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Goodwin Bio to partner with Indian biopharma cos for contract manufacturing

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Y.V. Phani Raj, Hyderabad

Goodwin Biotechnology Inc. (Florida, US), a fully-owned subsidiary of the Goa-based Wallace Pharmaceuticals is keen to offer contract manufacturing services to Indian biopharmaceutical companies.

Karl Pinto, chairman, Goodwin Biotechnology Inc. (GBI) and Wallace, US told Pharmabiz, that the company was extending its GMP mammalian cell culture capabilities by deploying a 500l stirred tank train (including multiple smaller tanks) with variable working volume capacities in the US. This would be completed by the third quarter of 2006.

"In this round, we are also expanding our US process development capabilities (to be completed before the third quarter of 2006), which will be followed by building similar process development capabilities in India during the later half of the year. As a private company, we have not made public the actual investments, but the investments will be in multiple millions of US dollars," he said.

"The company is looking at the possibility of partnering with bio-pharma companies of India for contract manufacturing. We see India as a tremendous resource for us, both on the 'Buy' side as well as the 'Sell' side of our business," Pinto added.

He continued, "On the 'Buy' side, we are creating presence and relationships in India to outsource certain components of our 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."

On the 'Sell' side, innovative Indian biopharma companies (sponsors) developing new drugs (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.

These uncertainties are due to ever-changing and complex nature of GMP process development, upstream manufacturing and downstream purification processes, as well as the fact that in these stages, proof of principle has not yet been well-established. These uncertainties reduce as one moves further along the road into phase III and beyond. Navigating successfully through these earlier (pre-phase III) stages requires an intimate knowledge of what the US FDA expects, how to deal with the FDA and ultimately, the flexibility to protect the drug sponsor's investment by continuously evolving the processes to the FDA's satisfaction. To do that successfully from India would prove extremely difficult. Hence, there is Indian firms show interest to work with a US-based company like ours, especially during these earlier phases, at a cost-point that is acceptable to them; which will provide assurance to the India-based company that their US based partner understands such regulatory intricacies and provides a roadmap that will take them eventually through their phase III clinical stage, Pinto explained.

"We are currently talking to two Indian biopharma companies along these lines and plan to make it a core part of our business, not only for India, but also for innovative drug companies in other countries. Case in point, in 2005, about 70 per cent of our business was derived from clients outside of the US. We are seeing more and more of our international clients beginning to also look to GBI's unique position to assist them with access to both sourcing new disease targets/products in the US as well as access to potentially working with Asian (Indian) companies," he informed.

Goodwin has a fourteen year history as a CMO. GBI's predecessor (Goodwin Institute of Cancer Research) manufactured biologics since the mid-sixties. Through its history, GBI has worked with small to mid-sized biotech companies, prestigious research organisations such as Memorial Sloan Kettering and MD Anderson, branches of the US Government such as the US Army and the National Institutes of Health (NIH), as well as large pharma companies including Centocor (now J&J), GSK, Roche, and Menarini.

Replying to the question when India itself is attracting lots of attention from the US and Europe for its efficient and economical contract manufacturing services, how feasible is it for Goodwin to succeed in attracting contract manufacturing activity from Indian

bio-pharma companies and how will it justify the economies of scale, Karl Pinto said, though part of the larger pharmaceuticals industry, biotech is very different from the chemistry-based, small molecule pharma industry. These differences lie in the way the drugs are financed, researched, manufactured, tested and even approved. As a case in point, India is extremely competitive in the small molecule generics market due to robust global regulations relating to generics, but unfortunately biologics is still far behind as far as this is concerned due to the reluctance of the US FDA and the EMEA to use similar paradigms. This creates an opportunity for a firm like ours to convert our years of expertise in biologics and make it available on a global platform (to companies in India, for example).

"We believe that smart Indian biopharma companies will look at working with GBI as an opportunity to reduce their risks, while enhancing their chances of success with the global regulatory authorities. A key element of our strategy involves manufacture and process development and the front end, where expertise, not low cost, is the key driver. Once a process has been developed and a product has demonstrated efficacy in the clinic, the cost of goods becomes a driver, and that is where manufacturing in India will take on great importance," Pinto added.

As part of GBI's strategic expansion plan, building a larger scale manufacturing capacity in India is on the horizon. This way, we will partner with our clients through the full drug development process while providing them the inherent economies that India provides, he further stated.

Today, GBI is among the world's top 21 recognised CMOs (according to HiTech Business Decisions, a California-based specialty research firm). In five years time, we plan on being recognised among the top ten global CMOs and have a sizable presence in India, thus being a pioneer in our industry by successfully building the first truly global development platform in the biotech contract manufacturing industry, he added.

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