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Bio-outsourcing holds promise for India

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An increasing number of global biopharmaceutical companies are outsourcing biomanufacturing (bio-outsourcing) to bring their products to market in a cost-effective and timely fashion

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This article explores the pros and cons of bio-outsourcing and provides some insight into the prospects for future growth of this newly emerging industry both globally and from an Indian perspective.

During the past 25 years, the biopharmaceutical industry has transformed itself from a research and development enterprise into a robust, product-driven sector of the global economy, with worldwide sales of biopharmaceutical products topping $80 billion (about Rs 3.76 lakh crore), an estimated 174 approved products, and 800 plus products in various stages of clinical development.

Historically, biopharmaceutical companies have chosen to bring biomanufacturing 'in-house' to retain control over personnel, production schedules, intellectual property (IP), and regulatory and quality concerns. However, many smaller companies do not possess the internal expertise or the financial resources to manufacture their own products and they turn to contract manufacturing organizations (CMOs) for clinical or commercial production of their products. This helps those companies that are not equipped with expensive facilities.

Outsourcing of bio-manufacturing globally grew at annual rate of 20 percent for the last decade, and is expected to cross $4 billion (about Rs 18,837 crore) by 2011 from $2.8 billion (Rs 13,191 crore) in 2008.

What is Getting Outsourced?

Two distinct philosophies have been seen to be at work. One trend has seen large companies outsource their clinical manufacturing, which requires flexible manufacturing facilities, uncertain quantities, and less focus on cost of goods, while they retained commercial manufacturing, where they could maintain control over cost of goods, consistent quality and reliability of supply. The growth of large, specialized CMOs has also seen a reverse trend, where the product companies retain their clinical manufacturing, which is tied into their core business of research and development, and outsource the routine job of commercial manufacturing, which they no longer see as their core competence.

Biologics CRAMS in India

India, with more than 80 US FDA-approved manufacturing facilities and efficient, low-cost production models resulting from the highly competitive domestic generic pharmaceuticals market, is one of the most preferred locations for outsourcing manufacturing by global pharmaceutical companies. The Indian pharmaceutical contract manufacturing market stood at $1.21 billion (about Rs 5,697 crore) in 2007, and is estimated to reach $3.16 billion (about Rs 14,878 crore) by 2010.

Last year, India's Biotechnology Industry grossed revenues of $2 billion (about Rs 9,420 crore) and is amongst the top countries in the Asia Pacific region. Some of the active players in the biologics development and manufacturing space are Syngene, Biocon, Intas Biopharmaceuticals and Avesthagen. Other product companies such as Reliance Biopharma, Shantha Biotech, Panacea Biotec, Wockhardt and Dr Reddy's are also eyeing contract manufacturing as the scales of operation become bigger and facility utilization and operational cost control become critical.

As an industry we in India are moving from the 'hundreds of litres' to the 'thousand-litre' scale on the mammalian side and these scales become a good entry point for such bio-manufacturing opportunity. With the increasing titres of today's expression systems, scales of a 1,000L are likely to be adequate for a great proportion of clinical as well as commercial requirements of future products.

The size of the overall biologicals market in India will remain small due to the high cost of therapy as well as the changes in the IPR landscape, with the introduction of product patent regime. As a result, unlike the traditional pharmaceutical sector, the contract manufacturing business in biologicals may not piggyback only on the generic manufacturing capacity, but may develop as an independent business segment. The biosimilars (biogenerics) sector still has an important role to play, as it will demonstrate that high quality biologics can be manufactured in India, and it goes a long way towards establishing a critical

mass of scientific, technical and engineering talent.

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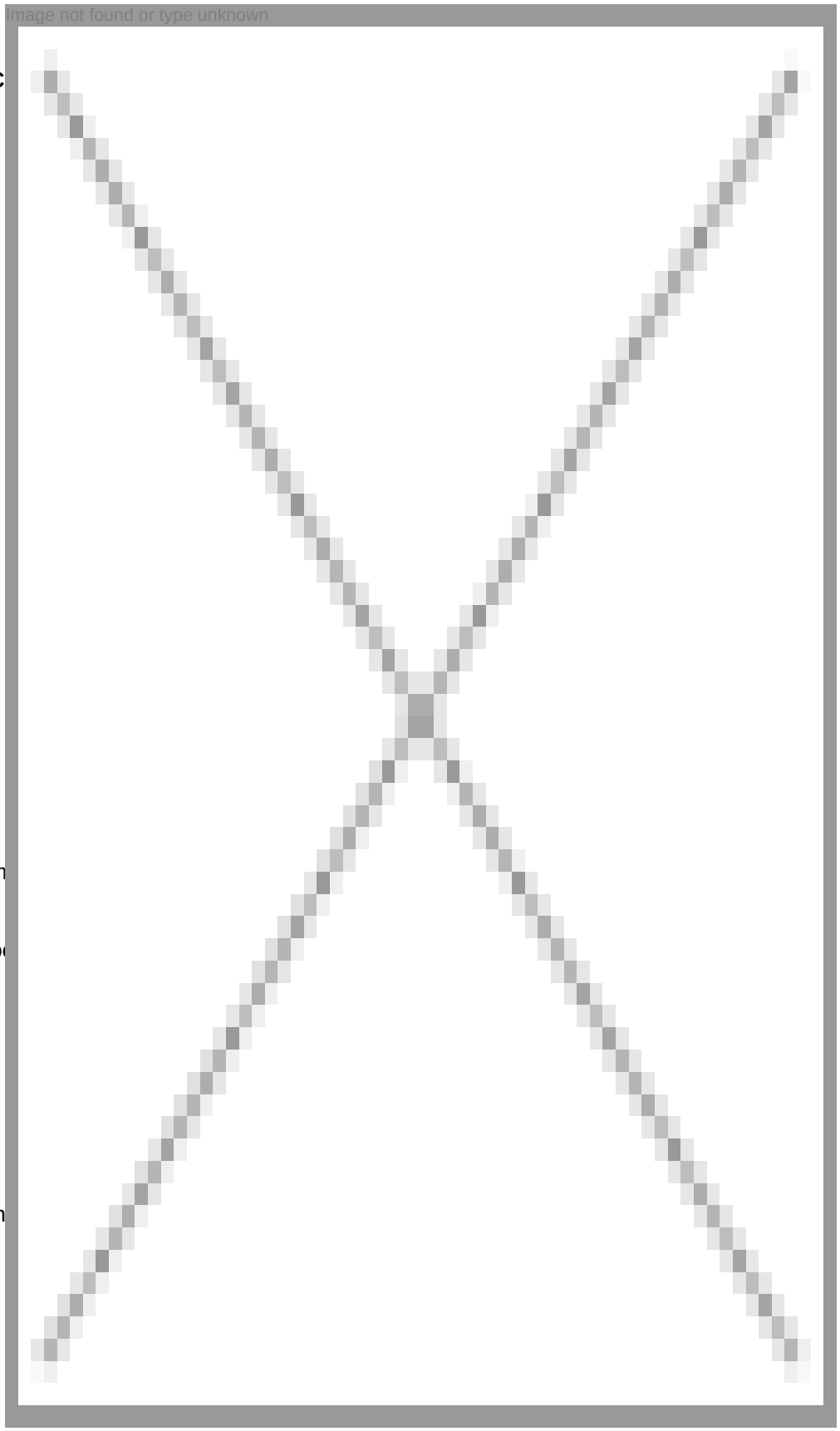

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Intas Biopharmaceuticals in the

Intas Biopharmaceuticals Limited (IBPL) is bullish on the opportunity for contract development and manufacturing in India and has a dedicated business segment for pursuing this business. IBPL is India's first and only biotechnology manufacturing facility EU-GMP certified by a European regulatory authority. It has the capability to meet requirements of small to medium scale GMP production microbial-as well as mammalian-derived products, including fill-finish of liquid and lyophilized products in syringes and vials. The company has expanded its Contract Research and Manufacturing Services (CRAMS) business with the acquisition of US-based biotechnology company, Biologics Process Development Inc., which is fulfilling the requirements of its clients in North America and Europe. A new facility under construction, meeting both US FDA and EMEA GMP requirements, will add 5000L of cell culture capacity for

Contract Manufacturing in India:

There are 'push' and 'pull' factors that make outsourcing a prudent option. The 'push' factors are pressure on the company to reduce cost, time-to-market, and the 'pull' factors are proven track record of the CRAMS company to handle product development and comply with GMP as per

These are challenging times where the global financial crisis has affected many smaller biotech's that may be forced to license out earlier than they would have liked to, while larger companies will be constrained in their ability to pursue the entire pipeline. These 'push' factors combined with the 'pull' factor of companies such as Intas Biopharmaceuticals with demonstrated capabilities and the required scale could

create significant opportunity to bring such development and manufacturing business to India.