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Suven Sets the Stage for Contract Research in India :

After 10 years of running pharmacies in New York and New Jersey, Mr. Venkat Jasti decided to return to his native India in 1989 to pursue a new venture-a drug discovery company. His most formidable obstacle was India's lack of patent protection. But Jasti, who founded Suven Pharmaceuticals Ltd.(Hyderabad) in 1989, says he foresaw the day when laws would change, and spent the last 13 years laying the groundwork for launching a contract research business as soon as patents gained suitable protection.

Jasti got a target date in 1994 when the World Trade Organization set 2005 as the beginning of developed-world style intellectual property protection in India. With that deadline approaching, Jasti says he is investing Rs400 million ($8 million) this year in bringing the company's non-cGMP pharmaceutical intermediates plant into cGMP compliance. Suven, with sales of E12.5 million ($12.3 million), will be one of a small number of privately owned Indian firms ready to work on discovery of new pharmaceutical entities in 2005, he says.

PHARMA CITY. Jasti, also president of the Indian Bulk Drug Manufacturers Association (Hyderabad), is spearheading efforts to establish a "Pharma City" in India, a state- sponsored pharmaceutical research technology park comparable to India's "High-Tech Cities" information technology parks at Bangalore and Hyderabad built in the 1990s. The association has lobbied the Indian government/ and received approval last year for the use of 1,900 acres at Vizag for Pharma City. The area will be jointly developed by private industry and the provincial government of Andhra Pradesh. An additional 4,000 acres will be made available as needed, Jasti says. Development will begin next year, he says.

Suven set out to build relationships and a track record in pharmaceutical intermediates manufacture, pursuing partnerships with drug discovery-based pharmaceutical and fine chemical companies outside India, Jasti says. The firm also began developing a niche in cyanation chemistry, which was new to the Indian fine chemical market at the time, he says.

The company also formed a partnership with Borregaard (Sarpsborg, Norway) in 1993 under which Suven does front-end chemistry work on intermediates, handing the work over to Borregaard Synthesis (Newburyport, MA) for work on advanced intermediates and API manufacture. The partners have done work for several major U.S. and European pharmaceutical companies. About 30% of Suven's work is done in conjunction with Borregaard. Borregaard purchased a 15% stake in Suven last year for E4.5 million, says Hargovind Rathore, president and CEO of Borregaard .

A timetable for patent/protection prompted a three-stage business development program for Suven, Jasti says. The first stage was to gain entry into the market as a contract manufacturer of non-cGMP pharmaceutical intermediates for drugs at any point in development from phase I to commercial launch. The second stage is to modernize facilities, bringing them up to cGMP standards. The final stage is to enter the drug discovery market, identifying new chemical entities.

"We'll begin working on regulated drug intermediates, and by 2005 we'll be working on APIs," Jasti says. His ultimate goal, however, is to establish an R & D based drug discovery business. "The real value in the pharmaceutical supply chain is in contract research," he says. The company's production plant, which has capacity of 300,000 liters, will not be dramatically expanded after gaining cGMP compliance, BUSINESS MODEL. "Suven has in mind the contract research organization business model for drug discovery and clinical research," Rathore says. "Its approach will be to work with major pharmaceutical companies, doing medicinal chemistry on lead drug candidates," he says, "If the drug succeeds. It will license the compounds it develops." A main area of focus will be therapeutic compounds for central nervous system drugs, he adds.