Ranbaxy CEO planning expansion in US, elsewhere

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(AP) — The head of Indian drugmaker Ranbaxy Laboratories Ltd. says he's charging ahead with plans to expand sales in the crucial U.S. market, despite extra oversight from American regulators over quality questions that have blocked imports of 31 of its medicines.

Ranbaxy, which almost exclusively makes generic pills, particularly is aiming to regularly be first on the U.S. market with just-approved generic drugs, CEO Arun Sawhney told The Associated Press in an interview Monday.

His goal is to nab the six-month "windfall" period when there's usually only one generic version on sale, for roughly 25 percent less than the price of the brand-name drug whose patent just ended. Companies can make tens of millions of dollars then, as Ranbaxy just did in selling the first generic rival to cholesterol blockbuster Lipitor, whose U.S. patent expired on Nov. 30.

After that half-year stretch, five or more generic versions of the brand-name drug hit the market and prices plunge 90 percent or more. That leaves razor-thin profit margins for all the competing generic companies, Sawhney said, joking about the difference between brand-name and generic drug companies.

"They make profits. We make drugs," said Sawhney, who became CEO in August 2011.

Discussing his plans during a visit to Ranbaxy's U.S. headquarters in central New Jersey, Sawhney noted his company has just launched its first brand-name drug, a malaria treatment called Synriam that is the first brand-name drug ever developed in India. That's because the hundreds of drugmakers based in India all make inexpensive generic medicines, as most of the country's 1.1 billion people cannot afford brand-name drugs that can cost thousands of dollars.

Sawhney is hoping to sell some brand-name drugs in the U.S. eventually and plans in about six months to start selling a recently approved generic version of acne drug Accutane.

"The US, as a total business, will remain the most important to us," he said.

Ranbaxy, the top-selling pharmaceutical company in India, is just the 12th-largest generic drugmaker in the U.S. by number of prescriptions filled. But in just a few years, its U.S. sales have risen from about a quarter to a third of its total revenue, which was about $2.1 billion last year.

In the first quarter of 2012, global sales jumped 55 percent to about $736 million. That's partly because of strong U.S. sales, particularly from new generic versions of Lipitor and a combo pill containing Lipitor and blood-pressure medicine Norvasc.

It's quite a turnaround after the black eye Ranbaxy suffered when the U.S. Food and Drug Administration in 2008 banned the import of 31 of its generic medicines — including generic versions of the popular antibiotic Cipro and the cholesterol pill Zocor. The FDA cited manufacturing quality concerns at two plants, in Dewas and Paonta Sahib, India, and months later it accused Ranbaxy of lying about some test results on its drugs.

"It hit our bottom line big-time," Sawhney said. "It did slow down our growth plans in the U.S."

The ban took away about half Ranbaxy's sales in the U.S., but factories not affected were able to continue shipping other generic drugs here. However, a third factory involved in the probe, in Gloversville, New York, was shut down because it was too small to make a major investment there worthwhile, Sawhney said.

Sawhney, who had just joined Ranbaxy when the scandal broke, said there were no problems with the safety or effectiveness of the drugs from those factories, just "sloppiness in documentation."

After lengthy investigation and discussion with the FDA, the two parties reached an eleventh-hour agreement that requires improvement of various procedures and five years of intense oversight and review by an independent third-party, which is currently preparing an action plan. That's likely to be announced in August, but some changes have already been made.

The agreement came late on the night of Nov. 30, the day the patent expired for Pfizer Inc.'s cholesterol fighter Lipitor, which had long been the world's top-selling medicine, with peak sales of $13 billion. One of Ranbaxy's two factories in New Jersey was able to immediately start shipping generic Lipitor to pharmacies around the country, averting what would have been a huge missed opportunity.

Instead, from December through May Ranbaxy sold about $953 million worth of generic Lipitor, called atorvastatin, according to health data firm IMS Health. Several other generic drugmakers then began selling their own versions.

Along with its U.S. plans, Ranbaxy is working to expand generic sales in emerging markets. Those are heavily populated countries with a growing middle class and rising government spending on health care, from India and China to Brazil and Russia.

Down the road, Ranbaxy is hoping to be an innovator in the generic drug field by making tweaks rather than just chemical copies of the original drug. Those could include changing twice-a-day pills to daily ones or reformulating tablets, which are tough to swallow for many older patients, into liquids or tablets that dissolve on the tongue.