BioSpectrum
the business of Bio & Health Sciences

Product failure leads to public, investor scrutiny

11 October 2011 | News

Image not found or type unknown

Image not found or type unknown

Mr Sanjeev Saxena
Chairman & CEO Actis Biologics

The author brings over 22 years of experience in bio-pharmaceutical industry. Mr Saxena founded Actis Biologics in California in 2003 with well-known scientist Dr Dave Toman. Then, he founded Actis Biologics in Mumbai in 2005. He further expanded the group to Malaysia by forming Actis Biologics Malaysia in 2007. He also founded ProGenix Biotech in California and Sepragen Corporation in the US.

While the much-awaited economic recovery was a major let down in the last couple of years, it is interesting to note that many biopharmaceutical and biomedical companies reported record-breaking profits in 2010.

The current year is expected to be very challenging as a result of patent expiry and impending generic competition frommany pharmaceutical and biotechnology companies. This brings about great opportunities for the research-based biotech industry. Big pharma companies have no place to go for innovation, except to acquire smaller companies who have already taken the risk on new drug development. Consolidation has accelerated in the last two years because the capital markets are tough, making M&A an attractive exit strategy for investors.

Challenges in marketing
Biotechnology companies have their own set of challenges in marketing drugs by themselves. One of the major issues they face is financing. The financing they gather goes into the development of various molecules and, hence, marketing and sales become an issue. Also, the sales and marketing professionals prefer to be employed by more robust and well-established

brands and companies, so recruitment is a key issue.

There is also pressure from investors to provide quick returns on investments and are unwilling to wait for the length of the product life-cycle. So, the biotech companies are forced to look for partners in the large pharmaceutical companies, though they are no more or no less successful than the pharma giants when it comes to drug development. Presently, it takes 10-to-12 years for a biotech drug to make it to the market. It is also interesting to note that while the industry starts with over 10,000 leads, only about 250 make it to the preclinical stage and only 50 make it to phase I trials, of which only three to four make it to phase III trials. Out of these promising molecules, the industry makes a decision on which drug to take forward into phase III and the market based on market potential, competition and cost of manufacturing.

While it is true that most phase III molecules work, the market realities can make a company drop the product from its pipeline. Some of the phase III drugs are then repositioned as was in the case of Viagra, for a different indication. Hence, for biotechnology start-ups, the stakes are extremely high. Large companies have many successful products in the market. A biotechnology company's continued existence depends on the success of those one or two products. Therefore, failure is much more public and highly scrutinized. It leaves investors and the public with little or no incentive to remain supportive of the company.

As a result, business development deals or strategic partnerships have emerged as a vital part of resources that biotechstart-ups leverage to become successful. Pharma MNCs are currently confronted with a number of blockbuster drugs coming off patent, so corporations are increasingly looking at biotech start-ups for access to new products to fulfill their development pipeline. About one-fourth of the new drugs launched in the past year were the result of collaborations between companies.

There are three major forms of strategic alliances that biotech firms can utilize: licensing technology, full collaborations on R&D and commercialization, and limited agreements on co-marketing or co-promotion. The benefits go beyond financial resources. For instance, the pharma companies can provide the biotech companies with development experience and expertise, regulatory approval support, commercialization capacity (sales and marketing), and manufacturing expertise and resources, all of which are essential for the success of the product in the market.

Need for early involvement

People outside the biotech industry tend to assume that marketing biotech products is easy because of a built-in demand for cutting-edge products that extend life or enhance the quality of life. They assume that the customers will come to their doorstep the minute an exciting new product gets FDA approval. In fact, the opposite is true. Unlike funding, where most people agree on its importance for the success or even the survival of biotech start-ups, the understandings of the marketer's role in the company are often mixed. Because most biotech companies are founded and managed by scientists, marketing is often introduced late, as if the marketer's role only becomes important once the is product is available for sale. We, at Actis, have realized the importance of marketing and the importance of telling this story early and, hence, have brought together a diverse group of individuals to build the company.

There are several reasons why the management should involve marketing early in the process. First, marketing needs to be involved to better assess market potential and commercial viability to guide investment decisions. Based on the analysis of the market size, growth rate, and unmet medical need, the firm can determine therapeutic areas to focus on and develop the product to ensure a high commercial potential. In addition, management should involve marketing in the clinical trial design process as well to make sure that the end points of the trials are commercially meaningful. For example, an end point of 15 percent reduction in cholesterol level would have a very different commercial implication than the end point of 10 percent reduction on cardiovascular associated mortality and morbidity events for a cardiovascular product.

Furthermore, it is important to align the company's scientific messages with its marketing messages early in the pre-market process to ensure a successful launch. It is critical for scientists and management to start communicating the potential value of a product at conferences and seminars or though scientific publications before the product launch. This enables them to get key opinion leaders on board early enough to build a solid foundation for a successful launch.

The biotech industry today faces a lot of hype and attention and it's difficult to combat the over-generalized press. Marketing in biotechnology needs to foster objectivity, report facts and steer clear of hype. Truth needs to be communicated to both stakeholders and the public.

Annual reports are good story-tellers

So, what is the best vehicle for marketing in life sciences? I believe, it's the annual report of the biotech company. Despite the fact that privately funded life science companies aren't required to publish annual reports and despite the fact that most hardcore biotechnology and life sciences drug development companies — besides the CROs and the instrument manufacturers — don't profit until after 10 or more years of trying to develop a successful product, the annual report gives them a vehicle to communicate their processes and the investments made in their efforts. It communicates the commitment to the cause.

Most biotech companies use it as a way to communicate their company’s story, passion and motivation to succeed. They show the process of what it takes to make it happen, the larger global benefit of the contribution. The readers of the report get an appreciation for the challenge at hand and take a long-term view of the efforts. Hence, annual reports can be an intelligent and an extremely powerful way to communicate with your stake-holders, doctors and the media. Smart companies will even want to use that power more than once a year with periodic reports focused on portions of their companies’ endeavors.