

Pharmaceutical Industry Reinvents Itself, While Maintaining its Position as “Medicine Chest to the World”

By April W. Klimley, Contributing Writer

Still wrestling with change, the pharmaceutical industry managed to pull out of the doldrums in 2006, with growth and profits which seem destined to continue this year.

In New Jersey, the pharmaceutical sector strengthened in 2005 (based on the HealthCare Institute of New Jersey’s most recent economic impact report) with employment remaining around 60,000. The overall economic impact of the sector jumped substantially to \$27 billion, up 20 percent from \$22 billion a year earlier.

“Our industry continues to pace New Jersey’s economy and is a primary driver in many quality-of-life sectors that impact our state,” said Bob Franks, president of the HealthCare Institute of New Jersey (HINJ) in his opening message to the HINJ 2005 “Strong Medicine” report.

2006 was a good year for the pharmaceutical industry — despite a spate of safety problems and the huge growth of generics. Worldwide, the pharmaceutical market grew 7.0 percent. This was the result not only of an 8.3 percent increase in prescribing traditional medicines in the U.S. (due to changes in Medicare Part D), but also medical innovations, particularly in the field of oncology, where there was 20.5 percent growth in the global markets, according to IMS Health, a leading provider of market intelligence in life sciences.

A Pharmaceuticals Mecca

Overall, the pharmaceutical sector in New Jersey benefited from these trends, especially since it has a good portion of research and development (R&D) facilities. Many of the giant pharmas located in the state have their roots here. At least 12 of the world’s largest



Lee Babiss, vice president of preclinical research and development, Hoffman-La Roche, Nutley. He is slated to head Roche’s global R&D operations next month.

pharmaceutical companies have operations in the state, and four of these giants are headquartered here — Johnson & Johnson (J&J) in New Brunswick, Merck in Whitehouse Station, and both Wyeth and Schering-Plough in Madison. Even some major non-U.S. subsidiaries have selected New Jersey as their headquarters location, such as Eisai Corporation of America, the U.S. subsidiary of powerful pharmaceutical company Eisai, in Japan and Novartis in East Hanover.

No wonder New Jersey retains the title of “Medicine Chest to the World.” The state’s government, education and industry leaders have been working to ensure that continues. Last year, the state pledged \$270 million for stem cell research, and part of that investment will go for the launch of a Systems Biology Institute in life sciences created by four existing New Jersey medical institutions.



The search for new cancer drugs involves multi-disciplinary approaches. Here, Roche scientist Bin Vu, Ph.D., uses a high-powered microscope to inspect crystal structures fused with proteins for potential drug candidates.

There are other reasons New Jersey has maintained its lead position in the pharma sector. One factor lies in the innovativeness of companies such as Hoffman-La Roche, with its large campus in Nutley and strong reputation for keeping on top of trends and embracing innovation.

The Importance of Innovation

“You have to create a culture that fosters innovation,” explains Lee Babiss, vice president of preclinical research and development at Roche. “You have to explore creatively in partnerships with innovation and then bring products to market.”

Hoffman-La Roche is a leader in new drug formulations and alliances. Currently, the company is involved in reorganizing its global pipeline structure. Of this effort, Babiss says, “The time to change is when things are going well. You can take a relaxed and thoughtful approach.”

When Babiss talks about change, he’s talking about coming to grips with a number of daunting trends: the era of generics (impacting virtually all drug firms as their blockbuster drugs go off-patent); safety issues (read: Vioxx); the threat of price controls for Medicare Part D drugs; limited internal pipelines at many pharmaceutical firms; and the lower number of approvals by the Food & Drug Administration of most

of these small molecular entities (SME), the lifeblood of the drug companies.

Of course, drug firms continue to spend huge amounts of money on internal R&D. Total U.S. healthcare market R&D spending was estimated at \$50 billion in 2006. One company alone, Johnson & Johnson, for instance, spent \$5 billion on R&D in 2006, up 9.9 percent over 2005.

However, 2006 was another year in which drug approvals were relatively low. And annual prescription drug sales growth was certainly slower than in the double-digit 1990s, leading some analysts to predict slower overall growth for pharmaceutical companies over the next five years.

Another challenge faced by the industry is the continued erosion of its blockbuster franchise. In fact, 42 blockbuster drugs are scheduled to lose their patents in 2007, which account for an amazing \$82 billion in sales. A significant number of biologics started going off-patent last year, leading to the current debate in Congress over how to regulate biologic generics.

Using Different Strategies

Each pharmaceutical company has been taking its own approach to grappling with these problems. Many, like Roche itself, have increased their reliance on third parties through collaborative research, licensing and outsourcing agreements in order to strengthen their pipelines. The latest trend, however, has been acquisitions, many of them of smaller biotech companies or generic drug companies. There was a rash of these this year and last year including Novartis’ acquisition of generic firms Hexel and Eon Labs; Roche’s own acquisition of 454 Life Sciences, as well as Human Polyclonals Inc.; and Eisai’s completion of the acquisition of Morphotec® Inc.

In early 2007, Schering-Plough announced an agreement to acquire Organon Biosciences (OBS). The acquisition will strengthen Schering’s late-stage pipeline by adding five compounds in Phase III development and a number of promising projects in Phase II. Organon has strong expertise in central nervous system and women’s health care products that will fit in well with Schering’s other offerings.

“Our strategy is one of balance and diversity,” explains Tom Koestler, head of research and development. “When it comes to small molecules and mechanisms of action, we are taking on an approach that it is better to go after known targets for better efficiency and safety and also go after some novel targets.”

The acquisition will put Schering-Plough in a better position, in terms of its pipeline, than it has been in the last five years, since it suffered when its \$3-million-a-

year blockbuster Clarinex went off-patent. The acquisition is part of the overall turnaround strategy led by company CEO Fred Hassan.

2006 FDA Approvals

As the industry struggles to improve its pipeline, a number of new drugs and indications (new applications for existing drugs) were approved in 2006. During that year, the FDA approved 29 new therapies: 18 of these were new molecular entity (NMEs) drugs - small molecule drugs that are the traditional bailiwick of the large drug firms; 11 were biologics, therapies produced from living organisms — therapeutic or otherwise.

Some of the new treatments are very promising. Of most interest in 2006 were two from Merck – Gardasil®, the first vaccine to prevent cervical cancer; and Januvia®, the first-in-class oral treatment for Type II diabetes; Pfizer has Sutent®, a treatment for renal cancer; and Schering-Plough has Naxavil. Naxavil is useful for bone marrow transplant situations where infections are likely to occur.

Meanwhile, J&J received FDA approval for Prezista (darunavir), an anti-HIV medication; Invega (paliperidone) Extended Release tablets, a new atypical antipsychotic for the treatment of schizophrenia; and Ionysis (fentanyl iontophoretic transdermal system), the first needle-free, patient-activated anal-gesic system, which also received European Commission approval. Jurnista prolonged-release tablets (Hydromorphone HCL), a new prescription treatment for severe pain, received approval through the European Mutual Recognition Procedure in 2006.

The approval of Prezista was a milestone for J&J. It marked the company's first step into the field of HIV/AIDS, and was developed



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by Tibotec, a Belgian pharmaceutical company J&J bought four years ago.

Clearly, many pharmaceutical firms were having success strengthening their R&D pipelines, according to IMS Health, either internally or through acquisitions. At the end of 2006, there were more than 2,000 molecules in Phase I and Phase II development, up 7 percent from 2005 levels. A broad range of different categories

were in Phase III clinical trials or pre-approval stages (with a concentration in oncology products, viral infections and treatments for arthritis/pain).

When it comes to individual companies, Novartis, for instance, says it has a total of 138 development projects in the pipeline, with a significant number of launches ahead for 2007 and 2008. The company sees two areas of development as particularly

significant and key to its growth: oncology and cardiovascular diseases.

Other Strategies Adopted

Several other trends seemed particularly notable. Companies are trying to control costs through establishment of facilities abroad, either for R&D or manufacturing. In addition, they are looking at new patient populations, particularly in developing countries such as India and China, where the market for certain drugs that seemed unprofitable before, such as vaccines, has mushroomed. In fact, there has been a resurgence in vaccine development within the industry.

Most significant, however, in the long term, were the strategic reorganizations of companies such as Roche. That company has long been known as a leader in alliances with biotechs (Genentech, one of the largest, is, in fact, partially owned by Roche).

In February, Roche announced a new operating model for its global R&D activities, clustering them around five Disease Biology Areas (DBAs). Each area will encompass a range of activities from R&D to marketing. One of these — oncology — will be based at the company's Nutley campus. Babiss is in charge of this DBA now, although he is slated to take over Roche's global R&D in July. The status of Nutley as the company's oncology DBA is sure to have a positive impact on the state, since oncology is one of the world's fastest-growing therapeutic areas.

Smaller Pharmaceuticals Flourish in New Jersey

While the big drug companies in the state are fighting back with the help of acquisitions, innovations and looking at new markets, New Jersey is also attracting smaller,


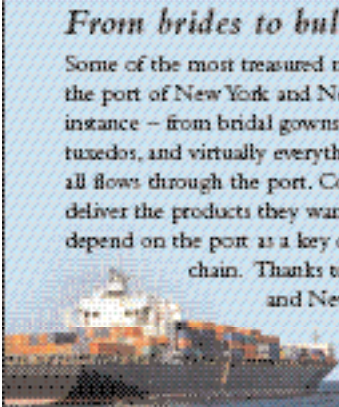
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mid-sized firms due to its appeal as a center of pharmaceutical R&D and manufacturing. These smaller (NJ) firms include Celgene Corp., NexMed Inc., Ino Therapeutics and VioQuest Pharmaceuticals, to name a few.

VioQuest, headquartered in Basking Ridge, specializes in the targeted therapies of personalized medicine. CEO Dan Greenleaf says he is pleased with the company's location in New Jersey for a number of reasons, including its deep talent pool.

"Where else could you get this kind of talent looking for opportunities to make a difference?" he asks. Several of the company's top officers come from strong backgrounds, having worked at giants like Schering-Plough and Daichi (the fourth largest pharma in Japan).

Greenleaf also praises New Jersey for its proximity to New York City. "For a company like ours, where we are constantly meeting with investors in New York, this is great." It is also excellent for the large pharmaceuticals, science and education mass that centers in the New York metropolitan area.