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R&D Spending on the Rise

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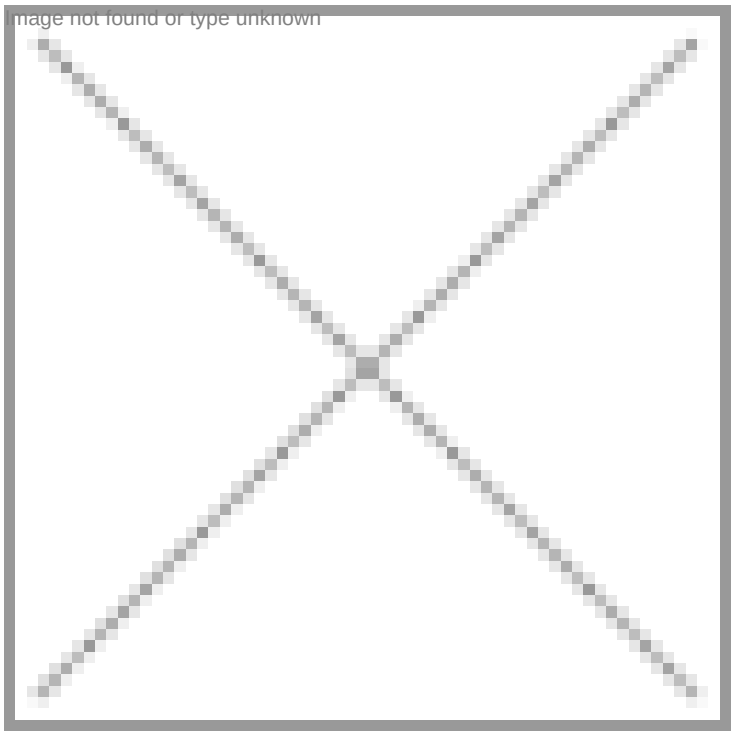

R&D Spending on the Rise

Dr Anji Reddy, founder and chairman, Dr Reddy's Labs, said â€œThe trajectory of innovation is unpredictable and there is risk involved to those who undertake this journey. It takes courage and vision to look beyond today's vicissitudes and find hope. But if we don't seize the moment and challenge our capacities we will remain pygmies in this world of giants. The future belongs to those who merely seek opportunity, but to those who create it.â€?

This pioneering spirit not only drives the research efforts for drug discovery and development at Discovery Research, a strategic business unit of Dr Reddy's Laboratories Ltd but also at other leading pharmaceutical and biotechnology companies who are looking at entering global market for their products. The Indian pharmaceutical and biotechnology companies have achieved significant milestones in the last few years. These companies have helped India attain self-sufficiency in case of formulations, vaccines and gained global recognition as a producer of low cost high quality vaccines/bulk drugs. In the recent past, leading companies have demonstrated their ability to engage in commercially viable research and development (R&D) activities and grow to be major players in the international market.

Now Indian companies are in the new era with the introduction of the IPR regime. Introduction of product patent law would mean that the companies would no longer be allowed to reverse engineer molecules that are under patent protection globally. However, they would still be able to compete in the domestic market for generics, i.e. drugs on which the patent has expired. As a result, the number of product launches in the domestic market would decline. The option left for them would be to either operate in the generics market or invest in R&D and invent new chemical entities and dosage forms so as to achieve growth

in the long run. It is also likely that the Indian players who do not have strong R&D capabilities and a diversified product portfolio may become contract manufacturers for other players â€“ local as well as multinational. In the long run, introduction of new products through innovative research or inlicensing agreements would be critical for their growth.

R&D expenditure tops Rs 1,500 crore

Leading companies like Biocon, Ranbaxy, Dr Reddy's Laboratories, Nicholas Piramal, Lupin and Wockhardt have increased their focus on R&D. The R&D activities at these companies are targeted both at New Drug Development (NDD) as well as Novel Drug Delivery Systems (NDDS). The R&D expenditure of leading Indian pharmaceutical companies has crossed Rs 1,500 crore during 2004. In value terms companies like Ranbaxy and Dr Reddy's Labs led the way in R&D spending. Ranbaxy topped the list with an R&D expenditure of around Rs 331.39 crore during the year ended December 2004 (it follows January-December as financial year) against last year's R&D spent of Rs 238 crore. Dr Reddy's Labs, with R&D expenditure of about Rs 283 crore in 2004-05 against last year's expenditure of Rs 191 crore, followed it. The other leading R&D spenders include Biocon (Rs 27 crore), Cadila Healthcare (Rs 71.1 crore), Lupin (Rs 87 crore), Panacea Biotec (Rs 24 crore), Sun Pharmaceutical (Rs 145.9 crore), Torrent Pharmaceuticals (Rs 51 crore), and Wockhardt (Rs 94 crore). In addition to these, several companies are spending about 5-6 percent of their total sales on R&D activities.

BIG R&D SPENDERS

Company	Rnd Spend In Rs Crore
Ranbaxy	331
Dr Reddys Labs	283
Sun Pharmaceutical	146
Wockhardt	94
Lupin	87
Cadila Healthcare	71
Torrent Pharmaceuticals	51
Biocon	27
Panacea Biotec	24

With increase in R&D expenditure in terms of setting up new infrastructure facilities and running costs, most of these companies are unable to reap the profits for the year and even recorded fall in revenues. On the contrary to the pharmaceutical companies, most of the biotechnology companies are still engaged in R&D activities depending on government support for funds.

Firms on the lookout

Dr Reddy's Laboratories Ltd has planned a large number of discoverystage and clinical development stage programs. The research programs at Discovery Research are focused towards developing promising drug candidates in the key therapeutic areas of metabolic disorders and cardiovascular indications. In the second quarter of 2005, its investments in R&D have decreased by 2 percent to Rs 51.5 crore from Rs 52.5 crore in Q1 2005. As a percentage to total revenue, R&D spend was at 9 percent as against 10 percent in Q1 2005. This includes reduction of Rs 7.4 crore under the partnership deal with ICICI Venture. During the quarter, of the total reported R&D spend, the company invested Rs 28.1 crore in drug discovery and specialty compared to Rs 29.6 crore in Q1 2005. However, it has strengthened its war chest to support research and litigation costs incurred by it by formalizing a $56-million (an estimated Rs 245 crore) agreement with ICICI Venture Funds Management Company for the development and commercialization of generic drugs filed in the US in 2004-05 and 2005-06.

Dabur Pharma Ltd too is planning to make investments of over Rs 300 crore for expanding its manufacturing capabilities and increasing its R&D activities. It is trying to rope in foreign investors including IFC to invest in the company. IFC is exploring a possible equity investment of $15 million in the company. The proposed investment of Rs 300 crore will be spread over the next three years. While 40 per cent of this would be utilized in expanding manufacturing units, the rest will go towards R&D. On the research front, Dabur is the market leader in oncology formulations and active pharmaceuticals ingredients (API or bulk drugs) in India

Nicholas Piramal India Ltd (NPIL), one of the leading pharmaceutical players in the country, has invested about Rs 90 crore in setting up a state of-art R&D facility in Mumbai and is planning to spend Rs 1,215 crore in R&D in the next seven years. NPIL is already working closely with leading institutions like IISc and Anna University for R&D activities. Now it has signed a letter of intent with BioSyntech, a Canadian biotech research company that specializes in the discovery, development and manufacturing of cost-effective and physician-friendly biologic implants for therapeutic delivery and regenerative medicine. NPIL's R&D focus will be on four therapeutic areas-oncology, inflammation, diabetes/metabolic syndrome, infectious diseases, with specific biological targets in each area. Oncology is NPIL's most successful program, with the lead molecule (P276) slated to enter Phase I human clinical trials in first half of 2005. The molecular target for this drug, cyclin-dependent kinase- 4 (Cdk4) belongs to a class of enzymes involved in regulation of the cell cycle and causing enhanced tumor cell proliferation.

Having one of the finest R&D centers in the country and driven by a mission to become a research-based international pharmaceutical company, Ranbaxy has built expertise in chemical research, pharmaceutical research, fermentation research as well as Novel Drug Delivery Systems Research (NDDS) and New Drug Discovery Research (NDDR). It is committed to channelise close to 6 percent of its global sales into R&D and are accelerating its initiatives in NDDR and NDDS. It presently has around 8-10 programs in the area of NDDR including two NCEs (New Chemical Entities) that are in the clinical phase of development. The urology molecule, RBx 9841, successfully completed single and multiple safety and tolerance studies in normal volunteers and the Phase-II proof-of-concept (POC) clinical trials will be initiated during this year. The collaborative research program with â€œMedicines for Malaria Ventureâ€? (MMV), Geneva, for the development of Anti-Malarial Drug,

RBx 11160, is progressing well. The POC Phase IIA clinical trials have been completed and the results are expected by September 2005. R&D expenditure in the quarter ended June 2005 also increased substantially to $26 million, registering an increase of 105 percent. The surge in spending is attributed to the company's increase in bio-studies for generic filings and an increased number of product filings, worldwide. Dr Brian W Tempest, CEO and managing director, Ranbaxy added, â€œWe have committed ourselves to a series of strategic and investment initiatives that will equip the company favorably to achieve its mission of $2 billion sales by the year 2007.â€? Continuing its effort to strengthen the R&D team, Ranbaxy appointed Dr Pradip K Bhatnagar as Head- New Drug Discovery Research in July this year. Dr Bhatnagar brings with him wide-ranging experience covering the areas of drug discovery and alliance management, from his 23 years of association with GlaxoSmithKline, USA.

Biocon, an integrated biotech company, continues to make investment in R&D. Biocon's R&D efforts are directed towards five key domains: recombinant DNA technologies, bioprocess development, fermentation-based small molecules, enzymes and biotransformation and clinical development. Kiran Mazumdar-Shaw, chairman and managing director, Biocon added, â€œR&D investments will be key to our growth. Discovery-led R&D will be the differentiator and transforming R&D from generics to discovery led R&D is a priority at Biocon.â€? R&D has enabled Biocon to develop innovative processes, products and technologies. By pioneering novel ways of collating and managing information and knowledge, Biocon has strengthened and extended its R&D activities to diverse domains. Biocon has recently announced a joint R&D program with North Carolina (USA) based Nobex Corporation for Oral Insulin based on Nobex's proprietary conjugated peptide delivery platform. The two partners expect to file an INDA with USFDA by the end of 2005. The company plans to significantly increase its R&D to support a discovery led research strategy. It believes this approach will deliver superior shareholder value over the medium and long term. Consistent with its stated research strategy, it has made significant progress in its collaborative in-licensed R&D programs viz. h-R3/ cancer vaccines (CIMAB), oral insulin (NOBEX) and human antibodies (VACCINEX). Biocon sees these as rapidly developing into very large global opportunities over the next three to four years.

â€œThe goal at Panacea Biotec is to develop value added drug products through concerted research in the fields of drug delivery and discovery in the fields of small molecules, vaccines and biopharmaceuticals,â€? informed Rajesh Jain, joint managing director, Panacea Biotec. With more than 40 research-based products in the market, the company's R&D division was involved in developing 20 new vaccines both in combination and single categories under the â€œeasy immunizationâ€? umbrella. The R&D center is focused on the following activities: formulation design and optimization based on in-vitro and in-vivo studies, pharmacokinetic and pharmacodynamic studies in animals, analytical and bio-analytical method development and validation, stability studies, impurity profiling and synthesis, chemical process development and optimization and manufacturing of clinical trial batches. It is also strengthening its R&D activities in view of the market expansion plans it has undertaken. â€œBy 2007 we would have seven R&D centers with 500 scientists from the present capacity of three R&D centers with about 150 scientists,â€? added Jain. Besides, by 2010 it expects R&D spending to near 10 percent of turnover from the current six per cent. The new R&D centers include: new drug discovery research centre at Mohali in Punjab to develop new chemical entities; biopharmaceutical research centre in New Delhi to churn out novel therapeutics; and global R&D centre at Navi Mumbai to develop advanced drug delivery system based products.

Shantha Biotechnics, a pioneer in developing and commercializing a recombinant- DNA based healthcare product in India, used to spend at least 5 percent of its gross revenue on R&D. It is involved in the development of biologicals that are going out of patent, shortly. These products will earn the company the status of a leading generic biopharmaceutical company in the next decade. It has taken up in-house as well as collaborative research projects aimed at developing innovative biopharmaceuticals including vaccines against HCV, HEV and TB and therapeutic antibodies.

Torrent Pharmaceuticals Ltd based out of Ahmedabad is currently expanding its R&D facility to cater to the needs of regulated markets. The enhancement in R&D infrastructure and increased focus on R&D will strengthen its product pipeline. It may be noted that the company has received $3 million as license income subsequent to the license agreement entered with Switzerland-based Novartis Pharma AG. The agreement grants global rights of patented AGE (Advanced Glycosylation Endproducts) compound to Novartis and envisages a long term arrangement involving subsequent milestone payments as the molecule passes through various phases of clinical development, regulatory approvals and ultimate commercialization. Currently, the Rs 513 crore Torrent Pharma has seven discovery projects in pipeline-one in cardiovascular, four in metabolic disorders and related complications, one in central nervous system and one in obesity. Torrent Pharma has earmarked Rs 100 crore to double its R&D infrastructure and operations over the next 18 months.

GLOBAL BIOTECH R&D PRODUCTIVITY ON THE RISE

The productivity of big pharma has been remarkable over the past 25 years.

In each of the last 10 years, the pharmaceutical industry has ranked at the top of Fortune s most profitable industry list. But this top ranking has eluded the industry in recent years, during which the productivity of the biotech sector, for many years poor in the aggregate has strengthened markedly.

An emerging distinction between biotech and big pharma is the productivity of R&D.

According to Arthur D Levinson, chairman and CEO, Genentech, R&D spending by large pharmaceutical companies has been steadily increasing over time, while the number of new drug approvals (NDAs) coming out of these companies has been decreasing. In 2004, the pharmaceutical industry spent about $50 billion on R&D, compared to $10 billion spent on R&D by publicly traded US biotech companies, and an estimated $20 billion spent by the global biotech industry.

In spite of huge R&D expenditures, big pharma's NDAs have been declining steadily, while biotech has accounted for an increasing share of NDAs over the past five years.

In 2003, the biotech industry hit a milestone when it surpassed big pharma in the number of new drug approvals from the Food and Drug Administration (FDA) in a given year.

The trend continued to favor biotech in 2004. In 2005, an estimated 35 new pharmaceutical or biotechnology products with sales potential of at least $150 million each will enter the market. Of these, 20 are expected to be products from biotechnology companies, and will be marketed directly by these companies or in collaboration with pharmaceutical partners.

In addition, there are more than 700 compounds from biotech firms at various stages of development, with more than 400 compounds in clinical trials. More than four out of five therapies currently in drug development are founded on biotech discoveries or employ biotech tools.

Source: Ernst & Young

Biotechnology is a thrust area of research at Cadila Pharmaceuticals Ltd (CPL). Over the past few years, it has established a strong R&D base in biotechnology and developed working relations with key R&D institutes in the country for outsourcing of R&D. The R&D team has a demonstrated track record of biotechnology absorption through collaborative research. At CPL, collaborative R&D is being carried out in half a dozen national and international research laboratories like IMTECH, Chandigarh, NII and CBT, New Delhi, ICGEB, New Delhi & Trieste, Italy. Development of rDNA proteins for prophylaxis, therapy and diagnosis, isolation, purification and characterization of biopolymers from natural sources (proteins, enzymes and carbohydrates) for development of surgical aids, therapeutics and prophylactics, immunodiagnostics development, development of PCR-based gene probe assays, development of polyclonal antibodies for use in passive immunizations (passive vaccines) and immunodiagnostics are some of the R&D focused areas at CPL.

Manipal Acunova, promoted by the Manipal Group, is investing Rs 45 crore to position itself as a biotech and clinical research company and branch into stem cell research. In the clinical research space, the company has tieups with Biocon India, Pfizer, and AstraZeneca for cancer drug trials. As a contract research organization, Manipal Acunova will focus on drug discovery work for the bio-pharma companies using basic biology and chemistry route. Cancer and diabetes are its focused areas. Besides it is focusing on stem cell research. For stem cell research, it is setting up facilities designed by Zanders of Germany in Bangalore.

Since its inception, Serum Institute of India Ltd, India's leading vaccine manufacturer, relied greatly on its R&D activities. A distinctly separate autonomous body, Serum Institute of India Research Foundation, was instituted with an aim of doing research in the fields of medical sciences and in natural and applied sciences.

Instead of focusing on fundamental research, Serum Institute's thrust is on applied research. It used to take up ongoing projects, those in concept or pilot scale technology and then do the R&D on the actual development of the product and scale-up of the product. This is actively supported by Serum Institute to develop very high quality products with higher yields. At Serum, about 25 percent of its premises is used for R&D facilities. One can't find an independent R&D facility at Serum Institute.

Biotechnology too is Wockhardt's R&D thrust area. Its DNA-based biotechnology team has succeeded in developing recombinant Erythropoietin. Several other products are under development including interferon alpha 2B and other anti-cancer drugs. In the short-term, Wockhardt's R&D is aimed at providing new products in India and technology-based pharmaceutical bulk active and dosage forms for the US, European and other markets. In the longer-term, Wockhardt's R&D strategy is to discover a series of new drugs, especially in the field of anti-infectives, antibiotics and anti-bacterials.

Wockhardt has invested Rs 350 crore in recent years on R&D activities. This includes the Rs 30 crore R&D centre at Aurangabad. Wockhardt is investing Rs 125 crore in R&D in 2005, up from Rs 94 crore in 2004.

Home to 160 scientists, the Lupin Research Park at Pune near Mumbai, is creating new families of life sciences products and services. The Park houses dedicated prototypes and pilot plants for the development of a range of drugs in several therapeutic segments. R&D at Lupin is organized around three focus areas: generics drug master files (DMFs) for APIs and abbreviated new drug applications (ANDAs) for finished products, new chemical entities (NCE) using the synthetic and herbal routes and noveldrug delivery systems (NDDS). Lupin has increased its R&D spend to 6.9 percent of net sales and also entered into a tie up with Cornerstone BioPharma Inc. for anti-infective products. Similarly at Bharat Biotech International Ltd, R&D is an ongoing process. The R&D team has undertaken projects of immense social and scientific relevance. At Bharat Biotech's labs, the following products are currently in the stage of clinical trails: Rabies, Japanese Encephalitis, epidermal growth factor and malarial vaccine. Bharat Serums and Vaccines Limited (BSV) too has recognized the criticality of R&D and has established in-house R&D capabilities. BSV's R&D team focuses on developing new generation recombinant therapeutics that replaces the traditional plasma products, which are in short supply worldwide due to dependence on human donors.

Narayan Kurlkarni with Ch Srinivas Rao