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Biocon: Launching a New Cancer Drug in India

In summer 2006, Dr. Kiran Mazumdar-Shaw, CEO of Biocon Limited, was reviewing the phase-2 results of the new cancer drug, BIOMAb. The results were even more impressive than she had expected. Based on these data the company had filed for accelerated approval. Early indications suggested that the Drug Controller General of India (DCGI), the equivalent of the US Food and Drug Administration (FDA), would likely grant permission in the next few months to market BIOMAb in India.

Mazumdar-Shaw knew the euphoria would be short-lived if Biocon failed to make good decisions in two critical areas. First, many senior executives believed that even if BIOMAb received accelerated approval from DCGI based on the phase-2 results, the firm should stay on track and continue phase-3 trials to gather more evidence of BIOMAb's safety and efficacy. They maintained that for a small biotech company with no history in this area, it was critical to build strong evidence to compete against the large multinational companies. Others, though, favored an early launch, arguing against expending precious time and resources on further clinical trials and risk losing the first mover advantage.

Second, various aspects of product launch strategy for BIOMAb had yet to be determined. This was Biocon's first launch of a proprietary drug and Mazumdar-Shaw wanted to ensure that it was successful. She was anxiously awaiting recommendations from the BIOMAb marketing team on issues of product, pricing, sales force, channel, and communications strategies.

Evolution of Biocon

Biocon India was incorporated in November 1978 as a joint venture between Biocon Biochemicals of Ireland and Dr. Mazumdar-Shaw, an Indian entrepreneur. In 1979, Biocon became the first Indian company to manufacture and export to the United States and Europe enzymes for the food processing industry. In 1989, Unilever acquired Biocon Biochemicals in Ireland and held an equity share in Biocon India. From 1978 to 1997, during which time it was primarily an enzyme manufacturing company, Biocon developed expertise in various fermentation processes.

Professors Sunil Gupta and Das Narayandas prepared this case with the help of Sara Simonds, Research Associate, and Prabhakar Kothandaraman, Interim Executive Director, India Research Center. HBS cases are developed solely as the basis for class discussion. Select numbers in the case have been disguised for confidentiality purposes. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

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Statins

Syngene International, a subsidiary custom research company, was established by Biocon in 1994 to address the growing need for outsourced R&D in the pharmaceutical sector. In 1996, Biocon leveraged its technology platform in fermentation to enter biopharmaceuticals.¹ Mazumdar-Shaw explained her rationale for entering this new business.

During the mid-1990s we went through a visionary exercise. We recognized that although we were well known in enzymes, the market opportunity in this area was low. Even today, the global enzyme market is about \$2 billion with an annual growth rate of 5%-10%. As a specialty enzyme company, the total addressable market for us is only about \$1 billion. Even if we achieve a 10%-15% global market share, the maximum potential for us is only about \$100-\$150 million. Add to it the commoditization of enzymes, and the profit potential looks limited.

In contrast, the global biopharmaceutical market is \$10 billion today and growing rapidly. It is emerging as a major competitor to traditional pharmaceutical firms and is likely to become over \$40 billion in the near future and more than \$80 billion by the year 2016.² We faced two challenges to successfully enter this market. The first was the technological challenge. This turned out to be the easy part since shifting from fermenting enzymes to proteins is not that hard. The second challenge was to develop the market. This was a bigger challenge since, unlike enzymes, pharmaceuticals is a more regulated market. Therefore we started with generic pharma molecules to learn about this market.

The decision to enter the biopharmaceutical market in 1996-1997 as a manufacturer of generic drugs led Biocon to statins. Statins inhibited the enzyme HMG-CoA reductase in the liver thereby reducing the low-density lipoprotein (LDL), or “bad cholesterol.” With its expertise in enzymes and the fermentation process, Biocon had the technical capability to manufacture statins. In addition, statins represented a large and growing market. Major brands such as Mevacor, Zocor, and Lipitor dominated the market in late 1990s, but the patent for Mevacor (Lovastatin) was set to expire in 2001 and the patents for Zocor (Simvastatin) and Pravachol (Pravastatin) were set to expire in 2005. Finally, statins were small molecules that were relatively easier to manufacture.

Biocon’s move into statins coincided with Unilever’s decision to sell its shares of Biocon to the Indian company. In 2001, freed from Unilever’s resistance to its move in the biopharmaceutical arena, the newly independent Biocon became the first Indian company to be approved by the U.S. FDA to manufacture Lovastatin, which it sold to the U.S. market through a Canadian company Genpharm. Biocon subsequently began to manufacture Simvastatin and Pravastatin, gaining a 15%-20% share of the statin market in the United States and Europe. Mazumdar-Shaw reflected on Biocon’s success in statins and the company’s future:

Within 2-3 years in the late 1990s and early 2000, we developed a unique process to manufacture statins, we got customers who could market them in the U.S. market, and we obtained approval of the U.S. FDA. This was a remarkable success in a short period of time. Statins gave us significant profits for a few years and then the prices started coming down. To

¹ Fermentation involves converting sugar and other carbohydrates from enzymes (proteins that accelerate chemical reactions) produced by bacteria or yeasts into food products such as beer and yogurt.

² Whereas pharmaceuticals are produced by chemical synthesis, biopharmaceuticals are derived from life forms through biosynthesis. The first such substance approved for therapeutic use was recombinant human insulin, developed by Genentech and marketed by Eli Lilly in 1982. The industry typically does not regard small molecule drugs (e.g., statins) to be biopharmaceutical in nature, but the terminology is often used by the media and business and financial communities.

continue the company on a growth path we needed to go beyond statins. We succeeded with small molecules and now we were ready to move into large molecules.

Insulin

The desire to move into large molecules led Biocon to the insulin market. This choice was governed by three factors. First, insulin represented a large global market dominated by Novo and Eli Lilly. Second, India's 32 million diabetics in 2000 accounted for almost one-fifth of the global diabetic population, and were expected to grow to 79 million by 2030.³ Third, no biotech company had been able to make inroads in this market because their fermentation capabilities were limited to 1,000 liters, whereas cost considerations dictated the capability to ferment 100,000 liters or more at a time. As an expert in the fermentation process, Biocon was uniquely positioned to produce insulin.

Over the next few years, Biocon developed a novel process to make insulin from the yeast *Pichia*, a particularly good host for recombinant DNA (rDNA).⁴ Being based on large molecules, insulin, unlike statins, required clinical trials to show the bioequivalence of the generic version to the approved drug. Anticipating this need, Biocon formed the subsidiary Clinigene in 2000 to pursue clinical trials of drugs in India. Tasked to validate Biocon's insulin product, Clinigene successfully conducted clinical trials that compared it to market leader Novo using a large-scale base of more than 500 patients instead of the existing government requirement of just 30 patients.

Aimed initially at the domestic market, the drug was priced 20%-30% less than Novo. The 150 person sales force with which Biocon began to market its insulin in 2001 grew to nearly 250 in the span of two years.⁵ By 2004, Biocon had gained just over 10% share of the Indian insulin market and was generating 25%-30% of new insulin prescriptions. "Prior to insulin's launch, we had no marketing experience," acknowledged Mazumdar-Shaw. "With insulin we had to develop this skill from scratch. I credit our senior team for developing this talent pool in such a short time."

Proprietary Drugs

Mazumdar-Shaw did not let the success of insulin and statins deter her from planning for the long haul. Recognizing that the maturing of the Indian drug market would put enormous price pressure on generic products, she believed that Biocon's future lay in shifting to the development of proprietary drugs. This encouraged Biocon to start development of its own proprietary oral insulin, a product a number of firms worldwide had been attempting, without success, to develop. Biocon had made some progress with this product, which was currently in phase-2 trials. Although the odds of success were as yet not very high, the potential payoff could be huge.

Having successfully evolved from the industrial enzyme company it had been in the 1980s to a fully integrated biotech company (**Exhibit 1**), Biocon's strategy (**Exhibit 2**) was the basis for a hugely successful IPO in March 2004. Biocon became only the second Indian company to cross the \$1 billion mark on the day of listing (see **Exhibit 3** for company financials).

³ World Health Organization, http://www.who.int/diabetes/facts/world_figures/en/index.html, accessed on 7/1/07.

⁴ Recombinant DNA (rDNA) is an artificial DNA sequence that results from combining two other DNA sequences. The DNA molecules in the new combination are not found together naturally. Werner Arber, Daniel Nathans, and Hamilton Smith were awarded the 1978 Nobel Prize in Medicine for the discovery that enabled this technique.

⁵ Typically, a pharma sales rep earned \$4,500 to \$6,700 per year. For a firm, the fully burdened costs of a sales rep (including sales related expenses and variable compensation) could run to twice that figure.

BIOMAb

BIOMAb, a proprietary drug for head and neck cancer, marked the latest and perhaps boldest move in Biocon's evolution to a fully integrated biotech company. Biocon had stumbled upon the drug accidentally. In 2002, Mazumdar-Shaw was visiting Cuba with several senior executives to explore promising research on microbial proteins. When the scheduled meetings finished earlier than expected, on a whim, Mazumdar-Shaw decided to visit CIMAB, the commercial branch of the Center of Molecular Immunology (CIM), which had been working for several years on oncology drugs. During the visit, the Biocon team discovered to their surprise that the Cuban center had done superb research using monoclonal antibodies (Mabs) that could specifically target cancer cells.

Mabs stimulated a patient's immune system to attack malignant tumor cells and prevent tumor growth by blocking specific cell receptors. CIMAB had done extensive research on BIOMAb with promising phase-1 results for head and neck cancer patients. Mazumdar-Shaw was quick to realize that Biocon could leverage this opportunity to its own benefit.

I was excited about getting into this new market. No doubt there would be challenges that we needed to address, but the opportunity was too good to pass on. BIOMAb would allow us to learn about the mammalian cell technology, which was the future of the biotech industry. In addition, it gave us a chance to develop a new market and build new research and marketing capabilities, essential skills for ensuring the long-term success of the company. We would also be the first Indian company to launch a proprietary drug in India.

But the prospect of producing and marketing BIOMAb was attended by some serious concerns, which were summarized by Biocon's marketing president, Rakesh Bamzai.

There were many strong reasons to go with BIOMAb. However, there were many associated risks. We did not know anything about this new technology. We were a microbial fermentation company and had no knowledge of dealing with mammalian cells. We did not know how to manufacture the product and the financial investments required in plant and equipment were significant.

Our challenges were not limited to manufacturing. We also had no experience in marketing and selling oncology drugs. We did not know the patients or the physicians and specialists in this field. This product would also need clinical trials and we were just beginning to learn that aspect through Clinigene. Finally, BIOMAb would also need regulatory approval for new drugs, something we had never obtained before. Neither were the Indian regulatory authorities familiar with the approval process of new drugs.

BVS Prasad noted that BIOMAb would require a new manufacturing plant at an estimated investment of about \$25 million. M. B. Chinappa, VP of finance, estimated that the cost of goods would be roughly 25% of revenues, R&D would account for 15%, and marketing costs would be 25%-30%, leaving the rest for profits.⁶ Chinappa also recognized that the economics of BIOMAb were fuzzy, depending on a host of factors that were difficult to pin down.

Arun Chandavarkar, the COO, agreed with Mazumdar-Shaw that launching BIOMAb was not only an economic but a strategic decision. The timing for BIOMAb coincided with dramatic changes in India's patent laws, which, until 2005, permitted domestic companies to produce generic versions of patented drugs as long as the production process by which the drug was made was unique. Being

⁶ These estimates were based on a price of \$1,000 per dose.

based on process rather than product patents, this system enabled Indian pharma companies to reverse engineer and quickly copy the latest blockbuster drugs developed in the West. The legislation had not been well received by large multinational pharma companies, which argued for the protection of their intellectual property and capital.⁷ In early 2005, under pressure from the international community, India brought its laws into compliance with the World Trade Organization.

After much discussion and negotiation, Biocon entered into a joint venture with CIMAB. The Cuban company would license Biocon to develop and market the molecule on the Indian subcontinent. CIMAB had already licensed the drug to a Canadian company, YM Bioscience, for distribution throughout Europe, North America, and the Pacific Rim, excluding China. Mazumdar-Shaw explained Biocon's long-term objective.

In simple terms, our game plan is to look for interesting products to develop from all over the world. There are firms that have discovered potential biotech drugs, but do not have the ability to get the product through the various trial phases and then commercialize the drug. We will provide this expertise in return for a joint ownership of the intellectual property. We will also manufacture the product for the Indian market and, if possible, for the entire world. Finally, we will seek marketing rights for India and other geographies. It is a unique business model for a biotech company at the moment.

Biocon's development efforts got an unexpected boost in July 2004 when CancerVax, a California biotech firm, received rare US government approval to license three drugs of Cuban origin developed by CIMAB. Soon, CancerVax had exclusive rights to complete the clinical development and commercialization of these drugs within the U.S., Western Europe, Canada, Japan, Australia, New Zealand, and Mexico. "This is great news for Biocon and a terrific endorsement for CIMAB's cutting edge science," remarked Mazumdar-Shaw. "Biocon is indeed fortunate to have such a valuable JV partner which has enabled us to generate a truly unique proprietary product pipeline."

Cancer⁸

Cancer was commonly characterized in terms of the affected body part such as lung, liver, breast, prostate, and head and neck. In medical terminology, it was commonly described based on its point of origin, for example, carcinoma in the skin, sarcoma in bones, leukemia in blood-forming tissues such as bone marrow, and lymphoma in the cells of the immune system.⁹

Incidence and Prevalence

Cancer affected young and old, rich and poor, men, women, and children. According to the World Health Organization (WHO), it was one of the leading causes of death in the world, particularly in developing countries. More than 7.6 million of the 58 million people who died worldwide in 2005

⁷ Proponents of process patents argued that developing countries with significantly large poor populations would not be able to afford the expensive patented drugs.

⁸ This section is based largely on information from the World Health Organization, Globoscan – an International Agency for Research on Cancer, American Cancer Society, American Association for Cancer Research, and Biocon. Variations in reported numbers are likely due to different organizations reporting data for different time periods.

⁹ Cancer is a disease in which abnormal cells divide without control, the masses of cells or tumors invading nearby tissues and spreading through the bloodstream and lymphatic system to other parts of the body.

succumbed to cancer. Cancer deaths were expected to rise to 9 million in 2015 and to 11.4 million in 2030. In the United States, cancer was the second leading cause of death after heart disease. In 2003, more than half a million or 22% of all deaths in the United States were due to cancer. But more than 70% of all cancer deaths occurred in low- and middle-income countries in which resources available for prevention, diagnosis, and treatment were limited.

Exhibit 4 shows incidences (numbers of new cases), mortality (numbers of deaths), and prevalence (numbers of diagnosed patients still living) for various types of cancer in India, the United States, and the world. Among all cancers, the incidence rate for head and neck cancer, the target market for BIOMAb, was highest in India. Nearly 21% of cases and 27% of deaths worldwide from head and neck cancer occurred in India.¹⁰

Survival and Prevention

Cancer survival rates varied with type of cancer and stage of diagnosis. The five-year survival rate in the United States varied from 5% for pancreatic cancer to more than 98% for prostate cancer.¹¹ The five-year survival rate for head and neck cancer varied between 50% and 60%, but could be as high as 90% if detected early. Because nearly 80% of patients in developing countries sought treatment only in advanced stages of cancer, survival rates were generally lower, treatment results being approximately 20% lower than for similar conditions in developed countries.¹²

According to the WHO, more than 40% of cancers could be prevented by lifestyle changes such as quitting smoking and better diet. Over 85% of head and neck cancers were due to excessive use of tobacco or alcohol. Cancers that could not be prevented could, if detected early, still be treated and cured. The sooner a cancer was found and treatment begun, the better a patient's chances for survival. Even for patients with late stage cancer, suffering could be relieved with good care.

Treatment

Four broad types of treatments were available to cancer patients. *Surgery* involved removal of the entire organ affected by a tumor, often including a large amount of surrounding tissue. *Radiotherapy* involved accurately directing beams of radiation at affected tissue. *Chemotherapy* referred to drug therapy that employed chemical substances known as cytotoxic agents to inhibit the growth of tumor cells. *Biological therapy* used drugs that relied on mechanisms that put the immune system on a higher level of alert with respect to cancer cells. Unlike other treatments, biological therapy used the body's own defense mechanism to fight the disease and attack cancer cells without harming normal cells. Physicians generally employed these treatments in various combinations.

Recent developments included the emergence of targeted therapies whereby a drug was used to block the growth and spread of cancer. These therapies were designed to be more effective than current treatments with limited side effects on normal cells. Drugs such as BIOMAb, a class of biological therapy drugs, were engineered to specifically target and block the epidermal growth factor receptor (EGFR) responsible for the proliferation of cancer cells. Globally, as of 2006, most targeted cancer therapies were in early stages of development.

¹⁰ Head and neck cancer generally includes cancer of the mouth, lip, tongue, oral cavity, salivary glands, larynx and pharynx.

¹¹ This means that only 5% of patients diagnosed with pancreatic cancer were expected to live beyond five years.

¹² M. Krishna Nair, Cherian Varghese, and R. Swaminathan, "Cancer: Current scenario, intervention strategies and projections for 2015," NCMH Background Papers – Burden of Disease in India.

BIOMAb Market

By the time the collaboration was finalized, CIMAB had already completed successful phase-1 trials for using BIOMAb to treat head and neck cancer. Although it could have directed phase-2 trials at other cancer indications, Biocon decided to retain the initial focus on head and neck cancer because of its high incidence in India – a consequence of the propensity of many Indians, especially lower income blue-collar workers, to chew tobacco and smoke cigarettes.

India's health care system consisted of both public and private sectors. The government-sponsored public sector, which provided free health care to consumers, accounted for 20% of overall health care expenditures in India.¹³ The remaining 80% of services were provided by the private sector, with virtually all of private sector costs paid out-of-pocket. While private sector health care was more efficient and accessible than public sector care, it was far more costly. A single major illness or hospitalization could consume, on average, 60% of a family's annual income.¹⁴

Venky Rao, senior manager of business strategy, expected more than 95% of BIOMAb patients would be self-paying. Given the high cost of cancer drugs, he estimated that just a few percent of patients could potentially afford the drug. However, he expected this number to go up over time, given that the Indian economy was growing by almost 9% annually – a trend that was expected to continue for a while. Potential market size could also be improved by educating end customers, targeting government and insurance companies, and charging a lower price for BIOMAb. Finally, India's annual population growth rate of 1.4% could also increase the market potential in the future.

Rao expected doctors to be more willing to use BIOMAb in conjunction with radio or chemotherapy during advanced stages of the cancer. He estimated that only 20,000 of the projected 190,000 patients per year would fall into this category. Finally, Rao knew that although BIOMAb's potential approval would be for head and neck cancer, off-label usage for other indications was common in India (see **Exhibit 5** for details on market size).

Competition

Although surgery, radio and chemotherapy were established treatments of cancer, Biocon saw Erbitux as its main threat. Erbitux was developed by ImClone Systems in the U.S. and approved by the USFDA in February 2004 for colorectal cancer. In the United States, ImClone had partnered with Bristol Myers Squibb to market Erbitux; outside the United States, the drug was distributed by Merck KGaA of Germany. Already available in 53 countries, Erbitux was introduced in India for treatment of colorectal cancer in April 2006. Total worldwide sales of the drug in 2006 exceeded \$1 billion.

Since 2004 Merck had been conducting clinical trials to extend the use of Erbitux to other indications such as head and neck cancer. In February 2006, it received approval from the European Medicine Agency, and in March 2006 from the USFDA, to use Erbitux in the treatment of head and neck cancer. Approved on the basis on an extensive, phase-3 study of more than 400 patients, Erbitux was, according to Merck, the first new drug in the head and neck market in more than 30 years.

¹³ "Country Health Profile – India; Development of the Health System," World Health Organization: Regional Office for South-East Asia, 9/8/04, http://www.searo.who.int/EN/Section313/Section1519_6810.html (cited 4/24/07).

¹⁴ Dr. Jayaprakash Narayan, "Healthcare as a Broad Public Challenge," The Financial Express, 12/29/06, http://www.financialexpress.com/columnists/full_column.php?content_id=150157.

Biocon learned that Merck expected to get formal approval from DCGI by late 2006 to use Erbitux for treating head and neck cancer in India. Erbitux, like BIOMAb, was based on a monoclonal antibody that targeted EGFR, but had the added benefits of three years of market usage experience for colorectal cancer and strong evidence from its clinical trials of efficacy for head and neck cancer. In the phase-3 study of 424 patients, combining Erbitux with radiotherapy prolonged median survival from 29.3 months to 49 months.¹⁵ Merck had initiated another phase-3 study with 442 patients to compare Erbitux combined with chemotherapy to the use of chemotherapy alone.

Although it lacked Erbitux's long history and phase-3 results, BIOMAb had significant advantages over its competitor. First, the Phase-2 results had shown 100% response in patients who used BIOMAb in combination with radio- and chemotherapy. Second, unlike Erbitux, BIOMAb did not produce skin rash among patients because it was only 5% (compared to 30% for Erbitux) chimeric (i.e., containing mouse cells). Finally, Biocon was hoping to leverage BIOMAb's "Indian" origins, it being the first ever proprietary drug developed and marketed by an Indian firm for Indian patients.

Launch Decisions

Mazumdar-Shaw had assembled a talented team of individuals to launch the product. In addition to Bamzai, Subir Basak was a key player. Basak joined Biocon as general manager of oncology after spending more than 15 years in the United States, most recently with Amgen.

Clinical Trials

The process of commercializing a drug typically began with preclinical trials with animals to gather sufficient evidence to justify clinical trials with humans. Four phases of trials followed. In phase-1, a drug was tested on a small number of volunteers (approximately 12-14), to evaluate its safety, determine a safe dosage range and determine its side effects. CIMAB had successfully conducted this phase for BIOMAb. In phase-2 trials, a drug was administered to a larger group of about 100 patients to determine its effectiveness and further evaluate its safety. Biocon had already successfully completed this phase for BIOMAb in India. Phase-3 trials involved administering a drug to larger groups, usually hundreds, of people to confirm its effectiveness, monitor side effects, and compare results to those obtained with commonly used treatments. Erbitux had recently conducted these tests for head and neck cancer. Biocon had not yet initiated phase-3 testing for BIOMAb. Phase-4 studies were conducted after a drug had been marketed to gather information on possible side effects associated with long-term use.

A. S. Arvind, COO of Clinigene, the clinical trial arm of Biocon, recounted the challenges in conducting phase-2 trials for BIOMAb.

We faced significant challenges in conducting phase-2 clinical trials for BIOMAb. It was a new molecule, not a me-too drug. Further, at that point, Clinigene was a new company with only a few years of experience in clinical trials. Add to it the fact that neither the regulators nor the doctors in India were used to doing a clinical trial for a new molecule. We had to first overcome the doctors' skepticism before they would even allow us to do the trials. We were able to leverage our personal rapport with the investigators at some of the major cancer centers such as the Kidwai Institute of Oncology. It also helped that there were only a few such oncology centers in India. This made the trials cost effective and relatively easy to monitor.

¹⁵ J.A. Bonner et al., "Radiotherapy plus Cetuzimab for Squamous-Cell Carcinoma of Head and Neck," *New England Journal of Medicine*, 2006, 354: 567-78.

Clinigene conducted phase-2 trials in which it compared the following four scenarios: radiotherapy only; chemo and radiotherapy; radiotherapy and BIOMAb; and chemo and radiotherapy with BIOMAb. Each cell contained 92 patients. Only 40% of the patients responded (i.e., the tumor was killed) when treated with radiotherapy alone. The results for the other combinations were 70% for chemo and radiotherapy, 80% for radiotherapy and BIOMAb, and a remarkable 100% for chemo and radiotherapy in combination with BIOMAb.¹⁶ It was on the basis of these spectacular results that Biocon had filed for accelerated approval with DCGI.

While these phase-2 results were sufficient to gain DCGI approval, Basak was not sure if they would be enough to convince oncologists to adopt BIOMAb given that BIOMAb had to compete against Erbitux, an internationally recognized drug strongly supported by evidence from phase-3 trials. With Erbitux for head and neck cancer expected to launch in India in late 2006, did it make sense to delay BIOMAb's launch? Could Biocon afford to risk forsaking the claim to being the first company to launch a head and neck cancer drug in India?

At the same time, Basak wondered if successful phase-2 results for multiple indications such as colorectal cancer would better position BIOMAb to compete against Erbitux. With time and marketing costs as the main constraints, Basak and the Biocon marketing team had to decide whether to launch BIOMAb for head and neck cancer with phase-2 results, wait for phase-3 results for this indication, or invest in phase-2 trials for other indications.

Product

The launch timing and market selection decisions were linked with the product portfolio decision. Among the options being discussed were to launch BIOMAb immediately, launch a group of cancer generics first and BIOMAb later, or simultaneously launch BIOMAb and other cancer generics.

Those who believed that the results of the phase-2 trials were sufficiently compelling for Indian oncologists to readily consider adopting the product argued for launching BIOMAb immediately. This group also believed that Biocon should field its own sales force to sell the product. "BIOMAb offers us a great opportunity to develop sales capabilities," maintained Basak. "The Indian pharma companies and the multinational firms have great sales organizations, and we need to build our own if we want to be a serious player in the oncology marketplace."

Concerns about the immediate launch option revolved around several issues. One was competitive reaction. "Erbitux is an established product and has proven phase-3 results," explained a senior manager, "we can expect competition to use this against us. It is easy for them to spread the message that BIOMAb had still not proven itself." Sales capability was another issue. "Selling insulin is not a good enough base for us to get into the oncology market," insisted a marketing manager, "we should first build our own sales capability by starting with a suite of cancer generics that we can very easily source from others and sell under our label. This will give us a chance to sell commodities to begin with and then migrate to high-end specialty products like BIOMAb around the time the phase-3 results become available."

Yet another group proposed launching BIOMAb along with a suite of cancer generics. This group argued that a single product would not be sufficient for Biocon sales rep to make a compelling pitch to oncologists who were inundated by other pharma reps. Rao explained, "While BIOMAb would be

¹⁶ The typical head and neck cancer patient in India lived for 12 months after initial diagnosis. Current studies had shown BioMab to be expected to extend patient life by, on average, three years, a number expected to go up as more long-term patient survival data became available.

the jewel in the rep's bag, the generics would help the rep get more face time with the doctor. Also, to go after multiple indications, we need to have a revenue base that justifies building a new sales organization. Others, however, worried that selling generics with BIOMAb might dilute Biocon's image as the first Indian company to have developed a proprietary drug.

Price

The BIOMAb team expected Erbitux to be priced at or near international price levels of approximately \$4,000-\$5,000 per dose. Given its superior trial results, BIOMAb could be priced at par or even higher than Erbitux. But it was common practice for local players to set prices in their own bands at a substantial discount to the global firms' prices. "The two-tier price structure is called the Indian brand discount," remarked Basak. "Customers expect it and the reps are locked into this mentality." This approach would put BIOMAb's list price at \$1,000 per dose. But Mazumdar-Shaw had mandated that the product team not fall into any stereotype: "We are an Indian firm that does novel things. Let's carve our own niche." Lack of any price elasticity data also made it hard to estimate the impact of price on market demand.

Mazumdar-Shaw's personal reputation and Biocon's image in the Indian market, however, would not permit a value-based pricing approach. "Unlike the United States," explained Rao, "most Indians do not have any health insurance. This completely changes the dynamic. Kiran wants us to come up with a price that is affordable, yet meets corporate objective."

While pricing below Erbitux made economic sense from the customer perspective, the BIOMAb team was concerned that a low price would affect the drug's credibility. "A low price on BIOMAb can very easily be used by doctors to rationalize a low quality image," observed Basak.

Further complicating the pricing decision was the difference between the treatment cycles of BIOMAb and Erbitux. BIOMAb's successful phase-2 trials were based on a six-dose treatment cycle. In contrast, Erbitux's trials were based on an ongoing (and indefinite) treatment plan. Explained an oncologist, "Once they get past the shock, the patient's next question revolves around the bottom line. It is an easier conversation for me when I can offer a clear treatment cost to the patient and their family." Some were concerned though that a total treatment cost approach could backfire were competition to emphasize that BIOMAb's numbers were based on limited trial data.

Channel

BIOMAb could be sold directly to doctors or through the traditional pharma channel. Like other bio-pharma drugs, BIOMAb's anticipated shipment volumes were not very large. "We are talking about very small batches of product to be shipped," explained Rao.

Further, unlike most other products, BIOMAb has to be refrigerated all the time and handled carefully. Given all this, the local pharmacy adds very little value. We can literally courier the product overnight to any oncologist using our own refrigerated packaging. All we need is the support of the clearing and forwarding agents (CFA). They typically have offices in each town that are ideally located. We could use this base to support our field sales organization as well. Going direct also cuts out the channel margins and has a significant economic benefit to the customer.¹⁷

¹⁷ BioMab's list price would be marked up 1%-2% by the clearing and forwarding agent (CFA). To this, the local distributor added a 10% markup. Finally, the retail pharmacist would further mark the price up by another 10%-15%.

Some team members still preferred the traditional channel option (Biocon → CFA → wholesaler → retail/hospital pharmacy → doctor), arguing that most physicians and oncologists had close, long-term relationships with a select set of independent and hospital pharmacies, and commonly recommended these outlets to their patients. The need for doctors to procure other drugs from this channel afforded an opportunity for the channel to push their way into the BIOMAb supply chain. Finally, there was the convenience factor. Doctors liked to have the flexibility to deliver treatment as and when appropriate. It was common for pharmacists to deliver drugs 24/7 to doctors' offices or patients' homes. It would be difficult for Biocon to offer this level of service were it to go direct.

Marketing Communication

The marketing team agreed that detailing would be the major means of communicating BIOMAb's benefits to oncologists. Explained Basak:

Detailing is a given in our plan. We are talking of an entire universe of less than 300 oncologists. Our initial target market would be less than a hundred of the leading specialists. Once the doctor has made the decision, the patient is not going to second guess.

But there was an opportunity to go beyond traditional detailing. Being a life-threatening disease, cancer caused high anxiety among patients and their families who could get only a limited amount of face time with doctors and specialists. Biocon could gain competitive advantage by providing much needed support and information to patients and their families. "We could provide information, help, and support to our patients through our web site, consumer help lines, our sales force, and direct to consumer advertising," explained Basak. "Some are even suggesting a campaign using celebrities. There are numerous stories of Indian brands getting a huge lift from celebrity endorsements."

Naresh Hasija, sales manager for North India, commented on the role of sales force,

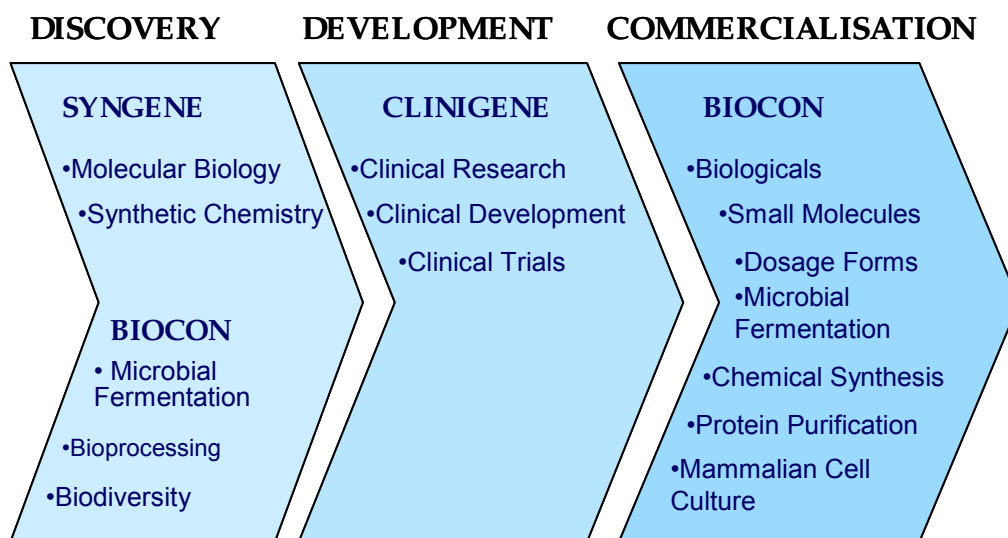
The doctors depend a lot on sales reps to educate the patients and their families. It is common for a sales rep to spend two to three hours with the patient explaining the product and its usage. The contact time and frequency is at its highest during the treatment period.

While recognizing all these possibilities, Basak cautioned,

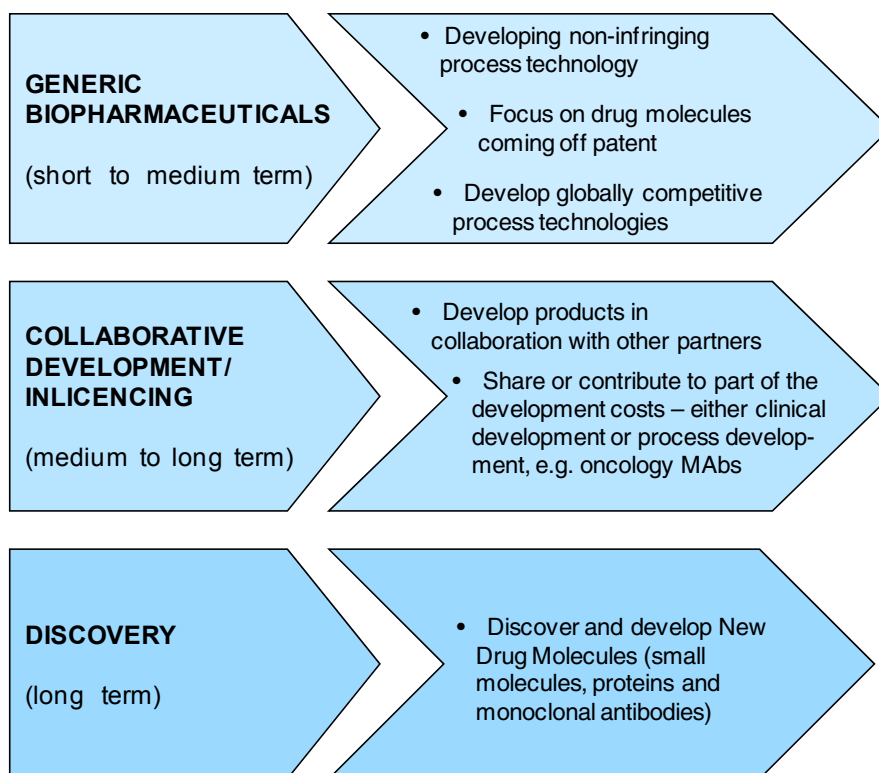
At this stage I want to make sure that we don't spend our valuable resources doing too many things. Also, I don't want us to do anything that would be seen as a publicity stunt and divert the attention of the doctors and patients from the true value of the product.

What Next?

Basak had a meeting scheduled with Mazumdar-Shaw the following week to discuss the marketing plan for BIOMAb. "We need an integrated launch plan," Basak concluded. "BIOMAb represents a unique opportunity for Biocon to redefine itself and alter the face of the fledgling Indian bio-tech market. We have to succeed."

Exhibit 1 Biocon's Integrated Business Model

Source: Company documents.

Exhibit 2 Biocon's Business Strategy

Source: Company documents.

Exhibit 3 Biocon's Profit and Loss for the Years Ending March 31, 2006, 2005, 2004

	2006	2005	2004
Rs. in Thousands ^a			
Income			
Gross Sales	7,246,713	6,824,047	5,309,108
Less: Excise Duty	371,789	378,423	290,284
Net Sales	6,874,924	6,463,624	5,018,824
Technical Licensing/Contract Research Fee	-	1,474	6,382
Other Income	56,911	156,513	9,256
	6,931,835	6,621,611	5,034,462
Expenditure			
Material Costs	3,790,109	3,441,546	2,553,672
Employee Costs	420,600	420,935	352,847
Operating and Other Expenses	867,009	673,189	498,934
Interest and Finance Charges	16,887	19,931	15,677
	5,094,605	4,555,601	3,421,130
Profit Before Depreciation and Taxes	1,837,230	2,066,010	1,1613,332
Depreciation net of transfers	228,496		
Depreciation		182,521	140,200
Less: Amount transferred from revaluation reserve		1,606	1,670
		180,915	138,530
Profit Before Taxes	1,608,734	1,885,095	1,474,802
Provision for Income Tax			
Current Taxes	208,633	98,298	194,453
Deferred Taxes	60,141	42,197	33,623
Fringe Benefits	5,130		
Net Profit For The Year	1,334,830	1,743,880	1,043,725

Source: Compiled from Biocon, 2006 Annual Report (Bangalore, India, 2006), p. 60, and Biocon 2005 Annual Report (Bangalore, India, 2005), p. 65.

^aUS\$1 was about Indian Rs. 45 in 2006.

Exhibit 4 Estimated Incidences, Mortality and Prevalence of Cancer for 2002 (in thousands)

	World			India			US		
	Incidence	Mortality	5-Year Prevalence	Incidence	Mortality	5-Year Prevalence	Incidence	Mortality	5-Year Prevalence
Lung	1,352	1,179	1,362	44	38	34	205	160	282
Breast	1,151	411	4,406	83	45	269	210	43	969
Colorectal	1,023	529	2,830	33	23	80	166	59	559
Stomach	934	700	1,474	34	29	46	22	13	37
Head & Neck	785	387	2,202	163	104	375	55	12	200
Prostate	679	221	2,369	17	11	43	240	32	1,037
Cervical	493	274	1,410	132	74	370	13	5	52
Liver	442	417	275	14	13	7	15	13	13
Esophageal	315	261	295	51	44	43	14	13	21
Pancreas	232	227	143	9	8	6	32	30	21

Source: Compiled from J Ferlay, F Bray, P Pisani, et al., "GLOBOCAN 2002, Cancer incidence, mortality and prevalence worldwide," *IARC CancerBase*, No. 5, version 2.0, (IARC Press. Lyon, France), <http://www-dep.iarc.fr/globocan/database.htm>, accessed April 2007.

Incidence: The number of new cases occurring.

Mortality: The number of deaths occurring.

5-Year Prevalence: The number of people diagnosed with cancer and still living after five years.

Exhibit 5 Market Potential of BIOMAb in India, 2007

Cancer Type	Incidence	Affordability	Number of Patients
Head and Neck	190,000	1.0%	1,900
Breast	93,326	3.0%	2,800
Lung	39,205	1.85%	725
Colorectal	37,213	3.0%	1,116
Brain	22,150	2.0%	443
Pancreas	10,325	1.25%	130
Total	392,219		7,114

Source: Biocon estimates.