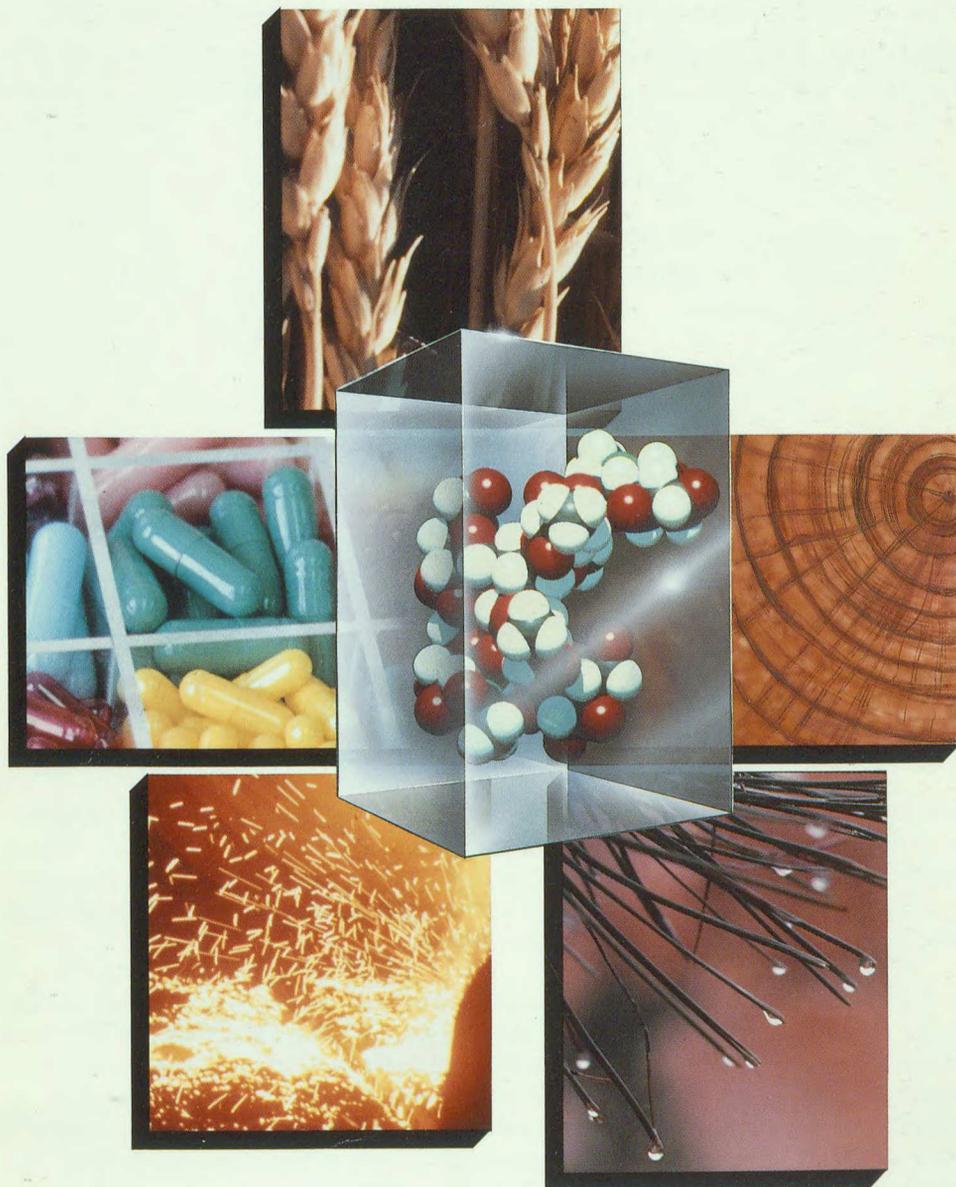


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Executive Summary

# Canadian Biotech '89: *On the Threshold*



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A survey of business and financial issues

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## Cover

Biotechnology is revolutionizing industry around the world. This revolution is based on the discovery of powerful new techniques for manipulating genetic material. These advances are important to future economic development since, as our cover illustration depicts, biotechnology will have very broad applications to the various industrial sectors including human health care, agriculture, forestry, the environment and mining.

The central molecule in the illustration is a model of the polysaccharide antigen from the bacterial cell wall surface of salmonella. At the National Research Council of Canada's Division of Biological Sciences in Ottawa, the Carbohydrate Laboratory specializes in interpreting the antigen-antibody interaction underlying the immune response in terms of its biochemical properties and molecular structures. Cell surface carbohydrate antigens, like the one depicted, have been modified to produce a new generation of vaccines to diseases such as meningitis, gonorrhoea, and enteric diseases caused by salmonella and *E.coli*.

Photos: Industry, Science and Technology Canada  
Molecular model: The National Research Council of Canada

Executive Summary

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# Preface

In the past, information on the challenges and successes of industrial biotechnology in Canada has been mostly anecdotal. No single source of consolidated and current information on biotechnology existed.

Through a collaborative effort among five players, Ernst & Young's High Technology Group, Winter House Scientific Publications Inc., Industry, Science and Technology Canada, the National Research Council of Canada, and, most importantly, the industry itself, a detailed study was undertaken in November of 1988. The objective: to gather qualitative and quantitative data on the Canadian biotechnology industry that could serve as a useful baseline of information against which the future performance of the industry could be measured.

The outcome, *Canadian Biotech '89: On the Threshold*, presents a dynamic picture of an industry, active in almost all parts of the economy, emerging as a force to be reckoned with in international markets. It is our hope that the results presented in this publication will be of value to policy makers, the financial community and the industry itself, both in Canada and abroad, in their deliberations.

Many individuals were responsible for collecting, analyzing and publishing the results. A first effort is always infinitely more onerous than could possibly be imagined at the outset. All those who participated in this venture are to be congratulated. Statistics Canada deserves special thanks for assistance in the evaluation of financial data.

I look forward to reconvening the entire team in the future to measure the progress of this exciting sector once again as it moves beyond the threshold.

**Peter Winter,**  
**Winter House Scientific Publications Inc.**  
**December, 1989**

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Inside Back Cover: Geographical distribution of biotechnology firms in Canada

# Executive Summary

**B**iototechnology in Canada is in a dynamic state of investment in new technology, new manufacturing facilities and new markets. Optimism pervades the sector. Challenges abound. With strategies based on innovation and partnership, Canada's biotechnology companies are poised to take their place among the pioneers in international markets.

Biotechnology is breaking even in Canada. Total sales hit \$660 million last year, R&D accounted for aggregate spending of \$275 million, and the net loss after taxes for the entire industry was only \$3 million, with half of the companies reporting profits.

Canadian biotechnology firms are on the threshold of a period of rapid growth. With an average of six products in production and another six in development, companies plan to spend almost \$7 million each on new manufacturing facilities by 1992. The industry expects to hire 5000 new employees by 1992, almost doubling the present workforce, and forecasts sales that total \$5 billion industry-wide by the same year, for an annual growth rate of 46 per cent.

These are somewhat modest plans as viewed from a North American perspective: U.S. firms plan to spend \$51 million each on manufacturing facilities, eight times as much as Canadian firms; U.S. firms expect to grow to 321 employees each by 1992 while Canadian firms grow to 53; and U.S. firms forecast an increase by a factor of 4.9 in their revenues by 1992 to total \$72 billion on an industry-wide basis.

The products and processes invented and sold by Canadian biotechnology companies involve nearly every industrial sector. They include cloned varieties of ornamental plants, bioleaching in the mining of uranium and gold, quick tip-of-the-tongue tests to measure blood alcohol, anaerobic digestion systems for the treatment of pulp mill effluents, the world's first conjugate vaccine, cattle improvement through nuclear transplantation and embryo cloning, monoclonal antibodies for blood typing, soil microbes to improve plant growth, diagnostic kits for AIDS, the brewing of beer, biological pesticides, and mass production of biological reagents from eggs and plants. This list just scratches the

surface. The common theme is that all involve the harnessing of living systems to carry out specialized tasks or to manufacture tailor-made products.

Canada's traditional strength in the natural resource-based industries has had a significant impact on the way biotechnology has developed here. A much higher proportion of Canada's biotechnology companies is involved in activities such as mining, forestry, fishing, agriculture and environmental industries than in the U.S., the U.K. or Japan. Many of Canada's largest biotechnology companies are well-established members of these conservative industrial sectors. Founded in the early part of this century, these companies have been attracted to biotechnology in recent years in part as a result of strong government incentives for collaboration among industry players, university scientists and government laboratories. These firms make up a significant fraction of the large biotechnology companies in Canada. They continue to be quite conservative.

In what is the first survey of its type conducted in Canada, some extremely valuable insights were gained into the current status and future directions of Canada's emerging biotechnology industry.

Taken as a group, Canada's biotechnology companies are ambitious. The challenges for the future, if these ambitions are to be realized, will be to find the capital to finance the building boom of new manufacturing facilities; to educate and attract the people needed to fill the 5000 new jobs in industrial biotechnology; to create and maintain the linkages with scientists who can ensure a continuing stream of innovative products; and to cement the commercial partnerships that will permit Canadian companies to compete effectively in international markets.

## *The Survey*

Eighty-four companies, representing 38 per cent of the 220 companies known to be involved in biotechnology in Canada, were selected so as to reflect the geographical, sectoral and size distribution of the industry.

The survey addressed an extensive range of business and financial topics which included human resource requirements, intellectual

property issues, regulations, liability concerns, manufacturing capabilities, partnering strategies, availability of capital, obstacles in commercialization, approaches to marketing, sources of revenue and future plans.

Results were analyzed by size of company and by sector of activity. Company size was determined based on the total number of employees: very small, 1-10; small, 11-50; mid-size, 51-135; and large, over 135. Companies were placed into ten groups to permit sectoral analysis: diagnostics, therapeutics, agriculture, suppliers, environmental, aquaculture, food and beverage, forestry, mining, and consulting and contract research firms.

The key findings of this survey of industrial biotechnology undertaken in Canada between November of 1988 and February of 1989 follow.

## Key Findings

### *Commercialization*

- ❑ **Over 10,000 products of biotechnology:**  
The 84 surveyed companies collectively have 4078 products at all stages of product development. If this is extrapolated to the entire industry, this leads to an estimate of 10,600 products of biotechnology in the roughly 220 biotechnology companies in Canada.
- ❑ **Most products are in development:**  
These products include 2542 (62%) at the stage of research and development, 617 in testing (15%) and the remainder, 919 (23%) at the stage of production.
- ❑ **Seed companies account for 76 per cent of all products:**  
Seed companies surveyed account for a disproportionate number of these products - a full 76 per cent of the aggregate 4078 products, or 3089 products in all. Of these, 2200 are at the stage of research and development, 437 are at the stage of testing and 452 are in production.
- ❑ **Health care companies have strength "in the pipeline":**  
The remaining 989 products (24%), distributed across all of the other sectors surveyed, included 342 at the stage of research and development, 180 in testing and 467 in production. Diagnostics companies have the highest number of products "in the pipeline", with an average of 9.2 each in R&D or testing. Therapeutics firms are a close second with an average of 8.7 each.
- ❑ **Small companies lead in number of products:**  
When seed companies are excluded, the average number of products in production per company decreases

with increasing company size. Small companies with 11-50 employees have an average of eight products in production while companies with greater than 150 employees have an average of only three.

- ❑ **More than half of the companies surveyed have manufacturing facilities:** Fifty-six per cent of the companies surveyed already have in-house manufacturing facilities. Fifty per cent expected to build new facilities within the next two years.
- ❑ **Over \$1 billion will be invested in new Canadian manufacturing facilities by 1992:** Companies surveyed expect to invest a total of \$546 million in manufacturing facilities between 1988 and 1992. If this is extrapolated to the 220 biotechnology firms doing business in Canada, this leads to an estimate of \$1.4 billion for the entire industry. According to those surveyed, 76 per cent of this investment will be for domestic facilities with the remainder targetted for investment abroad.
- ❑ **Small companies have ambitious plans for growth:** Between 1988 and 1992 they expect to commit an average of \$4 million per company on domestic manufacturing facilities. Large companies report plans to spend just over double this amount in the same period.
- ❑ **Direct sales figure prominently:** The companies surveyed indicated a range of different approaches for distributing their products. The most frequently cited technique for both the domestic market and Japan was direct sales. On the other hand, wholesalers were cited most often for the United States, and distributors for Europe.

- ❑ **Companies predict their sales will quadruple in five years:** Canadian biotechnology companies expect their annual sales figures to more than quadruple between 1988 and 1992 from an average of \$4.6 million per company to \$21.1 million. This leads to an estimate of \$4.6 billion revenue from the products of biotechnology for the entire industry in 1992.
- ❑ **Exports to grow faster than domestic sales:** At the time of the survey, the ratio of domestic to foreign sales of Canadian biotechnology companies was roughly 50:50. However, these companies predict that their export sales will increase so that by 1992 their domestic to foreign sales ratio will be 35:65.
- ❑ **Research cited as top competitive factor:** The companies surveyed rated research expertise, management expertise and products as the top three determinants of their competitive advantage.

## *Combining Forces*

- ❑ **Alliances are a common feature of Canadian biotechnology companies:** Eighty-seven per cent of companies surveyed have alliances with other firms and organizations, with an average of 8.3 per company.
- ❑ **Half of the alliances are foreign:** Alliances with other companies are distributed as follows: 47 per cent in Canada, 33 per cent in the United States, 13 per cent in Europe, 3 per cent in Japan, and 4 per cent elsewhere.

- ❑ **Universities are the most frequent partners:**  
The top three categories of alliances in terms of frequencies were those with universities (22%), government laboratories (14%) and other biotechnology companies (13%).
- ❑ **Companies look for credibility when choosing partners:**  
Credibility, access to technology and research capability were the top three factors involved in selecting a domestic alliance partner. For foreign alliances the top factors were credibility, marketing expertise, and access to technology.
- ❑ **Acquisitions are expected to be high:**  
The firms surveyed expect 60 per cent of Canadian biotechnology companies to be acquired within the next ten years. Only 17 per cent expect to be among those to be acquired and 29 per cent expect to acquire a company.

## *The Human Dimension*

- ❑ **Industry-wide requirement for 5000 new employees over five years:**  
The 84 companies surveyed expected their aggregate total of employees to grow from 2510 in 1988 to 4476 in 1992. This increment of almost 2000, when extrapolated to the whole industry, reveals a requirement for over 5000 new employees for Canada's biotechnology industry during this five-year period. Approximately 1500 of these will be bioscientists, 400 will be engineers and 700 will be in sales and marketing.
- ❑ **Highly qualified personnel are hard to find:**  
Companies report that bioscientists and

engineers, especially those with multidisciplinary capabilities and industrial experience, are hardest to find.

- ❑ **Government is seen as a competitor for staff:**  
Industry views its top three competitors for highly qualified personnel as other biotechnology firms, government and educational institutions.
- ❑ **Best technical advice is not from scientific advisory boards:**  
Only 44 per cent of the companies surveyed have scientific advisory boards. When asked to rank their three most valuable sources of advice about technology, companies identified universities (63%), in-house expertise (62%) and the federal government (44%).
- ❑ **Boards of Directors feature prominently in financial decisions:**  
Eighty-three per cent of the companies surveyed have Boards of Directors. They rank their three most valuable sources of advice about financing as their own Board of Directors (55%), the federal government (47%) and in-house personnel (46%).
- ❑ **Consultants provide advice in many areas:**  
In-house personnel, consultants and trade associations were ranked as the three most valued sources of advice on manufacturing and marketing. The survey found that over 45 per cent of companies hire consultants to obtain advice on marketing, 40 per cent for advice about technology, and 30 per cent for advice about financing and manufacturing.

## *Financial Indications*

- Half have positive net incomes:**  
Over half of the companies surveyed reported positive net incomes after tax in each of the two most recent fiscal years.
- Only the therapeutics sector had average net incomes which were positive:**  
Average net income after taxes was negative for all size categories except the large companies and for all sectors except therapeutics.
- R&D spending almost doubled:**  
Average expenditure on R&D per company per year was found to be \$1,250,000 in the most recent fiscal year, representing a growth rate of 89 per cent over the previous one.
- Diagnostics firms increased their R&D by a factor of 12:**  
R&D growth rates from 1986 to 1987 were highest for mid-size firms and for diagnostics companies.
- Strong growth in revenues reported:**  
Total revenue per company grew by 28 per cent from \$2,590,000 in 1986 to \$3,322,000 in 1987.
- Mid-sized companies showed highest revenue growth rate:**  
The average revenue per company in 1987 increased with size of company from \$267,000 for very small companies to \$19,365,000 for large companies. Annual growth rates between 1986 and 1987 were 40 per cent for very small companies, 33 per cent for small, 72 per cent for mid-size, and 24 per cent for large.
- Over \$70,000 revenue per employee:**  
Revenue from sales of biotechnology products per employee devoted to biotechnology also increased with company size in 1987 from \$10,089 for very small companies to \$113,246 per employee in large companies, with an overall average of \$72,530 per employee.
- Contract research important to small firms:**  
Small companies derive most of their revenue from contract research (66%) and large ones derive essentially all of their revenue from sales. Revenue from royalties is important only in very small and small firms.
- Liquidity ratio is high:**  
The overall average per company for current assets in 1987 was \$2,835,000, and for current liabilities, \$1,100,000, yielding a median liquidity ratio of 2.3. This was up from 2.0 in 1986. These values are at the high end of the range defined by other industrial sectors.
- Mid-sized firms displayed the highest liquidity ratios:**  
The liquidity ratio was highest in mid-sized firms and in the therapeutics sector with median values of 6.5 and 2.6 respectively.
- Debt-to-equity ratios are low:**  
The average debt per company in 1987 was \$2,434,000 and the average equity was \$5,418,000 with a median debt-to-equity ratio of 0.47. This was down from 0.68 in 1986. These values are much lower than other Canadian industrial sectors in the same year.

## ***Legal and Tax Environment***

- Companies believe in patenting:**  
Seventy-five per cent of the companies surveyed believe that patenting is worthwhile. At the same time, half of the companies do not believe they can defend their patents.
- Relatively few patent disputes:**  
Only 20 per cent of the companies surveyed had ever been involved in patent disputes. Only four companies have actually been involved in litigation in connection with a dispute.
- Many companies patent abroad:**  
More than half of the companies reported first-hand experience with patenting products in Europe, the United Kingdom and the United States. Forty-three per cent of the companies have experience with patenting in Japan.
- Most file first in the United States:**  
The majority of companies file their patent applications in the United States first, to obtain a one-year protection during which they file in Canada, Europe, Japan and elsewhere.
- Suppliers and therapeutics firms concerned about liability issues:**  
Over 80 per cent of the companies in the survey reported no liability concerns. Supplier firms and therapeutics manufacturers showed the highest level of involvement with this issue. All sectors expect liability concerns to increase, with 38 per cent of those surveyed believing their ability to commercialize products in the future will be impaired by product liability.
- Regulatory approval takes on average 15 months:**  
Eighty-two per cent of the companies surveyed have products which require regulatory approval by one or more agencies. Of those surveyed, 49 have products regulated by Health and Welfare Canada, 30 by Agriculture Canada, 20 by Environment Canada, and 20 by other agencies. Regulatory approval takes on average 15 months, ranging from eight months for diagnostics firms to 22 months for therapeutics firms.
- Awareness of CEPA regulations was low:**  
Only 29 of the 84 companies surveyed were familiar with the Canadian Environmental Protection Act (CEPA) and its implications for industrial biotechnology. All but six of these had serious concerns about the proposed regulations as drafted at the time of the survey, (November 1988 to February 1989).
- Research tax credit system drew criticism:**  
The Scientific Research and Experimental Development (R&D) Tax Credit was criticized by many respondents for having too narrow a definition of research, for being cumbersome to apply for, and for taking too long to receive.
- Research tax refunds are arriving sooner:**  
The streamlined system for R&D tax credits introduced in the spring of 1988 has shortened the waiting period for cash refunds from an average of 20.9 months to 5.2 months. Approximately equal numbers of respondents fall into each of these two categories as might be expected since the survey took place in late 1988 and early 1989.

## *International Perspective*

- ❑ **Product sales per employee are higher in Canada than in the U.S.:** Canadian firms reported sales of biotechnology products per employee of \$33,000 for small companies and \$113,000 for large companies. U.S. firms reported \$30,000 for small companies and \$70,000 for large ones.
- ❑ **R&D as a percentage of sales is like that in the U.S.:** Canadian companies spend, on average, 42 per cent of their sales revenue on research and development. Their U.S. counterparts spend 43 per cent.
- ❑ **Canada's biotechnology companies are older than their U.S. counterparts:** Forty-nine per cent of the firms now engaged in biotechnology in Canada were founded before 1980. These include many established natural resource-based firms that have only recently taken up biotechnology activities. Only 31 per cent of U.S. biotechnology firms and 17 per cent of U.K. firms were founded before 1980.
- ❑ **U.S. companies will invest eight times as much in manufacturing facilities:** Between 1988 and 1992, Canadian companies plan to spend an average of \$6.6 million each to build new manufacturing facilities. During the same timeframe, U.S. firms will spend an average of \$51 million each.
- ❑ **Canadian and U.S. firms forecast similar growth rates in revenue from sales:** Between 1988 and 1992, Canadian firms expect their sales revenues to grow by a factor of 4.6 to reach an industry-wide aggregate revenue of \$4.6 billion in 1992. Over the same interval, U.S. firms forecast growth by a factor of 4.9 to reach aggregate industry revenue of \$70 billion.
- ❑ **U.S. companies have more patents than Canadian firms:** Canadian firms hold an average of 2.4 patents per company and have another 2 patents pending. U.S. firms hold an average of 6 patents per company and have an additional 21 pending.
- ❑ **Canadian firms rely more on export sales than do U.S. firms:** In 1988, the sales of Canadian biotechnology companies went 52 per cent to foreign markets. This is expected to increase to 62 per cent by 1992. U.S. firms, on the other hand, sold only 17 per cent of their products to foreign markets in 1988 and expect this to increase to 30 per cent by 1992.

This survey provides a baseline for industrial biotechnology in Canada against which future performance may be measured. It also provides a wealth of information to help investors, policy makers, scientists and the industry itself understand the sector in more depth.

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