

## Life Sciences: Major Market Challenges

To understand the major market challenges facing life sciences companies, one only has to think about how the industry is changing. Greater cost pressures are forcing companies to become leaner and more efficient. Fiercer competition is driving increased pressure for innovation and shorter time-to-market. And the aging world population is creating increased demand for new and better drugs and medical devices. Balancing the response to these changes is challenging—it takes clarity of vision, strong leadership, and a willingness to accept that the business practices, philosophies and strategies of yesterday are not cut out for tomorrow.

*“I believe treatments that would have been regarded as miraculous ten years ago will be in common use in the future.”*

**Sidney Taurel**  
CEO & Chairman, Eli Lilly

### Executive Summary

Ask an executive from the life sciences industry what keeps him or her up at night and you'll hear a long list of concerns: driving innovation, filling the product pipeline, accelerating speed-to-market, managing costs, competing with generics and dealing with an increasingly complex regulatory environment.

Executives are right to be concerned. For starters, new product development is not keeping pace with the loss of patent protection. This year alone, drug companies will absorb \$16 billion in patent losses. Among them, Sanofi-Aventis will lose its patent on Ambien, GSK will lose its patent on migraine medicine Imitrex, and Pfizer's patent on Lipitor, which has earned the company \$12.9 billion since it hit the market, will expire in 2011. While expiring patents can be good for consumers, drug companies are barely able to recover their huge investments before they're forced to compete with less expensive generics.

At the same time patents are rolling off, the pipeline of new products is growing shorter. In 2006, U.S. regulators approved only 18 new drugs, close to an eight-year low.

It's not for the industry's lack of trying, however. Between 1993 and 2004, drug companies saw research and development costs rise 147 percent—from \$16 billion to \$40 billion. The reason is that niche products are replacing blockbusters as the source for future growth. As companies attempt to treat more complicated and targeted diseases, they're spending more on research but developing fewer drugs.

Meanwhile, with the cost and demand for newer, better drugs and devices continuing to rise, public and private payers are putting increasing pressure on the industry to bring prices down and make more generics available sooner. According to the Generic Pharmaceutical Association, generic drugs accounted for 56 percent of prescriptions in 2005, up from 20 percent two decades ago. That's due at least in part to health care payers using formularies, tiered co-pay plans and marketing to sway consumers to generics.

With so many external pressures, which market challenges should life sciences companies focus on? We believe the top priorities should include:

- Improving operational efficiency
- Integrating IT with the business
- Contending with emerging players
- Adjusting to a changing political climate
- Embracing emerging biotechnology

Making smart business decisions and implementing industry best practices will provide the solid foundation from which these challenges can be addressed.

## Improving Operational Efficiency

It's challenging—running an efficient, effective and profitable business while stimulating cutting-edge innovation. That's why for many companies, achieving operational efficiency remains an elusive goal...and why the benefits from integrated systems, supply chain optimization and outsourcing are yet to be fully realized. Still, there's no question that the operating models that have been in place for more than four decades will not support the current market environment.

The single most important aspect of improving operational efficiency will be tied to creating robust and diversified product pipelines. The blockbuster drugs of the 1980s and 90s are losing patent life and the pipelines to replace them are nowhere near the level necessary to support current business models. Large drug companies are spending upwards of \$1 billion annually on product development life cycles, which are running at an efficiency rate of 5 to 7 percent. This is not sustainable in a market that is increasingly competitive and cost conscious. Moreover, the therapeutic categories that hold the most promise require complex and expensive clinical studies, further increasing development costs and time-to-market.

**Implications:** Restructuring efforts—such as increasing productivity, making quality control improvements, divesting excess capacity at manufacturing and distribution facilities, and right-sizing workforces—will continue to be a common theme. New system implementations also will play an important factor. Business analytic tools, for example, provide the ability to consolidate and analyze data that can be used to make better-informed decisions. Executed effectively, business analytic strategies improve supply chain operations, sales and marketing results, and financial performance.

Forming new strategic partnerships also will contribute to operational efficiency. University-based consortiums will have the potential of keeping costs low while reducing the number of early development failures. In addition, beneficial combinations of products will bring new alignments between the makers of pharmaceuticals and medical devices which could lead to more horizontally integrated firms. The challenge here will be managing the different development approaches and approval processes for drugs versus medical devices.

## Integrating IT with the Business

Despite the fact that information technology plays a large role in operational efficiency, IT departments within life sciences firms still lag behind their counterparts in other industries when it comes to being viewed as a strategic business partner. According to a recent survey conducted by Clarkston Consulting, 86 percent of IT executives say they are not actively involved in formulating their company's business strategy. Furthermore, the majority of respondents said the IT strategy is not an explicit part of the enterprise strategy. As a result, budget allocations, resources and priorities are often misaligned. Ultimately, when CIOs are left on the sidelines as observers of the business planning process, IT departments are less able to respond to the changing technology needs of the business.

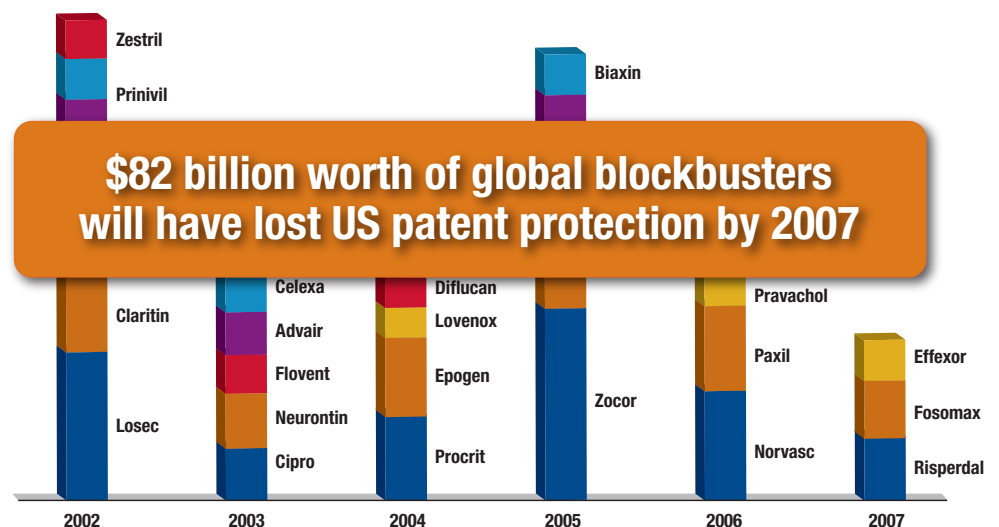
**Implications:** With IT spending at most life science companies growing faster than revenues, closely aligning the business and IT strategies is more important than ever in developing a successful enterprise strategy.

IT departments should also be mindful of the perception they create with end users. To be viewed as a strategic partner, they need to improve support and training, standardize business processes and provide quality customer service.

The more tightly integrated IT becomes with the business, the more benefits the business will realize. IT can help a company track research and development progress, measure the effectiveness of sales and marketing initiatives, and help it better manage the unique compliance and reporting requirements that come with operating in a highly regulated environment.

### Blockbuster US Patent Expires, 2002-2007

Source: Datamation, Orange Book



## Contending with Emerging Players

Industry growth is shifting from mature to emerging markets. For years, the Far East was a key player in the manufacturing of active pharmaceutical ingredients (APIs)—fine chemicals that were then meticulously combined in the United States and Europe to create blockbuster drugs such as Allegra, Cialis, Lipitor, Nexium and Viagra. However, over the past several years, firms in countries like India, China and Singapore have gone beyond the role of producing APIs to becoming full-fledged, multi-national pharmaceutical firms with the capability to research, develop, test, produce and market their products worldwide. These companies operate in countries with an enormous pool of low-cost resources, and the population base they could serve far exceeds those of the industrialized West. In short, they have become a force to be reckoned with.

**Implications:** Life sciences companies based in the United States need to determine whether these emerging players can be leveraged as effective outsourcing or off-shoring resources. However, U.S. companies must proceed with caution because many countries have not yet enacted laws and regulations that effectively protect the integrity of intellectual property. Established companies must also explore ways to modify the structure of clinical studies to address differences in the healthcare delivery systems of these nations. By doing so, they'll be able to eliminate inefficiencies associated with current development cycles. Supply chain issues also may prove challenging, as moving products—particularly biologics—halfway around the globe could be costly.

U.S. based life sciences companies also will face many of the same obstacles that come with operating any type of global business, such as addressing communication and cultural barriers, implementing consistent operating platforms, facilitating the transparency of data across markets, managing a global workforce, and dealing with varying compliance requirements at home and abroad. As the IT and manufacturing industries have demonstrated, these challenges should not be underestimated.

## Adjusting to a Changing Political Climate

For the first time since 1994, Democrats are in control of both houses. This shift in power could alter the landscape of the life sciences industry. From drug pricing, to the Medicare Part D initiative, to the authority Congress has over the Food and Drug Administration (FDA), the changing political climate will have a significant impact. Already on the agenda for this year are plans to reform the FDA, improve drug safety, and reauthorize the Prescription Drug User Fee Act (PDUFA).

**Implications:** The life sciences industry will need to work more collaboratively with government and regulatory organizations to find solutions that effectively balance the needs of the industry with those of consumers. Biosimilars is one such area. Barr Pharmaceuticals Inc., the second-largest maker of generic drugs

in the U.S., is petitioning Congress to allow generic drug makers to sell competing versions of biotech medications when they lose patent protection. These products have been making their way into European markets at a significantly reduced price to consumers. Both PhRMA and BIO are lobbying Congress and attempting to influence the FDA on standards that allow the introduction of these products into the U.S. while minimizing the negative impact on the original manufacturers.

Another area of possible concern is the Medicare Part D initiative, which is highly dependent upon leveraging generic drugs. With the federal government accounting for 60 percent of the buying power in the pharmaceutical industry, it has a profound impact on how drugs are priced and marketed and how quickly generic drugs are able to go to market. This could lead to added pressure for companies to lower their prices...and possibly rekindle the debate on Medicare's ban on direct government price negotiation with pharma companies.

One of the first visible impacts of pricing controls has been the Deficit Reduction Act of 2005, which will have its first key milestone in early 2007. The challenges for reporting companies (any firm that currently does business with the federal government) will be to produce monthly reports for all price-related impacts and then calculate back their best price to the government. As of now, it's still unclear what the government is asking for specifically and whether or not manufacturers will realistically be able to produce this information.

Two years ago, the FDA announced the Critical Path Initiative to modernize the process through which a drug, biologic compound or medical device goes from being a new discovery to an approved medical product. This bi-partisan initiative, which is most likely at the top of Von Eschenbach's agenda, has the potential to form a stronger and more operationally-minded agency that is poised to tackle the challenges of a complex and evolving industry.

Ultimately, how the Democrats' orientation toward social causes and government-run programs will affect the nation's fifth most profitable industry remains to be seen. Concerns about product safety, the high cost of promotional efforts, and the inefficiency of the development process are all issues the industry must work to improve. The key take away from this dynamic political backdrop is companies that organize themselves to partner with a more business-friendly FDA could find the benefits far outweigh the investment.

“We all recognize that we can't just say no to every new proposal or regulation anymore. If we want to start being seen as part of the solution—rather than the problem—we need to be proactive.”

**Billy Tauzin**  
President & CEO, PhRMA

## Embracing Emerging Biotechnology

The rapid growth of the pharmaceutical industry in the last century was fueled by chemical companies that leveraged the science of organic chemistry to form beneficial medicines. However, it's biologics—genetically engineered versions of human proteins such as enzymes and growth hormones—that will fuel the industry's future growth. These new products promise to treat complex conditions, such as cancer, diabetes and neurological disorders. The growing importance of this industry is already apparent. In 2005, biologics generated \$32.8 billion in revenue, accounting for 13 percent of the \$251.8 billion in prescription drug sales to U.S. pharmacies that year. And while 94 percent of the industry's investment in research and development is in pharmaceuticals, 70 percent of newly approved drugs come from the biotech sector.

**Implications:** More collaboration between large pharmaceutical companies and emerging biotechnology firms will be required to feed the pipeline for future drugs as well as the combination of drugs and medical devices. However, the emerging players responsible for developing and manufacturing biotech products will face their own challenge: translating great science into good business. Their limited focus on shareholder value, combined with a lack of strong business controls and processes, will prove challenging to the larger, more established companies that partner with them. In addition, the intricate manufacturing processes for protein-based products and the controlled environments necessary to sustain their potency is very different from existing business processes and facilities for traditional pharmaceuticals, adding yet another layer of complexity.

Nevertheless, companies must figure out how to build biotechnology into their business models. With pipelines short, many large pharmaceuticals are racing to buy up biotech firms. According to life sciences merchant bank Burrill & Co., large pharmaceuticals spent more than \$17 billion on 250 biotech deals in 2006, compared to only 150 in 2003. Other large companies are making sizeable investments to grow their biotech businesses organically. Recently, for example, Eli Lilly and Company announced its intent to invest significant resources into the manufacture of biotech medicines. It expects to produce one new biotech product per year beginning in 2010, with biotechnology-based programs projected to account for more than 30 percent of its drug portfolio and pipeline.

## Conclusion

Life sciences companies have a small window in which to make the necessary changes to deal with these challenges. Business leaders must be courageous enough to choose long-term strategies over short-term pressures from Wall Street and focused enough to stay the course. A company's ability to effectively manage organizational change, while keeping its focus on managing costs and driving innovation, is what will determine its success or failure.

The industry lies on the brink of exciting new breakthroughs in pharmaceuticals, biotechs, medical devices and various combinations of each that provide hope to many living with untreatable or incurable disease. With so much promise for better treatments—even cures—there's high hope for the future.

### About Clarkston Consulting

Clarkston Consulting is a leading management and technology consulting firm that provides strategic business solutions for clients within the life sciences and consumer products industries worldwide. These market leaders turn to Clarkston to help them bridge the gap between strategy and execution to sustain a competitive advantage. Clarkston is a sought-after business partner because of its recognized industry thought-leadership and superior client relationships, as measured by The Conference Board's survey on client satisfaction. For more information, visit [www.clarkstonconsulting.com](http://www.clarkstonconsulting.com).

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