Cure for sure

Our pharmaceutical companies are now all set to prescribe remedies for the ailing international drugs business, writes **N.B. Rao**

THE past few months have been action-packed for the Indian pharmaceutical industry, as leading domestic players have gone about making stunning acquisitions around the globe, even as international giants have made impressive investments in the country.

Ranbaxy Laboratories, the country's largest drug-maker, which made eight major acquisitions in 2006 – including Romania's Terapia for $324 million, Spain's Mundogen, Italy's Allen SpA, and South Africa's BeTabs – is now eyeing the generics business of German giant Merck KGaA.

A few other leading Indian drug-makers, including Cipla and possibly Dr Reddy's Laboratories (DRL), are also interested in acquiring Merck's generics business, which has been valued at around $5 billion. Incidentally, Ranbaxy aims to be a $5 billion company in another five years.

The pharmaceutical sector topped the M&A (mergers and acquisitions) league in India in 2006, with over $2.2 billion worth of inbound and outbound deals under its belt. The biggest was the acquisition by US-based generic-drug maker Mylan Labs of a 71.5 per cent stake in Hyderabad-based Matrix Laboratories for a whopping $736 million.

According to Matrix chairman N. Prasad, the deal provides greater growth opportunities for the Indian manufacturer of active pharmaceutical ingredients (API), which are supplied to the country's leading generic-drug makers. "It will allow us to accelerate our existing plans in India and abroad," adds Prasad, who is relocating to Singapore as head of global strategies for the US firm, of which he is now a director. Matrix had a few months earlier paid $263 million for a Belgian firm, Docpharma NV.

Indian pharmaceutical firms, both large ones like Ranbaxy and Dr Reddy's Laboratories (DRL), and smaller ones, have been on an acquisition spree. The biggest was by DRL, which paid $570 million for an all-cash acquisition of Germany's fourth largest generics firm, Betapharm. According to Dr Anji Reddy, chairman of the Hyderabad-based group, the acquisition was part of its "strategic initiative towards becoming a mid-sized global pharmaceutical company with a strong presence in all key pharmaceutical markets.

The Betapharm deal was on the back of a $59 million acquisition of the Mexican API business of Swiss giant Roche. The move was part of DRL's strategy to strengthen its position in the custom pharmaceutical services (CPS) business. International pharmaceutical firms are increasingly outsourcing both R&D services and CPS.

Mumbai-based Nicholas Piramal India Ltd (NPIL) also acquired three firms in the UK, including a unit of Pfizer, the world's largest drug-maker. It also bought a company in Canada, and is now planning acquisitions in the US, ranging from $20 million to $200 million. According to Ajay Piramal, chairman, NPIL, this is part of a strategy where it plans to use its European and North American assets to manufacture niche high-value drugs, while keeping lower cost manufacturing in India.

With the acquisition of the UK facility of Pfizer, NPIL will emerge among the world's top-10 pharmaceuticals outsourcing companies. It will also become the biggest supplier, in terms of spend, within Pfizer's global contract manufacturing network. Custom manufacturing is expected to contribute to 50 per cent of NPIL's sales by 2010.

Kemwell, a Bangalore-based formulations contract manufacturer, also acquired another Pfizer plant recently. The facility, which produces both API and finished drugs, is based in Uppsala in Sweden, and has been approved by several regulatory authorities, including those in the US, Europe and Japan.

Subhash Bagaria, chairman and managing director, Kemwell, notes that the purchase builds on its extensive experience in contract manufacturing, "and demonstrates our commitment to strengthen and broaden our pharmaceutical business through strategic global acquisitions."

The acquisition of European firms is part of the strategy adopted by the Indian pharmaceutical sector to expand its custom manufacturing business, ranging from APIs and intermediate development and manufacturing into final dosage forms. According to Frost & Sullivan, contract manufacturing and research services in the global pharmaceutical sector is expected to balloon to $168 billion in just about two years. In the past, American and European companies dominated the global pharmaceutical contract manufacturing sector, but Indian and Chinese companies are now aggressively expanding into this segment.

TRANSFORMING PHARMA BUSINESS: India is emerging as a low-cost, high-quality option for research outsourcing, manufacturing and other services

HIGH PROFILE: Biocon's Kiran Mazumdar-Shaw

DRAMATIC CHANGES: India could become preferred global supplier for bulk drugs, dosage forms

Frost & Sullivan estimates that India and China could potentially account for nearly 40 per cent of the outsourced market for APIs, finished dosage formulations and intermediates.

Most of the Indian pharmaceutical companies that are making aggressive forays abroad hope to see more than half their total revenues originate from overseas sales. NPIL, for instance, saw an over 200 per cent jump in global sales for the quarter ended December 31, 2006, and international sales account for over 45 per cent of its overall revenues.

But it is not just the large Indian drug-makers who are eyeing overseas acquisitions. Even medium-sized firms and smaller ones are hunting around the globe for such deals.

Vadodara-based Sun Pharmaceuticals, for instance, has prepared a war chest of $500 million for acquisitions in the US. According to a company spokesman, it wants to acquire a generic business in the US, where it has seen strong growth in recent months. Sun's annual revenues in the US market are expected to touch $100 million this fiscal, as its business has been growing by a robust 30 per cent.

Unichem Laboratories, another mid-sized firm, is planning to acquire a company in the world's fastest-growing pharmaceutical market, Brazil, and also in Europe. The company will be investing about $25 million for the Brazilian unit.

What are the factors triggering off the flurry of activities in the Indian pharmaceutical sector, and the spate of deals that have been negotiated around the globe by domestic companies? There are many reasons for these developments, which will ultimately help boost the prospects for the Indian pharmaceuticals – and increasingly, also the biotechnology – sector.

The most important is the emergence of India as a low-cost, high-quality option for outsourcing of research, manufacturing and other services, which is bringing about dramatic changes in the global pharmaceuticals business.

Other factors include the global slowdown in the sale of patented drugs, the growing opportunities for generics-drug makers, the absence of new billion-dollar blockbuster drugs internationally, and the increasing pressure on Big Pharma; its critics include not just members of healthcare NGOs, but even shareholders on Wall Street and many western governments, that are facing a crisis in the healthcare sector and are seeking a sharp reduction in the price of prescription drugs.

Industry observers note that India's pharmaceutical industry is at the crossroads, and the country could become the preferred global supplier for bulk drugs and dosage forms, and a hub for contract research and manufacturing (CRAM), contract research organisations (CRO) and R&D activities.

The country is among the top-five manufacturers of bulk drugs and ranks among the top-20 pharmaceutical exporters in the world. The Indian pharmaceutical industry ranks fourth globally in terms of volume, and 13th in value terms.

PHARMA SCENE

EXPORT AND FLOURISH: India has the largest number of US FDA-approved plants

India also has a vast pool of talented professionals – every year, nearly 125,000 chemical engineering graduates and chemists pass out of its universities. There are about half a million pharmaceutical scientists and pharmacists, working in the manufacturing, R&D, hospitals and retailing sectors.

The industry is growing at a compound annual growth rate (CAGR) of 13.6 per cent, and revenues are projected to touch $12 billion by 2010. Exports add up to about $3.8 billion, with formulations accounting for 55 per cent, and bulk drugs the rest. Exports are projected to touch $6 billion by 2010.

Increased abbreviated new drug application (ANDA) approvals from the American regulator are seeing exports zoom. The domestic industry is geared to catering to the US market. For instance, India has the largest number of plants (at over 100) that have been approved by the US Food and Drug Administration (FDA).

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The US is the biggest drug market in the world, and companies from around the globe are interested in increasing their sales there. Most leading Indian drug-makers now sell in the US, and Indian companies account for the maximum number (nearly 30 per cent) of drug master filings (DMFs) with the FDA.

They also have the largest number of patents approved by the administration, allowing them to market their drugs in the US.

India's strength traditionally has been in the area of generic-drugs. And this is one area that is witnessing record growth internationally. The generic-drugs market is worth over $60 billion globally – out of a total drugs market of around $300 billion – but the next three to four years will see an additional $60 billion worth of branded drugs going off patent, providing tremendous opportunities for Indian drug-makers.

Nearly three-dozen top branded prescription drugs are expected to go off patent over the next two to three years, and Indian manufacturers will be the main beneficiaries. Analysts expect this to accelerate the growth of the domestic pharmaceutical sector.

The enactment of the Patents Act in 2005, ensuring that India met its World Trade Organisation (WTO) obligations

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MODERN INFRASTRUCTURE: Pharmaceutical firms are investing in upgrading infrastructure

MANUFACTURING HUB: International majors are attracted by the country's vast scientific talent

under the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), is also leading to dramatic changes in the sector.

The Indian pharmaceutical sector is now focusing on R&D, especially in the area of new chemical entities and dosage forms. About a dozen companies are developing 60 new compounds, and the average spend on R&D in the pharmaceutical sector has gone up to 10 to 12 per cent, from around 8 per cent before the enactment of the patent legislation.

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G.V. Prasad, CEO, Dr Reddy's, notes that the Hyderabad-based group is spending about $80 million every year in R&D. "For companies like ours, who aspire to be a major player in the global generic space and also an innovative player the R&D spend is very significant. This is likely to go up significantly once we increase our portfolio in generic business."

International drug giants are also looking at India as a potential R&D hub, thanks to the availability of skilled professionals including scientists, and the relatively lower personnel costs. Western pharmaceutical firms are confronting major challenges, including squeezed margins because of the growth of generic-drug makers, and soaring R&D costs.

SOARING COSTS: International companies are increasingly outsourcing research activities to India

> Frost & Sullivan, a New York-based consultancy, estimates that outsourcing of drug discovery to India has grown significantly, topping the $1.2 billion mark.

According to estimates, it costs anywhere between $500 million and $2 billion to launch new drugs in the market. UK-based Centre for Medicines Research International (CMR) Ltd, notes that it now takes an average of 12 years from the identification of a suitable drug target to the first market launch.

"Although scientific innovation can only be sustained if it is commercially viable, the time period between the discovery of any novel medicine and its commercial application is lengthening as development times increase," says a CMR report.

The amounts being invested in R&D are soaring (from around $35 billion a year in the 1990s, to over $60 billion at present), but the numbers of new drugs that are launched have declined from about 40 to less than 30.

Consequently, many companies are outsourcing a significant chunk of their research activities to India. Frost & Sullivan, a New York-based consultancy, estimates that outsourcing of drug discovery to India has grown significantly, topping the $1.2 billion mark.

Similarly, pharmaceutical multinationals are entering into alliances with Indian partners, and also going in for contractual outsourcing arrangements and setting up CROs (contract research organisations), which carry out medical and scientific studies for several clients. CROs carry out clinical research including clinical trial management, data management, statistical analysis, protocol design and final report development.

Frost & Sullivan estimates that over $1.6 billion is spent every year on clinical development in India.

Biotechnology firms in India are also raising their profile in both the domestic and international pharma sectors. Companies like Biocon, Shantha Biotech, Serum Institute, Bharat Biotech and Panacea are entering into alliances with both Indian and international partners, especially in areas like drug discovery and development of new vaccines.

The cost of developing new biopharmaceutical drugs is much higher than traditional chemical drugs – an average of around $1.2 billion – and it takes over eight years for a company to get it through clinical development and regulatory approvals. International biotech firms are under pressure to cut down costs and hasten up the production cycle.

And one way to do that is to again go in for outsourcing. India's biotech industry is geared up to meet these challenges. Ernst and Young has identified India as one of the five emerging biotech leaders in the Asia Pacific region.

Bio-generics is another area that is opening up, as many of the biotech drugs that were launched about 20 years ago are at the end of their patents. Indian biotech firms hope to repeat the success of the generic-drug makers in the western world.

Reliance Life Sciences, for instance, is investing $63 million in UK-based GeneMedix, which would help it to launch its bio-similars in the European and US markets.

Many Indian drug majors are eyeing smaller biotechnology companies in the US, and venture capital firms are helping them identify potential targets. Some of these firms are finding it difficult to raise funds in the US, and are eager for tie-ups with Indian companies.

India is also making rapid progress in stem cell research and development. The All India Institute of Medical Sciences (AIIMS) is focusing on stem cell therapy for treating diabetes, while Bangalore's Manipal Stem Cell Research Centre has initiated clinical trials using these cells to treat patients.

The Department of Biotechnology is also planning to set up a Stem Cell Research Institute in Bangalore. According to Kiran Mazumdar-Shaw, chairperson, Biocon, India's IT capital will also see a biotech park - the Bangalore Helix – coming up shortly. The facility has been declared a special economic zone.

For the Indian pharmaceutical and biotech sector, the outlook is indeed bright. The industry is now all set to prescribe remedies for the ailing international drugs business.