# What's Your Opinion?

## 2005 — A LOOK AHEAD

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

## The model needs to evolve

Many issues face the industry in the near term, including the possibility of price controls, importation, and maintaining an innovation-friendly environment. There is, however, a large structural issue that needs to be overcome before the environment will change for the better.

The computer-chip industry faced a similar type of structural issue. That industry prospered for decades on a model of ever-faster chip speeds, until the incremental gains in speed no longer yielded increased productivity and growth slowed. While speed is still important, the model now is to produce multifunction chips that do more but operate with the least amount of energy necessary.

For the last two decades, the pharmaceutical industry has worked under the "blockbuster theory," and new agents had to be in high-incidence disease states, such as hypertension, allergy, or depression. But, like the chip industry, the model has changed. The possibility of continually developing a blockbuster in the big categories has diminished as continual therapeutic advances have yielded a wide variety of very effective drug choices. Thus, the model needs to evolve to discovering agents in multiple specialty disease states where there are fewer options.

The number of newly approved drugs is at an all time low and the corresponding loss of patent protection for many products will put pressure on companies as they try to maintain profits and shareholder value, while facing tremendous scrutiny about raising prices on in-market products. This may lead to more consolidation and/or more collaborations and alliances.

The challenge will be in weathering the storm while the innovation model transforms to focus on more targeted disease states as well as completely new discoveries.

*Guy Dess*
PRESIDENT
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**SHANAHAN.** In life sciences, the current approach of connecting lab informatics silos to accelerate R&D is at a point of diminishing returns. Storing valuable lab information in office document formats, restricting collaboration through rigid lab databases, and relying on IT programming to support new projects are failing propositions as the margin pressure on R&D continues. R&D productivity can break through the current lab informatics barrier only when a flexible software solution supports the entire life cycle of lab research and closes the loop between design, experimentation, analysis, and reporting.

**CARABELLO.** The pharmaceutical industry will continue to invest an exorbitant amount of capital and human resources into patient recruitment. Whether results improve depends on whether the industry adopts new approaches, such as the use of aggregated healthcare data. Rather than relying so predominantly on traditional marketing-driven recruiting methods, a data-driven approach would enable the industry to more accurately and rapidly develop clinical-trial study models and protocols as well as to initiate and complete the patient-recruitment process. The old ways are time-intensive and consume significant funds; new data methodologies help sponsors reach their endpoints faster, with better targeting and more control of risks and outcomes. The increased availability of managed-care data is significantly changing the landscape for today's R&D professionals.

**ZELDIS.** Dealing with the journal editors' demands for public databases that discuss ongoing and completed trials is now a challenge. While straightforward in concept, the devil is in the details. For example, if the database lists the results before publication of the trial in a peer-reviewed journal, will a journal refuse to publish the manuscript because of "embargo" rules? Investigations will be disclosed to the public and this could lead to increased interactions/distractions from the external audiences. If the time of last patient visit and the time of database lock are listed (as demanded by the editors), will this lead to unfair benchmarking of the pharmaceutical companies by analysts and others?

**S. LEVY.** Regulatory bodies and other stakeholders are demanding greater disclosure of all clinical trials conducted to research pharmaceuticals. Whereas in the past a clinical trial was considered the private property of the pharmaceutical company that sponsored it, if many groups get their way, trials and their results will be disclosed in a comprehensive public database. Many players, such as New York's Attorney General Eliot Spitzer, medical journal editors, physician groups, and several members of Congress, are lining up to make this a new reality for drug companies. Pharmaceutical companies are leaning toward self-regulation on this matter and are hoping that voluntary databases of clinical-trial information will suffice. Whether voluntary or under federal mandates, pharmaceutical companies will be forced to disclose more information about their clinical trials, and this will have implications on strategy. Clinical-trial programs can highlight a company's market-launch strategy, and this strategy will be made public for the first time in 2005. In theory and in practice, competitors will be able to study each other's trial designs and results, revealing safety and efficacy data early, as well as the company's life-cycle plans for future indications. Being the first-in-class in the industry will no longer be a strict advantage, as additional disclosure will allow late fast followers to learn from the mistakes of innovating companies for the first time. Also, there may indeed be fewer, but more successful, new studies since pharmaceutical companies will learn collectively which trial protocols succeed or fail. The pharmaceutical industry will face interesting choices in 2005, because transparency is here to stay, but so is privacy, at least in 2005.

## ▶ FINANCING

**KOLODNY-HIRSCH.** As a long-time participant in this industry, it is certainly encouraging to finally see that more biotech companies are on the verge of profitability. Nonetheless, there are still hundreds of private and publicly traded biotech firms that are in the red and struggling to survive. This issue is not likely to go away soon and is compounded, in part, by the lack of access to lower cost, public equity financing. In the face of capital challenges, companies must sharply focus their spending plans, investing in activities that support near-term commercial opportunities. This means concentrating on core competencies and seeking partnering programs outside the scope of each company's key strengths. One pressing issue facing the industry is that the number of biopharmaceuticals entering clinical trials and gaining regulatory approval has far outpaced existing industry capacity. Construction and validation of these facilities typically require long lead times of four to five years at a cost of $500 million or more. In a depressed market environment, increasing internal capacity is not a viable option. The need to balance financial risk in the face of growing demand will drive the industry to outsource protein manufacturing and other core competencies. This

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## Altering the business model

I believe several factors — the revisions to the Medicare Act to provide prescription drug coverage, the growing number of baby boomers moving into the Medicare system, rising medical costs, importation, liability issues, the higher costs of R&D, doing business globally, and less competition because of consolidation — will force the remaining industry players to alter significantly the way they do business.

These companies will likely have to operate under some level of price-control restrictions in the United States, imposed by the federal government, despite the reelection of President Bush. Pharma companies will become much more selective about how they invest in R&D and for what projects. They will have to rely more on strategic and collaborative alliances/partnerships with other companies for greater access to combined resources. And they will have to redefine their customer mix and focus more on marketing and distribution than on research and innovation. Profitability and accountability pressures will be more challenging. Expectations and standards for these may need to be redefined.

*Teri P. Cox*
Senior Managing Partner
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**DR. KLEANTHIS XANTHOPOULOS**
Anadys Pharmaceuticals Inc.

There is a lot of pressure from investors to deliver approvable products as quickly as possible. Many investors don't want to wait the 10 years to 14 years it takes to develop a drug from scratch.

bodes well for contract manufacturing organizations with spare capacity and innovative platforms.

**BONNEY.** To get to the point of filing a NDA a company needs substantial investment and staying power and this requires real patience from the investment community — from VCs to mutual funds. If the investors see or perceive a threat to the biotech industry because of the popular attacks on the economically challenged pharmaceutical industry in general and on drug pricing in particular, investors ask themselves, why invest? If this happens there will be fewer NDAs and fewer new drugs brought to the patient population. So, we need to make sure that politicians and voters connect the dots and understand the long-term damage that will be done to the biotech industry if the investment cycle is threatened.

### GLOBAL ISSUES

**BUA.** Corporate citizenship in the global society will face increasing pressure to provide innovative pharmaceutical products to third-world countries at a discount and to provide products that have no IP protection in the interest of public health. This will create opportunity losses for pharma, instead of the opportunity gains that could result from focusing manufacturing capabilities in more profitable areas. In addition, increased globalization and improved communication will create pressure to equalize pricing across countries. This, in turn, could remove incentives for R&D innovation.

**BARRETT.** Recent health issues, such as SARS, have demonstrated that disease doesn't respect national borders. Neither can companies running clinical trials. With patient recruitment becoming more difficult and clinical trials requiring more specialized populations, the healthcare industry needs to find easier and better ways to globalize its efforts. Of course, with globalization compliance issues explode. Companies need to ensure they are meeting all the regulations worldwide, pointing to standardization and automation.

**BONNEY.** Infection does not have boundaries, and there is a need for new therapies in many countries. We must deal with multiple regulatory regimes around the world. The payers are very different in each region/country and that can add complexity and challenge the profitability of the company. And, of course, the largest issue is the disparate contribution to R&D made by the various developed countries of the world. Overall, the cost and efficiencies of healthcare delivery in the United States compared with other developed countries are challenges.

**XANTHOPOULOS.** Infectious diseases continue to present a growing healthcare problem on a global basis, especially as more and more patients develop resistance to available treatments. For example, hepatitis B affects about 350 million people worldwide. For hepatitis C, the CDC estimates that by 2010, the number of deaths attributed annually to the virus could surpass HIV/AIDS. As these viruses develop resistance to existing treatments such as lamivudine, Anadys is focusing on the development of novel, high-potency, low-toxicity treatment alternatives that either show activity against resistant strains or use a novel, immune-stimulating mechanism of action that is less likely to result in resistance.

**CAUWENBERGH.** With the price gap getting bigger, it is likely that developing countries will follow the lead of South Africa and decide that on an "as-needed" basis for diseases that become a national threat, they will not respect patents anymore. Parallel import and protectionism will become global issues, as will acceleration of infectious diseases in developing regions of the world in the presence of a lackluster interest in pharmaceutical companies to seek solutions.

**TURETT.** The lines between the developed and developing world are blurring with the entry of Eastern European countries into the EU, the