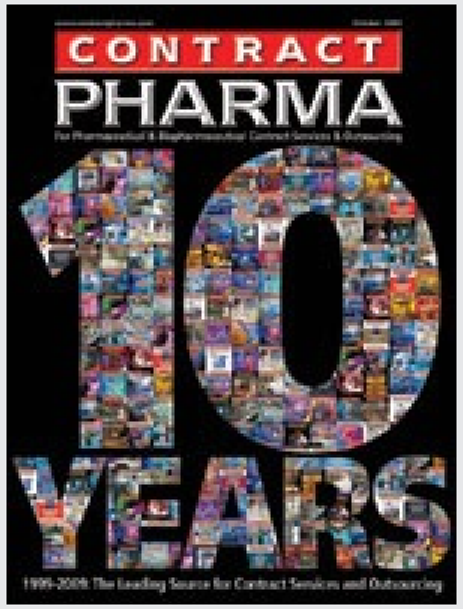

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The Emerging Second Wave

High-quality, low-cost bio-CMOs rally forth

By S. Harachand

It was probably the French drugmaker Sanofi's buyout of Shantha Biotechnics in June that suddenly turned the global spotlight on India's biotech scene. Sanofi's vaccine unit Sanofi-Pasteur paid a huge premium to Merieux Alliance — which owned majority ofshares in Shantha Bio through its subsidiary ShanH — to acquire controlling stake in the Hyderabad based bio firm.

At around $783 million, or roughly eight times more than Shantha's expected annual $90 million sales in figures, the deal has set a new valuation benchmark for the Indian biotech companies.

Justifying the high valuation, Sanofi's chief executive Christopher Viehbacher said the deal underscored the growing importance of the emerging second wave of strong portfolio based companies from India. Extremely high quality low cost manufacturing capacities made Shantha a good fit for Sanofi as a hub to pursue Sanofi's global biotech goals, Mr. Viehbacher added.

Shantha, which claims to have launched the first desi version of recombinant hepatitis B vaccine in India, has already bagged $340 million worth of three-year contracts from the United Nations to supply a pentavalent vaccine in September.

If Shantha-Sanofi deal is any indication, then strong manufacturing capabilities, together with the potential to generate intellectual property, has started attracting strategic investors to India's biotech space.

This year, San Diego-based Amylin forged an alliance with India's Biocon for a new peptide drug to treat diabetes. Amylin is expected provide phybrid technology in peptide hormone development for the candidate molecule, while Biocon will utilize its expertise in recombinant microbial expression to manufacture the compound and develop it through preclinical and early human studies.

Strong Portfolios, Steady Pipelines.

These (sort of) trail-blazing deals have added further momentum to the Indian biotherapeutics sector, which is already ignited on the follow-on biologics prospects.

A very recent sector update indicates that Indian companies could become key players in a global biosimilars market that could approach nearly $20 billion in the next few years.

The market for biosimilars is bound to reach $19.4 billion growing at CAGR of 89.1% from 2009 to 2014, mainly triggered by the legislative changes in U.S. favoring generics. And by that time, Indian firms such as Biocon, Dr. Reddy's, Intas, Ranbaxy, Reliance Life Sciences and Wockhardt, along with other generic majors like LG Life Sciences, Sandoz and Teva, would emerge as fore-runners in the industry, according to the report Biosimilars (2009-2014) from Markets and Markets.

Indian companies appear to have touched upon almost every biologic coming off patent. Huge capacities are also being built by them to catch the opportunity.

Biocon, which sees its recombinant insulin reaching the U.S. market by 2011, has G-CSF and monoclonals in pipeline. Using its trademark Pichia-based expression platform, Biocon launched the insulin analog glargine this year. This Bangalore-based biotech firm has also commercialized an indigenously produced MAb, Biomab EGFR, to treat head and neck cancer in India.

Meanwhile, India's second largest generic player, Dr. Reddy's, which has filgrastim (G-CSF) and rituximab on the market, claims to have a pipeline of eight generic biopharmaceuticals in various stages of development, including two in clinical phase. Dr. Reddy's has identified generic biopharmaceuticals as an integral part of its mid- to long-term growth strategy and thinks that building depth in development and manufacturing capabilities will be critical in accessing this opportunity.

Interferon, human growth hormone-somatropin, insulin and G-CSF are expected spur demand in the recombinant non-glycosylated proteins segment, which is forecasted to grow faster at a CAGR of 87.9% to reach $11.5 billion.

Recombinant erythropoietin biosimilars will lead this segment with a predicted sales of $6.1 billion by 2014, says the report. Erythropoetin biosimilar is brought out in India by Wockhardt, apart from its versions of hepatitis B vaccine, recombinant insulin and insulin glaritus. (Shantha Bio also has erythropoetin generic.)

Eyeing MAbs

Reliance Life Sciences (RLS) is also currently conducting clinical studies for erythropoetin along with its G-CSF in Europe. However, RLS, promoted by India's top business group Reliance Industries Ltd led by Mukesh Ambani, sees that production of MAbs holds the key.

"The key opportunity for RLS in the contract biomanufacturing space would be production of MAbs for innovator as well as biosimilar companies," said KV Subramaniam, chief executive officer of RLS.

World-class quality at competitive cost is the key advantage in outsourcing biomanufacturing services from India, averred Mr. Subramaniam. RLS, which operates India's largest mammalian cell culture facility, is presently working on biologics in segments such as hormones, growth factors, interleukins and blood factors, besides Mabs.

Intas Bio is another bio firm eyeing monoclonals. Based in Ahmedabad, western India, Intas Bio is reportedly setting up a $32 million on MAb facility in Gujarat, which is expected to go onstream by 2011.

Several other companies, including Zydus Cadila and Cadila Pharma of Ahmedabad, are believed to be working their way to the promising land of biosimilars.