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Business development: A barometer of future success

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Abstract

In the pharmaceutical and biotechnology industry, an excellent barometer of potential future success is a company's ability to find and execute accreditive deals. The key factors that differentiate successful companies are: (1) visionary leadership that sets aggressive but achievable, coordinated, measurable individual business development objectives to be met by designated dates, and (2) a proactive results- versus activity-oriented corporate culture. In these companies, senior management, from the Chief Executive Officer down, are focused on business development efforts to ensure that future product line gaps are filled before they materialise. Business development is supported by systems and processes that facilitate the timely identification and execution of accreditive deals. This paper discusses how successful companies set and achieve realistic business development objectives. Failure to fill future product line gaps through in-licensing, joint ventures or acquisitions will result in many companies being downsized, acquired or merged, or going out of business.

INTRODUCTION

The differences between successful companies and those at risk of being merged or acquired, or going out of business are often subtle. Generally, they can be attributed to the company's leadership and culture. These translate into management's ability to execute its strategic plan. In the pharmaceutical and biotechnology industry, an excellent barometer of potential future success is a company's ability to find and execute accreditive deals.

Declining R&D productivity, third/fourth products in established categories, triple-tier co-pay product positioning, generic competition, downward pricing pressures and an evolving industry structure (ie increasing co-development, co-marketing, joint venture, and unique merger and corporate structures) are putting significant pressure on business development. For many pharmaceutical companies, licensing plays an equivalent, if not a more important, role than R&D. Failure to identify and fill product line gaps in a timely manner will affect sales, profitability and company valuations. As a direct result, the company either will be required to downsize significantly (if private) or will be acquired or merged or go out of business.

For many companies, what is expected from business development is not realistic. These are the companies that fail to execute their strategies. These are also the companies that generally fail to execute accreditive deals.

A review of different companies over the past few years indicated that the key factor to success is visionary leadership. The factors that affect strategy and expectations/results include competition, the planning and goal-setting process, the number of available products, corporate culture, organisational structure, financial resources, realistic valuations and management's willingness to pay the requisite prices, the amount of time business development has for pursuing strategic opportunities, and the prospecting, due diligence, approval and negotiation processes, etc. Observation of a number of successful companies showed that effective management teams coordinate and orchestrate the business development process and hold management accountable for results to be

Demand for products is increasing

The cost of licensing deals is going up

achieved by designated individuals within a specified time frame. This paper presents some of these observations.

BACKGROUND: THE CHALLENGE

A total of 25 products, representing over US$24.3bn in 2002 US IMS audited sales, will be losing patent protection between 2003 and 2005; see Table 1. Major patent expirations and successful patent challenges put pressure on the companies losing protection to increase their licensing and/or acquisition activity. Virtually all major products have had Paragraph IV Certification[1] applications submitted to the Food and Drug Administraion (FDA) – some will lose protection earlier than expected owing to patent challenge (and are not listed on Table 1).

Declining R&D productivity in the face of an increasing number of generic approvals and generic competition from multiple companies puts additional pressure to act. Figure 1 clearly demonstrates that the number of amended new drug applications (ANDA)/generic product approvals by the US FDA grew between 1999 and 2002. During the same period, the numbers of approved new molecular entities[2] (NMEs; a medication containing an active substance that has never before been approved for marketing in any form in the USA) and biologics licence applications (BLAs) have been decreasing – even in light of increasing R&D investments (see Figure 2).

The number of available licensing opportunities varies by geographical area, therapeutic area and/or indication, and by phase of development. Certain indications/therapeutic areas have extremely limited licensing opportunities; see Table 2. The limited number of opportunities, in the face of increased demand, especially for late-stage opportunities, explains why the cost of licensing deals has been going up across all phases of development, except mid-stage products, as well as for marketed products; see Figure 3.

SUCCESSFUL COMPANIES

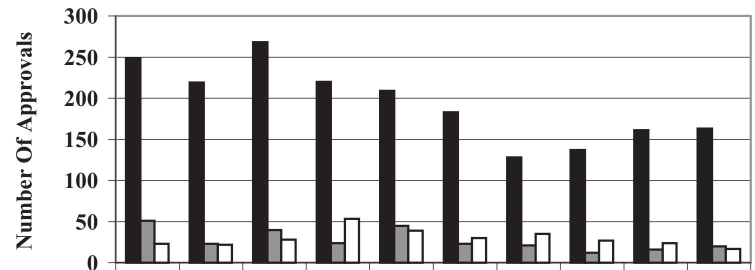
Successful companies have demonstrated an ability to make deals and thereafter to effectively integrate externally acquired products, to develop in-licensed compounds and, once launched, to successfully commercialise them. On the other hand, many companies spend considerable time and money evaluating and chasing opportunities, but no meaningful deals are ever consummated.

The successful companies are often referred to as being lucky. However, analysis indicates that these 'lucky' companies are successful because they

Table 1: Products losing patent protection

2002 US IMS sales in millions of US$								
Expiring in 2003		**US $**	**Expiring in 2004**		**US $**	**Expiring in 2005**		**US $**
Cardura	Pfizer	38	Diflucan	Pfizer	625	Aredia	Novartis	106
Cipro	Bayer	1,020	Engerix-B	Glaxo	153	Combivir	Glaxo	572
Flonase	Glaxo	813	Lovenox	Aventis	1,000	Lamisil	Novartis	497
Flovent	Glaxo	684	Lupron	TAP	884	Paxil	Glaxo	2,300
Serzone	BMS	272	Paraplatin	BMS	587	Pravachol	BMS	1,767
			Procrit	Monarch	5	Prevacid	TAP	3,659
			Wellbutrin SR	Glaxo	1,501	Zithromax	Pfizer	1,465
			Zyban	Glaxo	78	Zocor	Merck	4,174
			Xenical	Roche	134	Zofran	Glaxo	951
						Zoladex	AstraZeneca	228
						Zoloft	Pfizer	2,546
Totals		**2,827**			**4,967**			**18,265**

Sources: compiled by MMC® from NDC Health and IMS Health data.



	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002
■ ANDAs	249	219	268	220	209	183	128	137	161	163
▒ BLAs	51	23	40	24	45	23	21	12	16	20
□ NMEs	23	22	28	53	39	30	35	27	24	17

Figure 1: Decreasing NME and BLA approvals. Sources: FDA[2] and Biotechnology Industry Organization[3]

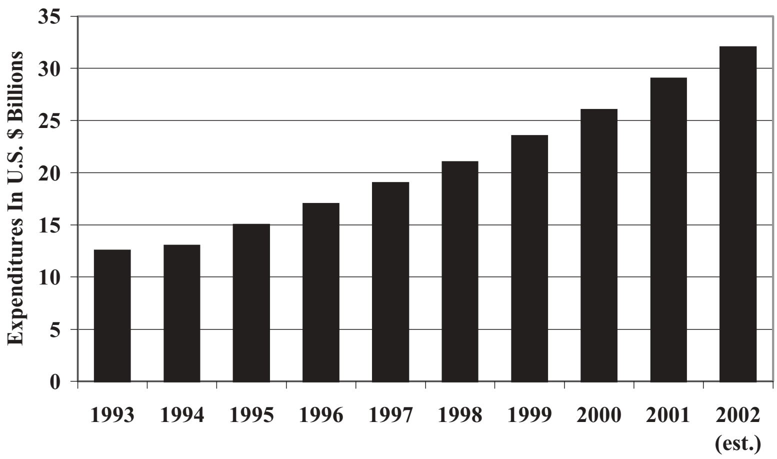


Figure 2: Increasing R&D investments (Pharmaceutical Research and Manufacturers of America (PhRMA) member companies R&D expenditures)

The product portfolio dictates the difference between success and failure

have visionary leadership (to include their Board of Directors) and have developed systems and processes that reward achievement of carefully thought-out measurable milestones by designated personnel by defined dates. They also use their systems and processes to force conduct in keeping with the company's culture – which is results- versus activity-oriented.

VISIONARY LEADERSHIP

The key differentiating factor for successful companies, regardless of size, is visionary leadership that can effectively communicate expectations and transform them into actionable milestones. The Chief Executive Officers of successful companies communicate their vision of where they want to take the company. The vision, in the absence of a major transforming event, remains unchanged over time. However, strategy to move the company towards realising its vision is adjusted on an ongoing basis to allow the organisation to be proactive rather than reactive to marketplace changes.

By having a clear vision and by positioning the company to be proactive, these organisations are in an excellent position to capitalise on opportunities early on. This is the time that requires the least investment and when investment will yield the greatest marketplace advantage. Successful company managements understand that processes have to be in place to transform the vision into measurable goals that must be translated into measurable individual objectives to be met by specific dates. Furthermore, compensation and promotions need to be tied to achievement of defined objectives and individual objectives must be challenging but simultaneously realistic/achievable.

PRODUCT PORTFOLIO

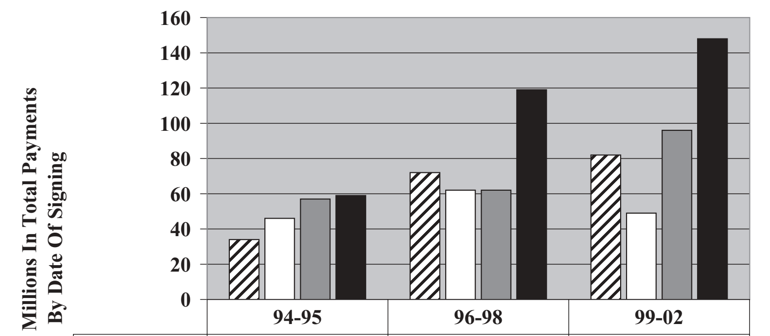
The product portfolio, in both pharmaceutical and biotechnology companies, dictates the difference between success and failure. The product portfolio, comprising marketed and/or pipeline products as well as patents and know-how, dictates annual and long-term sales and profitability. It defines how a company will manage product life cycles, its ability to obtain investment/capital and financing, and its product development strategy.

Successful companies, such as Pfizer, have used portfolio analysis to continually transform and increase the size of the

Table 2: Number of potential licensing opportunities in June 2003 by select therapeutic areas registered through Phase III development products (based on the status of development in the respective country(s)

	USA	Western Europe	Japan
Allergy/immunology			
Registered	0	0	0
Pre-registered	1	1	0
Phase III	6	1	0
Cardiovascular			
Registered	0	0	0
Pre-registered	0	1	0
Phase III	7	5	1
Cancer			
Registered	2	1	0
Pre-registered	5	5	0
Phase III	26	15	5
Gastroenterology			
Registered	1	0	0
Pre-registered	2	1	0
Phase III	2	4	0
Infectious diseases			
Registered	1	0	2
Pre-registered	6	4	0
Phase III	11	7	2
Neurology			
Registered	0	0	0
Pre-registered	3	2	0
Phase III	7	5	2
Respiratory			
Registered	0	0	0
Pre-registered	0	1	0
Phase III	3	2	1
Urology			
Registered	1	0	0
Pre-registered	1	0	0
Phase III	1	0	1

Source: MMC International®. Data compiled from MMC's proprietary WebReporter Systems databases.
Note: Western Europe based upon opportunities in France, Germany, Italy, Spain and the UK.



	94-95	96-98	99-02
Early Stage	34	72	82
Mid Stage	46	62	49
Phase II	57	62	96
Late Stage	59	119	148

Figure 3: Average payments in biotechnology alliances
Source: adapted from Recombinant Capital's Average Payments in Biotech Alliances chart[4]
Note: dates for late stage deals are 1996–97, 1998–99, 2000–01.

organisation. At one time, Pfizer was felt to have a very weak product pipeline. It initially fixed this shortcoming by heavily investing in R&D. When it conducted its portfolio analysis, it developed a plan to manage the life cycle of its most significant products. An example includes the replacement of Procardia with Procardia XL and then Procardia XL with Norvasc. When it saw gaps in its pipeline that would affect its overall vision and financial results, it first transformed itself into the ideal marketing partner for other companies and biotechnology companies, and second pursued key strategic accreditive acquisitions, eg Warner-Lambert and Pharmacia. Experience with these acquisitions has positioned Pfizer not only to be the ideal marketing partner but also to be an effective acquirer that is able to integrate acquired companies quickly and cost effectively.

On the other hand, companies such as Adria Laboratories, which at one time was considered the 'cancer company', have failed to adequately prepare for the patent expiration of their key drugs. In the case of Adria, it did not prepare early enough for the patent expiration of Adriamycin, its billion dollar drug. As a result, it was acquired by Pharmacia.

The biotechnology industry is replete with examples of companies that had unrealistic expectations relative to the value of their compounds. In turn, they were unable to get financing and, if lucky, were acquired or, if unlucky, went out of business. Many of these managements blamed poor timing or the downturn in the financial markets for their failures. For the vast majority, the failure was in leadership. Management failed to marry its expectations with the realities of the marketplace. Unrealistic expectations precluded deal making and resulted in the eventual demise of the enterprise as a standalone entity.

REALISTIC OBJECTIVES

Successful companies, regardless of size, set realistic business development objectives. They are based upon objective information organised in a manner that allows management to set clearly defined, measurable goals to be achieved by specified dates by designated individuals. The process requires determining the sales gaps to be filled, the number of potential targets available, the organisation of responsibilities, the due diligence and approval processes, and the reporting structure.

Defining annual sales gaps allow companies to be proactive

Defining the sales gap

Successful companies define their future sales gaps to establish business development's measurable product in-licensing, joint ventures and/or acquisitions objectives.

Sales for existing products are forecast by marketing (incremental sales from new presentation forms, additional approved indications, and erosion from the introduction of competitive products and generic competition are factored into the sales forecast).

Launch probability weighted sales tables for internal R&D projects are established and launch dates estimated. The forecasted product portfolio and probability weighted pipeline sales are subtracted from the sales required to meet the company's long-range plan in order to define annual sales gaps.

Prioritised target lists increase the probability of success

Identifying and prioritising potential targets

Successful companies use multiple sources/databases to ensure that the maximum number of products potentially available for licensing/acquisition is identified. The records in the respective databases are carefully reviewed and discrepancies corrected. Any records with dated information are eliminated. Ranking criteria are then developed and the opportunities are ranked.

There are three types of opportunities:

(1) those where the company has stated that the product is available for licensing,

(2) products that should be available for licensing based upon analysis of the originator/licensor company's management, strategy, competencies, investors and/or financial resources, etc, and

(3) non-traditional opportunities that may be constructed based upon potential deals that would be attractive to the licensor/marketer.

To rank opportunities, each prioritised product is given a percentage probability that the company can in-license the product. Then probable launch dates and sales estimates for the planning period are developed for each product. Multiplying the probability that the company can in-license the product by the sales estimate for the product gives the weighted sales forecast by planning year. The total of the weighted sales for the potential products target list will yield the forecasted annual sales generated by business development. These sales deducted from the gap forecasts for each planning year indicate whether or not business development has sufficient compounds in its target list. If the number of compounds is insufficient to fill the gap, other therapeutic areas and/or diagnoses/indications and/or physician targets are added until the gap is filled.

CORPORATE CULTURE

Any business development activity contains potential risk. People do not take risks unless they see that they personally have a potential gain (greed) or potential loss (risk). In the absence of either, the individual prefers not to make a decision or take a risk because it will change a very content lifestyle. This is especially true in very large, established organisations. This is the reason that many companies find it almost impossible to successfully in-license or acquire meaningful products. For many companies, breaking these 'silos' of resistance within the organisation is the difference between success and failure.

A number of people within the company are usually involved in the in-

Successful companies have results-oriented corporate cultures

licensing/acquisition decision-making process. In successful companies, the process exposes everyone involved to the most senior management levels and makes them accountable for their participation and their opinions/positions. The process fosters a culture that values both internal development and in-licensed/externally developed products. It is also a culture that rewards risk taking.

MEASURABLE OBJECTIVES

To transform the business development plan into action, successful companies designate the responsibility for pursuing/in-licensing specific compounds by defined dates to specific individuals. These people are responsible for contacting the target company as well as for coordinating the internal process to review, value and set negotiating parameters for negotiations, and for the transfer of responsibility for the compound once it is in-licensed or acquired.

Once responsibilities have been assigned, successful companies set measurable monthly targets/activities with completion dates/due dates that are designed to meet each individual's defined annual objectives. Progress is then formally monitored on a monthly basis. Adjustments to plans are made as required to ensure timely achievement of the overall business development plan. Formal, regularly scheduled business development meetings force the organisation to have ongoing business development activities.

Competing demands

Typically, business development is pulled in many different directions. Opportunities are presented to the company that were not contemplated in the original priority list. Deals begin to move forward and milestones for other projects begin to be missed. Input promised to business development is late and, as a result, business development staff have to shift priorities in order to move the most critical projects forward – doing other people's work at the cost of their own.

To ensure objectives are met on schedule, successful companies have a formal process in place for business development to get relief from senior management before business development priorities can be/are shifted. This forces the organisation to communicate and responsible individuals to provide input on a timely basis. This allows management to measure business development and other personnel objectively and to replace those who fail to achieve their objectives. Replacing ineffective personnel reinforces the results-oriented culture. Replacing personnel results in continually increasing the professionalism of the organisation and the focus of achieving results.

Formal meetings

In successful companies, regularly scheduled, formal business development meetings have multiple purposes. The meetings are attended by senior management to tell the company/organisation that acquiring compounds is important and a key strategic imperative. The objective of the formal meetings is to make decisions and to resolve issues in order to move the process forward expeditiously. This allows the company to successfully compete for the compounds. The meetings also expose business development to senior management, familiarising senior managers with business development personnel and make the business development staff feel at risk.

Accountability

Successful companies hold their people accountable. They are put at risk, and as a direct result, objectives are met. People are held accountable for delivery of defined, measurable results by committed dates without relief, except in exceptional circumstances. As a direct result, people focus on the assigned objectives rather than what they think may be most important at the time. The formal meetings move the organisation's culture towards a focused, results-oriented organisation.

Computerisation

To minimise duplication of effort, business development is supported by computerised systems for tracking opportunities. Opportunities are ranked based upon whether or not the company is pursuing them or is potentially interested. Archived records are maintained for products that have been reviewed and where management has decided that the company is not interested. The system allows for minimal time investment when an inquiry comes in via senior management and the company has previously looked at the opportunity. Senior management gets a timely response without requiring a re-evaluation.

Outside validation of business development strategy/target lists is inexpensive insurance

Financial resources dictate the type of deals

OUTSIDE VALIDATION

Owing to the importance of the business development effort on the overall performance and future value of the company, successful managements are continually questioning whether all opportunities have been identified. Furthermore, they want to challenge the business development staff. For this reason, companies that can afford it will contract with outside consultants every two to three years to validate that all potential opportunities have been uncovered. They use this information to challenge their business development assumptions, identify areas that need improvement, and to make personnel and organisational changes that keep the organisation fresh. In the pharmaceutical industry, a missed business opportunity is measured in the tens of millions of dollars.

MANAGEMENT

Successful business development departments are staffed by a mix of experienced business development professionals and promising management talent. The business development professionals act as a cornerstone for the business development effort. They have the experience and contacts to make deals happen. Departments that lack experienced business development professionals are generally at a disadvantage.

Because of the importance of deal making to the overall success of the pharmaceutical enterprise, many companies rotate those individuals designated as senior management in training through business development. Familiarity with the process and personnel involved contributes to informal communication and facilitates the overall business development process. This increases the quality of the questions asked and decisions made by senior management, senior management support for business development, and enhances the ability to quickly execute deals. Some staffing brings special market research, marketing or scientific expertise. These may be permanent or developmental assignments.

FINANCIAL RESOURCES

The financial resources available dictate the types of deals that business development can pursue. The gaps that need to be filled by business development have to be supported by the company's financial resources and its financing strategy. In order to be opportunistic in some of its deal-making activities, the company needs to have any requisite financial relationships either in place or sufficiently lined up to allow the company to pursue its objectives with a reasonable level of surety that it will be able to finance potential deals. If the company is cash strapped, it needs to develop a business development plan to meet its strategy within its financial constraints or it needs to revise its objectives and, if required, its vision.

SUMMARY

The Chief Executive Officer, who is held accountable by the Board of Directors to ensure product line gaps are filled, must be actively involved in business development. Business development is the strategic function responsible for filling future product line gaps not filled by internal R&D efforts. It is a key strategic imperative that can positively affect long-term company performance, valuation and shareholder value/ shareholder returns. Failure to fill sales gaps will negatively affect a company's valuation and, if not corrected, will result in the company being downsized (generally for private companies), acquired, merged or going out of business.

Successful business development efforts are driven by aggressive but realistic/ achievable objectives that are supported by formal processes that allow timely decision making that facilitates deal execution. The corporate culture fosters internal R&D as well as product in-licensing, acquisition and joint venture activities. Business development departments are staffed by: (1) experienced business development personnel with the requisite industry knowledge and contacts, and (2) staff conversant with formal and informal internal processes. All efforts are guided by measurable goals tied to each individual's compensation. The corporate culture is results- versus activity-oriented and holds people accountable for achieving assigned objectives. Ineffective personnel are replaced and management on a senior management track are rotated through business development.

In the pharmaceutical and biotechnology industry, an excellent barometer of potential future success is a company's ability to find and execute accreditive deals.

References and notes

1. Paragraph IV Certification refers to the paragraph under the Hatch–Waxman Amendments that allows a company to launch an equivalent product to the brand-name if the company's patents are proved invalid, via patent challenge, or if the patents are not infringed by the Amended New Drug Application (ANDA).
2. FDA (URL: http://www.fda.gov).
3. Biotechnology Industry Organization (2003), 'FDA Approves 20 New Biotech Products, 15 New Indications', 9th January (URL: http://www.bio.org).
4. URL: http://www.recap.com