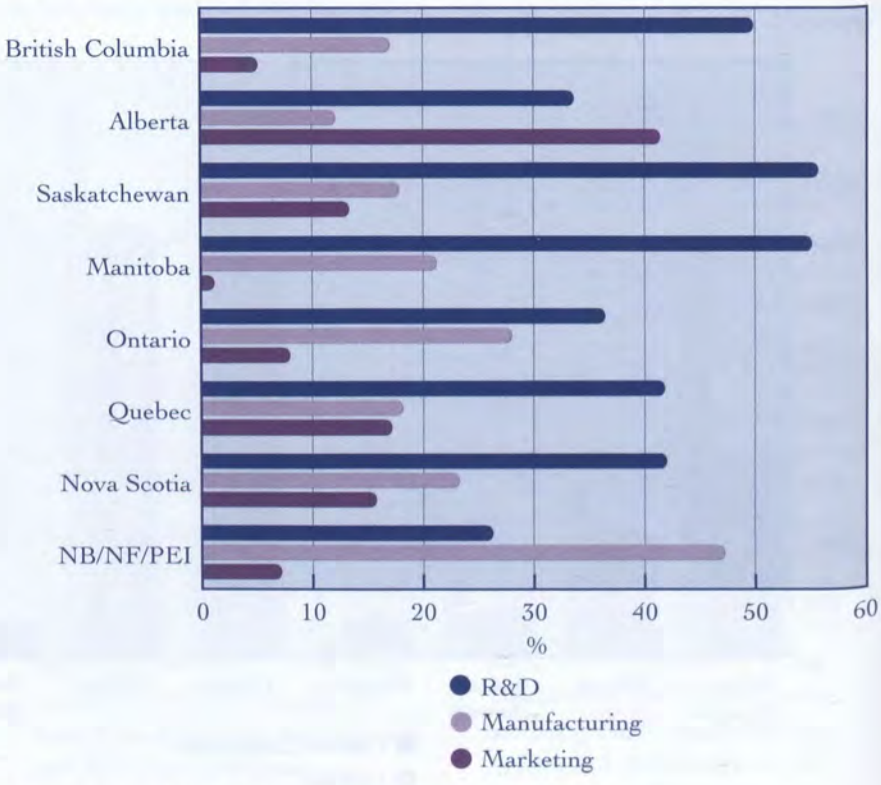
- Nova Scotia companies projected only modest increases in all functions except manufacturing where they project an eight fold increase.
- Ontario companies expect to more than double their marketing/sales people, but diminish their clinical affairs personnel. The latter projection may be linked to the trend to contract out such work to contract research organizations (CROs).
- New Brunswick, Newfoundland and P.E.I. as a group have more manufacturing personnel (primarily in P.E.I.) than any other function.

The relative current importance of R&D, marketing/sales and manufacturing in the different regions is illustrated in Figure 28. This shows, for example, in the combined New Brunswick, Newfoundland and P.E.I. case, manufacturing represents 47% of all the current biotechnology employment in that region.

Unfilled Positions and Recruitment Strategies

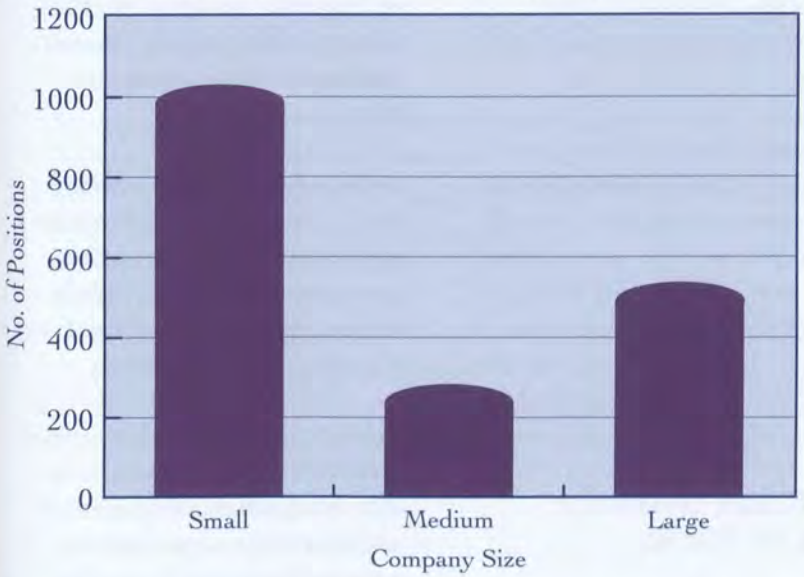
In 1997, 1,900 positions, approximately 20% of current employment, remained unfilled in the biotechnology industry. As Figure 29 illustrates, over half the vacancies are in small companies.

Figure 28: Selected Business Functions by Region (%)



Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

Figure 29: Unfilled Positions by Company Size



Note: Estimations for sector totals by Industry Canada and BIOTECanada

Source: Statistics Canada, *Biotechnology Firm Survey — 1997.*

Over 28% of firms surveyed experience problems recruiting technical, production, scientific and R&D staff. Of those affected, almost three-quarters were small firms and over half were in the health care sector.

Similarly, 26% of all firms (mostly small health care companies) reported difficulties recruiting business operations staff for finance, marketing, regulatory and clinical positions.

About 60% of the firms with staffing difficulties in either the technical area or in business operations describe themselves as DNA-based technologies companies. Since these technology areas are expected to become steadily more prevalent, recruitment problems may worsen.

Human resource development is an important activity: 35% of the respondents have dedicated human resource personnel, and 32% of companies have formal employee development programs.

To meet their personnel needs, over 30% of the firms reported efforts to hire from outside Canada. Two-thirds of these firms are in the health care sector, are small DNA-based companies and do not have human resource specialists on staff. The US is the favoured source of talent, with Europe a distant second. Recommendations to streamline the immigration process have been highlighted in some reports concerned with bringing skilled people into Canada. However, the survey results show that more than 70% of reported international staffing efforts

were successful. Only two companies suggested that immigration rules were an impediment to hiring foreign personnel.

Separate questions on barriers to commercialization also identified skilled human resources as an issue: over 32% of firms reported this to be a problem. Of these firms, 73% are small and close to 60% are health care companies. Almost 80% of the firms reporting such concerns are in Quebec, British Columbia, and Ontario, in that order.

► *BIOTECanada Commentary: Filling the Skills Gap*

It is frequently suggested that Canadian universities and colleges are able to handle the demand for skilled people and in fact, many institutions across Canada have been evaluating their programs to meet the specialized needs of the biotech industry. In spite of the impressive output from universities, and an important contribution from the community colleges, recruiting problems remain. While the sheer numbers of graduating students would seem to be adequate, many clearly do not match the skills gaps being experienced in the biotechnology industry. This accords with anecdotal information that many unfilled positions require multi-disciplinary backgrounds, combining two or more of the following: a related scientific specialty, intellectual property protection, product and process management, regulatory affairs, management and administration, and marketing and sales. Experience in international markets is also seen as a definite asset.

One key to overcoming the gap would be to 'match' course offerings with specific industry job descriptions so that students would have some understanding of the types of jobs for which they might train, and would know that job opportunities are likely to be available.

The industry would also benefit from increasing its investment in developing the appropriate skills. Creating more entry-level positions with well-defined training programs would help graduates enter the work force. For areas where greater depth in management or other expertise is required, industry may benefit from focussing on in-house development of existing personnel with potential for advancement.

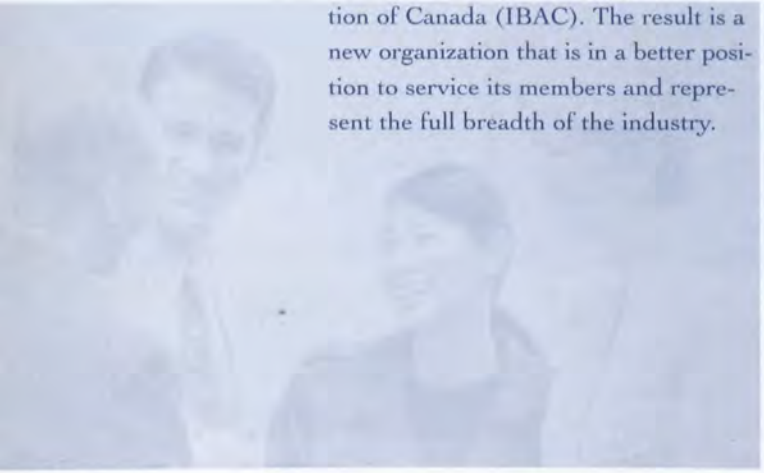
To assist in enhancing skill development for entry-level positions, one approach would be to establish one-on-one mentoring programs between individual students and biotech employees. This could be an extension of existing co-op programs: already, many colleges and universities are moving to expand their programs to include co-op work experience. Survey results, which indicated that over half the biotech industry already employs students from university co-op programs, suggest that such a program has potential.

Biotechnology Human Resource Council (BHRC)

- BHRC brings together corporate executives, owner-operators of smaller companies, employees, educators, human resource development specialists, and interested government officials. In cooperation with all stakeholders, BHRC designs, distributes and promotes programs and services of value to Canada's biotechnology industry for attracting, developing and retaining the highly skilled Canadian work force essential for its sustainable growth and international competitiveness.
- BHRC currently has four national task forces:
  - ***Skills Development:*** to put in place an integrated series of training and upgrading programs to ensure that current and future biotechnology employees are equipped with the skills, knowledge, information and personal competencies to fill the human resource needs of the expanding sector.
  - ***Labour Market Information:*** to put in place an Internet-based, self-sustaining system of labour market industry intelligence that provides firms and potential employees with access to the human resources information they need to pursue their objectives and to gain strategic advantage.
  - ***Standards and Certification:*** to identify and implement strategic partnership opportunities between Canadian post-secondary institutions and professional development organizations, and the biotechnology sector to ensure that these institutions and organizations produce graduates with the scientific and business-related skills necessary to meet the sector's future requirements.
  - ***Career Development:*** to guide the creation of information resources and other support services to assist students, and current and future employees, to identify and take advantage of, job opportunities and career development products and services.
- Employment projections estimated in 1995 that about 6,000 new biotechnology jobs would be created in the core industry during the five years leading up to 2000, encompassing research and technical support activities, commercialization functions and management positions. The growth pattern in the sector has not been smooth; nonetheless, the overall projected growth is taking place.

The biotechnology industry is a complex and heterogeneous continuum of companies. It ranges from those that are small, cash strapped and developing a single product to those where biotechnology is integrated into operations but forms only a small portion of total product sales. This is true across a growing number of sectors from Agriculture, Health Care and Environment to the newer areas of biotechnology such as Food Processing, Bio-informatics and Aquaculture. A range of issues and challenges face the industry. Dealing with them requires identification of the combination of industries affected, and careful articulation of policies in a number of areas. These include R&D, finance, intellectual property, product pricing, human resources and communications.

To deal with these issues facing the industry, BIOTECanada was formed in February 1998 through the amalgamation of Canada's national biotechnology organizations: the Canadian Institute of Biotechnology (CIB) and the Industrial Biotechnology Association of Canada (IBAC). The result is a new organization that is in a better position to service its members and represent the full breadth of the industry.



BIOTECanada provides a unified industry voice and focusses resources to:

- promote a supportive regulatory, policy and research environment
- communicate with members, government and the broader community
- facilitate access to human resources
- collect and disseminate industry statistics and market intelligence
- work with international partners on specific issues
- provide a range of member services and products

As a technology association, BIOTECanada represents many diverse sectors that use biotechnology. It also has representation from the research community. Active committees composed of volunteers from its membership include: human health care, agriculture, environment, intellectual property, ethics, government relations, science, and finance. BIOTECanada's activities aim to foster an environment that responds to the needs of the biotechnology community, both nationally and internationally.

BIOTECanada is the authoritative voice for the Canadian biotechnology industry. It represents over 100 Canadian member companies and organizations. The association seeks to complement the work of the regional biotech associations and also to work on behalf of the many early-stage companies in the emerging biotech industry. The association is always accepting new members.

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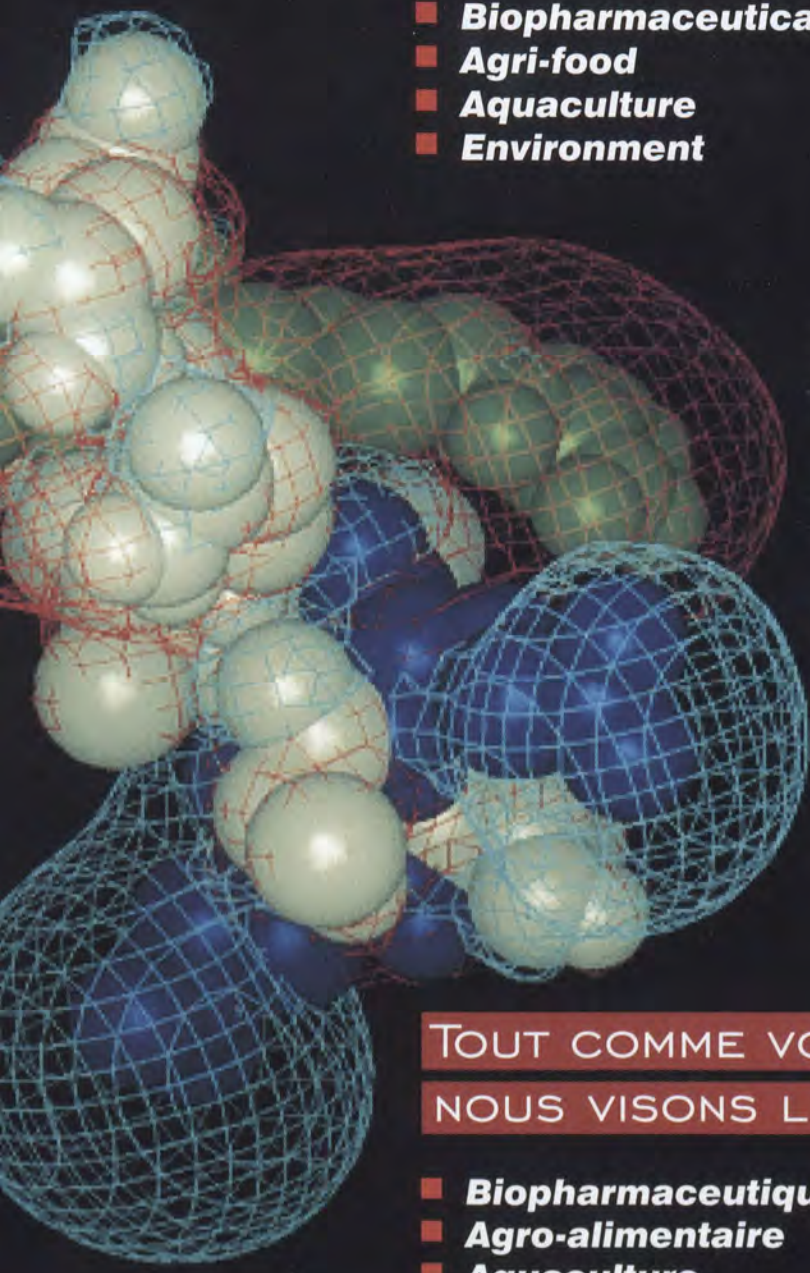

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