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Drug discovery firms turn to Asian countries to evade stringent regulations

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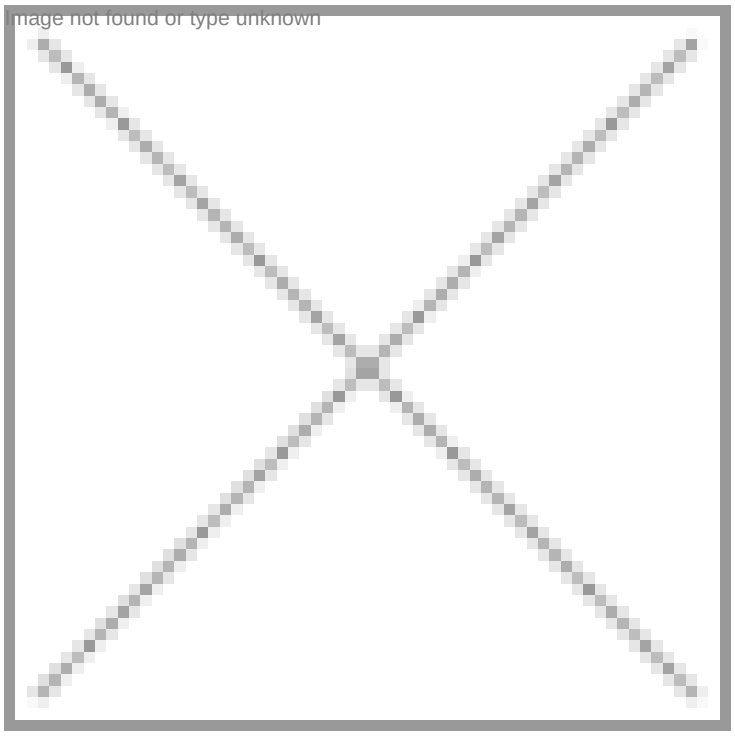

NEWS BYTES

Drug discovery firms turn to Asian countries to evade stringent regulations

The Indian and Chinese drug discovery outsourcing market is riding a crest with companies from outside Asia increasingly seeking to outsource drug discovery to these countries for greater cost savings. Other major factors driving this shift to Indian and Chinese companies are better access to expertise, productivity gains, process improvements, variable costs, avoidance of capital outlays and opportunities for companies to focus on specific niches.

According to Frost & Sullivan, the $7.3 billion Indian and Chinese drug outsourcing discovery market is evolving, with both gaining an edge in the global arena by producing a continual pipeline of drugs, which are approved faster than those produced in western countries. Both countries are uniquely positioned to manage and deal with the pressures to enhance clients' profitability, increase shareholder value and utilize the potential of new drug discovery technologies.

The governments of these countries have also proactively worked to attract outsourcing contracts through stringent regulations, mandatory good manufacturing practice (GMP) compliance and improved legislations for clinical trials. However, regulatory bodies will have to sort out the ambiguities in regulatory issues and legislation of intellectual property (IP) rights to lure a greater number of international pharmaceutical companies.

Both countries have inadequate patent protection, which can discourage global pharmaceutical and chemical companies,

especially those from the US, which stand to lose $450 million every year due to piracy.

"The development of patentable products requires healthy investment in R&D and suitable confidentiality of results to develop a strong IP portfolio. To ensure that technological innovation is commercialized to its best potential, companies need to continuously work with domestic government officials and key opinion leaders in establishing and defining standards to comply with regulatory standards," said Dr Amarpreet Dhiman, EMEA drug discovery technologies team leader at Frost & Sullivan. He further said that the governments' initiatives to diversify the industry's drug discovery portfolio and develop infrastructure are expected to drive the growth rate of the drug discovery outsourcing market in India and China to reach $19.8 billion in 2011.

Ventiv Health, SIRO form JV to deliver clinical data management services

Ventiv Health, Inc.'s Ventiv Clinical Services division and SIRO Clinpharm Pvt Ltd, India's largest domestic contract research organization (CRO), have formed Ventiv-SIRO (India), an exclusive joint venture offering drug companies India-based clinical data management services.

According a release, the Ventiv-SIRO (India) joint venture brings together Ventiv's broad statistical analysis and data management services and premier client portfolio with SIRO's strength conducting large-scale Phase II-IV clinical trial data management projects. Ventiv-SIRO (India) will provide pharmaceutical and biotech companies access to a broad pool of outsourced offshore talent who will design databases, conduct data and statistical analysis and analyze medical images and scans.

Dr Dilip Mehta, senior advisor to Ventiv-SIRO (India) and the former head of US clinical research for Pfizer Central Research, said, "This joint venture brings together two highly-experienced organizations that can support the clinical data management needs and enhance the productivity of pharmaceutical company R&D programs."

"The joint venture broadens our capabilities, allowing us to deliver high-quality clinical research and statistical analysis services both domestically and now offshore through this joint venture with SIRO, the premier India-based CRO," said Michael Hlinak, president, Ventiv Clinical Solutions.

"SIRO has steadily built its reputation as a key opinion leader and service provider in the contract research industry. Partnering with Ventiv and accessing its broad client base will offer us significant opportunities to provide high-quality, cost-effective, India-based talent and services to the companies that are researching and developing tomorrow's medicines," said Dr Gautam Daftary, executive director of SIRO.

Suven's foray into drug discovery yielding path-breaking technology in CNS

Since its initiation of drug discovery research program, Suven Life Sciences, a Hyderabad-based company has successfully reached the final stage of filing its first IND. The pathbreaking technology development in the area of Central Nervous System addressing the unmet medical need in the disease categories like Alzheimer, Mild Cognitive Impairment (MCI) and General Dementia has come within the short period of 36 months from the initiation of the program. Suven expects to file its first IND in the US before the end of 2006.

Indian researchers working on genome sciences set up global network

Realizing the need for Indian scientists devoted to genome researches to come over a single platform, a group of scientists initiated the Genome India International (GII) forum in January 2005. GII is now a fast growing global network of scientists involved in researches on various facets of genome sciences and its related fields.

Its endeavor is to provide a unique and versatile platform for scientific community having similar research interests. At present the forum has around 220 bona fide members representing more than 60 research institutes/ universities across the globe. It has a devoted portal (URL: http://genome-india-intl.org/index.htm) running round the clock and updated regularly for its activities which include a discussion forum, individual member mail IDs, and a host of valuable links to resources including details on scientific meetings, openings and protocols employed in research.

A number of senior scientists including Prof. MS Swaminathan, Dr RA Mashelkar, Dr NK Ganguly, Dr MK Bhan, Dr GS Khush, Dr CR Bhatia, Dr VijayRaghavan, Dr PK Ranjekar, Prof. PK Gupta, Prof. Anupam Verma, Prof. DPS Verma, Prof. SP Singh, Prof. Bhanu Chowdhary, Prof. Om Rajora, Dr Lalji Singh, Dr D Balasubramaniam, Prof. BD Singh, Prof. KS Gill, Prof. Deepak Pental, Dr SE Hasnain, Dr S Ayyappan, Prof. Swapan Datta are advising and guiding the scientists for a faster growth of the forum.

Prof. Chitta Kole conceptualized the idea and initiated the network of scientists with similar interest. His mission is to hold the Indian flag high in the march past of researches on genome science and related fields.

Shasun signs LOI with Rhodia

Shasun Chemicals and Drugs Ltd, a service provider to the pharmaceutical industry, has entered into a Letter of Intent with the Rhodia Group of France to acquire the pharmaceutical customs synthesis business of Rhodia Pharma Solutions (RPS). Both the parties have entered into an exclusivity agreement to progress towards the final Sale and Purchase Agreement, which is expected to be completed before March 31, 2006, subject to satisfactory due diligence and regulatory approvals.

A release noted that the transaction essentially includes all of RPS development and custom manufacturing services catering to innovator and emerging pharmaceutical clients in the US, Europe and Asia. The proposed transaction includes manufacturing sites at Dudley and Annan located in the UK.

Ranbaxy launches Volix (Voglibose) for treatment of diabetes

Ranbaxy Laboratories Ltd launched its branded product Volix (Voglibose) for the treatment of diabetes. The product, a novel Alpha-Glucosidase inhibitor introduced for the first time in India, will be available in dosages of 0.2 mg and 0.3 mg tablets.

Voglibose is indicated for improvement of postprandial hyperglycemia in diabetes mellitus only when diet and/or exercise or oral hyperglycemic drug or insulin preparation in addition to diet and/or exercise, does not result in adequate glycemic control. The avoidance of high postprandial (aftermeals) blood glucose level is one of the main advantages of drug.

Speaking at the launch, Sanjeev Dani, regional director, India and Middle East, Ranbaxy, said, "Volix further expands Ranbaxy's strategic diabetes portfolio and reiterates the Company's commitment to strengthen and build on its existing diabetes franchise." In July 2005, Nihon Pharmaceutical Industry Ltd (NPI), a joint venture between Ranbaxy and Nippon Chemiphar Limited (NC), launched Voglibose tablets under the brand name, Vogseal in Japan. This is Ranbaxy's first generic product in the Japanese pharmaceutical market to have gained market leadership amongst competing generic products, with a market share of 36 percent.

Commenting on the launch of Volix, Dr SK Wagnoo, senior consultant diabetologist and endocrinologist, Indraprastha Apollo Hospitals, New Delhi said, "Volix (Voglibose) will provide Indian doctors with an efficacious medicine which is a strong and selective inhibitor as compared to the available 'Alpha-Glucosidase'- Acarbose. The effect of Voglibose as an inhibitor of sucrase and maltase is 190-270 times greater than that of Acarbose."

Suven's net profit up by 194%

Suven Life Sciences, a Hyderabad-based life sciences company, pioneer in contract research and manufacturing services (CRAMS) surpassed previous year's revenue by the end of Q3. The revenues for the nine months stood at Rs 63.45 crore, which is 104 percent of previous full year's revenue of Rs 60.77 crore.

Net profit for the Q3 stood at Rs. 3.21 crore as against Rs 1.13 crore registering a 194 percent growth and the cumulative net profits up to the Q3 is Rs 6.21 crore as compared to Rs 3.20 crore for the corresponding previous period registering a 94 percent growth. The total income is at Rs 27.10 crore for this quarter against Rs. 13.94 crore of corresponding period of previous year.

Panacea Biotec Q 3 Net Profit zooms by 81%

Panacea Biotec has reported a remarkable performance with 81 percent rise in net profit in its unaudited financial results for the third quarter ended 31 December, 2005. Continuing its excellent show, Panacea Biotec has grown over its last year's corresponding period by a remarkable margin, posting turnover of Rs 113.07 crore and net profit of Rs 5.19 crore.

Turnover during the quarter have soared by 65 percent at Rs 113.07 crore as compared to previous year's third quarter turnover of Rs 68.56 crore. Operating profit during the Q3CY is higher by 247 percent at Rs 13.93 crore as compared to Rs 4.01 crore in the corresponding quarter in the previous year. Net profit after providing for appropriations and tax, is sharply higher at Rs 5.19 crore as compared to Rs 2.86 crore in the corresponding quarter in the previous year.

Profit before tax and exceptional items for nine months of the current year, has risen to a record high of Rs 78.96 crore as compared to Rs 36.57 crore during the corresponding period in the previous year recording a jump of 116 percent. For the nine months ended 31 December, 2005, turnover is at Rs 410.50 crore and net profit is at Rs 49.46 crore as against Rs

248.33 crore and Rs 22.70 crore, respectively, during the corresponding period in the previous year thus recording a growth of 65 percent and 118 percent, respectively. The nine-month period EPS (before Extra-ordinary item) stood at Rs 8.08 per share.

Rajesh Jain, joint managing director, said, "This is yet another great quarter from Panacea Biotec. These results are attributable to our investments in sales and marketing combined with execution excellence. R&D continues to be an important focus and we have consistently increased our spending on R&D. Even last quarter, we have significantly increased R&D spend, and we should be able to see more benefits coming out of increased spend in the next few years.

We give our scientists an environment and an opportunity whereby their capability is used effectively for producing significantly value added innovative products and technologies, and we are able to do that with relatively smaller investments compared to other companies, Jain added.

Manipal AcuNova opens its clinical research center

Manipal AcuNova, an emerging CRO, inaugurated its Asia Clinical Research Center at Whitefield near Bangalore on January 23, 2006. Sir William Castell, chairman, GE Healthcare, dedicated the facility. The new center marks the focus and thrust of Manipal Acunova to leverage its expertise in clinical research in the global market.

The center will carry out drug development and drug discovery research. It also houses a central reference lab, radiology core lab and a cardiac safety monitoring lab. The center will have 150 professionals.

DA Prasanna, vice chairman and managing director, Manipal AcuNova, said, "Today marks a milestone for us as we dedicate Manipal AcuNova's Asia Clinical Research Center at Whitefield. The growing clinical research industry in India, coupled with the vastness and reach of Manipal Group, have enabled Manipal AcuNova to achieve the growth we are seeing today. This clinical research center will bring under one roof our key offerings in drug development and research for the pharmaceutical industry. Locating the center in Bangalore, the knowledge capital helps co-locating with leading healthcare research companies like GE health care and the opportunity to integrate our clinical research practice with high quality IT infrastructure."

Speaking at the inauguration, Sir William Castell said, "I am very pleased to be opening this new clinical research facility in Whitefield and commend Manipal AcuNova for its decision to build it. The center is a fine example of India's growing role in the global knowledge economy and is testament to the country's availability of high caliber science."

"Manipal AcuNova is the only CRO to have an in-house expertise of 1,300 physicians of the Manipal network of hospitals as well as access to over 1.2 million patients per year. This gives Manipal AcuNova the extra edge to conduct innovative clinical research and provide speed to the pharmaceutical industry. Manipal AcuNova has seen impressive growth. It has conducted over 22 studies (phase II to IV) in varied therapeutic areas making it one of the leading players in Indian clinical research," said Dr Ramananda Nadig, chief operating officer, Manipal AcuNova.