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What is "Business Development"? – The Case of Biotechnology

Abstract

"Business development" (BD) is an often used, but not well defined, term in the business world. Taking a strategy-as-practice perspective as a background, we explore the daily activities of BD in the German biotechnology industry. We show how BD tasks are defined and how they are fulfilled, what resources are used for this function and how it is organized. We compare our results with insights from the strategic management literature and show that business development is an example of what a modern type of planning might look like, but that it may be misleading to see the BD function in biotech firms in the same way as the dynamic capability the literature assumes. By doing this analysis, we contribute to an understanding of how entrepreneurial biotechnology ventures operate, and how they do their "strategizing" and "organizing" work.

JEL-Classification: I22, L65, M10, M13.

Keywords: Business Development; Dynamic Capabilities; Planning Biotechnology; Strategy-as-Practice.

1 Introduction

"Business development" (BD) is one of those terms used by everybody, but nobody really knows what it means. This phenomenon is especially true in the context of biotechnology ventures, where the term seems to have an intuitive appeal, since most companies have not yet become profitable and must develop a successful future. As Franz Hossli, a financial analyst from the Suisse bank Sarasin, commented: "*You can't go to the grocery store and say I want a blockbuster. They have to do their business development work – look around, see when you have a chance and then jump*." (Dow Jones International News 24/01/2001).

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But how do biotech companies define BD and what tasks do biotech firms actually have to fulfill in their BD? How is the actual work structured? How is BD organized and who is responsible for its implementation? What kind of resources, and how many are needed in order to fulfill these tasks? Those are the major research questions we address in this paper.

The paper is organized as follows. In Section 2 we provide some theoretical background and illustrate some of the development options in the context of the biotechnology industry. In Section 3 we outline our research design, which is based on qualitative methods. We present our results in Section 4 and in Section 5 we discuss these results and draw some conclusions.

2 Theoretical background and initial illustrations

The term "business development" is a buzzword that business practitioners very often use. For example, in November of 2005 a search in Google showed 59.300.000 results, but did not provide a precise definition of the term, which is harder to find. The definition offered by Economic Development Services, Inc. is shown in *box 1*.

Box 1: A general definition of "business development"

Business Development:
...*enterprise development*; the activity that increases, or is intended to increase, the profit, production, or service potential of an enterprise; investment of capital and time that causes, or is intended to cause, the growth and expansion of an enterprise; the process of moving a business towards the point where it can provide its services and products to the entire outside group that wants them; the promotional side of business networking; persuading, or intending to persuade, prospects that appear to have the potential become customers, clients, or buyers; the process of promotion to build and sustain working relationships that relate to the business purpose.

Source: www.findmehere.com/glossary/index.htm (18/03/2003)

Surprisingly, few academic studies deal with the term "business development." Although the current literature certainly helps to explore a possible range of activities that fall under the category of business development, these studies do little to help us understand how the BD function is actually carried out in biotechnology firms, and in what sense BD can contribute to the creation of sustainable competitive advantages. Our study is focused on answering those questions.

We begin by using Ansoff's (1965) product/market matrix (enlarged by the concept of competencies; see Johnson and Scholes (1999)) to provide an interpretation of its meaning, and thereby introduce the reader to the specific characteristics and recent developments of the biotechnology industry.

Since most biotech firms still do not have any products on the market, their first option for how to successfully develop their company is not so much about market penetration, but about how to consolidate or withdraw from the market. On the industry level, a consolidation in biotech has long been expected (Persides (1999); Papadopoulos (1999)) but has not really taken place. M&A activities were rare events in the last decade (Ernst & Young (2002); Wess (2003); Patzelt, Schweitzer, and zu Knyphausen-Aufseß (2005)) and have increased only very recently (Van Brunt (2005; 2006); Edelson and Ward (2007)). In contrast, many biotech firms went bankrupt or had to refocus their business, as the Medigene example shows: after negative results with their Etomoxir drug in clinical phases II/III, the company completely shut down its cardiovascular program in 2002 and is now concentrating on the development of anti-tumor drugs.

A second option is to develop new products, e.g., drugs, which is at the core of most biotech firms. Recently, however, biotech firms have needed to develop new competencies, since pharmaceutical companies tend to in-license products at a later stage of their development. This change means that biotech firms must conduct at least parts of the clinical trials themselves.

A third option is to develop new markets. For example, a company can enter new market segments by using competencies from one area (e.g., DNA microarrays) to another (e.g., protein microarrays). It is also possible for a company to discover a new application of a drug, which usually happens by chance, not as a planned outcome of the development of the drug. Also, companies can find new markets in geographic areas that were not previously covered. Since most biotech companies still have no products on the market, this option has not often been realized. This is not to say that internationalization is not a key issue: Many biotech companies have a global perspective from their inception, meaning that, e.g., European firms tend to aim drug approval at the U.S. Food and Drug Agency (FDA). At the same time, those European firms want to have a presence in the U.S. so that they can develop their competencies by tapping into the relevant research networks (Zaby (1999)).

A fourth and final option is to diversify in order to realize economies of scale and scope (Teece (1980); Chandler (1990)) and to reduce risks. Zu Knyphausen-Aufseß, Zaby, and Kind (2006) show that many biotech companies do diversify their businesses, but find that the new areas they enter are more or less unrelated to their initial businesses, even if the new businesses can be classified as "biotechnology" in the sense of the Standard Industrial Classification (SIC) or the North American Industrial Classification System (NAICS).

The literature also offers insights on how to implement a BD program. The first option is to do it yourself, i.e., to use the company's internal resources and capabilities to bring products and services on the market. However, in the biotech industry, most companies must rely on external competencies. They must either acquire those competencies or engage in alliances. As mentioned above, there have been very few M&A transactions in the past, although investors tend to think that M&As are necessary and will lead to increased shareholder value (Champsi (1998); Esposito and Ostro (1998); Schweizer and

Zu Knyphausen-Aufseß (2006)). In contrast, strategic alliances seem to be an ubiquitous phenomenon in the biotech industry (see, e.g., Arora (1990); Powell (1998); Powell, Koput, and Smith-Doer (1996); Powell et al. (1999); Lerner and Merges (1998); Baum, Calabrese, and Silverman (2000); Rothaermel (2001a; 2001b); Audretsch and Feldman (2003); Rothaermel and Deeds (2004; 2006)). Many, if not most, activities have to do with partnering and aim at closing deals (Ernst & Young (2000); Burrill (2002)). Through these activities, products and technologies are jointly developed or licensed to other companies against upfront-, down-, milestone- and royalty payments, or sold on a fee-for-services basis. A bad deal can easily be a barrier to the company's survival (Moscho et al. (2000)). Thus, the problem does not seem to be negotiating the deal, but finding possible transaction partners. It is a buyer's market, a "bazaar" (French (2002)). From the perspective of the big pharmaceutical companies, there are thousands of technologies and products that are candidates for complementing their pipeline, but from the perspective of the biotech companies, there are only a few dozen big companies that can be approached. Therefore, a number of events, such as the *European Life Science Conference*, the *Californian Bio Partnering Global Forum* or the *Bio-Windhover Partnering Conference,* have been established to bring possible partners together. Moreover, there are a number of internet platforms (e.g., www.recap.com, www.windhover.com, www.pharmalicening .com, www.discoverydeals.com) that support partnering activities.

Overall, it can be said that the literature certainly helps to explore a possible range of activities that fall under the category of business development, but it doesn't do very much to help us understand how the BD function is actually carried out in biotechnology firms and in what sense it can contribute to the creation of sustainable competitive advantages. Our study is focused on answering those questions. Such a research focus is, first, in line with the so-called strategy-as-practice perspective, which was developed in the 1990s and which is based on theories of practice that have their origin in the social sciences (see, e.g., Giddens (1976); Foucault (1980); MacIntyre (1985); Bourdieu (1990)). Whittington (2002b) says, "Reading the Strategic Management Journal would not help anybody organize a successful strategy-making event," but in order to provide such help, it is necessary to find out what a manager's job really is (Mintzberg (1974, 54)), and to understand the daily work of practitioners. Empirical work (e.g., Whittington (1996); Samra-Fredericks (2000); Jarzabkowski (2002); Johnson, Melin, and Whittington (2003)) shows that strategizing and organizing are two sides of the same coin, which implies that the traditional distinction between strategy formation and implementation is no longer valid, and that these activities require resources and competencies that are hard to develop and maintain over the course of time. To quote from Whittington (2003, 119):

"It takes a lot of work to make a strategy or design an organization. Consider just the formal side. Data are gathered and analyzed, documents are written and presentations made. There are project meetings, board meetings, conferences, workshops and away-days. Midnight oil is burnt and weekends lost. The work is expensive. It calls on senior managers, middle managers, strategic planners, organization development experts, management consultants, communications specialists and sometimes lawyers and investment bankers. And there is even more work in getting these strategies or organization designs actually implemented. The work of strategizing and organizing is a serious business."

Our research focus may, second, also be in line with the so-called "dynamic capability" perspective that has recently gained much attention in the strategic management literature, and that seems to have outdated the traditional concept of strategic planning (see, e.g., Amit and Schoemaker (1993); Grant (1996); Teece, Pisano, and Shuen (1997); Winter (2003)). Indeed, it has been argued, especially in studies on organizational capabilities, that research has to be very context-specific and that we must delve into the details to make the concept meaningful (Ethiraj et al. (2005)). If, given the present context, we take skills in molecular biology as a resource that is fundamental to the competitive advantage of a biotechnology firm, then we can understand dynamic capabilities as "the antecedent organizational and strategic routines by which managers alter their resource base – acquire and shed resources, integrate them together, and recombine them – to generate new value-creating strategies" (Eisenhardt and Martin (2001, 1107)). Thus, the question is whether we can understand the BD function as such a dynamic capability.

Eisenhardt und Martin (2001) use different examples to illustrate their concept; the one that comes closest to BD is strategic decision making, which they define as "a dynamic capability in which managers pool their various business, functional, and personal expertise to make the choices that shape the major strategic moves of the firm" (Eisenhardt and Martin (2001, 1107)). In contrast, those researchers who work with the concept and who focus on biotechnology firms tend to emphasize the ability to access and integrate new knowledge from both within and outside the firm (Henderson and Cockburn (1994), or the ability to create and maintain alliance relations as at least one core capability, if not the sole core capability of the firm (Deeds, DeCarolis, and Coombs (1998, 1999); Madhok and Osegowitsch (2000); Rothaermel and Deeds (2006)). Moreover, Kale, Deyer, and Singh (2002) suggest that precisely this alliance capability only has empirical meaning when we find what they call a "dedicated alliance function" within the firm as a device for learning, observing the markets, mobilizing internal resources, and systematically evaluating the performance of alliances. Obviously, this dedicated alliance function could also be the core of a BD function in biotechnology firms, at least from the perspective of what we have learned so far.

3 Research design

We use a qualitative research design for two reasons. First, the research agenda of the theory-as-practice perspective in general, and our research questions on business development in particular, call for such an approach, because there is a need for an in-depth understanding of the use of methods and concepts (practices) that practitioners apply and generate in their day-to-day work (praxis) of strategizing and organizing (Turner (1994); Whittington (2002b)). Mintzberg (1973) and Balogun, Huff, and Johnson (2003) argue that access to the micro-activities of practitioners can only be gained by an ethnographic, or at least context-sensitive, research design. Such an approach also makes sense because the strategy-as-practice perspective integrates content and process aspects, and the latter, as well as the dynamic capability perspective (Ethiraj et al. (2005)), do indeed require a qualitative research design (Pettigrew (1990); Langley (1999); Johnson, Melin, and Whittington (2003)). Second, since there are no academic studies available on BD, and since the strategy-as-practice perspective is still in its infancy (Whittington (1996); Johnson, Melin, and Whittigton (2003)),

the degree of theoretical understanding is very limited, meaning that our research is still on an explorative level. Eisenhardt (1989) argues that in such a situation, a qualitative research design is appropriate, and that one or more case studies can be used to develop a more solid theoretical understanding (see also Pettigrew (1990); Eisenhardt (1991); Yin (1994)).

We follow these recommendations and conduct case studies of companies in the German biotech industry. The German biotech industry is still very young, compared to the U.S. and also the U.K. Therefore, it is reasonable for us to expect to find a fertile ground for BD activities.

We focus our research on entrepreneurial life sciences companies (ELISCOs), which we define as venture capital-financed, research-intensive, growth-oriented, small- and medium-sized companies that aim to commercialize modern biotechnology (Ernst & Young (2000)). In 2000, when we started our research, there were about 330 such companies in Germany, with an average of 32 employees (VBU (2002); A.T. Kearney (2000)).

We further narrow our sample size by focusing on those 150 companies that concentrate on the research and development of new drugs (product companies) and/or on the development of new technologies that help other companies in their research and development of new drugs (platform companies). We use the concept of "theoretical sampling" (Eisenhardt (1989)) and from this sample select 15 companies that we can use to represent the entire range of business models (product, platform, or "hybrids"; see Casper (2000)) and that differ significantly in their size. *Table 1* provides an overview.

Table 1: Case study companies

#	Company name	Employees (12/2001)	Business model (12/2002)	Year of foundation	VC financing until 2002 (Mill. €)
1	Axxima Pharmaceuticals AG	68	Hybrid	1997	56
2	Biofrontera Pharmaceuticals AG	74	Hybrid	1998	22.5
3	Curacyte AG	15	Product	2000	16.1
4	4S Cientific Computing GmbH	60	Hybrid	1997	19.8
5	GPC Biotech AG*	174	Hybrid	1997	29.3
6	IDEA AG	50	Platform	1993	20
7	Jerini AG	82	Hybrid	1993	24.6
8	Jomaa Pharmaka GmbH	19	Product	1998	6.85
9	MEMOREC Stoffel GmbH	50	Platform	1997	17.8
10	Mice & More GmbH & Co. KG	28	Platform	1998	4
11	Micromet AG	75	Product	1993	78.5
12	MPB Cologne GmbH	35	Platform	1998	7.7
13	NOXXON Pharma AG	79	Hybrid	1997	31.3
14	Wilex AG	20	Product	1997	38.5
15	Xerion Pharmaceuticals AG	53	Hybrid	1998	27.3

* GPC Biotech AG went public in 2000

We conducted one interview with each company. Interview partners were BD managers (directors or vice presidents) or members of the management board who were responsible for all tasks related to BD. The interviews lasted 90 minutes on average and were recorded and transcribed. We based the interviews on a standardized interview questionnaire that we pre-tested with 14 short (20-30 minutes) interviews at the 2001 "Biotechnika" trade fair in Hanover, Germany. The goal of the standardization was to make the cross-case analysis more convenient (Miles and Huberman (1994)). However, during the process, we slightly modified our interview questionnaires to adapt to our growing knowledge (Eisenhardt (1989); Bryman and Burgess (1994)).

We first triangulated the data with written information that we received from company- or industry-specific websites, year-end reports, press releases, analyst and industry reports and presentation slides. Second, we conducted 19 formal and informal interviews with representatives from other biotech companies, venture capital firms, and industry associations. Third, in November/December 2001 Sonja Kind, who is one of the authors of this paper and a biologist by education, worked for five weeks as an assistant in the BD team in one of our case study companies (*Curacyte*) and thus was able to make direct observations of the practitioners in their daily work. Furthermore, from August to December 2002 Sonja Kind worked as an assistant in the Dealmaking & Strategic Partnering unit of *Burrill & Company*, a leading biotech consulting and VC Company located in San Francisco, California. During this time, Sonja was able to make contacts within many U.S-based biotech companies and gain a first-hand knowledge of how their BD process is organized. These practical experiences again served as an excellent background for conducting, analyzing, and evaluating our case studies.

4 Results

We present our results in three steps. First, we explain how our case-study companies define the main tasks of their BD function. Second, we describe in detail three phases of the BD process (identification, evaluation, and negotiation) and the outcome of these phases. Third, we analyze who is involved in the process, what kind of education and competencies the people involved with BD have, how they interact with each other, and how the BD function is institutionalized during the evolution of the company.

4.1 How practitioners define "business development"

From our interviews, we found that practitioners tend to define the tasks of BD in terms of three categories: (1) refilling the research pipeline and the partnering of projects, (2) commercialization of products and technologies, and (3) network-building and pre-negotiation of deals (see *Table 2*).

(1) If companies have to ensure that their research and development pipeline is filled with products and technologies, and if they cannot generate them from their own projects, then new projects must be brought in from outside. If this is the case, then the task of the BD

function is to search for those new products and technologies that are candidates for what we call *pipeline* or *input deals*. Examples of case study companies that in-licensed products are *Curacyte* (TPO, FXa/FXIIIa, IL-4), *Wilex* (antibody G250), *Axxima* (inhibitor AXD 455), *Biofrontera* (project "inflammable skin diseases") and *Jerini* (Icatibant); examples of companies that in-licensed technologies to broaden their platform were *MPB Cologne* (transformation technologies), *Mice & More* (knock-out technologies), *Micromet* (activating HAB-Technology), *NOXXON* (SELEX™), *MEMOREC* (SAGE™) and *GPC Biotech* (e.g. DEUS-PS, Bryostatin-1). Another option is to acquire or merge with other companies that have a product or technology portfolio that is attractive to the acquiring company. However, in our research period, this option was realized only in two cases. In 2002, *Curacyte* merged with the U.S. based *VitaResc Biotech, Inc.* in order to get access to a Phase III product. In 2000, *GPC Biotech* merged with U.S.-based *Mitotix, Inc.* (*Jerini* announced a merger in the beginning of 2003 with Dutch alliance partner *Kiadis BV*, but later withdrew from this position.)

Table 2: Task descriptions of business developers (examples from our interviews)

Task description	Evidence (examples)
Re-filling the research pipeline and "partnering" of projects	"For us, BD means having the opportunity to continuously generate an inflow of project opportunities for the company's project portfolio, which means that we screen and evaluate projects in order to decide whether or not to include them in the project portfolio. Further down the road, when the company has grown and matured, we will have to get rid of some projects. This is also a form of BD! But right now this is rather irrelevant, because we are not that far yet. Currently, we are focusing on the input aspects, finding technologies and integrating them in our company." (Curacyte) "BD in our company is scouting for new technologies or products that are available for licensing." (Wilex)
Commercialization of products and technologies	"One main aspect of BD is the commercializing of technologies, products and intellectual property. Moreover, BD is responsible for the licensing of technology […] The whole purpose of BD is to develop relationships with the pharmaceutical industry and push those until the deal is closed." (GPC Biotech)
Network building and pre-negotiation of deals	"BD is the identification of the right partners and customers as well as the establishment of a network. For this purpose, the BD function continually represents the company to the outside." (Xerion Pharmaceuticals) "The most important task of BD is to develop business relationships with customers and partners. These relationships should be on a long term basis, which we try to establish throughout our various business divisions. Even if this is just a conventional service, the relationships with the customers are very important since they normally order larger amounts, and complicated contracts have to be negotiated. Additionally, in our Drug Discovery division, many in and out licensing projects are present which also definitely belong to BD." (Jerini) "For us, BD is mainly initiating business partnerships. You have to talk to people and develop contract models: How can such a partnership generate revenues? How much can you ask for? What are the costs? How high might the milestone payments be? In addition to the acquisition of customers, the development and negotiation of contracts is also part of my job." (4SC)

Operationalizing of corporate strategies and clarifying the strategic direction of the company; communicating the strategy to external stakeholders and potential partners	"BD belongs to the business operation: project definitions, in and out licensing of technologies and patents. BD is the positioning of the company, for example through mergers and acquisitions. BD starts with the definition of projects and identification of adequate partners." (NOXXON Pharma) "The strategy is mainly developed by the CEO and the senior management team; those are seven people in our company that basically do not come from the BD. The management and board of directors focus on the development of strategies. The task of the BD is to implement the strategies from the management team, which does not mean that our ideas do not influence the strategies. We can certainly communicate our ideas to the senior management, but, what we mainly do in the BD is implement strategies." (GPC Biotech) "First, communicating the strategic direction of the company. Second, the activities are focused on R&D. This is not always the R&D director's job, and sometimes he is not even able to do this work. That's why we do it together. Third, the projects have to be implemented outside, this means that the company and the strategies have to be 'sold' to the outside: […] On the one hand, I conducted a balance of the strategic direction. On the other hand, the projects were adapted to the strategic guidelines. We tried to identify the gaps and find out how they can be closed, if this can be done by ourselves, or if we have to try to acquire licenses." (MPB Cologne)

Moreover, BD has to ensure that there are *research and development* or *throughput deals* that enhance the value of existing products and technologies. Since most product companies specialize only on very few steps of the value chain, there are many opportunities for cooperation (partnering) with other firms in order to cover more steps of the value chain, and thus to strengthen their position vis-à-vis their contract partners (mostly big pharmaceutical firms). E.g., *Biofrontera* cooperated with *bioLEADS GmbH* to gain access to *bioLEADS*' substance libraries, and *Axxima* and *Wilex* partnered with *4SC* for screening and optimizing services. Similarly, platform companies often need to optimize their technology portfolios, leading to alliances such as those between *Xerion* with *T.I.L.L. Photonics GmbH* to improve *Xerion*'s XCALIbur® technology, or between *Micromet* and *Biovation, Ltd.*, to improve *Micromet*'s antibody technology.

(2) It is also the task of BD to support the commercialization of products and technologies, i.e., to make money by finding liquid contract partners for *output deals*. For product companies, those contract partners are usually the big pharmaceutical companies, such as the Italian company *Novuspharma,* which paid €4 million upfront to *Micromet* and was expected to make additional milestone payments for the completion of a joint Phase II study. (We call those deals *big pharma deals.*) Platform companies, on the other hand, must license their technologies to other research companies, either on a fee-for-service basis or by receiving milestone payments or a fixed fee in combina-

tion with royalties from the successful market introduction of the final product. Some examples of those *platform deals* are *4SC* (with *Axxima* and *Wilex*), *MEMOREC* (with *Bayer AG*, *Grünenthal GmbH* and *Henkel AG*), *GPC* (with *Altana AG*, *Evotec Biosystems AG* and *Morphosys AG*) and *Xerion* (with *Altana AG* and others).

(3) As we have seen so far, partnering and deal making are at the core of the BD function. To be successful, much of the daily work of a typical business developer includes networking and pre-negotiating deals. Network building means that possible new partners must be identified and approached, and that cooperation with existing partners must be maintained by exchanging information and communicating the company's strategic development. Good relations with other companies and external institutions enable a company to form alliances when needed. Therefore, business developers tend to react not only to the partnering needs of their company, but to proactively build up relations in order to be ready when concrete projects have to be negotiated. In this case, business developers support management by providing information and suggestions for the final deal terms.

Overall, we reiterate that BD is not strategy making (see again *Table 2*). Strategy making is the task of the top management of the company. The task of the BD function is to streamline the strategy and to implement or operationalize it, to make sure that the corporate strategy and, e.g., the research projects on which the scientists are working, fit together well. In this sense, the BD function must be deeply embedded in the organization of the firm.

Box 2 provides a definition of BD that summarizes our insights from the case studies.

Box 2: A definition of "business development" with respect to the biotechnology industry

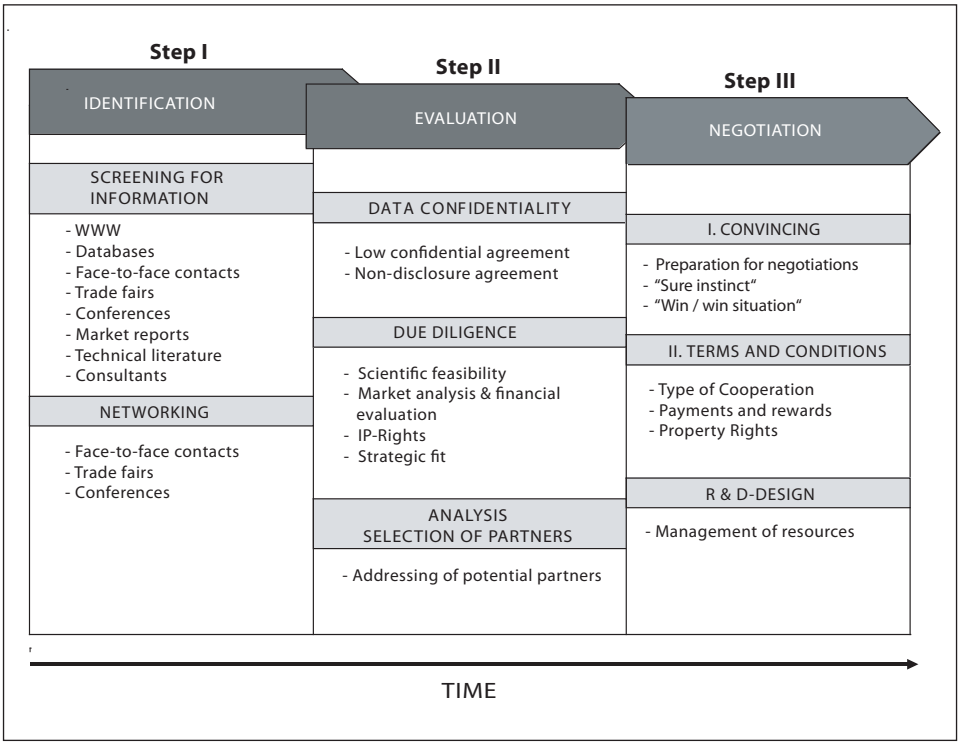
"Business development" describes a business function which has been widely established in biotechnology companies. Under the strategic guidance of top-management, its principal task is to prepare and realize input, throughput and output deals. BD entails all activities that aim at

- creating value and revenue potentials for the company,
- developing products and technologies so that they can be commercialized,
- building relationships with potential partners, customers and other stakeholders, and maintaining and enhancing those relations in the interest of the company.

4.2 Business development process

How do business developers fulfill their tasks? *Figure 1* gives an overview of the process and *Table 3* provides example quotations from our interviews.

Figure 1: Business development: A three-step process (overview)



Each step of the process consists of work packages, which are delegated to separate teams that work on and complete the packages. (For a more elaborated account of organizational issues, see the section below.) During the process, the team usually prepares decision foundations for the members of the top management who can then make a go/no go decision. Since the BD teams deal with work packages in a well-defined order, they gain more and more knowledge about the advantages and disadvantages of the development options, and can thus be helpful in consulting with the management team. Overall, the process is similar to what is known as the investment decision process in venture capital firms (Gompers and Lerner (2004)).

Table 3: The process of business development (examples from our interviews)

Step	Evidence (examples)
Identification of development options (information collection and market screening; network building)	"Stay up-to-date in the field: read newspapers, read newsletters, research data bases… I would describe it as 'Do your homework'. One should know what's going on at one's own location. On top of that, I try to stay informed through private contacts; visiting conferences is a big part of that." (Xerion) "We are permanently searching. We use tickers from different providers in the net that deliver news about deals on a daily basis. And then there are also the daily reports. One develops a kind of radar." (Axxima) "The process of searching takes up a lot of time. We thought about hiring an extra person just for the job, which in the end was too expensive as we do not search that much. The search [for patents] is being done externally from researchers of patent data bases; they have to do the evaluation themselves. Due to the high research costs we try to find a balance; how much costly information should we acquire, and where is free information sufficient? This leads to a dilemma for us: on the one hand you have high costs, on the other hand you really need the information." (MPB Cologne) "One of the highlights each quarter are the partnering meetings. They are very well prepared in advance each time. Appointments with the companies are scheduled two to three weeks ahead of time. You are busy making the appointments two to three weeks and afterwards you have to do the follow up business. This takes up about one month of your time four times a year. However, the best contacts are resolved during those meetings since you have the opportunity to talk in person." (Axxima)
Evaluation (Due diligence; partner analysis and -selection)	"The strategic fit of a project with the company is very crucial. You have to be very careful regarding tempting offers that promise high income, but are not manageable due to the lacking competencies and resources. The strategy has to set clear goals and one has to ask if the project fits into the current portfolio or not." (MPB Cologne) "We have a clearly defined process regarding evaluations. The scientists have certain tasks in their area of responsibility […] They have to say if a project makes sense and is practicable and how much capacity it will require." (NOXXON) "If you have the market data, the net present value analysis and risk calculation are quite easy. The real work load is the market analysis." (NOXXON) "The economic criteria are significant. We calculate the projects using the risk adjusted net present value to have the current value of the planned deal." (MPB Cologne) "[...] you also need the resources to evaluate. If you are in due diligence, a lot of time and money is needed for the experts to conduct an IP-analysis." (Wilex)

	"What we usually conduct is a balance of arguments, where the plus arguments are matched with the minus arguments – the arguments are additionally weighted. We do not have a ranking, but we try to manage the balance of the arguments. This is our method: If you had two or three arguments, you could say 1 is better than 2 and 2 better than 3 and then one would prioritize who to speak to first." (Mice & More) "When you start [as a biotech company] your wish is to generally find any partner. Once the development of the company continues, you have the desire to make better deals, where you get more money. Additionally, the wish of keeping product rights comes up. You analyze the partner to find out which product rights result from the partnering. [...] Currently, we are at the point where we are able to demand product rights." (GPC) "There is definitely a ranking in which you want chose the pharmaceutical companies, yet the luxury to be able to chose is rather seldom." (Xerion)
Negotiation	"[…] Once again, there are two phases of negotiation to be considered: The first phase contains creating concern, presenting and attracting partners, which might be the hardest of the two. The second phase is about defining the deal terms. […] To get the best out of a convinced partner and work out the win-win is more a legislative or contractual aspect. You play the game "who pays first, loses" – which has certain rules you have to know." (NOXXON) "Normally you reach an agreement quite fast during negotiations. If you take a look at the deals in the last 10 years, you find a very small margin regarding royalties, up-fronts, milestones. This is not really a secret." (NOXXON) "The negotiations can take anywhere between four weeks, which is very fast, up until several months. I would say three to four months; this means here you have a term sheet. Usually, it takes a bit longer until the closure of the deal, as you have to negotiate the contracts. They say a good deal needs nine months. This is just like a good pregnancy. But it is difficult to generalize, we have had deals which have taken even longer." (Wilex)

In the first step, the identification of development options, business developers use many information sources to identify opportunities. On the one hand, there are publicly available data sources, such as newspapers, the internet, or industry reports that BD teams can use for screening the market. They can supplement these sources by using proprietary databases, such as *ADIS*, *IDDB,* or *Pharmalicensing*. However, these databases are relatively expensive, in fact, too expensive for several our case study companies (e.g., *Curacyte*, *Jerini*). Other case study companies (e.g., *Biofrontera*, *Wilex*) have access, but see these databases merely as something "nice to have." Overall, the screening of all these data sources is a time- and money-consuming process, but it is part of the homework everybody in the field has to do.

On the other hand, all firms consider personal networks as a more valuable source of information. Many of the business developers spend about a third of their working time visiting workshops, research conferences, and trade fairs in order to present their companies and meet other people. Partnering conferences, such as *BioPartnering*, *BIO,* or *BioEurope*, which take place on average about four times a year, are especially interesting for the business developers. Again, these events are considered to be very expensive, and many business developers seem to be tired of the "conference inflation" around the globe.

The active search for BD opportunities is highly relevant for all our case-study companies. None of those companies consider that waiting until they are approached by other companies for partnering is enough. (In some cases, BD opportunities may have also been introduced by consultants or other players, such as venture capitalists.) However, companies such as *4SC*, *GPC,* and *Curacyte* try to involve their own scientists in generating new ideas. *4SC*, for example, allows its scientists to devote 10 percent of their time to screening information about new development options. They present their ideas to the chief scientific officer, who evaluates the ideas and may then ask the scientists to further check and develop the idea.

The second step, the evaluation of the business opportunity, consists, apart from closing low confidential- and non-disclosure agreements, of two core processes: (1) the due diligence and (2) the partner analysis and partner selection.

We subdivide the due diligence into four parts. First, business developers check whether an opportunity fits strategically with the company, using indications, type of therapy (e.g., small molecules, antibodies, peptides), and target class (such as kinases, serine proteases, receptors) as filter criteria. Without a proper fit, synergies cannot be exploited and resources may be wasted. Second, the scientists come into play. After an initial literature review that provides a basic understanding of the biological entity, data have to be exchanged and checked, possibly with the help of external experts. Within this phase, a very close collaboration between the R&D department and BD is necessary. Third, the BD team performs an economic evaluation to ensure that the project is feasible. The more advanced the project is, the more applicable are financial tools, such as net present value analysis. Fourth, the patent situation must be checked. Companies such as *GPC*, *Micromet,* and *Wilex* have their own intellectual property experts. Other companies have to hire external patent attorneys, which again takes time and is cost-intensive.

Regarding partner analysis and partner selection, there are clear differences between deal types. In input and throughput deals, in which biotech firms search for complementary resources and capabilities, the biotech companies can often choose from a number of possible partners. In such cases, the biotech companies have the opportunity of selecting their partner, e.g., by comparing the pros and cons of each partner. Output deals, which have the most profit, work differently. In platform deals, for example, it is often very hard to find a partner. Therefore, companies must take all opportunities, even very small ones in terms of the contract value (e.g., below US$ 100.000), in order to build up

trust and to qualify for more valuable deals. Big pharma deals, on the other hand, are always a challenge for the biotech companies because of the asymmetry in the negotiation power. Therefore, a careful selection is highly desirable. However, in reality, biotech companies do not have the "luxury of choice" (interview with Xerion).

In the third step, negotiation, the selected partner has to be convinced and the deal terms have to be fixed. To be well-prepared is key. Moreover, all our interview partners stated that negotiations can only be successful when there is a win-win situation and when there is trust between the team members of the involved companies. Building up trust is especially challenging when biotech firms want to partner with big pharma firms, where size differences certainly play a role. When everyone has done the homework, it seems to be relatively easy to specify the deal terms, since all partners usually know what those deals look like. However, it is important to engage legal expertise, particularly when the deal partner comes from the U.S.

The BD process can be very time-consuming, although there is a lot of variation between the phases and deals. The identification of an opportunity is more or less an ongoing process – "it takes a minute, a day, depending on, for example, what I find in a press release" (Xerion). The evaluation takes more time, usually between two weeks and three months. Finally, the negotiation phase can take up to one year. Input and throughput deals are usually more time-consuming than output deals.

4.3 Organizational and human resource issues of business development

The fact that the BD process is time-consuming is also reflected in the percentage of the overall time resources that biotech companies devote to the BD function. *Figure 2* uses *Wilex* as an example, where in the first four years after the company's founding, the amount of time devoted to BD grew from year to year until it reached 30 percent. However, the amount of time that the CEO was engaged in BD activities significantly decreased. This decreasing involvement of the CEO is a strong indicator that the BD function became more and more institutionalized over the course of time.

We distinguish between three different configurations in which the BD function can occur:

Implicitly:
- There is no official task description for business development within the company.
- BD tasks are carried out by the management without any deliberate, planned effort.
- The relevance of the BD function is only recognized over time.

Established:
- BD and its relevance are recognized within the company.
- There is an official label and task description for the BD function, e.g., CEO/business development.

Institutionalized:
- BD is established as an organizational unit.
- The main part of the function is delegated from management to a BD specialist.

Figure 2: Time resources spent for BD: Example

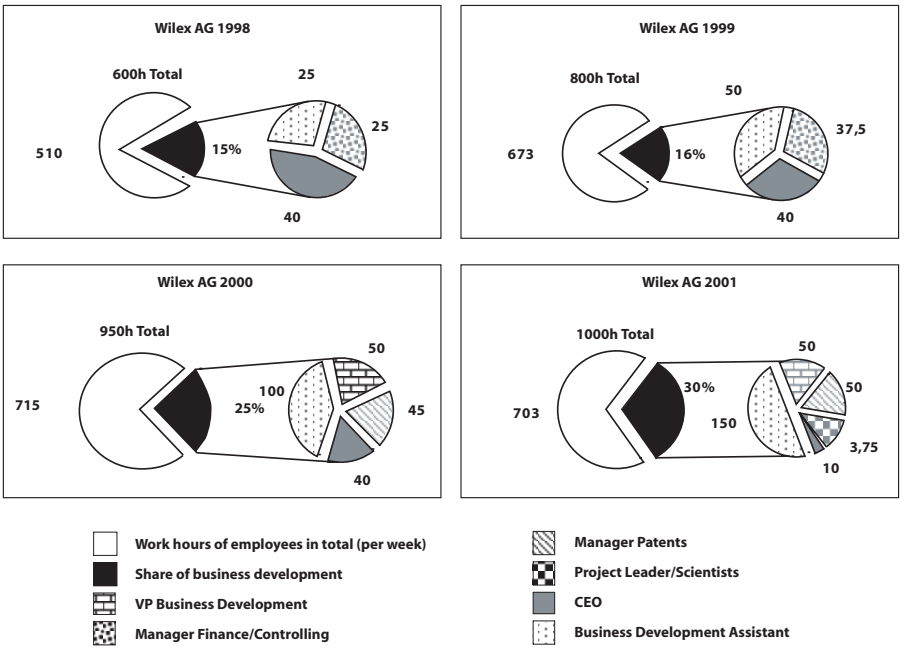


Figure 3 shows that most of our case-study companies evolve from an implicit or established BD function to an institutionalized BD function. Venture capital financing serves as a springboard for the institutionalization and provides money for the expansion of the BD team. Moreover, we observe that (market-oriented) firms, which have more founders with a business background and which are more oriented towards the commercialization of their products and technologies, tend to provide more resources, and to institutionalize the BD function earlier than research-oriented firms. To cite one of our interviewees from those latter firms:

"We did not see the relevance of the BD function; otherwise, we would have implemented this function earlier. We didn't have a clear profile for this function – which tasks a business developer has and how he or she has to qualify. Meanwhile, this has changed. The relevance of BD is becoming more and more acknowledged. It is difficult when you are

rooted in science. You need time to gain solid business knowledge. […] I think that's true for many firms. The founder has worked in basic science, in research institutes or universities as a lecturer or simply as a doctoral student, and therefore, he or she does often not have an understanding of companies and the circumstances within these companies." (Anonymous)

Figure 4 shows two alternative organizational solutions for the institutionalization of the BD function. At least by the end of the function's evolution, most companies in our sample have a vice president of BD who makes sure that there is a close relationship with the management of the company. Otherwise, the business developers would not be able to negotiate and it would take too much time to coordinate with those who make the final decisions. In the few cases (*Biofrontera*, *4SC*, *Jerini*) in which there is no vice president of BD, the CEO of the company is responsible for the team. The team itself usually consists of a team leader (a vice president or director) and a few BD managers and analysts. This team is occasionally supported by people from other units (e.g., R&D, IP) or external consultants.

Figure 3: Institutionalization of the BD function

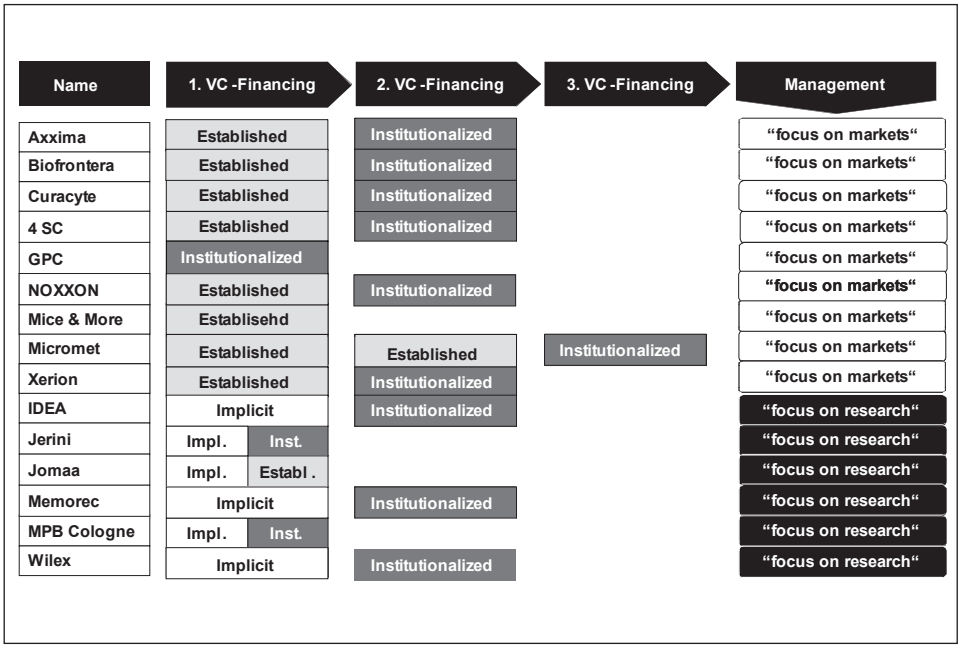
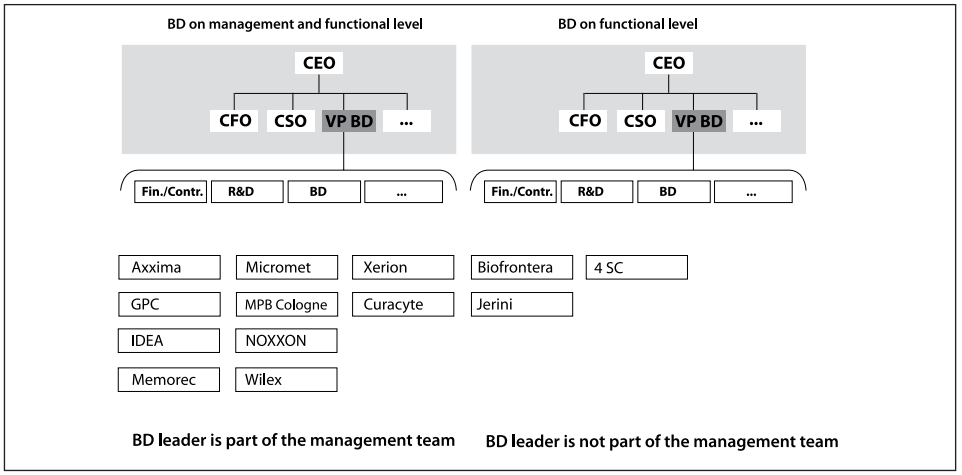
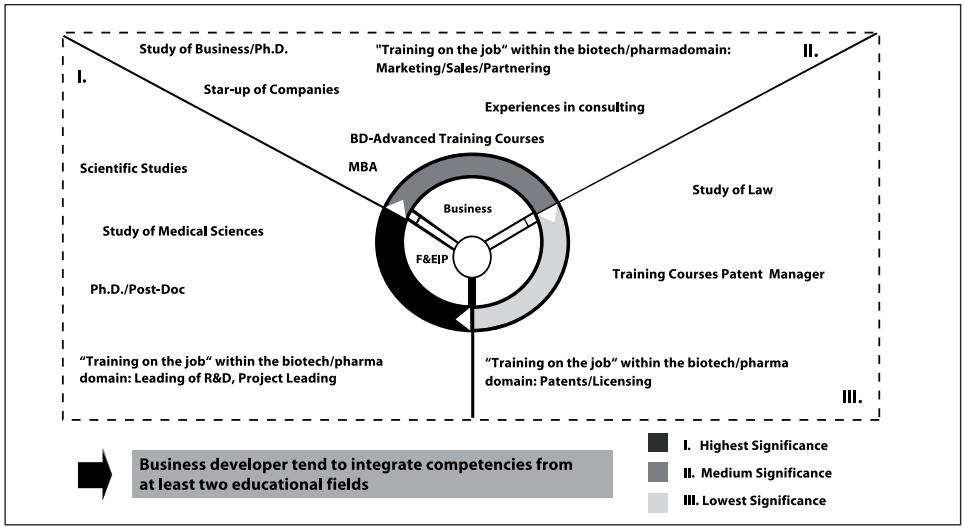


Figure 4: Decision-making authority of institutionalized business development



How do business developers (team leaders) qualify for their positions? Our interviews indicate that most business developers have a background of five to ten years of professional work and have a background in science, business or, in some cases (e.g., *GPC*) as lawyers with specific knowledge about intellectual property issues (see *Figure 5*). Aside from their knowledge of technologies, markets, and industries, and deal structuring and partnering, they need to have a broad network of contacts, good negotiation skills, and a certain amount of personal openness to succeed in fulfilling their tasks.

Figure 5: Educational background of business developers



5 Discussion and conclusion

Our research shows that in the context of the biotechnology industry, BD is characterized by a number of interesting features that have much in common with the refined concept of strategic planning that has been proposed in the literature (see Mintzberg (1994); Taylor (1997); Lorange (1998a; 1998b); Mintzberg, Ahlstrand, and Lampel (2005)).

First, the BD function seems to be heavily integrated into the overall organization, with strong connections to top management, and at the same time, to units such as research and development and the intellectual property department. This integration is only possible when key developers have personal skills that are rooted in a solid scientific education, and work experience that has also been related to the business side of the industry. At the same time, successful business developers tend to have strong external network links that bring new and sensitive information into the company.
Second, the BD function in the biotech industry seems to be very context-specific, in the sense that companies in this industry tend to be dominated by research and development-related issues. Such issues usually develop in a very dynamic way and require a pragmatic, opportunistic, and risk-oriented mindset from the business developers as well as all other people within the company.

Third, it is imperative for business developers to ensure that the company reaches favorable deal terms, which is a rather short-term perspective.

Fourth, the degree of formalization tends to be low; there are usually no written plans to help shape the future of the company. However, what is needed are written notes about the results of the due-diligence activities. Moreover, the deal terms must be fixed and stated in written contracts.

Fifth, we observe that the institutionalization of the BD function is a reaction to the expectations of external stakeholders, in this case, venture capitalists, who see the BD function as an integral part of a professional management.

Sixth, BD is not equal to strategy making; it is much more an operational activity that depends on orientation guidelines provided by the management board. However, in this respect, we must state that the BD function in biotechnology companies is often led by a vice president who is also a member of the board. Hence, it is not easy to draw a dividing line between defining and implementing or programming a strategy.

This last conclusion is a natural link to the dynamic capability perspective, as we have seen above. Indeed, we argue that the BD function can be seen as an empirical manifestation of a capability that may allow a company to adapt to changing technology and market environments. It is the organizational basis for the creation, development, integration, and recombination of the resources, such as research know-how (Henderson and Cockburn (1994)), development projects (Pisano (1994)), or alliance relations (Deeds, DeCarolis, and Coombs (1998; 1999) that define the competitive position of the firm. Thus, a BD function may be a necessity, but it is certainly not a sufficient condition for the competi-

tive advantage of the firm (Makadok (2001)). Therefore, it is not surprising that we find similar BD structures in firms that have significant performance differences.

Eisenhardt and Martin (2001) make a distinction between the characteristics of dynamic capabilities in moderately dynamic and in high-velocity markets. They predict that in moderately dynamic markets, "effective dynamic capabilities rely heavily on existing knowledge. Managers analyze situations in the context of their existing tacit knowledge and rules of thumb, and then plan and organize their activities in a relatively ordered fashion (…). They can develop efficient processes that are predictable and relatively stable with linear steps, beginning with analysis and ending with implementation" (p. 1110). In contrast, they point out that in high-velocity markets, dynamic capabilities "consist of a few rules that specify boundary conditions on the actions of managers or indicate priorities, important in fast-moving markets where attention is in short supply" (ibid). The two authors use biotechnology as a prime example of the latter, referring to Pisano's (1994) and Henderson and Cockburn's (1994) studies. However, our study shows that BD is now institutionalized in many biotech firms as a reasonably well-structured activity. This difference may reflect the fact that our study was conducted a decade later than the other studies. Many observers (e.g. Ernst & Young (2006)) now see the biotechnology industry as a relatively stable industry with defined boundaries and clear business models. Therefore, we argue that the maturing of the biotechnology industry and the institutionalization of the BD function have been mutually dependent on each other, that there is a co-evolution of firm capabilities and industry competition, as has been suggested by Huygens et al. (2001); Henderson and Mitchell (1997); and others (see Organization Science Special Issue, Sept./Oct. 1999).

Summing up, our study contributes to the literature in a number of ways. First, it clarifies a term that is widely used but seldom defined in a meaningful way. Second, our study helps to realize a new research program, the strategy-as-practice perspective, that seems to be promising but so far has not produced a lot of empirical evidence (Whittington (2003)). Third, it provides new knowledge about the current planning function and the concrete manifestation of organizational capabilities that have been discussed so extensively in the literature. Last but not least, our study also contributes to the biotechnology and entrepreneurship literature (see Patzelt (2005) for a recent review) because it helps to "unlock" biotechnology companies and offers insights how companies are managed in reality.

The limitations of our study are also obvious. We focus only on German biotechnology firms. Studies on companies from other countries and industries are a promising avenue for future research.

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** Postage rates are – depending on the currency you want to be charged in – $ 14, £ 8, € 12.

Payment

Payment is due within 14 days on receipt of invoice. You will receive the invoice directly from Verlagsgruppe Handelsblatt GmbH in Düsseldorf.

Address

Institute/Company

Position/Department

First and Surname

Street and Number

Zip Code City

State Country

Fon

Fax

e-mail

✘

Signature Date