

The most identifiable way for a company to suggest future success to the investor community is through the output of innovative new drugs.

capability to do this. The problem is that the number of new drugs being produced by the industry has been dropping for a number of years now. Therefore, it is going to be difficult for companies to convince shareholders that they can expect double-digit growth in the future through new drug output alone. An additional problem to deal with is patent expiration for existing products. Again, new drugs would prove to the investor community that companies are not being complacent about their future. There are a number of companies with very interesting pipelines, but it is not easy to predict which ones will prove successful when their product is launched. Some companies have chosen the merger route as an option to satisfy Wall Street (and foreign stock markets). If we look at other industries they are often highly consolidated (i.e., the oil industry), with a few players taking most of the market share, and there is an expectation for the pharmaceutical sector to take this route. But whether this route actually improves the R&D process and enhances productivity is debatable. Although some companies have stated that they expect mergers to help them achieve success in these areas, there are other companies that have stated that they do not think that mergers are an option for them and that they are confident in hitting their growth targets through their present organizational structures. Achieving a short-lived market-share boost may be the best that some mergers can achieve.

CAUWENBERGH. Large companies are too layered in their management structure. They still dream of being R&D driven but they are really financially and Wall Street driven. Their performance will suffer in the next five years while the global market dynamics bring order in the polarized international pricing structure of the pharmaceutical industry. Small companies will continue to focus on near-term opportunities and will, in general, be risk averse when it comes to longer-term investments in drug-development projects. This could slow down the genesis of new therapeutic breakthroughs. Early-stage companies will scramble to find the funding for long-term projects. Development of a corporate strategy that addresses the above points in a balanced manner will be the best way to generate shareholder value.

CAMPBELL. Pharmaceutical companies need to concentrate on the fundamentals of com-

munication when striving to maintain shareholder value. This can be accomplished by building more transparency into a company's corporate business plan and strategy for dealing with critical issues, such as clinical development, sales and marketing, manufacturing, and Medicare. Companies should be honest about their growth prospects and communicate key corporate events in an open and honest manner. By providing more detailed insight up front and along the way, executives can help their shareholders understand the long-term potential of their company and foster a greater understanding of the business of pharma overall.

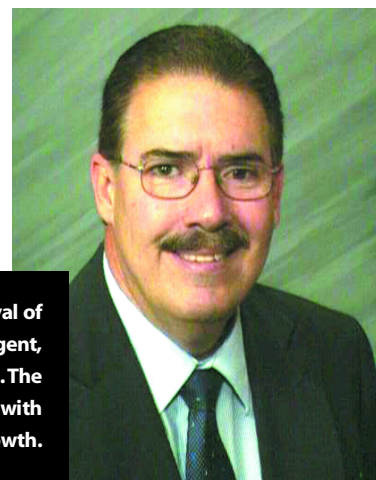
► SUPPLY CHAIN

SZWAST. Pharmaceutical manufacturers face the challenges of accelerating new product introductions, shifts in global sourcing and distribution, the intensifying need for companies to meet regulatory and customer compli-

ance rules, and enhancing shareholder value. Product introductions are a challenge because new products are frequently a poor fit within a pharmaceutical company's traditional supply chain. They tend to require a more responsive scalable conduit to reach the market, and this can be problematic for a legacy supply chain that reflects a company's history rather than aligning to a new strategy. This also is true of more established products as they transition from prescription to over-the-counter. This change in channel distribution has logistics requirements similar to a new product launch. The ongoing globalization of the pharmaceutical industry also brings inherent challenges. Today, pharmaceuticals are produced in diverse locations that previously have not been thought of as manufacturing epicenters. A finished product can easily have different production phases that happen in different countries or in some cases continents. How companies effectively and efficiently source products from these disparate locations without loss, delay, or diver-



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As a by-product of the Vioxx recall, the approval of new drugs is likely to grow increasingly stringent, further delaying the introduction of NCEs. The industry's biggest challenge will be how to cope with a drying well and still maintain double-digit growth.

What's Your Opinion?

2005 — A LOOK AHEAD

What are the most significant business challenges you believe the industry will face in 2005?

Higher development costs and deceleration of drugs to market

I believe technologies can become a reality, however, the resultant reduction in drug-development costs by 75% and cuts in lead time by nine years, as reported in a recent study, are way overestimated. With sustained FDA oversight (not altogether a bad thing), the need for continuous quality reviews, and the diminishing supply of successful drug candidates the tendency will be higher development costs and a deceleration of the number of drugs to market.

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sion is a key area of competitive differentiation and indeed profitability. It is not enough to source and distribute pharmaceuticals quickly; the tasks must also be done precisely. While meeting regulatory compliance (FDA, DEA, individual state pharmaceutical licensing regulations) has long been a core competency of successful pharmaceutical corporations, being compliant is a constantly moving and evolving target that requires continuous process improvement. Further, the ongoing migration of many products into the retail-sales channel drives the need for customer compliance in addition to adherence to regulatory requirements such as voluntary intra-industry compliance standards. The ability to meet the aforementioned challenges is a key demarcation between leaders and laggards in this industry.

GRAHAM. From my perspective, having worked for the FDA, DEA, and Pfizer before joining Purdue Pharma, the counterfeiting of prescription drugs is a growing patient-safety issue. New technology is now available that can help ensure the integrity of the pharmaceutical supply chain by tracking medicines electronically from production plant to pharmacy through the inclusion of RFID (radio frequency identification) "license plates" on each bottle. The FDA is encouraging all companies to incorporate this technology by 2007. Purdue began using this technology in

In a global market, trade compliance becomes every bit as important as regulatory compliance. The ability to cross borders with precision and speed are keys to being successful in the international marketplace.



AARON GRAHAM
Purdue Pharma L.P.

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November 2004 when it launched the industry's first integrated, anticounterfeiting, track-and-trace packaging for a scheduled pharmaceutical product. Each 100-tablet bottle of OxyContin Tablets provided to two of our largest wholesale customers now includes a RFID tag that can be scanned by special sensors. This will make it possible for our products to be tracked and validated along every step of the supply chain. We also are adding a special variable-effect, color-shifting ink to our labels to thwart would-be counterfeiters. We expect this to become the industry standard in a few years.

► TECHNOLOGY

CAUWENBERGH. Ideally, predictive tools, including assays, computer modeling techniques, and biomarkers could shorten development time, reduce the cost of development,