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## Firms Writing Prescriptions to Distant Shores

*N.J. drug makers discover growing demand in emerging economies*



By Shankar P

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Big pharmaceutical companies have always had a pan-global business model, but second-tier and much smaller companies in the industry have of late begun exploring overseas opportunities for contract manufacturing, marketing, and select research and testing work.

Japanese drug company **Daiichi Sankyo**, which has its U.S. headquarters in Parsippany; Canadian firm **Generex Biotechnology Corp.**, with U.S. offices in North Caldwell and Worcester, Mass.; and **Prolong Pharmaceuticals Inc.** of Monmouth Junction are among those exploring overseas markets.

Daiichi Sankyo last month set up operations in Puerto Rico, since if it were a state, "it would be within the top 20, in terms of the demographics of its cardiovascular population," said **Greg Barrett**, its vice president of marketing.

Barrett said Daiichi Sankyo's hypertension, cholesterol, diabetes, oncology and cardiovascular drugs do well in Puerto Rico. The company is especially optimistic about the prospects for its cardiovascular drug Benecar, "a blockbuster with more than \$1 billion in sales," he said.

U.S. pharmaceutical companies operating in Puerto Rico are required to secure new commercial licenses to market their products, even though they fall under the jurisdiction of the Food and Drug Administration, Barrett said.

Generex two months ago secured regulatory approval for its flagship drug Oral-lyn in India and Lebanon, and earlier in Ecuador, said **William D. Abajian**, senior executive adviser in charge of global strategic alliances and business development. The company has drugs in trials in the areas of diabetes, pain management and cancer.

Generex has more than 150 different molecules in various test stages, and nine products in the pipeline awaiting approvals in overseas markets, Abajian said. The company has drug registrations pending in Syria, Algeria, Iran, Iraq and Sudan, and recently opened an office in Dubai, Abajian said. He reeled off a long

list of other markets he is seriously exploring for Generex, such as East Africa, Senegal, Ghana, Vietnam and Korea.

Exasperated with the inadequacies in their health care systems, some of these countries welcome foreign pharmaceutical companies, according to Abajian. “They have pandemics of diseases like cancer, and people are dying of diabetes, renal and cardiac failure, or having their limbs amputated,” he said.

“India alone has 40 million people diagnosed with diabetes,” and maybe another 60 million with the disease and undiagnosed, Abajian said. “India should be able to bring us \$1 million in revenue a month for the first year, and then compound after that.” Generex’s revenue run rate is currently about \$1 million annually, he said.

Another small biotechnology firm that recently entered India is Prolong Pharmaceuticals, co-founded by **Abe Abuchowski**, former **Enzon Pharmaceuticals** chief executive. Prolong has technology that uses polyethylene glycol to improve the efficacy of existing biopharmaceutical drugs. The company has licensed its technology to develop anemia treatments for **Zydus Cadila**, a Mumbai drug firm, Abuchowski said.

Pharmaceutical companies tapping overseas markets are not necessarily attracted by what some perceive as reduced regulatory oversight on those countries, said **Neil Patel**, director of **PricewaterhouseCoopers**’ pharmaceutical research and development operations group in Florham Park.

“India’s regulatory system, for instance, is not easy to navigate,” he said. “If you are a non-Indian company, you have to have tested that drug in humans somewhere else in the world.”

Patel’s team published a report in December, “The Changing Dynamics of Pharmaceutical Outsourcing in Asia,” that focused on how western pharmaceutical companies have increased their reliance on sourcing clinical trials and other pieces of their drug research work from Asia and other emerging markets.

As a result, pharmaceutical companies in New Jersey and elsewhere have gotten more comfortable in dealing with emerging economies “and are now sourcing more complex, core-competency types of activities,” Patel said; he listed India, China, Latin America and eastern Europe among their hunting grounds.

Pharmaceutical companies head to those markets not because of the regulatory situation, but because of the incremental revenue — on top of what they get from the developed countries, Patel said. “In Turkey, for example, there is tremendous growth in population and affluence.”

But companies need to be careful in protecting their intellectual property rights in some emerging markets, said Lawrence Kogan, chief executive officer of the Institute for Trade Standards and Sustainable Development, a nonprofit in Princeton and Washington, D.C.

“Companies encounter governments that want to take their drugs for pennies on the dollar,” Kogan said. In some countries, the government could declare that a pharmaceutical company cannot keep its patent on a drug “in the public interest,” and pass the technology to local manufacturers. “Brazil’s constitution, for instance, guarantees its people free access to pharmaceuticals,” he said.