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Strategic management: A tool for growth in the biotechnology sector

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Abstract Biotechnology companies will find themselves confronted with a set of challenges in the next years. Internationalisation, cooperative activities, and mergers and acquisitions are the most important key drivers for the biotechnology industry. In order to respond successfully to new technological as well as market trends, it is crucial to recognise the importance of a strategic planning process. This study examines how traditional tools and concepts of strategic management are applicable to the business of biotechnology and how biotechnology start-ups can use these tool for their own business development.

Keywords: strategic management, strategic planning, portfolio, diversification, GAP analysis

Introduction

Biotechnology companies live in a world of uncertainty and change. Increasing costs of research and development, increasing globalisation and competition as well as the growing pace of biotechnological advances are some challenges in the biotechnology and pharmaceutical industries. In order to react flexibly to these challenges, small, innovative biotechnology start-ups are in a particularly good position. In the past these start-up companies were the most important key drivers for the emergence and development of the biotechnology industry.¹

However, biotechnology start-ups have to achieve a critical mass quickly in order to stay competitive.² Thus, the question is how can biotechnology start-ups develop their business successfully? In particular, it is crucial to recognise the importance of a strategic planning process. Studies on start-ups in the biotechnology industry show,

however, that management frequently does not give much attention to strategic issues during the entrepreneurial formation process.³ This results in a waste of resources and time and leads to misjudging of market chances, which can jeopardise the existence of the company. The cases of Amgen, Biogen and Genentech have shown that during the development of biotechnology companies several obstacles can occur. All three companies entered into some sort of collaboration with strong partners in their early days in order to overcome temporary financial problems (Amgen with Kirin Brewery, Biogen with Schering-Plough and Genentech with Hoffmann La Roche). Based on this problem this paper emphasises the value of business development activities for young start-up companies in the biotechnology industry. In doing so, we examine how traditional instruments and concepts of the strategic management are applicable to the business of biotechnology.

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The strategic planning process

The starting point of the strategic planning process should be the long-term objectives of the top management. The actual planning work begins with an analysis phase, in which the situation of the company itself and its environment are analysed thoroughly. This offers first insights for the formulation of strategic goals. After the goals are defined, the actual strategies are developed. There are often several strategic options, which must be evaluated based on different criteria. In the implementation phase various tasks are executed at project level. Figure 1 summarises the typical sequence of the strategic planning process.

Development of a company vision

Biotechnology has a high level of complexity and uncertainty. According to the Tufts Center for the Study of Drug Development the process of developing a drug takes on average 15 years from basic research to market introduction.⁴ During this time, up to US\$500m⁵ have to be invested. Moreover, it can be statistically shown that 5 out of 5,000 drug candidates go from the research to the clinical stage, and out of these 5 only 1 reaches market introduction.⁶

Knowing this high degree of uncertainty and complexity of doing business in biotechnology, vision for the development of the company is of great importance. For

instance, Biogen needed 18 years and approximately US\$500m in order to launch its first own product AVONEX. A clear vision helps to see decisions during such a long time in a larger context and not to lose sight of the superordinate goals. In Table 1 some visions of prominent biotechnology companies are shown.

Analyses of internal and external situation

After defining the vision, analyses of the external and internal situation are conducted. Here, the chances and risks should be worked out and confronted with the strengths and weaknesses of the company. The results of the external analysis and prognosis are information about relevant developments in the environment of the enterprise. Basically, political, social, technological and industry developments can be examined. These developments are usually outside of the direct control of an enterprise. For biotechnology companies for example the following analysis and prognosis fields are relevant:

- changes in the legal situation (eg law for the protection of embryonic stem cells);
- consolidation processes in the pharmaceutical industry (mergers and acquisitions);
- situation at the financial markets;
- emerging substitution technologies.

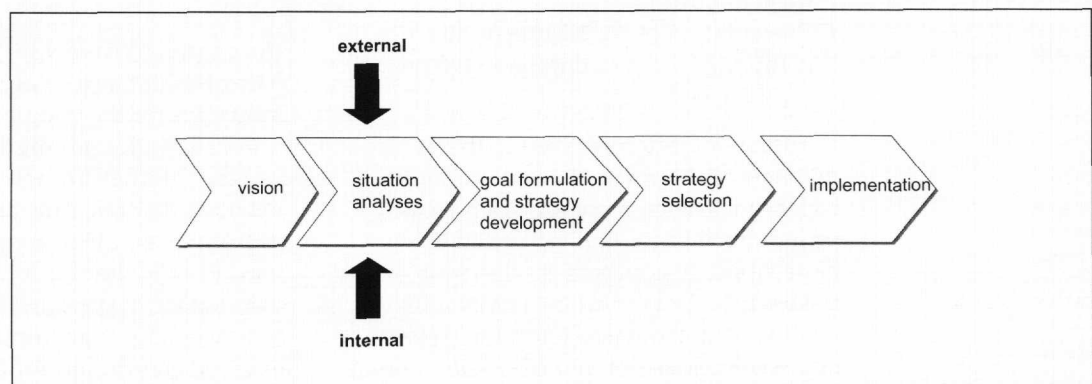


Fig. 1 Strategic planning process

Table 1 Visions of some leading biotechnology companies⁷

Company	Vision
Amgen	'We aspire to be the best human therapeutics company. We will live the Amgen values and use science and innovation to dramatically improve people's lives.'
Biogen	'Biogen will create a new standard for leadership in the biopharmaceutical industry ... that will enable us to build by 2010 the largest independent global pharmaceutical company established since 1953 as measured by market capitalisation.'
Chiron	'Chiron strives to be a premier biotechnology company by creating products that transform the practice of medicine.'
Genentech	'Genentech commits itself to the highest standards of integrity in contributing to the best interests of patients, the medical profession and its employees, and to seeking significant returns to its stockholders based on the continued pursuit of excellent science.'
Gilead Sciences	'To be a worldwide leader in advancing treatments for the most challenging human diseases.'
Incyte Genomics	'To be the world's leading genomics company, creating information standards for scientists working on the frontiers of healthcare worldwide.'
Millennium	'To provide personalised and precise medicine by integrating breakthrough therapeutic products and predictive medicines.'

While political and social developments affect primarily global planning premises, biotechnology companies can draw first concrete conclusions from an industry analysis, eg the company's relative market position within the industry.

General recommendations regarding the actual steps of an internal enterprise analysis are not possible since they depend on the context of each company. The following steps, however, are generally valid:⁸

- Determination of critical resources and potentials in consideration of the environmental trends relevant for the enterprise.
- Evaluation of critical success factors by comparison with direct competitors (benchmarking).
- Presentation of the results of this comparison in a strengths–weaknesses profile (see Figure 2).

Special attention is given to the management know-how and marketing capabilities since these are often weakly pronounced in research-oriented biotechnology companies. The chances and risks worked out from the environmental analysis ('look outside') and the strengths and weaknesses derived from the internal analysis ('look inside') can concisely be presented in a so-called SWOT matrix

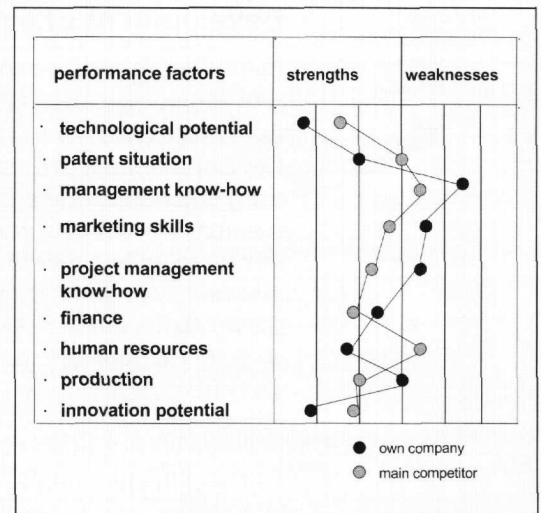


Fig. 2 Strengths–weaknesses profile

(Strengths, Weaknesses, Opportunities, Threats).⁸ It helps to derive first generic strategies for the company (see Figure 3).

SO strategies (strengths/opportunities) use the internal strengths in order to exploit external chances. This offensive strategy represents an ideal status, although it can be used only in the rarest cases for start-up companies. In contrast, WO strategies (weaknesses/opportunities) try to exploit external chances, in order compensate internal weaknesses. For instance, entering cooperation between biotechnology and

	+ ← 'look inside'	-
	Strengths 1. high technological potential 2. high motivation of personnel ...	Weaknesses 1. insecure patent situation 2. no marketing experience ...
+ ↑ 'look outside'	Opportunities 1. high market growth 2. new potential applications ...	SO-strategies 1. new R&D personnel 2. acquisitions ...
-	Threats 1. substitution technologies 2. fluctuations of currencies ...	WO-strategies 1. Strategic alliance in R&D 2. Marketing agreement ...
	ST-strategies 1. further development of technology platform 2. internationalisation ...	WT-strategies 1. selling of one business unit 2. repositioning of business ...

Fig. 3 SWOT matrix according to David⁹

pharmaceutical companies, in which both partners offer complementary assets, is such a strategy. Biotechnology start-up firms, on the one hand, possess the technological know-how but lack the financial resources required to take products through the costly clinical research phase. On the other hand, pharmaceutical companies commit primarily financial resources to the cooperation and expertise in dealing with the clinical trials. For instance, Millennium Pharmaceuticals' cooperation with Swiss drug maker Hoffmann La Roche in 1994 (just one year after foundation) has been clearly a cornerstone in its development.

ST strategies (strengths/threats) compensate the damage potential of external threats by the development of the own strengths. The development of WT strategies is defensive in its nature since it

reduces internal weaknesses and repels threats at the same time. The introduction of turnaround programmes can be regarded as a WT strategy.

Goal formulation and strategy development

After the analyses of the external and internal situation of the enterprise were executed, the formulation of strategic goals can take place. Strategic goals are the results of the strategic planning process. They are also the basis for controlling the efficiency of the implemented strategies. These strategic goals should be SMART, ie they should be specific, measurable, achievable, realistic and have a certain time frame.

A method for showing the potential

impact of strategies on the development of certain financial ratios such as annual sales or revenues is the so-called GAP analysis. It allows an early gap to be identified between the strategic goals set by the management and the current and future development of the company. Generic growth strategies can be developed by a differentiated view of the identified strategic gaps (see Figure 4).

The penetration of markets with the existing products can be achieved by intensifying marketing and sales efforts. Market development refers to internationalisation strategies in order to get access to geographically new markets. For instance, some German biotechnology companies have recently acquired US companies in order to have a better position in the largest market for pharmaceuticals (LION bioscience acquired Trega Biosciences, GPC Biotech acquired Mitotix and MediGene acquired NeuoVir Therapeutics). The basis for the strategy of product development is innovation, which is then introduced to existing markets. Gaining access to new business areas can be achieved by a diversification strategy. In this context diversification means access to new markets with the help of completely new products or technologies. Basically, three diversification strategies can be

distinguished: horizontal, vertical and lateral diversification (see Figure 5). Transferred to biotechnology the extension of therapeutic indications can be understood as a horizontal diversification strategy. However, this strategy requires considerable financial and personnel resources, which cannot be supplied mostly by small biotechnology companies. Therefore, several biotechnology companies have decided to focus on only a few indications, eg Gilead Sciences recently sold its oncology business to OSI Pharmaceuticals in order to focus on its core competence in infectious diseases.

Vertical diversification refers to the integration of further steps along the process of drug discovery and development. Some biotechnology companies have recognised that integration of activities along the value chain is crucial for sustainable growth. For instance, the German biotechnology firm Evotec has acquired the small chemical molecule company Oxford Asymmetry International in order to integrate further activities along the value chain. As more and more pharmaceutical companies out-source certain parts of their research and development efforts, specialised (biotechnology) companies have to offer a

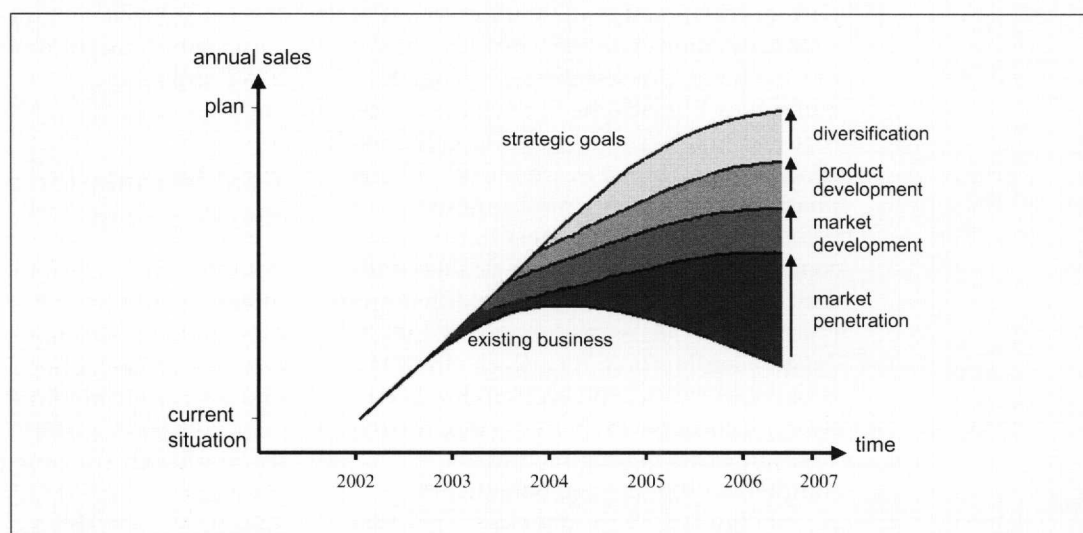


Fig. 4 GAP analysis

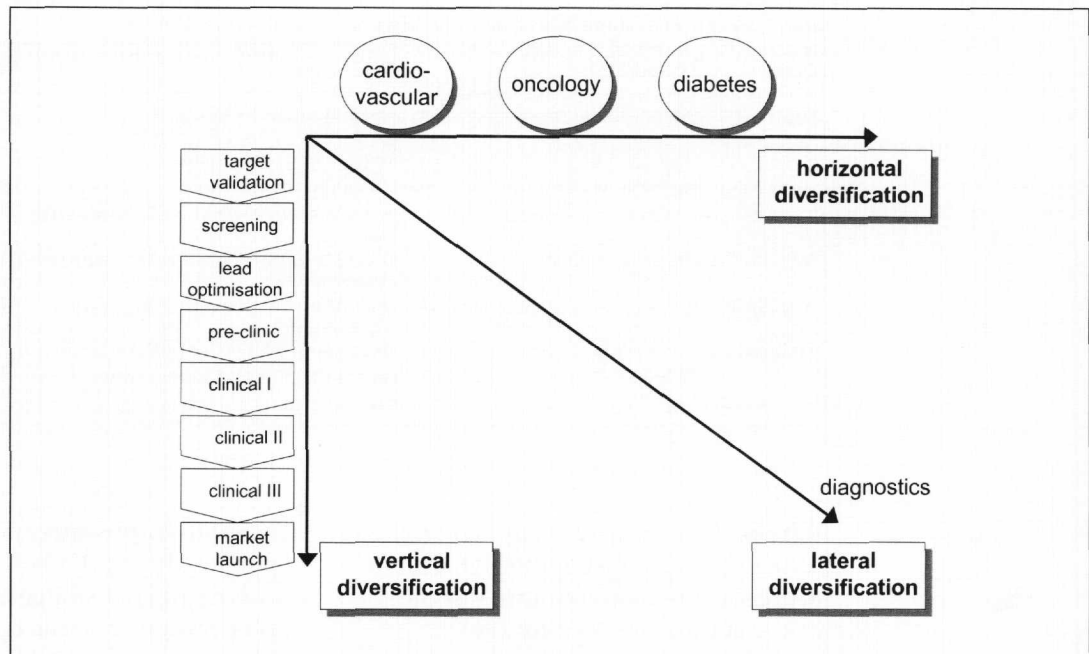


Fig. 5 Diversification strategies for biotechnology companies

set of integrated platform technologies (one-stop shopping). This forward integration is due to the increasing competition and the latent danger of the obsolescence of the own technology platform. Besides, this strategy offers prospects on higher profit margins. Because of the fusion of therapy and diagnostics, as we can see in the area of pharmacogenomics, lateral diversification, ie the migration into completely new areas, is of increasingly great importance in the future.

These still generic strategies require further thought. In order to reach a critical mass, different options are available: organic growth, cooperation, acquisitions or mergers. Each of these options has certain pro and cons, which are discussed below. The expansion by organic growth alone is difficult for biotechnology companies to achieve, since financial resources and know-how competencies are limited. The development to a fully integrated pharmaceutical company (FIPCO) is impeded by high entry barriers. Therefore, only a few biotechnology companies have integrated all activities along the value chain

in the past (eg Amgen, Biogen, Genentech). However, for niche markets, which require a much smaller sales force, this option can be implemented with comparatively smaller means. Nevertheless, a substantial advantage of organic growth is the perpetuation of management control.

Owing to the high entry barriers partner-oriented strategies offer an attractive alternative. An example is the establishment of a network of collaborations with other biotechnology and pharmaceutical companies, which specialise in different steps of the value chain. Cooperation can represent an important source of income in the early development phase (see some examples in Table 2). According to Robbins-Roth¹⁰ strategic alliances brought in more capital to biotechnology companies in 1998 than venture capital (US\$4.5bn to US\$3.5bn). The biotechnology companies Millennium and Tularik from the USA show that the break-even can be reached by upfront and milestone payments from cooperation without generating important incomes from product sales. Many biotechnology companies pursue a dual

Table 2 Selection of some biotechnology–big pharma collaborations

Date	Cooperation	Deal terms	Field of cooperation
Sept. 1998	Bayer–Millennium	US\$368.4m in funding and performance fees plus US\$96.6m for 14% equity investment	Drug targets
June 2000	Aventis–Millennium	US\$200m for technology access over 5 years plus US\$250m in three equity tranches	Target selection and drug development
Jan. 2001	Bayer–CuraGen	US\$39m funding plus US\$85m equity investment	Pharmacogenomics and toxicogenomics
July 2001	Bristol Myers Squibb–Exelixis	US\$200m size thereof US\$20 equity investment	Tumour suppressor genes for cancer
May 1993	SmithKline–Human Genome Sciences	US\$88m funding and milestone payments plus US\$37m equity investment	Gene sequencing for drugs

strategy. This strategy is based on milestone payments from collaborations in order to secure short to medium-term incomes, which, in turn, are used for the development of own products and technologies in other fields.

In addition, entering into research and development cooperation with Big Pharma is regarded as a good housekeeping seal of approval for biotechnology start-ups. It is assumed that the technological potential of the biotechnology company has been thoroughly validated by the large pharmaceutical firm. Basically, one or two important cooperations with large pharmaceutical companies are

extraordinarily important prior to an initial public offering (IPO). It is therefore not surprising that strategic alliances and cooperation are quite common in the biotechnology industry.^{11,12}

Apart from cooperative agreements, more aggressive options such as mergers and acquisitions (M&A) are further alternatives (some examples are shown in Table 3). For instance, the British biotechnology company Celltech became one of the largest biotechnology companies in Europe through the acquisitions of Cistron Biotechnology Inc., Chiroscience Group plc and Medeva plc. Mergers and acquisitions have the advantage that the growth of the company

Table 3 Selection of some mergers and acquisitions in biotechnology

Date (announcement)	Company acquired	Acquired/merged by	Transaction value (US\$m)
March 1999	NeXstar pharmaceuticals	Gilead Sciences	842
Nov. 1999	Medeva	Celltech Chiroscience	914
June 1999	Sugen	Pharmacia & Upjohn	634
Sept. 1998	Chiron Diagnostics	Bayer	1,100
Aug. 2001	Novazyme	Genzyme	118.7
Aug. 2001	EOS Biotechnology	Pharmacopeia	197
Nov. 2001	Genomica	Exelixis	110
July 2001	Rosetta Inpharmatics	Merck	650
May 2001	Gemini Genomics	Sequenom	242
April 2001	Aurora Biosciences	Vertex	592
June 2001	Axys	Celera Genomics	173.4
Feb. 2001	Cantab	Xenova Group	179
July 2001	Packard Bioscience	PerkinElmer	650
May 2001	Shearwater	Inhale Therapeutic Systems	164
July 2000	Oxford Asymmetry International	Evotec	474.7
June 2001	UroCor	Dianon Systems	180
Oct. 2001	Vysis	Abbott Laboratories	355

can be accomplished very quickly. However, the integration of another company is a complex task and requires a considerable amount of management resources. Particularly, in cross-border M&A activities cultural tensions can occur which hinder the successful integration.

Strategy selection

Frequently, several options exist. A common instrument for the evaluation and selection of products, projects and strategies is the portfolio analysis. Hereby, certain dimensions are visualised in a matrix against each other (see Figure 6). For instance, one dimension consists of the technical, commercial and financial risks of each strategic option and the other one refers to its attractiveness concerning width of application and market as well as development potential. For each strategic option the position is determined within the portfolio. After all options were evaluated and arranged, the position of the individual options can be judged regarding attractiveness and risk. Unfortunately, this method has a rather static character since it neglects dynamic developments, which are particularly important in biotechnology. However, on the basis of this portfolio analysis the decisions for or against a

strategic option can be made. For instance, Amgen started with more than two dozen projects in totally unrelated fields of biotechnology and, thus, it had to select a few of them.

Implementation phase

The results of the strategic planning process – strategic goals and the selected strategic option – are executed in the implementation phase. This requires that the strategic goals are translated into concrete activities which can be monitored and evaluated. Thus, the strategic question of the effectiveness (doing the right things) leads to the question of efficiency (doing the things right).

Future developments

Enterprises in the biotechnology sector see themselves confronted with a set of challenges in the next years. Internationalisation, cooperative activities, mergers and acquisitions are the key drivers for the biotechnology industry in the future. Only those biotechnology companies that position themselves as integrated product developers or service providers will be able to be competitive. In order to meet the performance expectations of their investors, biotechnology companies have to extend

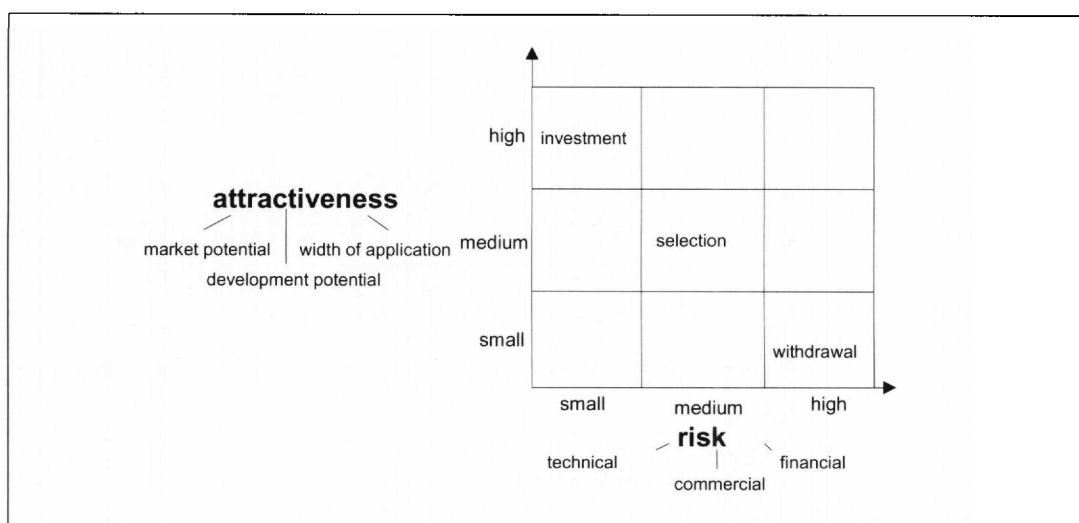


Fig. 6 Portfolio analysis for strategy selection

their business models. These enterprises must therefore offer a complete bundle of technologies, services or products (one stop shopping). Owing to the considerable amount of resources, biotechnology companies will be integrated in a network of large pharmaceutical and specialised small biotechnology enterprises. The ability to manage this depends particularly on the professionalism of the management. Therefore, strategic management will be of great importance to react successfully to technological as well as market trends.

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