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US-based Goodwin in talks with leading Indian BT cos, plans R&D base in India

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YV Phani Raj, Hyderabad

Goodwin Biotechnology, Inc., a Florida (US)-based fully integrated cGMP contract manufacturing organization (CMO) of monoclonal antibodies and recombinant proteins for preclinical and Phase I / II clinical trials, is scouting for partners in India and expanding its operations to India.

The top management of Goodwin Biotechnology has recently visited 8 to 9 leading bio-pharmaceutical companies in India including Hyderabad and Mumbai. The company is in advanced stages of discussion with some bio-pharmaceuticals companies already.

Karl Pinto, chairman of Goodwin Biotechnology, during his visit to Hyderabad told Pharmabiz, besides establishing business tie-ups with Indian biotech entrepreneurs, Goodwin is also keen to set up a research facility in India and is evaluating various cities including Hyderabad. It is also evaluating the options of occupying ready-to-use facilities currently available in the biotechnology parks.

The proposed Indian facility will act as an extension to the US operations. Progress on the facility can be expected by mid 2006. Initially, Goodwin Bio plans to hire a small team of scientists / researchers in India, who will be trained at Florida for about two months and will come back to India to spearhead Indian operations.

Goodwin is creating presence and relationships in India to outsource certain components of Goodwin's business which can be done more effectively there with India's competent skill sets and resources. "We find our clients amenable to such arrangements, as long as we control the projects in totality, including the components that are outsourced," Pinto said

Explaining why Indian companies would look for partnerships with Goodwin, Pinto added, innovative Indian biopharma companies (sponsors) developing new chemical entities (NCEs) usually aim for the US-FDA to approve their drug. In biologics especially, the earlier phases of drug development (pre-clinical, phase I and phase II) are where the most uncertainty and risk lies. Indian firms thus show interest to work with a US-based company, especially during these earlier phases, at a cost-point that is acceptable to them; which will provide assurance that the US-based partner understands such regulatory intricacies and provides a roadmap that will take them eventually through their phase III clinical stage.

Stephanie Finnegan, chief executive officer of Goodwin, said, the US and European pharmaceutical and bio-pharmaceutical companies are looking for collaborations with Asian countries such as Singapore, India, China and Vietnam. There is a growing interest in India. Those companies, which few years back were hesitant to collaborate with India, have turned in favour of establishing long-term relationships with Indian companies and putting up base in India. India should capitalize this change in mind set.

With over 12 years experience as an independent contract manufacturer, GBI has worked with companies of all sizes from small university spin-offs, major research institutes, government agencies and large established biopharmaceutical companies. GBI's expert services span the entire manufacturing process from cell bank creation through process development, GMP manufacturing, bio-conjugation, bulk packaging to final product fill, clinical site distribution and also assisting with regulatory consultation and documentation.