BY ROBIN ROBINSON

# An Industry OVERVIEW

**The strategic plans for 2008 in the industry appear to be business as usual, which may not bode well for its future, according to PricewaterhouseCoopers' (PWC) latest report. According to Pharma 2020: The Vision report, to make the most of future growth opportunities, the industry must fundamentally change the way it operates.**

This is also the advice of Diana Conmy, director of IMS Health. She says in forecasting for the coming year, pharma companies need to be mindful of such factors as the growth of biosimilars, changes in contracting in Europe, parallel trade practices, and FDA reform, to name a few.

"The top 10 pharmaceutical companies already have been adversely affected by patent expirations and safety events, and there will be a need for further restructuring and adaptation of the business model to reflect the realities of the new marketplace," she says.

The industry will need to go global as a way to sustain growth, Ms. Conmy says. Overall global industry growth is slowing, with the key seven mature markets experiencing only moderate growth. Mature markets face pressure from payers, aggressive genericization, and health technology assessments.

## GLOBAL PHARMA MARKET PREDICTED TO MORE THAN DOUBLE IN VALUE TO $1.3 TRILLION BY 2020:

The global pharmaceutical market will more than double in value to $1.3 trillion by 2020, according to a new report on the future of the pharmaceutical industry by PricewaterhouseCoopers (PWC). The increase is driven by soaring worldwide demand for medicines and preventive treatments as the population grows, ages, and becomes more obese and more prosperous.

By 2020, the E7 countries — Brazil, China, India, Indonesia, Mexico, Russia, and Turkey — could account for as much as one-fifth of global pharmaceutical sales. Further, the chronic conditions in the developing world will increasingly resemble those of the developed world.

But PWC's report indicates that the current pharmaceutical industry business model is both economically unsustainable and operationally incapable of acting quickly enough to produce the types of innovative treatments demanded by global markets.

To make the most of these future growth opportunities, the industry must fundamentally change the way it operates.

The PWC report — Pharma 2020: The Vision — Which Path Will You Take? — contends that despite unprecedented global demand for its products, the pharmaceutical industry is at a pivotal point in harnessing its ability to capitalize on these opportunities. Pharmaceutical companies are facing a dearth of new compounds in the pipeline, poor financial performance, rising sales and marketing expenditures, increased legal and regulatory constraints and challenges, and tarnished reputations. At the same time healthcare payers and providers everywhere have recognized that current healthcare expenditure levels are also unsustainable unless they deliver more demonstrable care and cost benefit over the long term.

Dr. Steve Arlington, global pharmaceutical research and development advisory leader, PWC, and principal author of the report, says the pharma industry will not be in a strong position to capitalize on opportunities unless R&D productivity improves. The core challenge for the industry is a lack of innovation.

"The industry is investing twice as much in R&D as it was a decade ago to produce two-fifths of the new medicines it then produced," he says. "It is simply an unsustainable business model. Over the next decade, the industry must shift its investment focus more toward research and less on sales and marketing. Pharma's traditional strategy of placing big bets on a few small molecules, and marketing them heavily to primary care with the aspiration of achieving blockbuster sales, will no longer suffice. It must focus on the development of medicines that prevent, treat, or cure. These must demonstrate tangible benefits and tackle unmet medical

**Worldwide Market Trends: 2008**

- Biosimilars arrive in the United Kingdom and Germany — regulatory approval for epoetin alfa in 2007
- Europe introduces contracting approach
- Payment by results gains visibility and traction in oncology
- Parallel trade picks up in Europe, driven by specialist products
- Therapeutic substitution becomes more common, with major classes losing patent protection in 2008
- Japan breaks log-jam in approving new oncology products
- Introduction of new postmarketing surveillance by FDA
- Coalescing of political sentiment toward healthcare reform in the United States

Source: IMS Health, Norwalk, Conn., Market Prognosis, September 2007.
For more information, visit imshealth.com.

## AROUND THE GLOBE

Global pharma will want to look toward what IMS identifies as the "pharmerging" markets, which include: China, India, South Korea, Russia, Brazil, Turkey, and Mexico. In the United Kingdom, value growth will be limited to areas of unmet needs as the industry undergoes increased scrutiny from government agencies.

By 2020, according to PWC, the pharmaceutical market is anticipated to more than double to $1.3 trillion, with the E7 countries — Brazil, China, India, Indonesia, Mexico, Russia and Turkey — accounting for about one-fifth of global pharmaceutical sales.

Analysts at PWC believe that the current pharmaceutical industry business model is both economically unsustainable and operationally incapable of acting quickly enough to produce the types of innovative treatments demanded by global markets.

Global market expansion appears to be on everyone's wish list for 2008, along with collaborations, mergers and acquisitions, and trimming costs via implementing more efficient manufacturing processes and by reducing the workforce. A review of the annual reports for the top 25 pharmaceutical companies reveal that these are the standard operating procedures in most long-term strategy plans.

## JOINT VENTURES AND COLLABORATIONS

Joint ventures will continue to allow companies to broaden their market base more expeditiously than if they tried to build a new pipeline in-house, such as the continuing collaboration between Baxter and Guangzhou Baiyunshan, which makes IV drugs accessible in China, or the partnership between Schering-Plough and Merck that produced Vytorin. Abbott and Takeda have a collaborative effort called TAP Pharmaceutical Products that researches the possibilities of developing new digestive disease treatments. Astellas has entered into several licensing agreements with other companies around the world and plans to continue to enhance its pipeline in this manner. According to the message from president and CEO Masafumi Nogimori, Astellas

## INDUSTRY MUST TRANSFORM TO CAPITALIZE ON OPPORTUNITIES

needs. Governments and payers must play their part and ensure the industry is rewarded for these efforts."

**Some of the major changes that PWC forecasts for the industry are:**

- **Emphasis on outcomes to increase.** The focus on outcomes and measurement of outcomes data will drive product development, pricing, reimbursement decisions, and risk-sharing agreements between industry, healthcare payers, providers, and regulators. Successful companies will prove that their products really work and add value. They also will be rewarded with a fair price for new therapies according to the level of improvement over existing medicines. Risk-sharing agreements will become mainstream with drug manufacturers adjusting prices according to the results of outcomes analysis data that demonstrate drug efficacy.
- **Compliance monitoring becomes win-win for patients, payers, and providers.** Solutions to monitor and ensure that patients are fully compliant with their medications could generate more than $30 billion of revenue a year in new sales and would improve outcomes and patient safety. One U.S. study found that 20% of Americans never fill their original prescriptions, or they use other people's medicines, and 60% of patients cannot identify the drugs they are taking. This not only affects safety and outcomes, it creates risk and revenue loss. Pharmaceutical companies will revise their proposition, employ new technologies, and develop personalized compliance monitoring techniques as a value-added service to patients, payers, and providers. Improved compliance would also help clinical studies and outcomes.
- **Focus will shift from treatment to prevention.** Preventative healthcare represents a huge opportunity for both healthcare providers and the pharma industry. Currently only 3% of healthcare spending on OECD countries is used for prevention, yet the WHO says up to 80% of heart disease, stroke, and diabetes and 40% of cancer could be prevented. Recognizing the cost-effectiveness of preventing diseases among healthy populations rather than treating sick populations, pharma will enter the realm of health management, with wellness programs, compliance monitoring, vaccinations, and other value-added services.
- **New technologies will drive R&D.** Transformational technological changes will reshape the business strategies of

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is making active use of in-licensing to reinforce new drug pipelines and will continue to seek more licensing opportunities.

Some collaborations result in subsequent acquisitions, such as in the case of Amgen, Abgenix, and Immunex. In 2000, Abgenix and Immunex partnered to jointly develop the molecule that would become Vectibix. In 2002, Amgen acquired Immunex and inherited the Abgenix partnership, and in 2006, Amgen acquired Abgenix and took full ownership of panitumumab. According to Kevin W. Sharer, chairman and CEO of Amgen, this is just the beginning for the company's oncology programs.

"Vectibix is our first cancer therapeutic, and we expect many more will follow," he told stockholders.

He noted, however, that for the first time the company will be facing new competition from biosimilars in Europe.

## ACQUISITIONS AND MERGERS

Acquisitions and mergers help build drying pipelines as well as afford pharma companies the opportunity to add biotech options. Patent expirations also drive the demand for innovative technologies and products to fill product pipelines, and in the past few years there has been a growing trend to push in-license biological products or to acquire biotechnology companies.

According to a recent article in *The Financial Times Deutschland*, Sanofi-Aventis is considering making acquisitions to catch up in the field of monoclonal antibodies. Other notable biotechnology/pharmaceutical deals include Merck's acquisition of GlycoFi and Abmaxis and Pfizer's acquisition of Rinat. In each of these acquisitions, a big pharma company and the smaller biotech company had prior strategic partnerships. In fact, Merck has collaborated with 16 biotech companies since 2000 and the acquisitions of GlycoFi and Abmaxis were its first strategic, long-term commitments.

Pfizer, on the other hand, is growing its biotech business internally, as it makes plans to establish a new biotech center in the San Francisco Bay area that will be "independent, able to pursue its own research interests, free to establish its own distinct culture, and empowered to recruit entrepreneurial scientists."

## MANUFACTURING: MORE LEAN AND MEAN

Companies also are exploring entirely new methods of manufacturing, restructuring manufacturing processes, and developing cycle time reduction strategies. Many are keeping the aging of the world's population in mind during the discovery process, and some have renewed their focus on vaccines and biologics. More individualistic directions include advancing nutritional products, exploring new disease areas, and developing patient-centered or targeted treatments with genetic medicines. ✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.

## THE LINEAR R&D MODEL WILL GIVE WAY TO IN-LIFE LICENSING; THE BLOCKBUSTER SALES MODEL WILL DISAPPEAR; THE SUPPLY CHAIN WILL BECOME REVENUE GENERATING *(continued from previous page)*

pharmaceutical companies. The role of genetic-based diagnostics in the development of personalized medicines already has shortened the R&D cycle for those products. Further research into the human genome will open up a new world of opportunities in molecular science and new ways of looking at targets. These new technologies will be used to improve the understanding of diseases and link genomic and clinical data. The development of molecular delivery platforms could speed the development of new products that leverage existing/approved platforms. The convergence of therapeutics and medical devices will continue, and they will become increasingly sophisticated, improving efficacy and reducing the risk profile of many existing therapeutic agents.

- **The linear phase R&D process will give way to in-life testing and live licensing.** The current R&D model, involving Phase I, II III, and IV clinical trials that typically end in a submission for a drug license and market approval, will be replaced by collaborative in-life testing and live licenses being issued, contingent on the performance of the drug over its life cycle. The industry will conduct smaller, more focused clinical trials, continuously sharing results with regulators. If testing confirms that a medicine is safe and effective, a live license will be issued allowing the company to market the drug on a restricted basis. Further in-life testing will extend the license to cover a larger number of patients or a different patient population.
- **The blockbuster sales model will disappear.** It will be replaced by a smaller, smarter, and more effective salesforce, led by key account managers who will negotiate tender-based contracts on therapeutic benefit and outcomes. The imperative will be who can add the most value, not who can sell the most pills. Under this model, most companies will sell integrated packages of medicines and services, and some services, such as patient monitoring and disease management, may be more valuable than the medicines themselves.
- **The supply-chain functions will become revenue generating.** The future supply chain will be responsible not only for distribution of all products and services; it will also create new channels through which to market products, so becoming revenue generating rather than a cost center.
- **More sophisticated DTC distribution channels will diminish the role of wholesalers.** The industry's reliance on wholesalers will be supplanted as the OTC sector grows and new technologies enable automated dispensing of medicines directly to consumers.