

New entrepreneurs and enterprises

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With innovative ideas and strong leadership the biotech industry is all set for an inimitable progress. The new start-up companies are springing up while the others continue to expand their existing businesses and making their presence felt. Get the real pulse of the booming biotech in the country...

The rate at which new companies are being created in India is astounding. With the venture capitalists looking for new places to invest their money, the number is all set to increase dramatically.

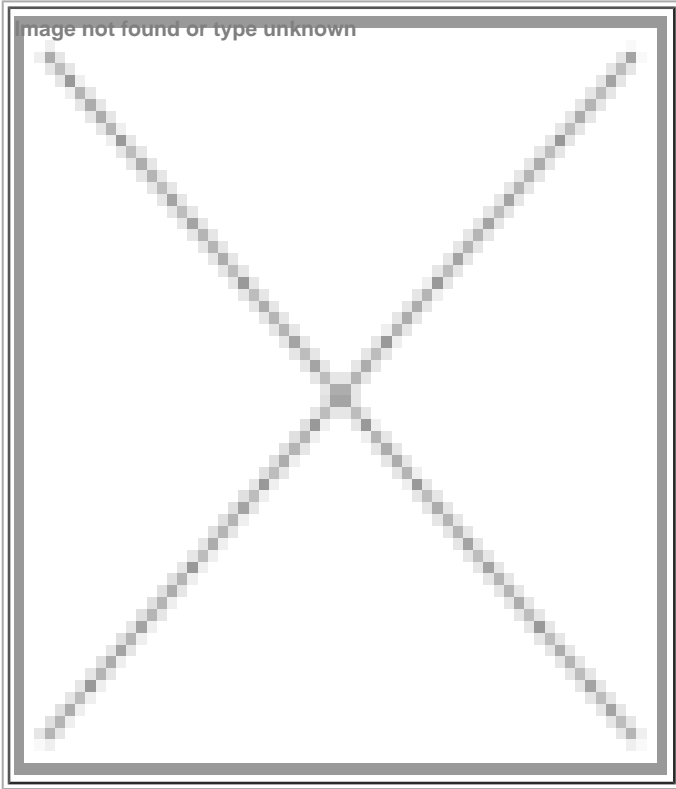
The government is also taking all necessary steps to enhance the development of biotechnology in the country and the new biotechnology policy focuses on promoting biotech research and extends support in the form of incentives, concessions and benefits to new players and entrepreneurs. The biotech incubators play a key role in enabling the new entrepreneurs to convert their research ideas into commercially viable technologies without making a big R&D investment.

The central government also took initiatives to encourage the growth of the biotech sector in India. The government instituted the YES program and the Small Business Innovation Research Initiative (SBIRI) scheme to facilitate and stimulate the start-up of innovative enterprises in the biotechnology sector. The scheme was started in 2005 with an aim to strengthen existing private industrial units whose product development is based on in-house innovative R&D, encourage other smaller businesses to increase their R&D capabilities and capacity and cultivate the entrepreneurial spirit by creating opportunities for starting new technology-based or knowledge-based businesses by science entrepreneurs.

The excitement and enthusiasm of the companies to the scheme can be gauged from the fact that within the first two months of advertising the scheme DBT received 71 full proposals and 17 concept proposals. So far, the biotech industry in the southern region has shown the maximum interest with Karnataka being the topmost state to submit proposal followed by Maharashtra, Andhra Pradesh, Tamil Nadu and Delhi. Since the last four years, BioSpectrum has regularly been profiling the new enterprises and while also keeping the readers updated with the continuous developments of the companies profiled

earlier.

New Entrepreneurs

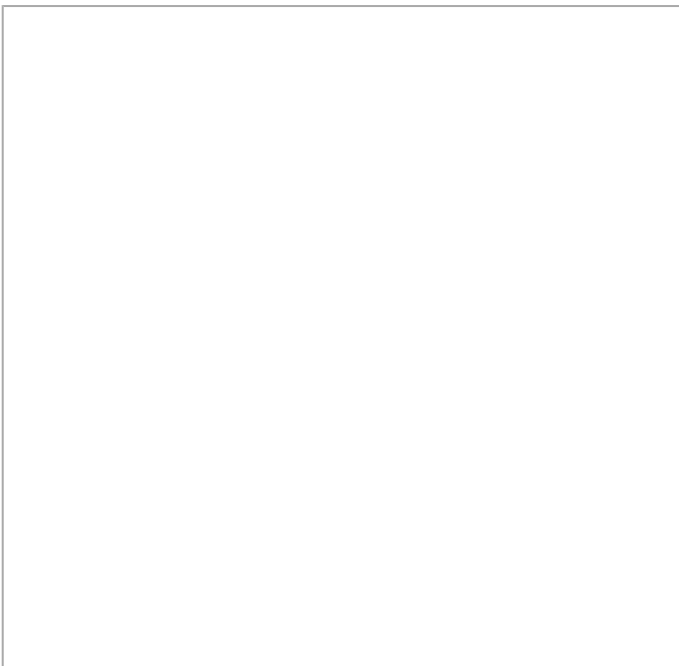


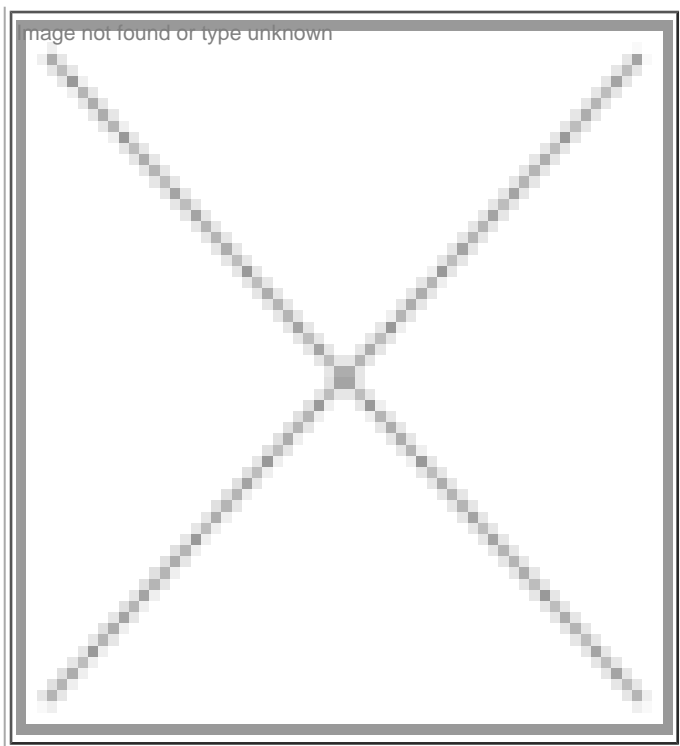
Acton Biotech (India) Pvt Ltd.

It has been a long road for the Sandeep Saxena, CEO and founder of the Pune-based Acton Biologicals who always aspired to be an entrepreneur in the business of life sciences and has his own start-up business. He joined Nirma University for an MBA course, the university later accepted his business proposal for the start-up, Acton Biotech.

Acton team is now working on cancer drugs and is educating doctors about the efficacy of different types of drugs on different types of genes. Acton has 10 collection centers all over the country. Unlike any other diagnostic company, which tests blood samples as per the requirements of the doctor or the patient, Acton collects blood samples from all over the country and then extracts the single nucleotide polymorphism (SNP) in the gene and checks the enzymes responsible for the metabolism of drugs for the disorder or disease and prescribes drugs accordingly.

“In a case like oncology, If you look at drugs for complex diseases like cancer they work only on 20 percent of the population on an average. The difference in efficacy is because the metabolism rate differs from person to person,” opined Saxena. Currently the company is working on genotype efficacies for oncology. Having a foothold in oncology, Saxena now has plans to move the company into other segments like cardiology, diabetes and asthma, to achieve next year's target revenue of Rs one crore.



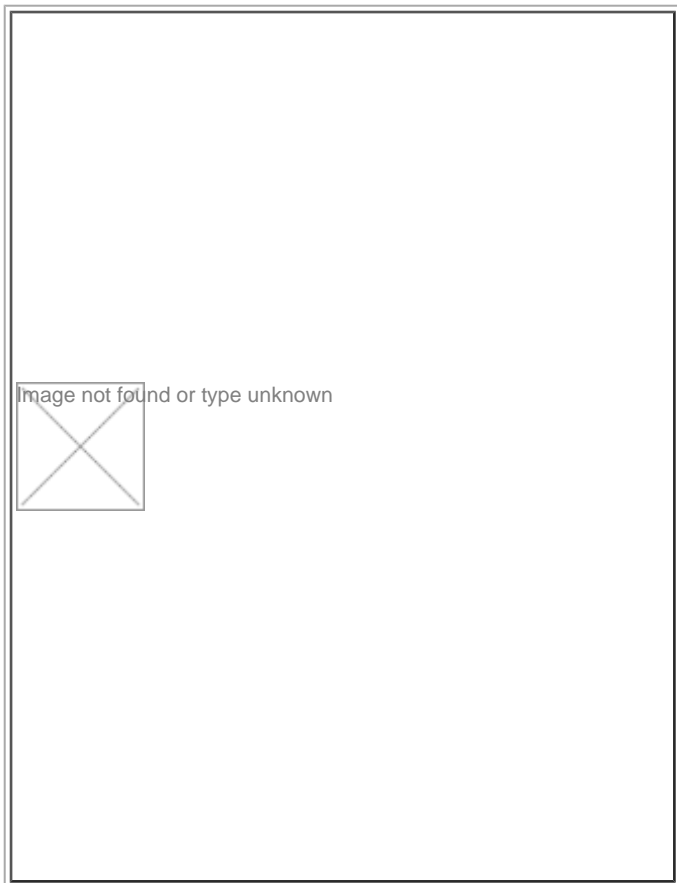


Ara healthcare Pvt Ltd

Ara Healthcare under the leadership of Dr Rama Mukherjee is focussed on developing novel biological entities and providing molecular diagnostic services for genetic and infectious diseases. Dr Rama Mukerjee has been the brain behind Dabur Research for quite a few years where she headed the R&D unit. She is now all set to synergize her scientific capabilities coupled with entrepreneurial spirit as she takes on the mantle of heading her own company, Ara Healthcare.

Ara Healthcare is based in Gurgaon. Dr Mukerjee has got together a team of six scientists from Dabur and recruitment is on to ensure that Ara is 30-people strong by this year-end. They already have three molecules from Dabur (for cancer) for further development out of which two are NMEs and the third is a biological entity.

It currently has facilities and labs for molecular biology, protein chemistry, protein purification, PCR and a preclinical analytical support lab. The company also received funding under the SBIRI scheme by DBT for developing three recombinant proteins and has close to 50 people now working in various capacities. The company is also developing an array of sophisticated and sensitive diagnostic assays for early disease detection and therapy monitoring.



Novalead

The genesis of Novalead Pharma is yet another example of a research division being hived out. Towards the end of 2007 Pune-based drug discovery software company, VLife Sciences divested its research arm and named it as Novalead Pharma. Supreet Despande, CEO and the brainchild behind Novalead said, "We wanted to be focused only on drug discovery research while VLife Sciences handle the computation technology part of it. We wanted to be specific and hence we separated the research pipeline for VLife Sciences and that of Novalead Pharma." Initial investment of one and a half crore rupees, came from personal funding and savings of founders and Angel investors.

The Series- A venture capital investment was raised in April, 2006 through the Kotak Mahindra - Private Equity Group. As of now, there is a big investor interested in investing, whom Despande did not want to name. Revenue churning will only happen after two years when the licensing of Intellectual property will kick start after human validation will be complete. At present the lead compound for Diabetic Foot Ulcer is in process. By 2011, it should be outlicensed, with the deal touching around \$400-700 million mark. The Co-Founder and COO, Atul Aslekar again has the main responsibility to lead technology development and sourcing to continuously improve on NovaLead drug discovery process. In the avenue of technology, Novalead has come up with virtual screening technologies like VLifeAmadeus screening platform and VLifeBiblica knowledge compendium (developed along with VLife Sciences).



RAS Lifesciences

Set up in March 2008, Hyderabad based RAS Lifesciences is determined to deliver the best and cost-effective solutions for healthcare. RAS offers cost-effective solutions for private and public biotech sectors. Dr Shesheer Kumar, MD, RAS Life sciences believes "Each client and program is as unique as the products they bring to our facilities, and we strive to provide the customized service they need." With the changing scene in the country, RAS Lifesciences is also involved in planning their priorities, analyze the research capabilities and foresee the need of the service sector in terms of biotech products. The start up is working on molecular diagnostics and engaged in design development and commercialization of cost-effective screening system for various infections, genetic diseases and various cancers. The company is also working as consultants in biotechnology providing personalized solutions for industries, academic biotechnology teams, individual investigators and investors.

RAS Lifesciences is currently doing many research projects in the area of molecular diagnostics, which includes identification of novel markers for detection of cancer, cost-effective assays for infectious diseases and development of Real-Time PCR

based quantitation assays. In the coming six months, RAS would be starting its cell culture facility, manufacturing and marketing of diagnostic kits and production of industrial enzymes. New Enterprises [New Enterprises](#)

Actis Biologics Pvt Ltd (ABPL)

ABPL, a 2005 start-up has successfully continued its business of developing new molecules using biotechnology and genetics. The company has developed a unique business model of first scouting for innovative processes or technologies for the discovery of new molecules in collaboration with scientists, entrepreneurs or inlicense the targets, then develop the process and spin it off as a different company and then go to market leaders and strike a deal. The company's first product, Angiozyme, which is used for the treatment of colorectal cancer is due to be out in a couple of months in the market. Other two technologies of the company includes, the VFF2, which enhances protein expression and the MSP36 that is aimed at curing breast cancer. As of now, the latest on the cards for ABPL is its Biocity initiative. Actis Biologics in Malaysia (ABM) holds the responsibility of setting up Actis Biocity, a ecosystem for biotech initiatives or companies to thrive in. ABPL intends to raise funds of approximately \$25-30 million through private placement of equity with reputed investors. Funds are proposed to be used for land and building, equipment, product development, technology transfer fee payment, working capital margin and other miscellaneous expenditure. The company has filed 65 patents in India.

Albany Molecular Research Institute

(AMRI), which started its operations in 2007 has recently announced the expansion of multi-purpose pilot plant facilities in Aurangabad, providing non-GMP manufacturing services of up to 1,000 liter scale. In addition to being a stand-alone provider, the new facility will serve as an extension to AMRI's kilo lab capabilities in Hyderabad. "We are pleased to offer another high value alternative to our customers seeking the cost benefit of doing business in Asia, while retaining the quality they expect from a US-based organization. We also look forward to realizing cost savings at our US manufacturing operations. This expansion further demonstrates AMRI's investment and focus on building a worldwide drug discovery and development platform," said Thomas E D'Ambra, chairman, CEO and president, AMRI. As a value-added service to its customers, the company is also investing in R&D in order to expand its contract services and to identify novel early stage drug candidates with the goal to outlicense that to a strategic partner

Biogen Idec Biotech India Pvt Ltd.

Biogen Idec, the US based biotech company headquartered in Cambridge, Massachusetts has established its wholly-owned Indian subsidiary in October 2007. The Indian subsidiary is headed by Dr Alpna Seth. The company specializes in drugs for neurological disorders, autoimmune disorders and cancer. Biogen Idec already has tie-ups with Roche and Nicholas Piramal for marketing its drugs MabThera and Avonex respectively. The company is working on developing drugs for several serious diseases such as, Non Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, solid tumors, Multiple Sclerosis, Parkinson's disease, Crohn's Disease, Heart Failure, Pulmonary Arterial Hypertension, Hemophilia B, rheumatoid arthritis, neuropathic pain, etc.

Biovel Life Sciences

Biovel Life Sciences is yet another example of a successful enterprise. The company within three years of its inception, has expanded its research facility and has set up a new production facility in Bangalore with an investment of Rs 50 crore. Biovel is setting up facilities for research work in drug delivery and monoclonal antibodies. "Our philosophy is to cooperate, collaborate and co-develop, and with this attitude Biovel has entered into the collaboration with several national and international companies for technology transfers and co-development of products," said Dr Durgaprasad Annavaajulla, director- Technical, Biovel Life Sciences. The company has entered into an inlicensing agreement with Dow Pharmaceuticals, USA, and obtained the technology with global marketing rights for producing the human growth hormone (HGH). Biovel is also developing a department which has the major focus on the delivery systems, either by inventing or by using the expired patents. Further, the company will be entering in the areas of peptides and monoclonal antibodies in the coming years.

Cryo-Save India

Cryo-Save India, the 100 percent Indian subsidiary of Cryo-Save group, has made its foray into the country by launching a full-fledged storage facility in Bangalore and marketing set-ups all across the country. The new facility is a part of their strategic plan for India and is envisioned to further strengthen the company's position in the Indian market. Cryo-Save India caters to parents growing need of providing bio-insurance to their offspring, the company has plans for a phased launch in key centers across the country. Cryo-Save India will be the only company in India with its unique offering of dual-storage system and this will be available for the first time in the country. They are also the only company that does automatic processing to avoid manual intervention and contamination. The company will be offering the collection and storage of adult stem cells derived from cord blood. The services will be available across all metros and other cities.

Genzyme

Genzyme India was set up on November 21, 2007, as a wholly owned subsidiary of Genzyme US. The company is headquartered in Gurgaon and looks after the operations of the South Asia region. The objective is to bring the products and services of Genzyme to India. Currently the products available in the country are Thymo globulin(rabbit ATG), Thyrogen(recombinant TSH) and Synvisc(Hyaluronic acid), of which the first two are marketed by Genzyme while Synvisc is

licensed out to an Indian partner. The company has set up a dedicated sales force for thymoglobulin and thryogen to cover the entire region and also initiated clinical trials in the country.

ICON Central Laboratories

ICON plc, a 2008 start-up is the global provider of outsourced development services to the pharmaceutical, biotechnology and medical device industries has opened a full service central laboratory in Bangalore. The purpose-built, 15,000 sq ft facility expands its existing network of laboratories located in Farmingdale, New York; Dublin, Ireland and Singapore. The new laboratory is in the process of receiving CAP (College of American Pathologists) and NABL (National Accreditation Board for Laboratory Testing) accreditation. The ICON Central Laboratory India is being headed by Dr Anuradha Rajput who has eight years of experience with Clinigene International.

ICON Central Laboratories is dedicated solely to support clinical trials by providing global capabilities and state-of-the-art testing services with over 98 percent of testing required for any clinical trial performed in-house. The new facility of ICON will provide a broad menu of testing services ranging from basic safety testing to biomarkers, on-site sample management service and storage, project management support for both regional and global trials, logistics support to ensure streamlined transport of study supplies and in-bound specimens and global data management support.

Lonza

Lonza is headquartered in Basel, Switzerland, the contract manufacturing base, has recently set up shop in India in 2007. In Indian operations they are focusing on five major areas – sales of the intermediates for the production of Active Pharmaceutical Ingredients (APIs) used in the ARVs (anti-retroviral) formulations for access-to-medicines markets under President's Emergency Plan for AIDS Relief (PEPFAR).

Recently Lonza acquired Amaxa, a market leader in gene transfection into primary cells. Shortly Amaxa product offerings will be available to R&D scientists engaged in biologics research in India. Other avenues include sales and business development of disinfectant formulations for hospitals and pharma clean rooms under the Lonzaguard brand, another arena is building the external manufacturing network of Indian companies to outsource production of small molecules to compliment internal capacities of their API plants worldwide. – Nutrition ingredients is the other major area where we will soon be exploring marketing opportunities in India in 2007, we acquired two businesses from Cambrex – Bioproducts, which we renamed Lonza Bioscience, and the microbial biopharmaceuticals business, which was integrated into the Lonza Biopharmaceuticals business after the acquisition, – concluded Dr Harry Rathore, president and country head, Lonza India.

Polyclone BioServices

We featured the company in 2006 as a new enterprise has today grown to a complete genomics service provider offering lab and computation based discovery, validation and analysis services to biosuppliers, biotech platform companies and drug discovery companies. With sales representatives based in Germany and the US, the company today caters to customers in Europe and North America. Polyclone has built a strong research background and has put in place a network of partners including Karnataka Cancer Therapy and Research Institute, TATAA Biocenter, Goteborg, Sweden and Center for Functional Genomics, State University of New York, Albany.

RFCL

What began in 2005 as a 100 percent ICICI venture owned company is today a successful and path-breaking company with interests in diagnostics, biomedical Sciences, veterinary healthcare and scientific laboratory solutions. The company stood 17th in the Biospectrum-ABLE biosuppliers annual survey in August with revenues of Rs 34 crore (Rs 90 crore including diagnova sales) RFCL announced its first global acquisition in the space of veterinary healthcare through a share purchase agreement with Marsing & Co Limited A/S for its Germany based subsidiary co. Bremer Pharma GmbH in March 2008. The company has been on a massive acquisition spree since 2007 with the acquisition of Wipro Biomed- a biomedical, health and life sciences company that strengthened its Diagnova(diagnostics) business. Again in January 2008, it acquired Godrej Medical diagnostics and Alved foods and Pharma. While Godrej Medical Diagnostics strengthened its position in infectious diseases portfolio with Malaria and TB point of care testing kits, Alved, the company's first inorganic acquisition complemented Vetnex (RFCL's Animal Healthcare business) in terms of product profile and distribution network.

The company launched its first world class manufacturing plant in Sidcul, near Haridwar, spread across 91,000 sq ft built-up area and designed to conform to the WHO GMP and US FDA standards. The facility currently has the capacity to manufacture 10 million tablets, 3 million dosages of liquids and 12 lakh dosages of powder injectables. This plant has been designed to cater to an increase in demand by 25-30 percent without any additional major investments in the facility. The company is also setting up a laboratory chemicals manufacturing facility in Panoli, Gujarat, at an investment of around Rs 60 crore to cater the demand from western India and is slated to come up in 2009 to cater to global requirements.

Xcelris Labs

With the global CRO market almost touching a \$800 million (according to a Mckinsey report), the opportunities that Gujarat-based Claris Life Sciences had foreseen was thumping. The result was the setting up of a new company named Xcelris Labs in 2006, with an investment of Rs 6 crore. The newly set up CRO provides product development, work largely for generics from regulated markets like the US and western Europe. Three projects worth \$3 million from European pharma companies were already bagged. The CRO undertakes product development, regulatory support, bio-equivalence studies and clinical

trials, contract research and development, and customized solutions.

Xcelris has been concentrating in the critical care segment. “A small unit of Xcelris was set up within Claris. To avoid conflict of interest around a year back, Xcelris Labs became a separate entity altogether. We did not want any conflict of interest with the parent company so we became an independent entity a year and half back,” said Dr Gita Sharma, head, R&D, Xcelris Labs. The CRO back in September 2008 entered into a strategic Alliance agreement with Drug Monitoring and Research Institute (DMRI), Mumbai to provide bio-analytical or bio-equivalence services. Under the agreement, Xcelris Labs will work with DMRI as a partner to provide BA/BE services to its clients. It is now waiting for the ISO certification.

New Products **New Products**

The nano product series

The last two years have seen nanotech showing some signs of commercialization. Dabur launched its indigenously developed product Nanoxel in 2007. Biocon in partnership with Abraxis BioScience, Inc. launched Abraxane, the paclitaxel protein-bound particles for injectable suspension (albumin-bound) in India for the treatment of breast cancer. The phase-III clinical trial in the US demonstrated that Abraxane nearly doubled the response rate, prolonged the time of progression, and improved overall survival in the second-line setting versus solvent-based Taxol in the approved indication. In the US pivotal head-to-head trial, the overall response rate of Abraxane was 33 percent as against 19 percent compared to Taxol. While, Abraxane achieved a 25 percent improvement at the time of tumor progression when compared to Taxol.

Champix from Pfizer

Towards the beginning of the year, Pfizer Limited launched Champix a non-nicotine smoking cessation prescription drug. Champix (varenicline), is developed specifically to act on reducing nicotine craving as well as smoking. Research shows that the odds of quitting smoking on Champix are twice that of bupropion and four times that of placebo. It is the first such product to be approved by the US FDA in the last 10 years. Varenicline has received a priority FDA review because of its significant potential benefit to public health. The cost comes to approximately Rs 9,000 per course. It has benefited over 5.7 million people since its worldwide launch in mid-2006. Champix has a novel dual mode of action. Unlike other smoking cessation solutions that work only on controlling the withdrawal symptoms, Champix reduces withdrawal symptoms and also the smoker's sense of satisfaction derived from smoking. It eases the nicotine withdrawal symptoms as well.

Recosulin from Shreya Life Sciences

Shreya Life Sciences, India, had announced the launch of its recombinant DNA human insulin spray under its brand name of Oral Recosulin with the technology, RapidMist, being developed by the company's US collaborator Genex Biotechnology. Oral Recosulin provides freedom from limitations of conventional insulin therapy. Genex's new technology delivers insulin through buccal mucosa directly to the vascular system. Shreya will also be launching its third generation Hepatitis –B vaccine somewhere in February or March 2009. The vaccine will be made out of mammalian cells.

Boostrix and Infanrix vaccines from GSK

In January, 2008, GlaxoSmithKline Pharmaceuticals Ltd (GSK), announced the launch of two new innovative Diphtheria, Tetanus and acellular Pertussis (DTP) vaccines- Boostrix and Infanrix. Unlike traditional vaccines, acellular vaccines provide far more comfort to parents and the children due to substantially reduced pain, fever and swelling. Infanrix is indicated for childhood immunization against Diphtheria, Tetanus and Pertussis for newborns from 6th week of age. When combined with Hib vaccines it reduces the number of pricks and visits to the doctor. Boostrix can be administered to older children above seven years of age, adolescents and adults and will boost the waning immunity against DTP.

Solostar from Aventis

Aventis Pharma Limited launched a new prefilled disposable insulin pen, Solostar for use with the 24-hour insulin Lantus. This disposable insulin pen is to be used for the treatment of hyperglycemia in people with type 1 or type 2 diabetes and was made available in India in April 2008. Solostar is a new, easy-to-use disposable pen for administration of Lantus. A Solostar test dose range of any disposable insulin pen comes with doses of up to 80 units adjustable in one unit steps. Solostar meets the applicable standards specified by ISO (International Standards Organization) including the standards for dose accuracy. Solostar, an easy-to-use insulin pen brings greater flexibility to patients and an opportunity for earlier initiation of insulin therapy which may contribute to better glycaemic control.

Gardasil from MSD Pharmaceuticals

In October 2008, MSD Pharmaceuticals (India) has launched Gardasil, India's first vaccine to help prevent cervical cancer caused by the human papillomavirus (HPV). The vaccine helps to prevent diseases such as cervical cancer; abnormal and precancerous cervical lesions, vaginal lesions, vulvar lesions; and genital warts, caused by HPV. Gardasil is recommended to females aged between 9-26 years. Cervical cancer, or cancer of the uterine cervix is caused by certain high-risk HPV types that can cause the cells in the lining of the cervix to change from normal to precancerous lesions. If these precancerous lesions are not diagnosed early and treated, they may turn cancerous after a few years. The quadrivalent vaccine is given as an intramuscular injection, in three doses over a period of six months.

Bonista from Ranbaxy

Ranbaxy Laboratories Limited (Ranbaxy) announced the launch of Bonista-Teriparatide injection (recombinant human parathyroid hormone) for the treatment of osteoporosis, in collaboration with Virchow Biotech. Hyderabad. Ranbaxy is the

