

Title	North American Biotech Companies : Strategy and Management System
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Description	一般論文

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**Abstract**

As competition becomes globalized, strategy and management system tend to be patternized and standardized. Quite a few successful biotech firms such as Chiron, Genetech, Amgen, Centocore, and Biogen have gone through similar transition, i.e., from a small privately held R&D firm to a full-scale pharmaceutical conglomerate. The purpose of this paper is to present Chiron's case study supplemented with best practices from other successful biotech firms in closely related field in order to clarify in what direction successful North American biotech firms are going.

**Methodology**

The research was conducted via a combination of primary and secondary research methodologies including:

Gaining access to and interviewing, as appropriate, selected members of successful biotech firms, as well as professional, technical, and trade associations in the area of biotech ventures.

Scanning the content of professional and scholarly books, journals, newspaper articles, dissertations, and various publicly available print media sources, including the annual reports of the targeted companies, when possible.

Utilizing subscription research services to identify and access pertinent industry reports, publications, patent information, and other potentially useful data.

Utilizing the Internet as a tool to identify and review relevant information and obtain referrals to information source that can be thoroughly investigated to deepen understanding of the areas of interest.

**Findings**

**A. Economic & Business Trends in Biotechnology**

As the industry is maturing, and markets are becoming saturated, corporate restructuring is taking place. Also, biotech firms are entering into direct competition with big pharmaceutical companies due to convergence of goals and methods in drug production, and the shrinking of profit opportunities in the traditional pharmaceutical industry. Basic strategies can be divided into two. Small biotech firms (less than \$10million) become highly specialized research companies affiliated with big pharmaceutical, focusing on niche markets. Big biotech firms (more than \$10million) develop organizational, marketing, R&D, and manufacturing capabilities that match those of big pharmaceutical. Inova Diagnostics Inc. dedicated exclusively to autoimmune disease diagnostics is the first case. Chiron, which merged with Ciba is a example of the second case. During a period of market saturation in new industries, companies experiment with organizational structures and strategies until a successful model emerges. The two strategies

mentioned above are derived from emerging patterns in the North American biotech industry. Financially speaking, biotech stocks have outperformed all other stocks on the NASDAQ, realizing a total gain of 48.28 (year-to-date) in 2,000.

**B. Types of Ventures in the Biotech Industry:**

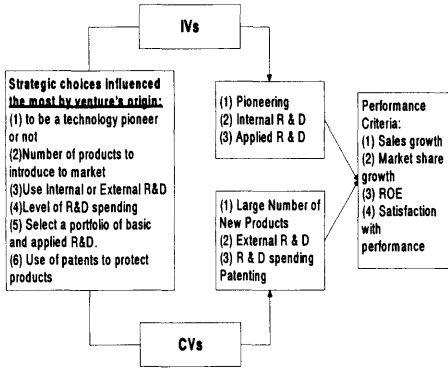
There are two types of biotech ventures according to their origin. The first one consists of independent ventures (IVs)-established by individuals (entrepreneurs). The second one consists of corporate ventures (CVs)-established by corporations. The different origins influence organizational structure, product development, and marketing strategies, often determining the choice of technology. The different origin also make the transfer of best practices, benchmarks, and metrics from one type to another impossible, unless the differences are clearly understood and taken into consideration in the transfer process.

**Differences between independent and corporate ventures.**

Differences Between Independent (IVs) and Corporate Ventures (CVs)		
Areas	Independent Ventures (IVs)	Corporate Ventures (CVs)
Goals	<ul style="list-style-type: none"> <li>• Employment and autonomy (independence) for the owner.</li> <li>• Profitability and wealth creation for the owner.</li> <li>• Opportunity to use owner's expertise.</li> </ul>	<ul style="list-style-type: none"> <li>• Market creation</li> <li>• Penetration into new technology</li> <li>• Growth and profitability</li> </ul>
Financial resources	<ul style="list-style-type: none"> <li>• More limited than CVs, because IVs draw from owners and venture capitalists.</li> <li>• Long term orientated.</li> </ul>	<ul style="list-style-type: none"> <li>• Rich corporate sponsors and venture capitalists affiliated with the corporate sponsors.</li> <li>• Short term oriented.</li> </ul>
Non-financial resources	<ul style="list-style-type: none"> <li>• Owners experience</li> <li>• Venture capitalist connections</li> <li>• Professional networks and affiliations</li> </ul>	<ul style="list-style-type: none"> <li>• Uses the corporate sponsor's established operations, excess capacity, expertise, etc.</li> </ul>
Decision making process	<ul style="list-style-type: none"> <li>• Simple and informal structure</li> <li>• Frequent communication</li> <li>• Quick feedback</li> <li>• Longer time planning</li> </ul>	<ul style="list-style-type: none"> <li>• Formal hierarchy</li> <li>• Communication through formal/official channels</li> <li>• Tight corporate controls</li> <li>• Shorter-term planning</li> </ul>
Decision Makers	<ul style="list-style-type: none"> <li>• Owners</li> <li>• Top management team</li> </ul>	<ul style="list-style-type: none"> <li>• Salaried managers</li> </ul>
Managers dominant skills	<ul style="list-style-type: none"> <li>• R&amp;D</li> <li>• Manufacturing &amp; Operations</li> </ul>	<ul style="list-style-type: none"> <li>• Marketing &amp; Distribution</li> </ul>
Employee Skills	<ul style="list-style-type: none"> <li>• More focused skills</li> <li>• More entrepreneurs in top management</li> </ul>	<ul style="list-style-type: none"> <li>• More diverse skills</li> <li>• More leader in top management</li> </ul>
Organizational structure	<ul style="list-style-type: none"> <li>• Simple</li> </ul>	<ul style="list-style-type: none"> <li>• Multi-layered with tight control from corporate sponsor</li> </ul>
Executive incentives and compensation	<ul style="list-style-type: none"> <li>• Tied directly to venture performance through equity and stock options</li> </ul>	<ul style="list-style-type: none"> <li>• Plan achievement incentives</li> <li>• Seniority and position in hierarchy in sponsor.</li> </ul>

**Note:** In developing an organizational strategy, a mixture of IVs and CVs elements can be selected, but the implementation has to take into account the origin of the venture and the necessary transitions. The transitional steps and goals have to be clearly defined and communicated to all employees.

**How origin influences strategic choices**



**C. Chiron's Growth Strategy and Organizational Development**

Chiron's case was chosen for the following reasons: Chiron is an R&D intensive firm. Chiron has gone through a complete organizational transformation. The transformation of Chiron illustrates the important connection between organizational structure, R&D and market strategy. Other successful biotech firms, including Genetech, Amgen, Centocore, and Biogen, have gone through similar transition, i.e., from a small privately held R&D firm to a full-scale pharmaceutical conglomerate.

Timeline					
Phase 1 New Business Venture 1981-1986		Phase 2 Intermediate 1986-1991		Phase 3 Big Corporation 1991 - present	
<ul style="list-style-type: none"> <li>◆ Incorporated in 1981</li> <li>◆ Went public in 1983</li> <li>◆ 60 employees highly experienced in R&amp;D</li> </ul>		<ul style="list-style-type: none"> <li>◆ In 1986 FDA approved Chiron's Hepatitis B kits, which had strong market potential.</li> </ul>		<ul style="list-style-type: none"> <li>◆ In 1994 merged with Ciba .</li> <li>◆ Chiron has 80 wholly owned subsidiaries in 97 countries.</li> </ul>	
<ul style="list-style-type: none"> <li>◆ Primary focus on research</li> <li>◆ Maintained strong relationships with universities</li> </ul>		<ul style="list-style-type: none"> <li>◆ The primary focus shifted to formation of joint ventures for commercialization of products.</li> <li>◆ Formed alliances with Johnson&amp;Johnson and Ciba Geigy.</li> <li>◆ Retained technology and manufacturing rights to core products.</li> </ul>		<ul style="list-style-type: none"> <li>◆ Primary focus shifted to acquisitions, operations efficiency and global expansion.</li> <li>◆ Diversified its portfolio of healthcare products.</li> <li>◆ Started selling directly into more focused markets.</li> <li>◆ Marketed nich products through operating subsidiaries.</li> </ul>	
Innovation and Product Development Strategies					
<ul style="list-style-type: none"> <li>◆ Focus on radical (pioneering) innovations.</li> </ul>		<ul style="list-style-type: none"> <li>◆ Focus on diffusion (commercialization) of radical innovation.</li> </ul>		<ul style="list-style-type: none"> <li>◆ Focus on systematic innovations.</li> <li>◆ The development of radical innovations is outsourced to reduce risks.</li> </ul>	
Ratio of Managerial Scientists to Total Employees					
1983	1986	1989	1991	1994	1997
4.48%	2.29%	1.96%	0.61%	0.37%	0.09
Number of Employees					
67	174	491	1810	2668	7200
Ratio of R&D Expenses to Total Assets					
0.69	0.10	0.47	0.08	0.15	0.21
Total Debt to Total Assets (Chiron's Leverage)					
The small ration prior from 1983 to 1989 is consistent with Chiron's strategies in Phase I & II		0.051	45	The rapid increase starting in 1990 is consistent with Chiron's strategy for Phase III	
<b>Note:</b> Case material was taken from doctoral dissertation, research papers and primary research of K. Chang, and was reviewed and updated by Dr. Kotorov.					

### Selected Biotechnology Practices from Various Publications and Companies

Alliances	Strategy	Unnamed Canadian Biotech	There is some evidence that research collaboration with universities facilitates new product development in biotechnology firms...according to Pisano et al., 1988, (p. 187): "The technical distance between a basic discovery [at universities] and a commercial product is distinctively shorter in biotechnology than in other technologies...Basic biomedical and biochemical research can generate know-how with a direct and identifiable commercial application." Thus, companies that are engaged in extensive research collaboration with universities make more value-added progress than companies with little or no research collaboration with universities. "We have a good molecular biology group, of world class but it's not big enough. That's why we tend to go to universities and contract, if you will, with them." (President, agricultural biotech. firm)
HR	Management	Press Overview	Measuring Team work Through 7 Metrics: Record and Review (team members should record info and review it to learn more), Filing (information should be easily and quickly accessible, can be positively related to overall new product success rate), Setting Goals (help establish a direction so that individuals know what to record, file and review; also provides a focus for motivating search for info to achieve goal), Team Stability (critical factor between successful and unsuccessful projects; teams should stay together for duration of product development and release into production), New Product Development Process (having a process provides framework to help new product teams achieve their goals; correlates with proficiency in pre-development activities, completing market activities, and in completing technical activities), Innovation Team Learning Model (establish clear vision of project, refrain from changing vision prior to launch, secure management support for vision; modify vision only if company and team management do not agree on vision; then establish system for documenting, filing and reviewing info. captured by team; lastly, maintain stability and institute systematic New Product Development process to correct problems uncovered along the way and to translate info. into actionable knowledge; Apply Innovation Report Card (grade teams in 12 categories: recording systems, review/meetings, filing systems, project process, vision stability, management support or agreement to vision, team stability, organizational learning through information acquisition, organizational learning through information implementation, speed of development, and overall project success)
HR	Management (leadership)	Merck Research Laboratories	Leaders need: (1) solid understanding of basic biomedical sciences; (2) be intellectually engaged and supportive of efforts of scientists, engineers and technicians doing the research; (3) be aware and involved in external environment changes esp. public support; (4) strengthen links with educational institutions.
HR	Org. Structure	Amgen, Inc.	Amgen has ensured that teamwork is important to the success of the company by making "working in teams" part of the company's values. Amgen defines a team as "a dynamic group of diverse people with common objectives but different responsibilities that is chartered with improving a process, a product or a service." New term created to define teamwork at Amgen -- "teamship"

HR	Strategy	Unnamed Canadian Biotech	<p>Cross-functional cooperation or team work -- significant contributor to effectiveness of product development. Companies in which the various organizational functions engage in extensive cooperation make more value-added progress than companies in which such cooperation is minimal or non-existent. "Particularly in the academic environments, you have a tendency for primadonnas to emerge. They think they can latch on to an issue and withdraw from the group, which usually leads to problems because at least in pharmaceuticals everything must be looked at from all these perspectives: production, quality control, clinicals, research, development. All of that needs always to be there as opposed to coming together at the end. And pharmaceuticals is a particularly good example of the team approach. That's why the big pharmaceutical corporations are as successful as they are because they have adopted the team approach to things, at all levels." (President, medical biotech. firm) "So what [the president] has done is to set up a management team; we have regular Monday morning meetings where lab managers and breeding and commercial people get together. This is very different from some larger seed companies that would have their commercial people in NJ, their research labs in TX, their breeding people in wherever. We have the advantage of being essentially in a single location." (Senior Scientist, another biotech company). "In the biotech industry, as in the pharmaceutical industry, maybe up to 2-3 years ago, the approach of almost all companies was to organize according to disciplines. You would have a chemistry division, microbiology division, pharmacology division, and so on, according to disciplines. What has been found in the last few years is that this kind structure tends to keep disciplines separated. Whereas to make any significant discovery, you need a completely interdisciplinary approach...So now quite a few companies are changing structurally so that they have research teams in specific areas of therapeutics. And the teams could consist of chemists, microbiologists, and so on." (President, medical biotech. firm)</p>
HR (assignment and training)	Management	New Genetics	<p>Depends on its research scientists for new ideas, which means increasing scientists' awareness of economic imperatives without dampening creativity and independence. Done by having all scientists write 1 or more short research proposals describing projects they wish to develop. Each proposal explains how research can lead to marketable product. Also, position of 'strategy executive' created to be responsible for helping scientists evaluate profit-potential of products. Mgmt. decides which proposals to approve. Employees allowed scheduling flexibility, within limits of expectation for project completion targets. Scientists encouraged to follow timetable convenient to them, including nights and weekends, so long as project completed within allotted time. This strategy places trust in personal judgment, thereby enhancing organizational effectiveness and employee commitment/dedication. Employees encouraged to participate in scientific conferences and external collaborations. To prevent information leaks to competitors, researchers search not only for information relevant to current projects, but on other topics too, through these collaborations and other research outlets, to mislead espionage agents. Also, firm's chief scientist reviews all work for publication prior to sending it out process accommodates scientific norms while preserving important economic survival goals of firm.</p>

HR (corporate culture)	Management	Press Overview	Organizational politics within the management team hinders product development and value-added progress. "It is important that everybody has an understanding where we are going and don't try to pull into different directions. If people want to work on their pet projects rather than on what was agreed on, it is not going to work." (President, biotech firm) Lack of a strong leader at the company might have contributed to destructive organizational politics. Similarly the fact that the managers had no previous working relationships -- the team had been assembled through headhunters -- might have contributed to the conflicts and politics. Others have found that managers who had worked together before were likely to facilitate successful product development, partially because relationships and effective patterns of information sharing have been established already, and time is not wasted on power struggles.
HR (culture)	Management	New Genetics	Culture is deeply affected by founder -- a highly innovative, charismatic entrepreneur who's unique abilities, original view, standard of excellence and excitement over scientific work flows throughout firm, even to scientists who have never met him. This commitment and trust transcends individual relationships and firm's identification with the charismatic entrepreneur, along with shared spirit of entrepreneurship, built a highly motivated and committed research team.
HR (Motivation and reward)	Management	New Genetics	Composite form of compensation to sufficiently motivate scientists while being cost-effective: recognizes individual scientific excellence through salaries, incentive rewards for successful projects, and shared rights to patents. Profit-sharing policy provides all scientists with stock options in company, to enhance commitment to overall organizational excellence. Income for scientists at New Genetics substantially higher than that of university counterparts and commitment to firm strengthened by combination of rewards based on firm and individual accomplishments.
HR (personnel selection)	Management	New Genetics	Teamwork encouraged to facilitate collaboration on creation of a new concept. Team leaders allowed some flexibility in team selection process. But team leaders constrained in choice of team members since selections generally restricted to firm personnel. Teams organized in self-organized structure, with heads of departments working for teams, which determine own needs for equipment and other resources. Self-organized teams considered important organizing strategy to enhance organizational effectiveness and survival (through generated trust and shared perspective).
IMS	Strategy	Press Overview	Traditional computing models for drug discovery inadequate. New models include object-oriented software technology, CORBA and JAVA. CORBA and JAVA both support graphically rich, dynamic programming that integrates well with Web server-based information delivery. They can be used to integrate variety of independent analysis tools running on different platforms and operating systems and to use these from a common interface.
IMS	Strategy	Press Overview	Use of bioinformatics is increasing in both large and small biopharmaceutical companies. Bioinformatics is used to reduce the time to find new targets.
R&D	Management	Press Overview	Process of strategic technology assessment review (STAR) helps to simplify the decision of funding projects and ensure that your team has not overlooked the most important strategic variables. STAR is based on real options reasoning. It involves a limited-commitment investment. If the investment looks attractive, continue funding. If not, option expires, and all that is lost is its price. There are a number

			of measures to work with, which are scored using a 7-point scale by a project team plus important functional colleagues. Areas reviewed are: Cumulative Revenue Potential, Sustainability of Cash Flows, Assessing Commercialization Costs, Assessing Development Costs, Timing and Investment Strategy.
R&D	Management	Press Overview	Highly successful R&D organizations: Build Internal and External Linkages (bridge involvement gap between R&D and other business functions - internal and external); Involve/Interact with customers, manufacturing, sales, service, senior mgmt, quality assurance, marketing, strategic planning, and finance to forge better alliances and understanding; Involve suppliers in new product development process to speed up development, lower development costs, reduce procurement costs, and leverage partnerships; Achieve Business Results by developing R&D and technology strategies in line with business strategies, but without neglecting need to encourage some high-risk basic research projects and providing incentives to pursue truly innovative research that may not have immediate business applicability; Speed Product Development by using tools and technologies such as computer models, simulation tools, software, etc., and use Launch-Learn-Launch mode; Senior Management Support critical to innovation process, especially how senior mgmt views R&D and its role in influencing business performance -- senior mgmt should provide strategic direction, vision, leadership, commitment, and discipline, especially in early stages of innovation processes, while being tolerant of failure.
R&D	Strategy	Unnamed Canadian Biotech	"We are building the company based on certain technology. Even if a product doesn't become successful, the expertise can be utilized in other products. I think it's wrong to build a company around a single endeavor. We'd always be in the peptide proteins area. Sometimes it's wrong to take the company away from its expertise. Companies that are trying to do that are unsuccessful. They grow rapidly, hire people, trying to do too many things. Our approach is: stay focused within the area of expertise. There is always risk, but less risk that way." (President)
R&D/Portfolio Management	Strategy	Press Overview	Portfolio management can be plagued by: 1) Too many project, not enough resources -- resource commitment must be aligned with business's new product objectives, strategy and processes; 2) Project Selection Methods Fail to Discriminate -- little discrimination between projects since most projects pass the hurdles rather than being prioritized; 3) Go/Kill Decisions without Solid Info -- Need early stage work to be done, such as preliminary market assessments, technical assessments, market studies, business analyses, etc., the better the early stage work, the better the project selection decision; 4) Too many Small Projects, Too Few Major Hits -- Impatience, lack of discipline, dynamic nature of markets and environment, and difficulty in finding major revenue generators lead to too many short-term projects which generate little revenue.
	Strategy (business models)	Press Overview	For smaller biotech companies, there are 3 new business models (select appropriate model to match the various drug development stages): 1) Toolbox model -- company develops tools that can be used by other companies to streamline drug development or to discover new targets and screen compounds; 2) Service model -- company provides services to other companies ranging from genomic and gene expression databases to in-house lead identification and contract screening of combinatorial libraries; 3) CRO model -- companies perform preclinical testing and conduct clinical trials for biotech and big pharma clients.