BY ROBIN ROBINSON AND DENISE MYSHKO

An Industry Overview

THE INDUSTRY STARTED FEELING THE PINCH OF BELT-TIGHTENING ALMOST A DECADE AGO, SLOWLY AT FIRST. BUT TODAY'S PRESSURES MUST FEEL LIKE A VISE GRIP. Being squeezed from all sides, life-sciences companies are having to counter multiple challenges of tremendous magnitude: increased regulatory scrutiny, the need to control costs, generic competition, pricing pressures, and reputation management, to name just a few. Historically slow to change course, but with a world of new obstacles to navigate, the industry will need to transform itself into a more nimble, forward-thinking, patient-centric entity.

CORPORATE CHALLENGES ADDRESSED FROM THE TOP

A review of the top 30 (by revenue) pharmaceutical/biotechnology companies' annual reports for 2008 show that industry leaders are taking the challenges seriously, and they have begun to institute new practices and changes to business models that will ensure the future of their products. These strategies include global market expansion, an increased focus on the consumer, reduction in costs through outsourcing, investment in employees, and collaboration with other companies.

"For companies to succeed they need to embrace different ways of thinking and acting," James Cornelius, chairman and CEO, Bristol-Myers Squibb, states in his address to stakeholders. BMS is on the road to recreating itself as a next-generation biopharmaceutical company, a hybrid model that joins the benefits of a traditional pharmaceutical company with the agility, entrepreneurial thinking, and flexibility of a biotechnology company.

THE ECONOMICS OF MARKET TURMOIL

EXPERTS AGREE THE PHARMACEUTICAL INDUSTRY IS AMONG THE SECTORS BEST PLACED TO WITHSTAND PRESSURES OF A TIGHTENING CREDIT MARKET.

Analysts from Datamonitor say the key impact of the credit crunch on the corporate world is the abrupt loss of cheap debt. Datamonitor believes that large pharmaceutical companies have wisely stayed out of the cheap debt game. The average net debt as a proportion of capital employed for the top 20 pharmaceutical companies is just 6%, while the average net debt carried by financial institutions is 95%.

But they point out that the outlook is far from positive for small biotech players. In recent years biotech's access to funding from other sources of capital has become easier. Financing became cheaper and the balance of power in the pharma-biotech relationship shifted: pharma's need for access to biotech products increased significantly, while biotech's need for pharma funding diminished. Recent economic events that have altered the credit market will undoubtedly impact this balance.

Analysts from IMS Health predict that economic conditions will be a complicating factor impacting the worldwide pharmaceutical market in 2009. In the United States, the correlation between economic factors and pharmaceutical growth is stronger in the current slowdown than in previous downturns, given the continued shift of drug-related costs to patients. IMS estimates that in 2009, the downturn will effectively reduce growth in the United States by two to three percentage points.

The global pharmaceutical market is expected to grow 4.5% to 5.5% next year, according to IMS Health. But in the United States, the world's largest market, growth is forecast to grow 1% to 2% to between $287 billion and $297 billion, down from the 2% to 3% rate expected earlier this year. Contributing to the slower growth is less-than-expected demand for recently introduced products, as well as the economic climate, both of which appear to be having an impact on doctor visits and sales.

Analysts from Global Insight took a look at how the credit crunch will impact R&D strategies. They say pharmaceutical and biotech companies are each facing their own unique challenges. Within the pharmaceutical sector, it seems that bigger is currently better when it comes to surviving the financial crisis. As a rule of thumb, big pharma companies are not as reliant on cheap credit for funding as other businesses. The cash-rich nature of big pharma players puts them at a decided advantage when it comes to seeking growth through acquisitions and helps provide continued funding for R&D.

This is not the case with small- and midsize pharma companies, nor with generic firms that are looking to develop a presence on the innovative drug mar-

According to Genentech's annual report, Arthur Levinson, Ph.D., chairman and CEO, is guiding his company toward more R&D collaborations.

"While we are proud of the caliber of our internal research organization, we recognize that Genentech is not the only place for great science, and therefore collaborations play an important role in our pipeline development," he says.

The leaders of UCB and Genzyme are becoming more patient-centric and focusing their strategies on the consumer. Roch Doliveux, CEO, at UCB, says the company's strategic policy is about connecting with patients and bringing people and science together in new ways.

Genzyme President and CEO Henri Termeer made it clear in his statements that the patient comes first in his business plan.

"We succeed by taking care of patients, not by marketing drugs," he says.

Although these initiatives are encouraging, market analysis firms PricewaterhouseCoopers (PWC) and Deloitte produced reports this year that suggest the industry must strive to do more to replace the $65 billion worth of products expected to go off patent in the next four years. Pharma 2020: Virtual R&D (a follow-on study to PWC's Pharma 2020: The Vision, published last year) breaks down the factors that will impact R&D productivity and suggests a move to virtual R&D as a way to succeed in the future.

To prepare themselves, companies must review what elements of the innovation process can viably remain in-house and which can be outsourced through strategic partnerships. The study also reports the need for operational changes to improve the speed of response for the differing types of innovative treatments, a migration from the current linear phase R&D process toward in-life testing and live licensing, new approaches to collaborating more closely with regulators and healthcare providers about pricing, and the need to demonstrate better efficacy.

"The pharma ndustry is at a pivotal point in its evolution, particularly in relation to research and development, and it faces an innovation deficit that has enormous implications for the industry as a whole," says Mark Simon, partner, health industries, U.S. pharmaceutical and life sciences assurance leader, PWC. "If pharma is to remain at the forefront of medical research, the industry must change radically to survive and to capitalize on future opportunities."

ket, according to Global Insights. These firms are much more reliant on private-equity funding and R&D pledges with larger companies to develop their drug candidates. If this funding is taken away, R&D is often put on hold or outsourced.

Global Insight analysts say, with the exception of the very largest players, biotech drug makers find themselves considerably more at risk from the credit crunch than their counterparts in the small-molecule pharma industry. Given their smaller size and lower cash reserves, biotechs are much more dependent on private equity funding to support their drug development projects.

FIVE MAIN R&D STRATEGIES FOR SURVIVING AND PROFITING DURING THE CREDIT CRUNCH

R&D STRATEGY NO. 1: NARROW THE THERAPEUTIC FOCUS

Choosing to narrow the therapeutic focus to a handful of areas with strong uptake, large patient populations, and favorable pricing and reimbursement conditions seems an obvious strategy, but for many companies it will involve making tough choices among their strengths in several R&D areas.

R&D STRATEGY NO.2: UPDATE IN-HOUSE CAPACITIES

Challenging times require new approaches to old business models, and R&D is no exception. Companies will need to pioneer flexible new approaches to drug discovery and development. Beyond the financial uncertainty brought on through generic competition to major drugs, companies may adapt their R&D strategies to counter the diminishing returns on drugs aimed at increasingly small subpopulations within individual disease areas.

R&D STRATEGY NO. 3: DEVELOP INNOVATIVE ALLIANCES

Drug makers within the biotech sphere are under particular pressure as a result of the credit crunch, and are now even more reliant on the pharmaceutical industry for financial assistance through R&D alliances. Recognizing this growing need from the biotech sector, pharmaceutical companies now have a unique bargaining advantage when such deals are discussed. Many will be inclined to press for more favorable terms for themselves, such as exclusive development and marketing rights to compounds within a therapeutic area, or will sidestep the licensing process altogether and opt directly for acquisition.

R&D STRATEGY NO. 4: OUTSOURCE DRUG-DISCOVERY RESOURCES

In the name of cost-cutting, both pharmaceutical and biotech companies may find that outsourcing certain parts of their R&D activities may be an attractive strategy. In line with sales and production capacities, R&D outsourcing contracts are increasingly being signed with companies based in emerging markets. Failing that, relocating R&D operations to lower-cost countries is another cost-effective option.

R&D STRATEGY NO. 5: CUT UNPROFITABLE DRUGS

While players opt to exit entire therapeutic areas, some will also drop individual drugs from their pipelines to reduce financial risk. Smaller drug makers will feel the negative effects of this strategy more deeply than their big pharma counterparts. In the biotech industry, the lack of private funding brought on by the credit crunch will accentuate the urgency of prioritizing expenditures on R&D still further, and cuts have already been made. Small pharma and biotech players with heavy losses and mounting debts will be the first to suspend R&D on treatments for disease areas deemed "unprofitable."

Source: Global Insight, London. For more information, visit globalinsight.com.

A MATURE MARKET IN NEED OF A FACELIFT

Technology is disrupting pharma's mature status quo, reports Terri Cooper, Ph.D., principal in the life sciences practice for Deloitte Consulting. Today's big pharma and biotech companies, blockbusters, factory-scale R&D, and massive detail salesforces are maturing. The resistance to change, the similarity in corporate strategy and structure, the intense focus on internal efficiencies and productivity, and the ongoing fall in innovation exemplify this maturity.

"Genotyping, biomarkers, and molecular-level disease understanding, all emanating from the advances in genetics, are fragmenting the industry's traditional mass markets and forcing the redefinition of diseases," Dr. Cooper says.

According to a Deloitte report, The Changing Face of R&D in the Future Pharmaceutical Landscape, R&D programs of tomorrow should focus on high-efficacy treatments developed for smaller patient populations based on specific genotypes, as opposed to mass-appeal blockbusters.

INDUSTRY LEADERS ARE STARTING TO INSTITUTE NEW PRACTICES AND BUSINESS MODELS.

"Continuing yesterday's R&D focus on developing blockbusters will not secure success in the future," Dr. Cooper says. "Pharmaceutical companies cannot rest on their laurels. They need to be looking outside of their four walls to develop partnerships and collaborations with a network of companies, scientists, and organizations to fuel R&D developments and reduce the time to bring new drugs to market."

The R&D model of the future, however, is configured for smaller genotyped market segments, which will create targeted treatments that focus on the patient over the disease life cycle. This approach will mean that all stakeholders will need to work intimately with one another in the healthcare network, both competitors and collaborators.

"This will lead to a virtual R&D process in a network of disease-specific organizations and patient groups," Dr. Cooper says.

THE CONSUMER: FRONT AND CENTER

Analysts cite in another Deloitte report, the 2008 Survey of Health Care Consumers, that the industry must take steps to truly learn about consumers' behaviors, attitudes, and unmet needs. The report suggests that there are distinct consumer segments with diverse unmet needs and preferences that present opportunities for pharmaceutical manufacturers, biotech firms, medical product, technology, and device manufacturers to fill the void. Companies need to engage in new strategies, capabilities, and investments that are based on consumers' unmet needs.

Life-sciences companies that want to reach an informed and targeted audience will need to leverage consumers' use of Websites for health information by redesigning their segmentation, messaging, targeting, and channel strategies.

All these developments will drive change in all aspects of the industry. What lies ahead for the industry depends on its reaction to the various market factors. With this industry disruption, some existing players will fade away, some will change and adapt, and some new entrants will rise to dominant positions. ✦

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

HEALTHCARE IN THE YEAR 2019

The Institute for Alternative Futures has made some predictions as to what healthcare might look like in 10 years. Excerpts from the Institute's nine papers are provided below.

HEALTH ECONOMICS: As the broader healthcare reform process moved toward universal insurance coverage in 2011 and 2012, a parallel and bipartisan political conversation was engendered to publicly emphasize that the anticipated growth of healthcare costs was unsustainable for both individual consumers and for the nation's immediate fiscal future. There also was the beginnings of a broad-based movement to emphasize the upstream prevention of chronic diseases.

PAYMENT SYSTEMS: Payment systems began to shift in 2009 when a new administration set a policy course that supported access, quality, and affordability for sustainable healthcare delivered to all Americans. Proposed broad legislation authorized formation of the Independent Health Board and funding for an open-source network for comparative efficacy to assess the value of therapies.

By 2019, all individuals are mandated to have healthcare insurance so the basic tier is available to all Americans. The cost of this basic tier is only allowed to increase at the rate of growth of the GDP. Those who want more than the basic tier of care can pay out of pocket or buy supplemental insurance, but tax incentives only go to support the basic tier. All coverage decisions are informed by evidence-based medicine that a network of entities organize with coordination of the National Quality Forum.

DELIVERY SYSTEMS: The healthcare system of 2019 is centered on the Health Home, a collaborative team of health professionals led by a primary-care specialist (family physician, internist, pediatrician, or advanced practice nurse) with special training. This team focuses on long-term, coordinated, comprehensive care, which addresses all health risks, including stress, social determinants of health, etc., and diagnosed medical problems. To be able to provide a Health Home for all Americans, a large number of primary-care professionals had to be recruited and trained, requiring shifts in educational capacities and financial incentives to make these career choices appealing.

SCIENCE AND TECHNOLOGY: The new scientific agenda is propelled by centers emerging in China, India, and other areas that will be linked by better tools for online collaboration. These tools will allow researchers to interact in real time in virtual worlds to share ideas and test hypotheses. These forms of collaboration changed the cultural silos of the global scientific community by including more Eastern values and focusing on scientific problems of the developing world.

By 2019, systems biology will contribute to better measures of risk for disease as well as better diagnostic tests for monitoring and managing health, heralding a form of personalized medicine where diagnostic tests are used to identify treatments most likely to help a patient.

Source: Institute for Alterative Futures, Alexandria, Va.

For more information, visit altfutures.com.

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