The Role of Marketing

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Professor Alicia Loffler

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Prepared by:

Dario Benavides
Lanier Coles
Gary Dulaney
Vanessa Rath
Carla Yarger

THE ROLE OF MARKETING

Once a new drug application (NDA) or biologic license application (BLA) is submitted to the U.S. Food and Drug Administration (FDA), the marketing role in biotechnology and pharmaceutical companies becomes more apparent. The traditional roles of product, placement, price and promotion become central to the success of the launch; it typically takes 12-18 months of planning to effectively prepare for a product launch (Garret 2002).[1] However, early collaboration between R&D and marketing, via market planning and development, are crucial and often overlooked by small biotechnology firms. Pharmaceutical companies, conversely, have a better understanding of the importance of this relationship.

By evaluating biotechnology and pharmaceutical firms and their successes and failures in new product launches, we can begin to understand the impact of marketing in the early development of new treatments. In this Chapter, we first present a series of general observations on the current status of the marketing role in biotechnology, we then evaluate the marketing function for three biotechnology/pharmaceutical products (Viagra, Enbrel, and Natrecor) and how it was incorporated or neglected in the development of the drugs. From these development cycle profiles, we formulate our hypothesis that sophisticated early-stage marketing enhances the value of the products being developed. Furthermore, we postulate that both biotechnology and pharmaceutical firms stand to create more productive alliances if they attain a solid understanding of their market opportunities before entering such partnerships. Finally, from the findings of this paper we will make several recommendations to optimize marketing efforts in the development of biotechnology and pharmaceutical products. These observations and recommendations are based on a series of interviews and analysis of a panel of 30 biotechnology companies.

THE EVOLVING ROLE OF MARKETING IN BIOTECHNOLOGY

The biotechnology industry has been undergoing a significant transformation over the last decade and a half. The traditional business model, which included projected earnings 10 to 15 years down the road, is no longer viable. In the former era, biotechnology companies were predominately pure research-based companies, with little focus on marketing and commercialization. In contrast, today's biotechnology firms are adopting a more pragmatic model to appease their shareholders. Biotechnology firms have come to realize that a successful product launch is strongly correlated with a clear understanding of the marketing and commercialization issues associated with the product and its potential competitive arena. As this is typically not a core competency of biotechnology firms, many firms are forming alliances with pharmaceutical firms, traditionally recognized as having a strong marketing and sales infrastructure. In 2002 there were 31 deals between pharmaceutical and biotechnology firms valued at over $200 billion[4]. While this is a decrease in the absolute number of deals in 2001, the overall total value of the deals increased[4]. This new model seeks to introduce earlier revenue streams to cash poor biotechnology firms. However, according to Burrill, the majority of the big deals occur for late stage products. Pharmaceuticals pay, on average, $115 million for phase III products and the number of phase III deals has increased 53% over 2001 (Burrill 2003)[4]. Late stage products offer pharmaceuticals expensive but proven "quick fixes" for their ailing pipelines. One notable exception to late-stage deals is Roche, who typically prefers pre-clinical and phase I deals. In 2002, Roche struck two deals over $200 million with companies which had early phase products. According to Kevin Sachs and Gary Pinkus from McKinsey & Company, pharmaceuticals are overpaying for late-stage products to correct for their own pipeline deficiencies. The risks associated with earlier stage products are offset by the value creating deals. Furthermore, the additional risk can be diversified over a series of benchmarks.

On the other hand, a few historically research-based biotechnology companies are becoming more marketing/sales orientated and now, in some cases, compete with pharmaceutical firms. Examples include Amgen, Genentech, Biogen-Idec, Genzyme, and Millennium. Biotechnology firms attempting to incorporate marketing early in the drug development process will face many challenges, including a major shift in culture.

MINI CASE: VIAGRA - MARKET SAVVY RESEARCHERS DRIVE SUCCESS

There are many successful examples of marketing in the pharmaceutical field. However, none are so poignant as the case of Viagra.

Viagra is a blockbuster product for pharmaceutical giant, Pfizer. However, Viagra's path from discovery to commercialization was not straightforward. According to Pfizer's 1998 Annual Report, "marketing of prescription pharmaceuticals depends to a degree on complex decisions about the scope of clinical trials made years before product approval." The history of Viagra clearly demonstrates that wise strategic decisions made by researchers during clinical trials can have a direct impact on the marketability of a drug. In particular, the success of Viagra can be attributed to the marketing acumen of the original scientists who recognized the potential for a drug that targeted patients with erectile dysfunction (E.D.).

*The road to discovery***.** The original discovery team at Pfizer was led by Nicholas Terrett and Peter Ellis. In 1985 the team submitted a research proposal for a type 5 (PDE-5) inhibitor for possible application to hypertension. The registered chemical, UK92480, which is now known as Viagra, generated coronary artery activity, anti-thrombotic activity, enhanced nitric oxide and had an anti-anginal effect. Based on these findings, Pfizer entered clinical trials. In 1992, when Viagra was in its 7^{th} clinical trial, the research team was focused on finding a drug which would treat angina patients who suffered from chest pain caused by blocked arteries. One half of the volunteers in one of the trial groups listed increased penile erection as a side effect. The researchers noted that Viagra was also increasing blood flow to the penis. Suddenly, what was little more than a side effect had potential as an application for erectile dysfunction. In 1994, Pfizer launched a trial with 12 patients who had erectile dysfunction and found the effects of Viagra to statistically improve their conditions. Viagra received approval from the FDA for E.D. on March 27, 1998.

*The erectile dysfunction market***.** Viagra revolutionized the way that E.D. is treated. Viagra was the first oral medicine for the condition. Prior to Viagra's launch, the most common method of treatment was an injection. Traditionally, urologists had treated patients with E.D. but after Viagra was launched, primary care physicians became the main prescribers of the drug.

*Marketing***.** The first week after Viagra was launched, in April 1998, an astounding 4.3 million prescriptions had been written. By the end of 1998, more than 200,000 doctors had written 7 million prescriptions for 50 million tablets and it was being sold in 40 countries. Pfizer's pharmaceutical revenue in 1998 grew by 29%, with 12% of this growth attributed to Viagra, which had total sales of $788 million. Few drugs in history have attained such widespread use so quickly. Viagra has been called stage II of the sexual revolution, after the contraceptive pill, because of the effects it has had on society and society's attitude toward sex.

The Viagra case highlights the importance of market understanding and indication identification in early stage development. Pfizer was able to capitalize on a previously untapped market because of its marketing savvy.

MINI CASE: ENBREL - THE UNEXPECTED WINNER

Enbrel provides another interesting case study on the role of marketing in the biotechnology industry. Enbrel's failure to adequately conduct early market research precipitated a series that culminated with the acquisition of Immunex by Amgen.

In November 1998, the FDA approved a treatment for rheumatoid arthritis (RA) that took a new approach - using a genetically engineered version of a natural body compound. The product was Immunex' Enbrel. Enbrel works by binding to and inactivating certain tumor necrosis factor (TNF) molecules before they can trigger inflammation. The RA market is estimated to be approximately 5 million patients in the economically developed regions of the world and 2 million patients in the United States alone. Though Enbrel was eventually approved for indications outside of RA, in addition to further indications within RA, this case study focuses only on the initial indication and the associated clinical studies.

*Brief history***.** During the 1990's, a new class of drugs designed to attack the cause of rheumatoid arthritis, not just the symptoms, was being evaluated and researched. These drugs appeared to be effective without causing the usual side effects, such as stomach damage, associated with currently available drugs for pain and inflammation. Clinical studies were started for some of them, including Enbrel.

In September 1997, Enbrel passed Phase III trials and Immunex was preparing to file with the FDA sometime during the first half of 1998. In an interview with Edward Fritzky, CEO of Immunex, Fritzky stated that 1/3 of RA patients in the United States were not adequately controlled on their existing therapies and would therefore be ideal candidates for Enbrel [5](Fox News 1997). Later that month, Immunex signed a deal with American Home Products Corp. (now Wyeth) worth $100 million to market Enbrel for all indications outside

oncology. Since all indications to date were unrelated to oncology, AHP would essentially be fully promoting Enbrel.

In March 1998, Fritzky stated his belief that the overall potential of Enbrel would be approximately 1.8 million patients[6] (Dow Jones News Service 1998). This number was larger than initial predictions since Immunex now believed the drug would eventually be approved for earlier stage RA patients as well.

*Forecasting phase***.** In July 1998, an analyst at Adams Harkness & Hill Inc. projected a US patient base of 400,000 to 500,000 patients for Enbrel[7] (Dow Jones News Service 1998). This number reflected the number of persons who failed all traditional therapies. This number was then expanded when the European market potential came on-line. Sales of Enbrel, according to the analyst, were expected to be $139 million in 1999, $341 million in 2000 and $441 million in 2001. Actual sales in 1999 alone were $360 million.

The FDA granted approval of Enbrel in November 1998 for patients as a last line of treatment. In the same month, Immunex announced its plan to file a supplemental biologics license application with the FDA by the end of 1998 to market the drug for children. Wyeth, AHP's pharmaceutical division, also filed an application with the European Market for approval of Enbrel in Europe. Based on Immunex' quarterly SEC filings, industry analysts stated that Immunex believed first year sales of Enbrel would be greater than $250 million. These filings provided the first public indications that Immunex believed it had a better drug in its arsenal than industry experts had initially imagined.

The Good, the Bad and the Ugly. The good news was that Enbrel surpassed nearly everyone's expectations. An interview in February 1999 with Fritzky provided some insight on why Enbrel became a blockbuster[8] (CNBC 1999). Fritzky attributed the initial explosion in sales to overwhelming approval of the drug from both patients as well as health care practitioners. Fritzky also stated that company executives were conservative about sales figures because they

were concerned the initial figures might simply be a spike from trial users. This misestimation seems to underlie the basis of this paper: Immunex did not do an adequate job in researching its primary (or for that matter its total) market segment to determine potential adoption rates of Enbrel. By March 1999, 20,000 patients were signed up, with an additional 1,000-2,000 signing up each week.

In May 1999 the FDA approved Enbrel for use in juvenile RA. This essentially doubled the market potential from 500,000 to 1,000,000 patients. By this time, Immunex and AHP realized the bad news, that their original sales expectations were grossly underestimated. To meet demand, additional facilities were dedicated to manufacturing Enbrel. However, demand continued to exceed supply. By July 2003, thousands were on the waiting list, meaning millions of dollars in lost revenue.

What went wrong? Immunex did not adequately perform market research which resulted in the underestimation of the Enbrel market. Though it seems Immunex correctly sized the market, they seem to have overestimated the 'attrition rate', or the rate at which patients would try Enbrel but would not continue with it. Immunex may have gained insight with a more rigorous marketing research campaign during the clinical trials. As it stands, AHP and Immunex did not realize Enbrel was a blockbuster until it was too late. Therefore, manufacturing constraints inhibited Enbrel's success for approximately three years. Had Immunex applied more marketing resources to their research efforts, Immunex's story might have been very different today.

*Hindsight is 20/20***.** It is easy to state the lack of effective marketing/market development which lead to negative results at early stages of drug development. But, what happens when a drug under development is a breakthrough product with no analogue for comparison, as was Enbrel?

Forecasting market demand for a first-in-class, revolutionary product is a more complex task than it is for an evolutionary product. Enbrel, a first–in-class

therapy for RA, exceeded the expectations of almost every expert in the field. According to Wyeth, Enbrel was the first biologic created to treat RA. Aside from Epogen and Procit, there were no other blockbuster biologic products currently on the market. "The FDA was very concerned about immunologic problems (cancer as secondary effects) with Enbrel but safety proved to be higher than anticipated. Dealing with Enbrel was about dealing with the unknown, with no analogue for comparison.[9]" (Wyeth's visit 2004)

Immunex recognized that it could not market the product alone and turned to Wyeth Pharmaceuticals for support. However, even with Wyeth's core competency of marketing, it was difficult to predict the uptake of Enbrel by rheumatologists.

The Enbrel life cycle has been a roller coaster ride of facts, claims, studies, additional indications, and FDA approvals. Bringing in a marketing-based pharmaceutical company to help promote the drug and size the market is a potential solution, but this does not absolve a biotechnology firm from conducting in-depth marketing research. In Enbrel's case, it is evident that more comprehensive and earlier-stage market research at Immunex would have led to millions more in revenue for Immunex and its partner, Wyeth. And perhaps it wouldn't have resulted in the acquisition of Immunex by Amgen

MINI CASE: NATRECOR - BETTER LATE THAN NEVER

Scios' drug, Natrecor, is an example of a drug that was successfully launched and marketed by a biotechnology company. However, when the company was sold to Johnson & Johnson ("JNJ") in 2003, the opportunities for the drug expanded because of the reach and the relationships of JNJ's sales force and the complementarities between Natrecor and certain existing JNJ products. Additionally, under the JNJ umbrella, Natrecor could be marketed in additional settings that Scios could not reach on its own. How much value could

have been created and captured had Natrecor addressed these additional markets from the beginning? Although Scios had partnered with GlaxoSmithKline (GSK) for the European marketing rights to Natrecor, they did not have a big pharmaceutical partner to help them with the marketing of Natrecor in the US until after the product was already on the market. Although it is difficult to quantify how much money Scios lost by delaying a partnership with a pharama giant, it is not difficult to recognize that the synergies created by JNJ/Scios for the promotion of Natrecor could have been realized earlier had Scios partnered for US sales prior to launch.

*About Natrecor***.** Natrecor (nesiritide) is indicated for the treatment of acute congestive heart failure. The product, a recombinant B-type natriuretic peptide, is a synthetic human hormone, which causes a vasodilatory response, and represents the first approved treatment for acute congestive heart failure (CHF) in nearly 15 years. The FDA approved Natrecor in treatment of acute episodes of CHF on August 13, 2001 and the drug was launched in September 2001.

Scios' marketing and commercialization plan. As of February 13, 2003, two and a half years after launch, Scios' marketing and commercialization efforts for Natrecor were still progressing. Approximately 88% of the targeted hospitals stocked Natrecor. Of those that stocked the drug in the third quarter of 2002, 87% reordered it in the fourth quarter. The FUSION (Follow Up Serial Infusions of Nesiritide) pilot study, which was evaluating the safety and feasibility of follow-up serial infusions of Natrecor, was nearing completion. The ADHERE (Acute Decompensated Heart Failure National Registry) Registry had enrolled over 35,000 patients. Over 350 clinicians and staff attended the second annual 2003 ADHERE National Meeting in Palm Springs earlier in 2003. Enrollment continued in the longitudinal study module of the ADHERE Registry that was set to follow patients with advanced heart failure for up to two years to assess change in quality of life as a function of medical management and disease progression. Six abstracts related to Natrecor and acute congestive heart failure

were scheduled to be presented at the 2003 American College of Cardiology (ACC) Annual Meeting in Chicago (March 30 - April 2).

Later in February 2003, Scios announced that it was selling the company to JNJ and the acquisition was completed on April 29, 2003. Under the terms of the transaction, Scios shareholders would receive $45.00 for each outstanding Scios share. The transaction was valued at approximately $2.4 billion, net of cash.

*Biotechnology/Pharmaceutical synergies***.** At the time of the announcement, analysts believed that Natrecor could probably develop at a much faster rate with JNJ's institutional sales force and marketing efforts. Morgan Stanley's analyst covering Scios at the time of the acquisition announcement estimated that US sales of Natrecor in 2006 would be $336 million, assuming a successful result from Scios' FUSION trial, which was exploring earlier-stage use of the drug. It was assumed that JNJ had seen this data prior to the acquisition and thus viewed it as a reason to move forward on this transaction. The Morgan Stanley analyst covering JNJ at the time of the announcement thought that JNJ could potentially grow sales of Natrecor to levels of $600 million in the US in 2006, suggesting the synergies between JNJ and Scios could lead to an increase of approximately $264 million in sales in 2006 for Natrecor. Together, Scios and JNJ were considering new formulations with new administration alternatives using JNJ's Alza drug delivery technology.

The primary area of potential synergy was believed to exist in JNJ's extensive sales force and relationships in its Centocor and Ortho Biotechnology divisions. Natrecor was launched in September 2001 and Scios has thus far addressed the congestive heart failure (CHF) opportunity through the clinical cardiologist. Centocor and Ortho Biotechnology would add their respective strong relationships in the emergency room and critical care unit – a potentially huge untapped market for Natrecor. Natrecor would complement the sale of Cypher, a sirolimus-eluting stent, and Centecor drugs ReoPro (abciximab) for acute coronary care, and Retavase (retaplase) for heart attacks. JNJ and Scios

also planned to expand Natrecor to the outpatient setting for less severe heart failure, based on results of Scios' FUSION phase II trial, as well as in hospital settings and emergency rooms.

In the case of Natrecor, Scios gained additional revenue from a product through synergies realized once it was purchased by JNJ. If Scios had identified these potential synergies earlier and done a more thorough assessment of its stand-alone ability to obtain sufficient reach for the product, it may have partnered (rather than sold) at an earlier stage and reached peak Natrecor sales sooner.

OPTIMIZING THE MARKETING FUNCTION

Based on our field study we were able to extract some general observations that help maximizing commercialization efficiencies:

*Partnering at early stage of drug development***.** Small biotechnology companies, specifically those without a commercial product but with a promising pipeline, can pursue different paths to profitability. Our field research suggests that one path, is for a firm to obtain funding and mitigate excess risk by partnering with a big biotechnology or pharmaceutical company that has experience bringing biologic products to market. CURIS, a Boston-based biotechnology firm that focuses on regenerative medicine, is a good example of a company that pursues this path. It has various promising molecules at the pre-clinical stage and has already signed a co-development agreement with Genentech for one of these drugs, in addition to two other deals with Wyeth and JNJ. These strategic alliances provide CURIS with upfront cash and a share of future profits if the drugs reach the market. Furthermore, they also increase the probability of these drugs making it to market based on the marketing and approval process expertise that the partners bring to the table. However, in order to maximize how much CURIS will receive in such strategic alliances, it must have an accurate picture of the

potential value of its pipeline. This will help to increase its negotiating power and ensure that it is not being taken advantage of in the deal making process. This assessment can only come through detailed, early stage market research.

*Early stage market development***.** Clearly an efficacious marketing effort in the early stages of drug development is critical to the success of a biotechnology company. However, small biotechnology companies are science-driven and have limited financial resources, the marketing role is often left to the corporate development or business development functions, if it is performed at all. Our field research suggests that in small biotechnology firms, functions are all interrelated and no marketing department exist[10] (Curis and Immunogen visit 2004). Typically, the strategic planning group conducts marketing for early stage drugs. Yet some of these small companies have been able to incorporate robust marketing functions within their business development departments. Again, CURIS is an example. "In the development process, it is extremely vital to determine early on which direction you put a product to market and into what indication. A successful product development effort must reflect commercial interests and consider reimbursement issues. Sometimes, biotechnology firms focus too much on science and can forget about the business part.[12]" (Missling 2004)

There are two key elements needed to establish an early development marketing function: 1) People, finding qualified people to conduct this activity; and 2) Attention, a serious realization from senior management of the importance of marketing.

People that will be effective in early development marketing should have a clear understanding of science as well as an understanding of pharmaceutical/biotech marketing principles. People that are comfortable dealing with very loose statements and thrive in unstructured environments and can make qualitative assumptions are usually high performers. "Human beings are not used to making assumptions, they tend to avoid them. (Missling 2004)[13]"

In the biotechnology industry, the earlier the assumptions are made for understanding the potential market, the better off the firm is in its ability to estimate the potential of a drug. The process for estimating a potential molecule market is an iterative process and therefore requires a person with good interpersonal skills to interact with many people, including scientists. "At CURIS, the process to estimate a market is an iterative process, and I always involve people in order to obtain buy-in. (Missling 2004)[14]"

It is also vitally important to gain senior management's 'buy-in' regarding the importance of the marketing role. Management is usually too focused on funding issues and forget about other, very important, functions of their companies. There is also a tendency to believe that the drug benefits alone will be enough to successfully sell an approved product.

Genentech has made the successful transition from a small biotechnology to a leading biotechnology company by both understanding the importance of marketing and cleverly integrating it with the science. Genentech still possesses a scientific culture by allowing its scientists to explore a wide array of drugs. However, the scientists are not completely free to explore. The marketing department has essentially created key disease areas that have market potential. Scientists are then allowed to explore molecules within these disease areas, and marketing understands that any developments have an identified market. This creates what almost amounts to a 'checks & balances' system between the R&D scientists and marketing groups. Furthermore, it gives the scientists freedom to innovate and the marketing group assurance that the new developments will have viable market potential.

A FRAMEWORK FOR EFFECTIVE MARKET PLANNING AND ANALYSIS

Strategic marketing and its incorporation throughout the drug development process is a key to the success of new product development at both biotechnology and pharmaceutical companies. There are several key marketing

considerations that should be examined well in advance of a product launch. In order to optimize the marketing efforts in the development of new biotechnology and pharmaceutical products, it is important for companies to examine these factors while the product is in development. Figure 1 provides some of these considerations at key points during the drug development process.

Although this model was designed for a large pharmaceutical company with a larger marketing staff than many small biotechnology companies, it can still be effectively utilized on a more informal basis at smaller companies. Smaller companies may find this model useful in identifying key marketing related considerations at various stages throughout the drug development process.

In the R&D phase, it is important to identify the intellectual property positions on the compounds and review the discovery efforts to ensure they are in line with the overall strategic priorities of the company. The marketing team at CURIS is very proactive about including themselves in the market planning process as early as possible in the R&D phase. Because the company is smaller and has limited funds for the very expensive development process, it must carefully select the potential products to pursue and then choose which ones to partner and which ones to develop alone. To do this, the marketing team makes assumptions and builds estimates of the potential US markets for the products and indications that might be coming out of its R&D department. It can then make more informed go/no go decisions and be more knowledgeable for potential partnering and alliance negotiations.

During the preclinical phase, it is important for companies to begin developing a vision for the potential product as well as to identify the key attributes and value drivers that will make the product succeed.

Once they enter phase I clinical trials, the company should be able to identify the minimum attributes that the compound must demonstrate in order to

achieve success. During phase I/IIa trials, the company should also start to examine the patient flow within the market they are hoping to enter, identify what clinical endpoints they will eventually have to achieve in order to effectively compete with products currently on the market, and begin to think about the potential economics and pricing of the product they are developing. During phase IIa trials, the company may also want to begin targeting key physicians, patient groups, and thought leaders in order to solicit important market research information and to increase awareness and acceptance of what the company is developing. After collecting this information, the company should be able to make some informed management decisions regarding the clinical trial strategy going forward and garner more clarity into likely investment levels. The company should also have a solid understanding of the competitive landscape and what the positioning strategy of their product will be.

During the phase IIb/III stages of development, the company should be developing a publications plan, identifying and communicating with key opinion leaders, and finalizing pricing and reimbursement strategies. During filing, the company should work to ensure that they have a competitive label and an appropriate channel strategy. After launch, the company needs to begin the process of life cycle management and start to examine new claims, indications and formulations for the product.

If companies are proactive about incorporating marketing earlier in the development cycle, they will be well prepared to launch and will be able to accelerate the time to peak sales. In biotechnology and pharmaceuticals, this is particularly important due to intellectual property concerns. Because there is only a limited amount of time that a drug is covered by its patent, companies should strive to attain peak sales as soon as possible in order to maximize their time at peak before patent expiry.

Biotechnology firms are often small organizations, with limited resources and a focus on early stage drug development. For these firms, the marketing

effort is often over-looked. Based on our analysis, we believe that these firms will be better positioned over the long run if they allocate human resources to the marketing function at an early stage in the development cycle.

Some general important reasons for incorporating this early stage marketing include:

1. Market planning contributions can include key insights into go/no go decisions, optimal indications, clinical outcome endpoints and economic benefits.

2. The market planning process gives information about potential end users and to determine the acceptance and adoption of new products. Similarly, clinical trial information that satisfies not only safety and efficacy but also commercial endorsement is essential for maximizing profits. Safety and efficacy endpoints help to guide decision makers towards the potential levels of success for a product. If the expected outcome of a drug falls short of end user expectations, companies avoid huge investments in further clinical trials.

3. Allows the selection of optimal indications (see Viagra case). Once the FDA accepts a drug for a certain therapy, that lead indication sets the tone for the entire product life cycle. Market size, competitive landscape, ease of data collection and physician preference are a few important factors to consider when determining the most advantageous indications for new drugs. "Quantitative market research that analyzes physician preferences measured against factors such as price and efficacy can help the project team determine what the lead indication will be. (Garrett 2002) [15]"

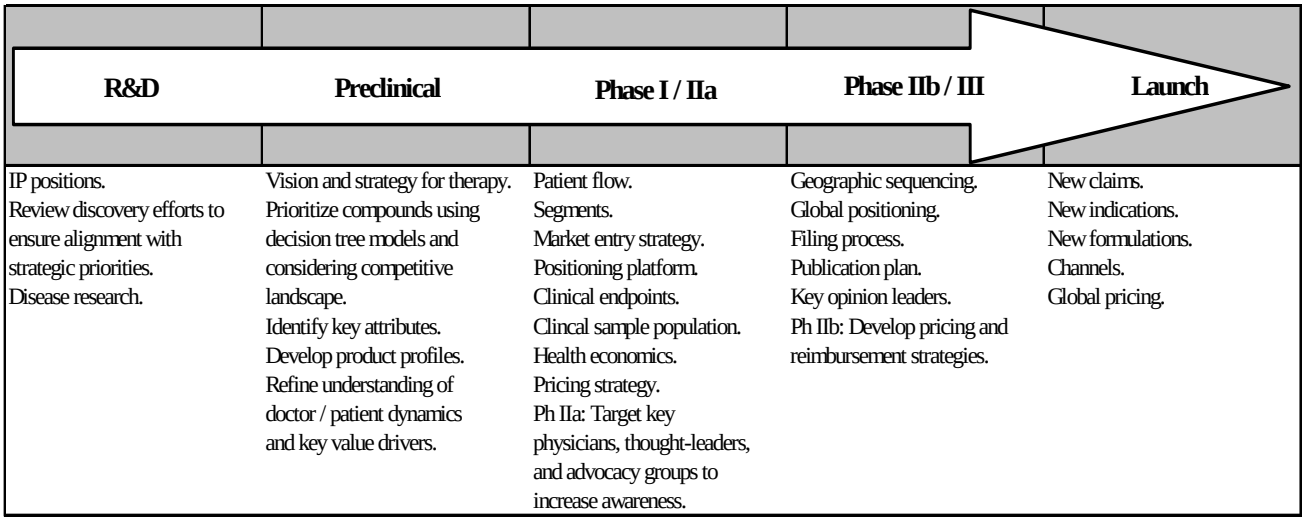
4. Market research, focused on future consumers, plays an important role in clinical outcome endpoints. Recently, the FDA has begun to require an 'outcomes' component for every NDA submission. This component

typically consists of significant differentiation for similar products. A clear example of this outcome is Viagra and Cialis, where the latter was the second to market product with clear and significant clinical improvements in outcome endpoints. Thus, by incorporating the marketing research function earlier into the development process, a firm can increase its understanding of consumer needs and its ability to create clearly differentiated new products.

5. Early marketing allows biotechnology companies to link economic benefits to clinical benefits. "The planning team must capture the appropriate pharmacoeconomic data in the clinical design of phase III clinical trials to generate economic benefit data that are consistent with managed care organization evaluation guidelines." (Garrett 2002) The objective of these firms should be to reduce organizational risk, maximize success potential, and avoid unprofitable investments.

Finnally, the benefits of incorporating marketing into drug development earlier are multiple. In the case of Enbrel, Immunex underestimated the size of the market and lost millions of potential dollars as a result. Early stage marketing incorporation will allow small biotechnology companies to make more informed decisions throughout the product launch process. It may also position smaller biotechnology companies more favorably in the negotiations of strategic marketing alliances. In the case of Natrecor, Scios gained additional revenue from a product through synergies realized once it was purchased by a larger pharmaceutical company. If it had identified these potential synergies earlier and done a more thorough assessment of its stand-alone ability to obtain sufficient reach for the product, it may have partnered at an earlier stage and reached peak Natrecor sales sooner. A distinguishing factor of a market oriented biotechnology firm is its ability to recognize the potential value of early stage pre-clinical molecules and form deals with the right partner, at the right price, and at the right time.

Figure 1. Framework for Marketing Planning Process



R&D	Preclinical	Phase I / IIa	Phase IIb / III	Launch
IP positions. Review discovery efforts to ensure alignment with strategic priorities. Disease research.	Vision and strategy for therapy. Prioritize compounds using decision tree models and considering competitive landscape. Identify key attributes. Develop product profiles. Refine understanding of doctor / patient dynamics and key value drivers.	Patient flow. Segments. Market entry strategy. Positioning platform. Clinical endpoints. Clincal sample population. Health economics. Pricing strategy. Ph IIa: Target key physicians, thought-leaders, and advocacy groups to increase awareness.	Geographic sequencing. Global positioning. Filing process. Publication plan. Key opinion leaders. Ph IIb: Develop pricing and reimbursement strategies.	New claims. New indications. New formulations. Channels. Global pricing.

Source: Johnson & Johnson and student interviews.

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