



Inside the Issue

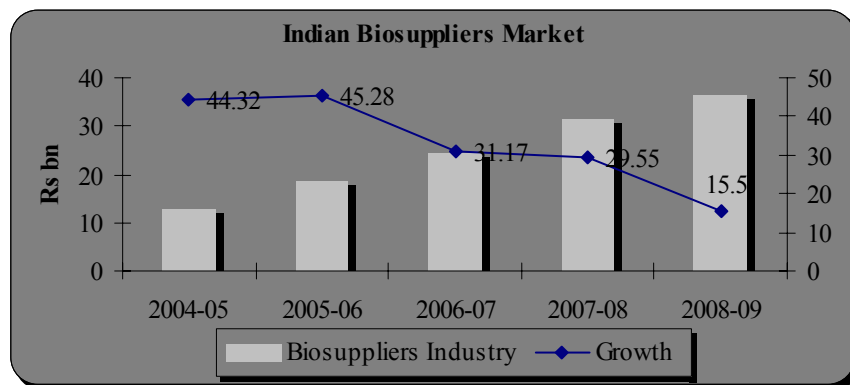
- In Focus: Indian Biosuppliers Market
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In Focus: Indian Biosuppliers Market - Decline in Growth

Biosuppliers Recorded Decline Growth Rate of Around 16%

In the past six years, biosuppliers industry has grown double digit at 30-40%, but last year (2008-09) it has recorded a decline growth at 15.5% in line with the trend observed in biotech industry, which is mainly



Source: BioSpectrum; Cygnus Research

due to Indian biotech sector deferment some of their infrastructure investments owing to the recessionary trends. Indian Biosuppliers market has registered revenues of Rs. 36.21 billion in FY08 and recorded growth rate of 15.5%, when compared with previous year revenues of Rs. 31.35 billion.

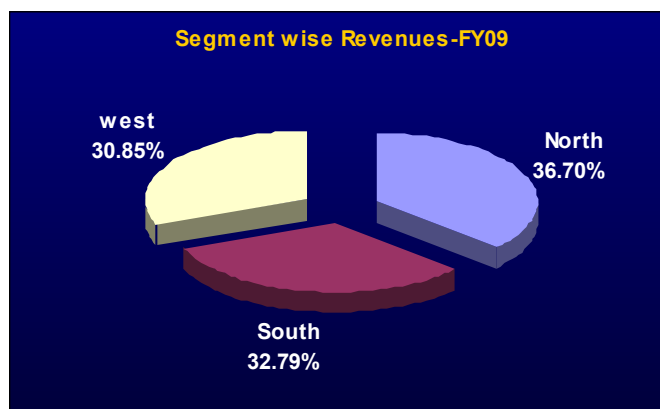
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Segmental Revenue- North region led the race (36.70%)

Biosuppliers market is segmented into three regions: north, south and west. Northern region was the largest bio cluster in terms of the revenues generated by companies with recorded revenues of Rs. 13.29 billion up from Rs. 11.04 in FY08, which has accounted for 36.7% of the total biosuppliers market. Second place is occupied by southern region with recorded revenues of Rs. 11.87 billion and



Source: BioSpectrum; Cygnus Research

accounted for 32.79% market share. West recorded revenues of Rs. 11.04 billion in 2008-09. Becton Dickenson was the leading player from the north with close to 17% share and was followed by imperial lifesciences with 8% share. In northern region, Top five players accounted for 44% of the total revenues of Rs. 13.29 billion generated by the companies based in northern region.

In southern region, top five players accounted 79% of the total business of Rs. 11.87 billion generated by the companies based in the south. Waters India is the largest player in south with Rs. 3.33 billion and 28% market share. Spinco biotech is the second largest player with 19% market share in south region. In west region, top five players accounted for 40% share of the total business of Rs 17.47 billion generated by the companies based in the western cluster.

Top Global Biosuppliers

The top ten global players of biosuppliers market recorded Rs. 14.27 billion in 2008-09, a growth of 45%, when compared to previous year Rs. 9.85 billion. Beckman coulter has recorded 96% growth when compared to previous year, Followed by GE Healthcare life sciences and Eppendorf Indian. Moreover, top five players accounted for 75% of the total global suppliers business.

Top 10 Global Suppliers (Rs billion)			
Company	2007-08	2008-09	Growth
Waters India	2.6	3.3	26.4
Becton Dickenson	1.8	2.3	30.1
Thermo Fisher Scientific	-	1.9	-
Millipore India	1.7	1.6	-7.44
Shimadzu Analytical	1.3	1.5	20.31
GE Healthcare Life Sciences	0.8	1.2	50.00
Sartorius	1.0	1.0	0.42
Eppendorf India	0.4	0.6	43.53
Beckman coulter	0.2	0.5	95.83
Perkin Elmer	-	0.4	-

Source: BioSpectrum; Cygnus Research

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Top Indian Biosuppliers

The top Indian biosuppliers have recorded revenues of Rs. 7.81 billion with growth of 14.29% when compared to previous year revenues of Rs. 6.83 billion in 2007-08. In top ten Indian biosuppliers, top five companies hold around 74.1% of the market, RFCL has shown tremendous growth with 171% when compared to

Top 10 Indian biosuppliers -2009 (Rs. billion)				
Sno	Company	2007-08	2008-09	Growth (%)
1	Spinco Biotech	2.1	2.3	7.15
2	Imperial Life Sciences	0.9	1.0	15.97
3	RFCL	0.3	0.9	170.89
4	Genetix Biotech Asia	0.7	0.8	14.29
5	DSS Imagetech	0.7	0.8	15.53
6	Towa Optics	0.5	0.6	20.18
7	Advanced Microdevices	0.8	0.5	-43.75
8	Jain Biologicals	0.3	0.4	23.88
9	MediSpec India	0.3	0.3	1
10	Axygen scientific	0.2	0.3	31.11

Source: BioSpectrum; Cygnus Research

previous year. Advanced Microdevices has shown decline growth with 43.75%. Spinco Biotech Company, which has recorded revenues at Rs. 2.3 billion with growth of 7.15%, is the largest company in 2008-09.

Top Biotech suppliers

- The top 10 companies with combined revenues of Rs. 17 billion, accounted for 47% market share.

- The top five companies accounted for 31.37% of the total biosuppliers market of Rs. 11.36 billion.

Top Biotech Suppliers (Rs billion)				
	Company Names	2007-08	2008-09	Growth
1	Waters India	2.6	3.3	26.4
2	Becton Dickenson	1.8	2.3	29.88
3	Spinco Biotech	2.1	2.3	6.96
4	Thermo Fisher scientific	-	1.9	-
5	Millipore India	1.7	1.6	-7.39
6	Shimadzu Analytical	1.3	1.5	20.31
7	GE Healthcare Life Science	0.8	1.2	50
8	Imperial Life Sciences	0.9	1.0	15.97
9	Sartorius	1.0	1.0	0.42
10	RFCL	0.3	0.9	170.89

Source: BioSpectrum; Cygnus Research

- The top three companies generated Rs. 7.91 billion in revenues (22% share of the industry).
- Waters India is the largest company with revenues of Rs. 3.3 billion and a growth rate of 26.4%.
- Becton Dickenson is the second largest company with revenues of Rs. 2.3 billion (good growth at 30%).



News Briefs

MARKETING

America

US: US Food and Drug Administration approves new H1N1 vaccine

The US Food and Drug Administration recently approved a new H1N1 vaccine. The vaccine is made by CSL Ltd of Australia; Switzerland's Novartis; Sanofi-Pasteur of France; and US-based Medimmune, which makes the only nasal-spray flu vaccine. The bulk of the vaccine is set to start arriving in October.

Asia Pacific

India: NPPA revises prices of five bulk drugs and 240 formulation packs

The National Pharmaceutical Pricing Authority (NPPA) has revised/fixed the prices of five bulk drugs used in medicines for pneumonia and pain killers. The national drug price regulator has also revised the prices of 240 formulation packs. According to the notification of the NPPA, the regulator has fixed the prices of bulk drug dextropropoxyphene napsylate and dextropropoxyphene Hcl at Rs5,535 per kg and Rs3,361 per kg, respectively. The drugs are used in preparing medicines to treat mild pain and as local anaesthetics. It has fixed the price of cephalosporin sodium used in manufacturing injection for the treatment of pneumonia and other respiratory infections at a price of Rs3,361 per kg.

India: IOL Chemicals to launch Proton Pump Inhibitor in 2010

Leading chemicals and bulk drugs maker, IOL Chemicals and Pharmaceuticals (IOLCP) is expecting to roll out its new drug Proton Pump Inhibitor-an antacid, in 2010 for domestic and export markets. Besides, the company has also plans to launch its anti-inflammatory drug Ibuprofen in over 15 countries under its own brand within this year in line with its plans to achieve Rs3 billion as export turnover by 2010-11. With Ibuprofen remaining the stronghold of company's pharma business, IOLCP is looking to tap 15,000 TPA export market of Ibuprofen in more than 15 countries with its launch this year.

India: PI Drugs receives HC's nod for merger

PI Drugs & Pharmaceuticals announced that scheme of amalgamation of Sequent Scientific, with the company has been approved by the High Court Mumbai vide its order dated June 16, 2009. PI Drugs is engaged in the business of human and animal health. The company manufactures bulk drugs, oral powders, oral suspensions, API, granules, albendazole.

India: Merck to launch 13 innovator drugs

The US-based Merck plans to launch 13 innovator drugs, including a blockbuster product in India, over the next two-three years with an aim to emerge as one of the top-five companies in the Indian domestic retail market by 2015. Besides the drugs launch; the company would go to smaller towns and cities where nobody has gone. The company's growth will be driven by patented drugs. Most of the products would be in the cardiovascular segment and vaccines. In addition to patented drugs, Merck will roll out other niche products which it believes that it would not face any competition from generic drug-makers in India. The low-cost rivals do not have the technological know-how to make them. Further, as part of its policy of differential pricing, Merck would sell drugs at affordable prices

Australia: Australia's Swine Flu Vaccination Plan to Test Global Interest

Australia will begin immunizing people against swine flu in 12 days, heralding a global health campaign that will test public interest in the inoculation. The nationwide program will start Sept. 30 after regulators approved CSL Ltd.'s pandemic vaccine, Health Minister Nicola Roxon said. More than 4 million doses are in major cities ready for delivery to hospitals and medical clinics next week.

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RESEARCH & DEVELOPMENT

USA: Medicaid patients often lack preventive care

Medicaid beneficiaries with health conditions are not always receiving the preventive services as per the recent study. In analysing national survey data and interviewing state Medicaid Directors and Federal Officials, the Government Accountability Office (GAO) found that more than half of all Medicaid adults ages 21 to 64 were obese or had diabetes, high cholesterol, high blood pressure or a combination of these conditions, yet the receipt of some preventive services was low. The data also suggested that a lower percentage of Medicaid adults received preventive services than those with private insurance, and that many Medicaid children were not receiving well-child checkups. Nearly all state Medicaid programs said they covered cervical cancer screening and mammography, but less than a third covered intensive counselling for obesity or high cholesterol.

USA: Increased risk of heart failure among childhood cancer survivors

Heart failure can be difficult to detect and diagnose in adult survivors of childhood cancers since patients may not fit the typical demographic profile of heart failure patients. Childhood cancer survivors are likely to present with heart failure symptoms earlier in their adult life. Females, those who received both radiation and anti-cancer therapy are at greatest risk. Specific side effects of treatment and diseases are dependent upon the type of cancer treatment patients receive. It is critical for the public to become aware that there are populations at risk for heart failure outside of the traditional demographic, according to Dr. Douglas Mann, President, Heart Failure Society of America HFSA.

USA: DHA improves cognitive skills in children

Research has shown that children who were breast fed as infants have superior cognitive skills compared to those fed infant formula, and it is thought that this is due to an essential fatty acid in breast milk called docosahexaenoic acid (DHA). Now a new study has found that babies fed formula supplemented with DHA have higher cognitive skills than babies fed regular formula. The study, which used a more sensitive test of the babies' cognitive abilities and higher concentrations of DHA than previous research, was carried out by researchers at the Retina Foundation of the Southwest and the University of Texas Southwestern Medical Center. The study results clearly suggest that feeding infants formula supplemented with high concentrations of DHA provides beneficial effects on cognitive development. Furthermore, because infants who display superior performance on the means-end problem-solving task tend to have superior IQ and vocabulary later in childhood, it is possible that the beneficial effects of DHA extend well beyond infancy.

USA: Early vaccination minimises the risk of damage by potentially harmful infections

Recent data shows that the immune system of newborns is able to respond to a world full of antigens already at birth. Therefore, vaccines should be given as early in life as possible to minimise the risk of damage by a potentially harmful infection, says Prof. Dr. Claire-Anne Siegrist, Head of the Center for Vaccinology and Neonatal Immunology, University of Geneva. Many parents would prefer to postpone the vaccination of their babies until these are older, by fear that their young immune system would be too weak or overwhelmed by the vaccines. In contrast, paediatricians insist that babies should be immunised as rapidly as possible after birth against the most dreadful microbes causing bacterial meningitis or whooping cough. These infections can cause irreversible damage or even kill the children.

USA: Restanza as an orphan drug for treating plague and tularemia

Advanced Life Sciences Holdings, Inc. announced that the United States Food and Drug Administration (FDA) has granted Orphan Drug Designation to Restanza(TM) (cethromycin), its novel, once daily oral antibiotic, for the prophylactic treatment of plague and tularemia. Both tularemia and plague are classified by the Centers for Disease Control as Category A Bioterrorism Agents, which is the highest priority classification. High-priority agents include organisms that pose a risk to national security because they can be easily disseminated or transmitted, result in high mortality rates and have the potential for major public health impact, might cause public panic and social disruption, and require special action for public health preparedness.

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USA: Medical Professionals urges families to get immunised against seasonal influenza

The American Lung Association is intensifying its seasonal influenza public education initiative to urge families to get vaccinated as soon as possible. The Faces of Influenza campaign aims to ensure get immunised against seasonal influenza, which each year causes an estimated 36,000 deaths and over 226,000 hospitalisations from the virus and its related complications. The Faces of Influenza campaign, which includes expanded awareness initiatives nationally and in many major cities, supports the Centres for Disease Control and Prevention's (CDC) call to get vaccinated against seasonal influenza this and every year. "Seasonal influenza remains a serious concern, even with the presence of the 2009 H1N1 virus," said Norman Edelman, MD, Chief Medical Officer of the American Lung Association. Vaccination against seasonal influenza is the best protection against this annual disease.

USA: Damaged heart tissue is significantly reduced with supersaturated oxygen

Recent study results indicates that Cardiovascular Interventions demonstrate that an infusion of blood that is "supersaturated" with oxygen (SSO₂) can reduce the amount of damaged heart muscle immediately following a life-threatening heart attack. "The benefit of this therapy increased with the scope of the heart attack," According to Gregg W Stone, MD, Professor of medicine at Columbia University. In the trial, the "supersaturated" oxygen was delivered via catheter directly to the area of the heart muscle affected by the heart attack. The size of the "infarct zone," or the amount of damaged tissue, was significantly reduced in the patients that received the "supersaturated" oxygen.

USA: Dramatic maternal weight loss prevents obesity in their children

Adolescent and young children of obese mothers who underwent weight-loss surgery prior to pregnancy have been found to have a lower prevalence of obesity and significantly improved cardio-metabolic markers when compared to siblings born before the same obese mothers had weight-loss surgery, according to the new research study. Obesity can lead to insulin resistance, cardiovascular disease and pregnancy complications and is a major contributor to causes of death in industrialised nations. Earlier, studies of obese pregnant women have shown that obesity and its co-morbidities can be transmitted to their children, which indicate that the intrauterine environment may determine whether a child at birth is already destined to become obese. According to John Kral, MD, PhD, of SUNY Downstate Medical Center in Brooklyn, NY, the study confirms that the intrauterine environment may be more important than genes and the post-natal environment when it comes to the association between maternal obesity and childhood obesity.

USA: Postpartum depression affects mother-infant relationship

The joys of motherhood for many women can also lead other new moms to experience postpartum depression and even worse. For these women contemplating taking their own lives, the mother-infant relationship and development was a negative experience, with greater mood disturbances, cognitive distortions, low maternal self-esteem, negative perceptions of their effectiveness as a new parent and noticeably less responsiveness to their infants' cues. Those are the findings of a new two-year study by Ruth Paris, Ph.D, Assistant Professor of Clinical Practice at Boston University's School of Social Work. All the new mothers in the study suffered from depression, isolation and extreme difficulties in parenting infants. They responded to a series of pre-treatment questionnaires, self-report symptom inventories and parenting stress indices.

EUROPE**Sweden: Alligator Bioscience enters into research and option agreement with BioInvent**

Alligator Bioscience AB announced a research and option agreement with BioInvent International AB to co-develop an antibody-based drug for oncology indications. This collaboration combines the strengths of both companies' technologies to develop a next generation immunotherapeutic treatment that could provide systemic anti-cancer effect and immunity, with minimal systemic side effects for the benefit of cancer patients.

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MANUFACTURING /OPERATIONS

Americas

USA: Wellcome Trust and Merck launch JV to develop affordable vaccines

Wellcome Trust and Merck launched first of its kind joint venture with a not-for-profit mission to develop affordable vaccines for low-income countries. The joint venture marks the first time a research charity and a pharmaceutical company have partnered to form a separate entity with equally shared funding and decision-making rights. Pairing two of the world's pre-eminent healthcare institutions provides an opportunity to integrate the best of both to drive the investment and expertise needed to develop and deliver vaccines to low-income countries.

USA: Genzyme starts work on new mass facility

US biotechnology major Genzyme has begun \$68m of refurbishment work on a new 211,000 sq ft manufacturing and shipping complex in Northborough, Massachusetts. The site will house office, laboratory and warehousing space, as well as a packaging and distribution centre. A considerable portion of the money being spent on the site will be used to install heating and air conditioning systems as part of Genzyme's bid to achieve Leadership in Energy and Environmental Design (LEED) certification. The new facility, which is scheduled to open late in 2010, is intended to bolster Genzyme's operations in the region, which including its manufacturing facility in Allston that has recently encountered a number of regulatory problems.

Brazil: Sanofi deal to supply H1N1 vaccine to Brazil

Sanofi Aventis says it has been contracted to supply the Brazilian government with up to 33 million doses of H1N1 "swine" flu. Sanofi Pasteur, the French drugmaker's anti-infectives division, said that it signed an agreement with Brazil's Butantan Institute to make 15 million doses of A (H1N1) vaccine for the government's stockpile. The deal, which was announced during a state visit by French President, Nicolas Sarkozy, includes an option for the supply of an additional 15 million doses of vaccine contingent on future World Health Organisation (WHO) guidance. Sanofi Pasteur plans to produce and deliver as quickly as possible the pandemic vaccine which meets the requirements defined by the Brazilian health authorities.

Argentina: Glenmark plans cancer drug unit in Argentina

Mid-sized pharma company, Glenmark Pharmaceuticals has decided to set up a facility to produce oncology drugs in Buenos Aires in Argentina to strengthen its presence in the global cancer drug market that is expected to grow by nearly 80% to \$85 billion in four years. Glenmark Pharmaceuticals currently makes oncology drugs on a loan-licensee basis—the company provides the products and technology but the manufacturing is executed by a third party—in Argentina. The proposed facility, which will be commissioned shortly, will be its only oncology drug making unit. The Argentina plant will have an annual production capacity of around one million vials and will be the global hub for Glenmark for manufacturing two types of injectibles—lyophilised and liquid—used in oncology therapies. These products will be sold in around 20 countries. Glenmark entered into the oncology space through the acquisition of an Argentina company, Servycal, a few years ago.

Asia-Pacific

Indonesia: B-MS sells facilities and product rights

Bristol-Myers Squibb (B-MS) is continuing to sell divisions, with the latest deal offloading its Indonesian unit and product rights to Japan-based Taisho Pharmaceutical for \$310m (€211m). In recent years B-MS has sold assets, such as its Japan over the counter (OTC) business, as it attempts to focus its business on the creation of innovative medicines. The big pharma took another step in this plan when it sold the rights to distribute some medicines to Sigma Pharmaceuticals. Taisho believes the acquisition will make it possible to enter into the Asian OTC drug business in earnest. Furthermore, the company plans to make B-MS' manufacturing facilities its future production centre in Asia.

India: Ranbaxy signs license deal with South Korean firm

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Indian drug maker, Ranbaxy Laboratories Ltd said it had entered into a licensing agreement with South Korean firm Medy-Tox Inc for selling a cosmetic product in India. Ranbaxy will launch Medy-Tox's anti-ageing medicine Neuronox in India to boost its presence in the dermatological segment, said a company statement.

India: Cipla to produce biotech drugs

Cipla will foray into the production of biotechnology medicines soon. The company is planning to set up a 50:50 joint venture partnership with a Chinese firm. The JV will be based in India and will manufacture and market bio-similar products for domestic and overseas markets. Confirming the development, a Cipla official said the identity of the JV partner cannot be disclosed until the JV is signed. However, the source pointed out that the Chinese counterpart is an established biotech company with products in the local market. Cipla has been on the lookout for a biotech partner after its JV with Bangalore-based Avestha Gengraine Technologies (Avesthagen) for a biopharmaceuticals development programme failed to take off.

FINANCE

AMERICAS

USA: Keryx Biopharmaceuticals, Inc. to raise \$20m in registered direct offering

Keryx Biopharmaceuticals has entered into definitive agreements to sell 8 million shares of its common stock at \$2.50 per share pursuant to a registered direct offering to several select institutional investors, representing gross proceeds of approximately \$20 million. Investors will also receive warrants to purchase 2,800,000 shares of the Company's common stock. The warrants have an exercise price of \$2.65 per share and are exercisable at any time on or after the closing date and prior to 366 days from such initial issuance date. The closing of the offering is expected to take place on September 30, 2009, subject to the satisfaction of customary closing conditions.

USA: Calif. hospital seeks Chapter 11 protection

Downey, California Regional Medical Centre has filed for Chapter 11 bankruptcy protection. The 181-bed hospital has had no cash reserves since March 2008, and lost about US\$20m annually over the past five years. A new management team took over the facility two years ago and in January began converting money-losing HMO and medical group contracts to PPO contracts. The hospital had about 32,000 captivated members in managed-care plans with five insurers, with a monthly fixed fee from all plans of more than \$3.5m in 2008. The hospital incurred a US\$25 million one-time charge to exit the capitation contracts. The 87-year-old community not-for-profit hospital has about 71,000 patient visits a year

INVESTMENTS

EUROPE

Russia to invest for manufacturing nano-vaccines and therapeutic biopharmaceuticals

A project for the production of vaccines and biopharmaceuticals has been approved by the Supervisory Council of RUSNANO. Project plans include—development of two vaccines for human flu and bird flu; three biopharmaceuticals for treatment of cancer-related toxicity; boosting of the immune system; increasing the efficiency of antibacterial and antiviral drugs; treatment of lower extremity ischemia; and motor neuron disease. RUSNANO and NTpharma intend to form a joint venture for putting the project to life. Research activity will be coordinated by the Gamaleya State Scientific Research Institute for Epidemiology and Microbiology of the Russian Academy of Medical Sciences of RAMS.

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Asia-Pacific

India: A Paradigm Shift in Ayurveda

Dr. Rajiv Vasudevan, CEO, of AyurVAID hospital opened a centre in Dharavi, as a part of hospital-chain expansion plan with the investment of Rs45m. Currently, AyurVAID has opened six hospitals in all, with the bed-strength totalling to 150. Dharavi hospital is opened to capture mass market since it is the hub for thousands of labourers involved in zari work and considering their working poor conditions, they peculiarly suffer from muscle and bone-joint problems, which 15-bed AyurSEVA treats very successfully. AyurVAID Hospitals makes use of the modern diagnostic tools of modern medicine and the curative practices of the traditional Ayurveda to treat their patients.

India: Fortis huge Investments on health care business

Fortis Healthcare and Wockhardt Hospitals recently announced the execution of a definitive agreement providing for purchase of eight operating hospitals and two hospital projects under construction. The purchase would be for Rs9090m and this includes Rs1900m towards capital work in progress for projects under construction. The business transfer is expected to be completed by end of December 2009 upon the fulfilment of agreed conditions precedent. The acquisition will enhance Fortis' footprint in Southern, Western and Eastern India, thereby strengthening the Fortis brand as one of the leading healthcare service providers in the country.

India: A New Medical College Hospital in Kochi

Gurudeva Charitable Trust (GCT), a non-profit organisation, has opened Sree Narayana Institute of Medical Sciences (SNIMS), a new generation medical college and Hospital with 350-bed in the coastal belt of Thrissur and Ernakulam district, providing all the speciality services. The group has plans to build dental and nursing colleges and paramedical courses. Also, in the agenda is to develop Ayurveda and other alternative medical systems. It plans to give free medical treatment to poor NRIs and road accident victims from the UAE who cannot afford the medical expenses in the UAE. The trust has raised Dh100 million for this project.

India: Siemens Provide High-end Healthcare Solutions to Medanta

Siemens Healthcare has entered into one of the largest technology partnerships in India to provide innovative imaging and IT solutions to Medanta-The Medicity, an upcoming 1,250-bed multi-super specialty healthcare institute in Gurgaon. It is one of India's largest multi-super specialty institutes. At Medanta, in addition to installing hi-end imaging products recently introduced in India, Siemens will also launch a range of products for the first time in India. This includes SOMATOM Definition Flash CT scanner, Artis Zeego cathlab, ACUSON SC2000 ultrasound system and Biograph mCT, a PET-CT scanner. According to D Ragavan, Sector CEO for Healthcare, South Asia Cluster, Siemens Ltd, Medanta-The Medicity is one of the topmost facilities in this part of the globe.

ACQUISITION

Americas

USA: Dainippon to buy Sepracor for \$2.6bn

Japanese drug-maker, Dainippon Sumitomo Pharma (DSP) has entered into a definitive agreement to acquire US pharmaceutical group Sepracor for \$2.6 billion (€1.8 billion). In a statement, DSP said that the deal fits with its strategy to strengthen its business foundation as a first step in becoming a global corporation, adding that the move will expand its US sales and marketing capability. DSP's efforts to bolster its US presence are timely given that it is preparing for the global launch of its new antipsychotic drug, Lurasidone. Sepracor will become a centre of excellence for DSP in the US and will make a significant contribution to DSP.

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Europe

UK: Novartis to buy HySolv technology from BTG

Swiss drug major, Novartis will buy UK specialty pharma firm BTG up to \$10m (€7m) for its HySolv drug delivery technology. As the name suggests HySolv uses a patent solvent system to improve the solubility of hydrophobic drugs. The technology was developed by recent BTG acquisition US group Protherics. The deal is in line with the firm's plan to realise value from its assets while continuing to build value in its development pipeline and establishing its US sales and marketing operations. Although Novartis has not yet commented on its latest acquisition, the nature of the HySolv technology suggests that it will be applied to both traditional small molecule drug candidates as well as biologics, for which solubility is often an issue.

Switzerland: Galencia extends global reach with OM Pharma deal

Pharmaceutical manufacturer, Galencia says its acquisition of Switzerland-based biotech group OM Pharma will bolster its international presence. Galencia said the deal, which is scheduled to complete on October 31, 2009 will also expand its pharma portfolio contributes to a better risk diversification. OM sells drugs in more than 90 countries around the world, with a focus on its four key products Broncho-Vaxo, Uro-Vaxom, Doxium and Dicynone which, Galencia believes, will boost its Vifor Pharma consumer healthcare unit. The acquisition, financial terms of which are not being released, includes OM's biotechnology production facility in Geneva that Galencia said will be an important asset for its manufacturing portfolio.

Germany: Sandoz completes acquisition of EBEWE Pharma

Sandoz announced that it has completed its USD 1.3 billion acquisition of EBEWE Pharma's specialty generic injectables business, paving the way for the creation of a global centre of excellence in generic oncology injectables. "We are delighted to combine EBEWE Pharma's portfolio and pipeline of high-quality injectables with our global leadership in biopharmaceuticals, anti-infectives and other innovative technologies", said Sandoz CEO, Jeff George. "This will greatly enhance the range of affordable generic anti-cancer medicines Sandoz offers to patients worldwide". In addition to globalising Austrian-based EBEWE's operations through its integration within Sandoz, the world's second largest generics company, the transaction offers Sandoz a complementary portfolio of differentiated generics, with more than 15 marketed products and a strong pipeline with several near-term launches.

UAE: Moorfields Eye Hospital partners with Hayati Healthcare

Moorfields Eye Hospital Dubai and Hayati Healthcare, the Middle East region's first ever dedicated Patient Financing company, have announced an agreement through which patients at Moorfields can access the financial services and benefits offered by Hayati. Hayati's financial services are designed for those without medical insurance or in cases where the medical insurance policy does not cover the treatment required, such as LASIK eye surgery or cosmetic surgery. Hayati Healthcare provides medical loans for elective and non-elective medical procedures which medical insurance companies do not cover and is now available for all forms of specialist eye treatment at Moorfields Eye Hospital, Dubai.

Technology

USA: Children's Hospital converts to Masimo Rainbow SET Pulse CO-Oximetry technology

Children's Hospital & Research Center Oakland has completed its system-wide conversions to Masimo Rainbow SET Pulse CO-Oximetry technology. Standardising to Masimo Rainbow SET makes Children's Hospital Oakland - the first children's hospital to pioneer new continuous non-invasive blood monitoring capabilities hospital-wide—allowing earlier and better clinical decisions without the intermittent pain and wait associated with drawing blood. By converting to Masimo Rainbow SET, Children's Hospital Oakland clinicians will gain all the benefits and Measure-Through Motion capabilities of Masimo SET pulse oximetry, along with the breakthrough innovation of the first-ever continuous and non-invasive hemoglobin monitoring (SpHb(TM)) technology. The ability to immediately detect and treat potentially life-threatening conditions earlier may help save lives and improve patient outcomes.

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Human Resources

Americas

USA: Lilly to cut workforce by 10%

US drug-maker, Eli Lilly plans to cut 5,500 jobs by 2011 as it prepares to enter the most challenging period in the company's history. In common, with most of the Big Pharma firms that have restructured over the last 18 months, Lilly said the move is designed to minimise the impact of patent loss and subsequent generic competition for several of its key products. The restructuring move, which Lilly hopes will cut costs by \$1 billion (€683m) over the next two years, is also intended to accelerate the progress of the most exciting pipeline in our history which has 60 molecules in the development. To aid this process, Lilly will set up a Development Centre of Excellence (COE) that is claimed will be distinguished from its peers through the adoption of one common set of priorities and a singular focus to streamline the development of new medicines.

USA: AstraZeneca cuts 113 jobs at Mass Pulmicort plant

UK pharmaceutical major, AstraZeneca will eliminate 133 US drug manufacturing jobs in response to increasing market competition for its asthma treatment Pulmicort Respules. According to a report in the Boston Globe the move, which cuts the workforce at AstraZeneca's facility in Westborough, Massachusetts by 10%, follows Food and Drug Administration (FDA) approval for a rival asthma drug made by generics firm Apotex. AstraZeneca, which also produces the heartburn treatment Nexium at the facility, has not yet issued a statement on the move.

OTHERS

GLOBAL

Global: FDA approves new drug to treat Psoriasis

The FDA approved Stelara (ustekinumab), a biologic product for adults who have a moderate to severe form of psoriasis. Plaque psoriasis is an immune system disorder that results in the rapid overproduction of skin cells. About 6 million people in the United States have plaque psoriasis which is characterised by thickened patches of inflamed, red skin, often covered with silvery scales. Stelara is a monoclonal antibody, a laboratory-produced molecule that mimics the body's own antibodies that are produced as part of the immune system. The biologic treats psoriasis by blocking the action of two proteins which contribute to the overproduction of skin cells and inflammation.

AMERICAS

USA: NIH extends \$9.4m grant to DOR BioPharma for vaccines development

DOR BioPharma has been awarded an approximate \$9.4 million grant from the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH). The grant will fund, over a five-year period, the development of formulation and manufacturing processes for vaccines, including RiVax, that are stable at elevated temperatures. The grant will also fund the development of improved thermostable adjuvants expected to result in rapidly acting vaccines that can be given with fewer injections over shorter intervals.

USA: Abbott to buy Solvay pharma unit in \$6.6bn deal

Abbott Laboratories (ABT) is continuing on its buying spree, muscling Nycomed aside and announcing a deal this morning to buy Solvay's (SVYSY) pharmaceuticals unit for about \$6.6 billion. The deal price includes \$440 million to cover milestones on products from 2011 to 2013. The deal gives Abbott sole ownership of a blockbuster cholesterol franchise along with other therapeutics for hypertension, hormone replacement and neurological diseases. It also underscores the pharma industry's strong belief that Washington is on track to deliver a health reform package that will leave their businesses highly profitable in the US.

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USA: Millipore plans more work with Gen-Probe spin-off

Millipore Corp. plans to keep working on molecular assays and portable instruments for biopharmaceutical production with a brand new company, following its spin out from Gen-Probe Inc. Millipore and San Diego-based Gen-Probe began collaborating in August 2005 to create faster, more accurate tests for bacteria, viruses, mycoplasma and other contaminants commonly found in biopharmaceuticals. The announcement made by Millipore coincided with Gen-Probe formally spinning out its industrial testing business as Roka Bioscience, backed with \$37.2 million in funding from three private equity firms.

USA: Symyx Technologies ventures into novel arena

Symyx Technologies recently launched a Contract Development and Manufacturing Organisation (CDMO) to help biopharmaceutical companies move drug candidates into clinical trials. "After discovery, the next critical milestone in drug development is getting to trials quickly with a reliable formulation. Our CDMO gives clients a fast, reliable route to clinical trials," says Richard Boehner, president of Symyx High Productivity Research (HPR). Due to less than optimal formulations, some clinical trials become a test of a drug's formulation limitations rather than its effectiveness. The Symyx CDMO, which is part of the HPR business unit, focuses on preformulation development, formulation optimisation and stability, and analytical methods development, all of which are intended to insure optimised and robust drug formulations. The CDMO also offers fill/finish services for products manufactured under cGMP conditions in quantities to meet preclinical and Phase II and II trials.

USA: Slump bad for North American APIs, but biotech to lead recovery

The global economic crisis has drastically reduced the growth of the North America API market, but brighter days are ahead according to new research by Global Markets Direct (GMD). The GMDs North America Active Pharmaceutical ingredients market analysis and forecasts to 2020 suggests that lower government spending in the downturn has shifted the market away from high-priced innovative drugs. This lower rate of spending they said has resulted in a significant slowdown in the revenue growth of the North American API market, which they expect to grow just 2% in 2009. However, the report also predicts that the market is poised for recovery predicting that growing consumer demand for biotech active pharmaceutical ingredients (APIs) and increasing technological capability in the drug industry will be the key drivers

USA: Skinvisible enters license agreement with Mayquest Pharma

Skinvisible announced that it has entered into an exclusive license agreement with Mayquest Pharmaceuticals Pte. Ltd. for the rights for DermSafe, Skinvisible's patented antimicrobial hand sanitizer lotion proven to kill the H1N1 swine flu virus. The license agreement includes Singapore, Malaysia, Thailand, Indonesia and the Philippines. Under the terms of the agreement, Mayquest will pay an upfront license fee in milestones for the exclusive manufacturing and marketing rights for DermSafe in the territory. Skinvisible will also receive on-going royalties from product sales.

EUROPE**Germany: Revotar Biopharmaceuticals AG receives 2.5m Euros Research Grant**

Revotar Biopharmaceuticals AG announced that the company has been granted 2.5 million Euros from the German Federal State of Brandenburg for the development of its pipeline of selectin antagonists in respiratory indications. The funding will be distributed over a 2-year period and is part of the European Regional Development Fund program. "We are very pleased that the State of Brandenburg has recognised the importance of our research," stated Dr. Martin Pöhlchen, CEO of Revotar. "We are also very encouraged by the professional support and the excellent scientific environment in Brandenburg and in Berlin." Revotar's lead candidate Bimosiamose is the clinically most advanced pan-selectin antagonist in the world. Already, Bimosiamose has successfully passed several clinical phase I and phase IIa trials in asthma, COPD and psoriasis and has shown excellent safety and efficacy profiles in these trials. A further phase IIa study of Bimosiamose in COPD is scheduled to start in 2010.

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Netherlands: Johnson & Johnson buys 18% stake in Crucell

Johnson & Johnson Inc. has bought an 18% stake in Dutch biotechnology company Crucell NV for Euro301.8 million (\$440 million) in hopes to develop a universal flu vaccine, the companies said. In a joint statement, the companies said their immediate focus would be on developing "monoclonal antibodies"—which bind to a target protein, alerting the body's own immune system to attack it. Crucell was awarded grants worth up to \$69 million by the US government in August to develop its range of monoclonal antibodies for influenza, which Crucell says have shown early promise in fighting "a wide range" of seasonal and pandemic flu viruses. In fact the company claims the antibodies can fight any influenza, including swine flu and bird flu, and including those flu strains resistant to Tamiflu—the medicine currently most often used to slow their progression.

France: Sanofi Pasteur gets additional order to produce Influenza A Vaccine

Sanofi Pasteur, the vaccines division of the sanofi-aventis Group, announced that the company has received an additional order from the US Department of Health and Human Services (HHS) to produce vaccine to help protect against the Influenza A (H1N1) 2009 virus. The new order is for the production of bulk antigen equivalent to 27.3 million doses based on 15 mcg of antigen per dose. Specifications for formulation and filling of this new bulk order will be the subject of a separate order. To date, Sanofi Pasteur has committed to the US government a total of 75.3 million doses of Influenza A (H1N1) 2009 Monovalent Vaccine.

Asia Pacific**India: Different ministries, stakeholders to discuss fake 'made in India' drugs issue**

Amid allegations of lack of coordination among the ministries, the Department of Pharmaceuticals held a meeting recently with other ministries at least in the case of spurious drugs with 'made in India' label but were produced by Chinese companies and seized by authorities in Nigeria. The meeting was scheduled originally for August 18 but could not be held. Importantly, at least in this case, different departments have been in coordination between them to address the issue and help Indian industry recover the lost esteem, even though there are constant allegations about dragging feet by different departments when it comes to coordination on other issues.

India: New guideline on spurious drugs law asks officials to ensure justice to legitimate cos

Following strong objections from drug manufacturers to the new spurious drugs law as per the Drugs & Cosmetics (Amendment) Act, 2008, the Union ministry of health has come out with a set of guidelines for the state drug control organisations to act on offences by ensuring justice to law abiding manufacturers and traders. The guideline, issued early August 2009 for framing a standard operative procedures in each state to examine and process various violations of the amendment act, suggests the state drug control organisations to have internal mechanism of checks and balances to ensure that law abiding manufacturers and traders of drugs are not harassed or put to a disadvantageous position.

India: Health ministry recommends CBI probe into seizure of fake bulk drugs from China

Denying the reports that the customs authorities have released the confiscated consignments of fake drugs for re-exporting, the health ministry has said it had recommended a CBI probe into the recent seizure of unregistered bulk drugs originating from China. The ministry has also sought the assistance of External Affairs Ministry to strengthen the intelligence abroad in tracing fake drugs destined to India.

India: Matrix gets tentative US FDA approval for HIV/AIDS drugs

Matrix Laboratories, a Hyderabad-based subsidiary of Mylan Inc. has received tentative approval from the US Food and Drug Administration (FDA) under the President's Emergency Plan for AIDS Relief (PEPFAR) for its New Drug Application (NDA) for efavirenz, lamivudine and tenofovir disoproxil fumarate tablets, 600 mg/300. Mylan's product represents the first-ever fixed-dose combination of efavirenz, lamivudine and tenofovir disoproxil fumarate and now provides Matrix with numerous tenofovir combination product opportunities. This new drug adds to the Matrix portfolio of important treatments for HIV/AIDS. The product may be used for either first- or second-line treatment in adults. People use second-line therapies if and when they develop resistance to initially prescribed treatments.

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China: Simcere's 42 generic drugs included in China's Essential Drug List

Simcere Pharmaceutical Group, a leading manufacturer and supplier of branded generic and innovative pharmaceuticals in China, announced that forty-two of its generic drugs have been included in China's Essential Drug List (EDL), which was issued by China's Ministry of Health (MOH) on August 18, 2009. In the 2009 second quarter earnings conference call, the company announced that seven of its generics entered China's EDL. These seven medicines are branded generics, which are currently manufactured with significant sales or large market potential. The other generics comprising the forty-two medicines are seldom manufactured or have had insignificant sales in recent years.

India: ISIC extends Network for 24x7 Health Line Service for Senior Citizens

'Peace of Mind', a unique 24x7 health line service by Indian Spinal Injuries Centre's (ISIC), has now been extended to other areas of South Delhi namely, Vasant Vihar, Munirka Enclave, Kishan Garh, Mahipalpur, etc. Earlier, this service was only restricted to the residents of Vasant Kunj. However, now, ISIC will also cater to the health concerns of senior citizens in the adjoining areas too. According to Major HPS Ahluwalia, Chairman, ISIC, in metropolitan life, not everybody get the opportunity to get regular health check-ups done, and it is the elderly population which suffers the most. Some times during prolonged sickness and old age, it becomes very difficult for them to visit the doctor/hospital all alone. Peace of Mind - 24x7 Health Line has been designed to cater to the health problems encountered by the senior citizens of South Delhi.

India: Hospital for Sick by Kohinoor Group

Mumbai-based Kohinoor Hospitals Private Limited is gearing up to open a super-specialty 175-bed hospital by December, 2009 with 100 beds in the first phase. The second phase with 75 beds will be operational subsequently. According to Dr. Unmesh Joshi, CMD, Kohinoor Group, Kohinoor Hospital will be one of its kinds 'hospital for the sick', and a recuperating centre for people needing medical supervision and aid. The hospital is being designed to get platinum rating under LEED certification for 'green building'. This hospital will have all the advanced diagnostics and critical care centres covered under Wi-Fi Zone.

India: Patented drugs market in India to touch \$8bn by 2015: Report

The increasing population of higher-income group in the country will open a potential US\$8 billion market for multi-national companies selling costly patented drugs by 2015, a FICCI-Ernst & Young study said. Besides, the report says the domestic pharmaceutical market is expected to touch US\$20 billion by 2015 from US\$7.1 billion in 2007, making India a lucrative destination for clinical trials for global giants. Patent-protected products have the potential to capture up to 8-10% share of the total market by 2015, implying a market size of US\$2 billion.

CREMA to start 2 PG diploma courses

Clinical Research Education & Management Academy (CREMA) is all set to introduce two new courses 'Post Graduate Diploma in Clinical Research & Regulatory Affairs (PGDCRRA)' and 'Post Graduate Diploma in Drug Development (PGDDD)', after receiving the overwhelming responses for the other CR courses offered by CREMA. PGDDD has been designed on special requests from MBBS graduates. It will be a six-month clinical research course exclusively dedicated to these graduates with classes only on Sundays. This course will have dedicated modules on regulatory affairs, a crucial aspect of clinical research, medical reporting, pharmacovigilance and clinical research.

Govt relaxes land norms for setting up medical colleges in states

The Union Health Ministry has decided to relax the land requirement norms for medical colleges from the current 25 acres to 20 acres throughout the country. The move is to facilitate setting up of more medical colleges in the country and thereby remove regional imbalances in respect of these institutions. However, in respect of hill states and north eastern states, empowered action group (EAG) states under National Rural Health Mission (NRHM) and Union Territories (UTs) of Andaman & Nicobar Islands, Lakshadweep, Dadra & Nagar Haveli and Daman & Diu, two parcels of land separated by a distance of not more than 10 kms will also be allowed.

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Product Focus – DIOVAN

Diovan

Introduction

Diovan (Valsartan) is a hypertension drug belonging to the Angiotensin II Blockers class. The drug is developed by Novartis Pharmaceuticals and is expected to lose patent protection by 2010 in the US, 2011 in Europe, and 2013 in Japan. Angiotensin II blocker drugs reduce the risk of Atrial Fibrillation (AF) by 28% that involves promotion of vasoconstriction, sodium and water retention and cardiac hypertrophy. Active ingredient of Diovan is hydrochlorothiazide. Diovan reduces the occurrence of atrial fibrillation, a faulty heartbeat that can lead to the formation of clots that can cause heart attack or stroke. The drug is also used for treating heart failure in patients who do not tolerate angiotensin-converting enzyme (ACE) inhibitors. The drug is currently protected by a patent that prevents any generic Diovan from being manufactured.



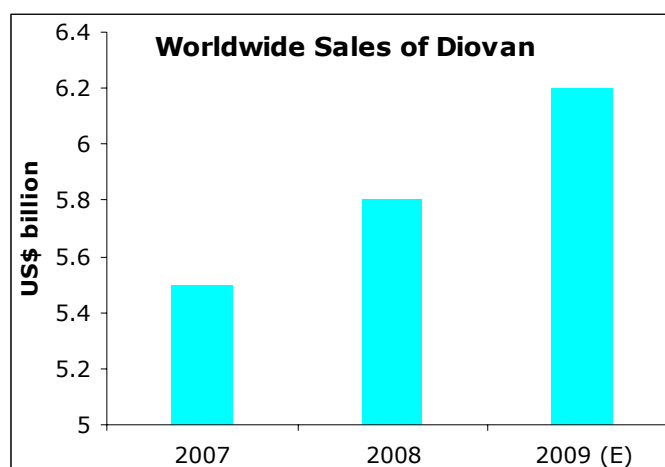
Working of Diovan

As the name implies, Diovan blocks angiotensin II receptors. This decreases the effectiveness of a chemical known as angiotensin II, which normally causes blood vessels to narrow (constrict). By blocking the effects of angiotensin II, Diovan causes blood vessels to relax, which can lower blood pressure. It also allows the heart to work more efficiently. Some of the common side-effects of the drug include dizziness, cough, and an increase in blood potassium levels. Some rare side effects of Diovan include impotence, hepatitis, constipation, itching, wheezing, and unexplained skin rash. Generally, Diovan is available as hard gelatin capsule form with 40mg, 80mg, 160mg, 320mg strength, but a Diovan suspension (liquid) is also available for use in children as young as six years old.

Drug Details	
Drug Brand Name	Diovan (Valsartan)
Active Ingredient	Valsartan
Company Name	Novartis
Tentative Approval Date	4th August, 2005
Chemical Type	Novel Molecular Entity
Drug Dose & Type	Capsule with 40mg, 80mg, 160mg and 320mg strength once daily
Patent Rights	Yes
Patent Expiry	2012

Market size

High blood pressure affects nearly one in four adults worldwide. The South East Asian market is potentially huge for the treatment of hypertension and Japan has a long tradition of willingness to participate in the battle to lower blood pressure by all means of pharmacological. Japan now accounts for about 20% of net sales of Diovan in the world. While it is easy to measure and can be successfully managed, nearly 65% of patients with high blood pressure do not have the condition under control. The field of hypertension treatment is still expanding driven by consumer demand for the newest agent,



Source: www.expresspharmaonline.com;
Cygnus Research

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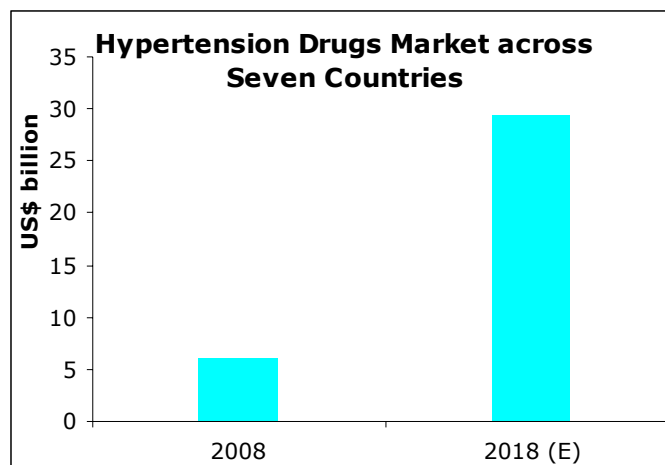
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and the reduced side-effects. Novartis has an important role in the area of Renin-Angiotensin System inhibition in the world. In the first half of 2009, Novartis generated around \$2.9 billion in sales for its hypertension drug, Diovan. The drug is expected to generate worldwide sales of over US\$6 billion in 2009 from the base of US\$5.8 billion in 2008. The drug is, however, expected to face generic competition in the next few years. The company is therefore lining up new drugs to counteract for the lost revenue.

Hypertension drugs market across seven major markets

Hypertension drugs sector across seven major markets in the world (US, France, Germany, Italy, Spain, UK and Japan) is expected to reach around US\$29.5 billion by 2018, a drop of over \$6 billion compared to 2008. With no promising novel pipeline agents, pharmaceutical companies have little choice but to adopt line extension life cycle management strategies introducing a number of new fixed dose combinations.



Source: Datamonitor; Cygnus Research

New drugs to drive hypertension drugs market

Major categories of hypertension drugs include Angiotensin-Converting Enzyme Inhibitors (ACEIs), Angiotensin II Receptor Antagonists (AIIIRAs), angiotensin II blockers, beta blockers, Calcium-Channel Blockers (CCBs), and diuretics. Presently, the hypertension drugs market is saturated with effective, well-established treatments and the market is declining. Cozaar's and Diovan's patent expiries in the US are expected to alter the structure of the antihypertensive market dramatically. Some of the fixed dose treatment already established in the market is CCB/Renin-Angiotensin-Aldosterone System (RAAS) inhibitors and CCB/RAAS/diuretics. The market is further expected to receive a boost with the introduction of new advanced drugs in the market including fixed-dose treatments such as Novartis's Exforge HCT, Daiichi Sankyo's olmesartan/amlodipine/HCT, and Novartis's aliskiren/amlodipine/HCT. The new therapies would offer greater convenience over currently available fixed-dose combinations that would help to reduce patients' pill burden.

Generic availability of Diovan

Worldwide, the first patent for Diovan currently expires in 2012. This is the earliest that a generic version of Diovan could become available. Typically, Diovan patent expiry is a multi-year event that varies by country through 2010-2015. India-based Ranbaxy Laboratories has received tentative approval from the US Food and Drug Administration to make and sell the hypertension tablets, Valsartan. The company is optimistic of its first-to-file application status, for the generic version of the Novartis drug sold under the brand name, Diovan. If successful, a first-to-file application will grant six-month market exclusivity once Diovan goes off-patent in 2012.

Indian scenario

Emerging markets including India forms around 18% of the global pharma market and it continues to drive its growth, contributing 49% of its total growth in 2009 over the previous year. Pfizer signed two licensing deals with India-based companies, adding 128 new off-patent products to its portfolio. Many companies are directing resources to emerging markets such as China and India and are evaluating their historical business models and cost structures. On par with the trend, Novartis introduced Diovan to India, which is presently marketed by CIPLA under the trade name Valtan and by Torrent Pharmaceuticals under the trade name Valzaar.

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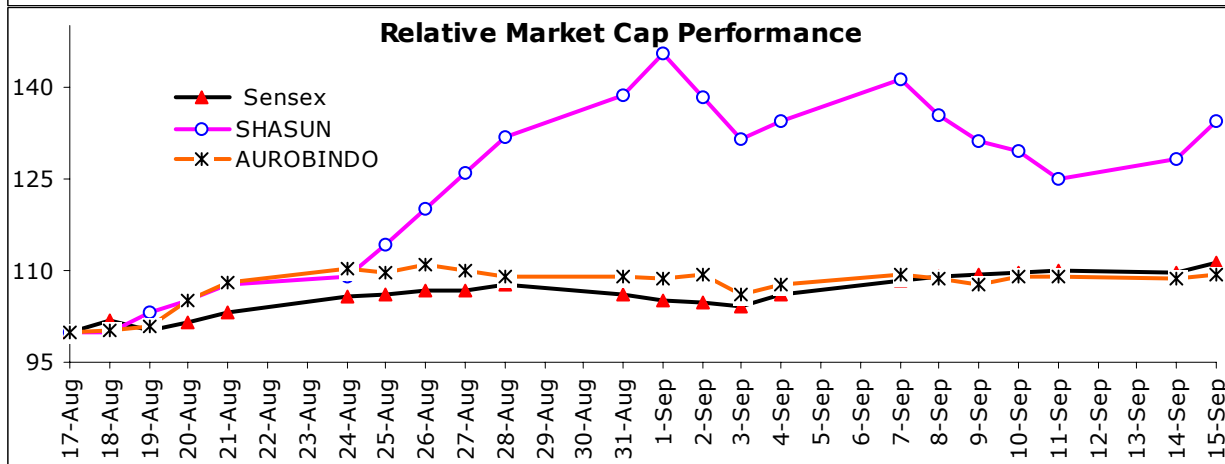
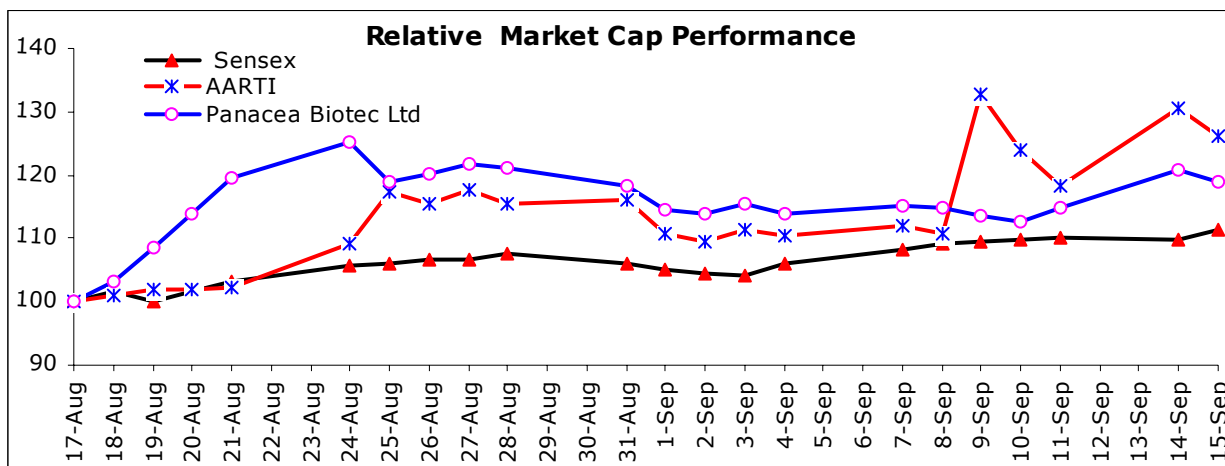
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Outlook

The generic competition is expected to become strong from 2010 to 2018 when many blockbuster drugs are expected to face patent expiry including Diovan in 2010. Irrespective of all these developments, hypertension drug market will experience only modest annual decline through 2018, despite generic erosion of many branded agents. It is expected that the hypertension drugs market would only decline by 1.4% annually and thereafter the annual decline will slow to just 1% through 2018 in the US, France, Germany, Italy, Spain, the UK and Japan. It is expected that by 2018, Diovan alone will lose more than \$1 billion in sales, driven by generic erosion of the agent which will begin in 2010 in the US, 2011 in Europe, and in 2013 in Japan.

Pharmaceuticals will face revenue losses between 2 to 40% from expiring drug patents by 2012. Diovan in combination with other drug would provide Novartis for future revenue stream after the patent expiry of the drug in the international market. Rasilez and Diovan are two hypertension drugs whose combo is untried and potentially best with difficulty, but a cleverly played segued of on them may reap dividends for Novartis and other players in the RAS inhibition field.

Stock Scan



Source: BSE India; Cygnus Research

	17 Aug- 21 Aug	24 Aug- 28 Aug	31 Aug- 04 Sep	07 Sep- 15 Sep
Sensex	Sensex ended on a positive note with an increase of 3.08% to 15,240.83 bps on increased capital inflow by funds as long-term investors looked to enter the market.	Sensex ended on a positive note with an increase of 1.88% to 15,922.34 bps as fund houses picked up stocks following strong global cues.	Sensex ended on a positive note by increasing slightly with 0.14% to 15,689.12 bps driven by bullish Asian markets and a strong start in European bourses.	Sensex ended on a positive note with an increase of 2.74% to 16,454.45 bps due to signs of US economic recovery added to the upbeat hopes for robust quarterly earnings.

AARTI	The scrip followed Sensex and marginally rose by 2% to Rs64.65.	Positive sentiments of the market made the scrip rise by 6% to Rs72.90.	The scrip moved against the BSE Sensex and declined by 4% to Rs70.45.	Good recovery is seen in the scrip and stood at Rs79.65.
PANACEA BIOTEC	The scrip went with the Sensex and rose by 20% to Rs191.80; this is due to the order worth of US\$222.37m bagged by the company from UNICEF.	The scrip declined by 3% and stood at Rs194.52.	The scrip made marginal movement in this week.	The scrip rose by 5% to Rs191.00, and went with the BSE Index.
SHASUN	The scrip followed Sensex and rose by 8% to Rs22.95.	The scrip continued the growth percentage and the price stood at Rs28.10.	Tamil Nadu Pollution Control Board (TNPCB) has revoked its closure notice of the Cuddalore plant situated at SIPCOT Industrial complex in Cuddalore, Tamil Nadu, so the scrip decline by 5% to Rs28.00.	Scrip remained flat during this week.
AUROBINDO	The scrip followed Sensex and increased by 8% to Rs697 during this week.	The company receives Swissmedic approvals for Amlodipine Besylate Tablets and Metformin Hydrochloride Tablets, which brought some consistency in the scrip.	During this week the scrip declined by 3% to Rs685.31 from Rs704.30.	Not much movement is seen in the scrip during this week.

Regulatory Issues

REGULATIONS

AMERICAS

USA: Keryx treatment gets special FDA status

Keryx Biopharmaceuticals Inc. said recently that the Food and Drug Administration gave its developing multiple myeloma drugs KRX-0401 or Perifosine, orphan drug status. Orphan drug status is given to drugs aimed at rare conditions or conditions that have a lack of treatments on the market. Incentives include seven years of market exclusivity following FDA approval, assistance in clinical trial design, a reduction in user fees, and tax credits. The company said a late-stage study is expected to start by the end of 2009.

USA: FDA places import alert on two Apotex facilities

The FDA has issued an import alert against products manufactured at two Apotex facilities after the agency issued a warning letter, which raised several issues that the company is now working to resolve. In a press statement, Canada-based Apotex sought to clarify that the import ban only affects two of its many facilities and is only applicable to products destined for the US. Apotex was issued with the warning letter on June 25. In the letter the FDA detailed significant deviations from Current Good Manufacturing Practices (CGMP) in the manufacture of non-sterile oral dosage products. After receiving FDA 483 observations Apotex initiated corrections, some of which were completed when the warning letter was issued, but the agency stated the actions failed to adequately address multiple and serious deficiencies

UK: GSK ends regulatory filings for Zunrisa/Rezonic

GlaxoSmithKline (GSK) has decided to discontinue the regulatory filings for Zunrisa/Rezonic (casopitant), which was being developed for chemotherapy-induced and post-operative nausea and vomiting. Regulatory applications were filed in a number of countries worldwide and GSK is currently communicating with those authorities and all study investigators. GSK has made this decision, after regulatory consultation, based on the company's assessment that significant further safety data would be required to support the registration of casopitant on a worldwide basis, which would take a considerable time to produce. Consequently, all on-going regulatory files for casopitant are being withdrawn.

India

Ministry of Micro, Small and Medium Enterprise (MSME) Ministry extends CLCS Scheme support to 179 products for SSIs

The Ministry of Micro, Small and Medium Enterprises (MSME) is launching a scheme for schedule M compliance of SSIs as an extension of the existing Credit Linked Capital Subsidy Scheme (CLCSS). The Scheme is offering financial assistance to an expanded list of 179 products to support the SSIs to comply with the revised good manufacturing practice standards. The scheme will support the SSI pharma units to avail the benefits of CLCS Scheme for financial assistance for an expanded list of products from 32 to 179 and 10 nodal agencies including SIDBI, which are issuing approval for the CLCS Scheme, will be implementing the scheme, according to the notification

A joint Initiative by **IPA** and **Cygnus** to enable Pharma Professionals to be more successful

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Upcoming Events

1	Event	Biotechnica
	Date	Oct 06-11, 2009
	Venue	Hannover Fairgrounds, Hannover, Germany
	Highlights	Biotechnica is the ideal platform where suppliers of equipment & consumables will meet engineers, research-personnel & procurement managers of Indian biotec-companies. BIOTECHNICA mirrors the successful development of one of the most important sectors of the future. More and more exhibitors and visitors from across the globe are taking advantage of Europe's leading biotechnology event.
	Contact details	Deutsche Messe AG, Messsegelände, 30521, Hannover, Germany Tel: +(49)-(511)-890; Fax: +(49)-(511)-8932626
2	Event	PHARMACY
	Date	Oct 07-09, 2009
	Venue	Lenexpo Fairgrounds, St. Petersburg, Russia
	Highlights	The international exhibition Pharmacy is the largest exhibition on public healthcare in the Northwest Region of Russia. The exhibition promotes the development of co-operation and the establishment of contacts in the area of medicine between the Russian and the international community and has a priority status for Saint Petersburg. Pharmacy 2005, expected to start with a full house of 140 exhibitors promising to showcase more new products and brands than seen in years previous.
	Contact details	Primexpo. Russia, Saint Petersburg, 23, Malaya Morskaya Street, "Belye nochi" Business-Center, Belye Nochi, Russia. Tel: +(7)-(812)-3806000; Fax: +(7)-(812)-3806001
3	Event	Health & Lifestyle Expo
	Date	Oct 07-10, 2009
	Venue	Sydney Showground, Sydney, New South Wales, Australia
	Highlights	The Health and Lifestyle Exhibition will be a unique opportunity to target 25,000 sporting individuals under one roof. For exhibitors, it is a fabulous chance to showcase new products and services to like-minded individuals who take pride in maintaining a healthy lifestyle.
	Contact Details	The Intermedia Group Pty Ltd. Unit 39, 100 Harris, Pymont, Australia Tel: +(61)-(2)-96602113; Fax: +(61)-(2)-96604419
4	Event	West African Health (WAH)
	Date	Oct 07-09, 2009
	Venue	The New Expo Centre, Ademola Street, PMB 12724, Lagos, Nigeria
	Highlights	West African Health (WAH) is an International healthcare event that plays a key facilitating role in the provision of health services and technology in the West African region. An international exhibition and conference that has found its niche as an important business to health forum for healthcare decision makers & solution providers.
	Contact Details	Global resources & Projects Nig. Ltd. 40, Adegbola Street, Anifowose, Lagos, Nigeria. Tel: +(234)-(1)-4800305; Fax: +(234)-(1)-2557542
	Event	West African Health (WAH)

5	Event	CPHI Worldwide
	Date	Oct 13-15, 2009
	Venue	Feria de Madrid, Comunidad De Madrid, Madrid ,Spain
	Highlights	CPHI Worldwide is the most comprehensive exhibition of manufacturers of active pharmaceutical ingredients, intermediates, excipients and natural extracts in the world. It also brings together experts in custom manufacturing and marketing services.
	Contact Details	CMP Asia Limited. 17/F, China Resources Building, 26 Harbour, Wanchai, China (Hong Kong S.A.R.) Tel: +(852)-(2827)-6211/25161677; Fax: +(852)-(2827)-7831/28029934
6	Event	BioPh: Bio-solutions for pharma
	Date	Oct 13-15, 2009
	Venue	Feria de Madrid, IFEMA Feria de Madrid Feria de, Madrid ,Spain
	Highlights	BioPh: Bio-solutions for pharma is a leading exhibition for Bio process and pharmaceutical industry. The BioPh: Bio-solutions for pharma expo will be at Feria de Madrid, Spain.
	Contact Details	United Business Media plc. Ludgate House, 245 Blackfriars Road, London, United Kingdom. Tel: +(44)-(20)-79215067
7	Event	International Dental Exhibition & Meeting (IDEM India 2009)
	Date	Oct 23-25, 2009
	Venue	Bombay Exhibition Centre - NSE Exhibition Complex, Mumbai, Maharashtra
	Highlights	This exhibition will present dentists, dental technicians and specialist dealers from the South Asian region with a comprehensive overview of the entire spectrum of innovative products, processes and know-how. Parallel to the exhibition user-oriented workshops will also take place which will highlight the scientific developments in the area of dentistry and dental technology.
	Contact Details	Koelnmesse YA Tradefair Pvt Ltd. B-501-502, Kemp Plaza, Mind Space Chincholi Bunder Extn., Off. Link Road, Malad (West), Mumbai - 400 064, India. Tel: +(91)-(22)-42107802; Fax: +(91)-(22)-40034433
8	Event	Indonesia International Pharma Expo
	Date	Nov 04-07, 2009
	Venue	Jakarta Intl. Expo (JIExpo), Gedung Pusat Niaga Lt, 1 Arena PRJ Kemayoran
	Highlights	Indonesia International Pharma Expo is an international exhibition on pharmaceutical, raw materials, active ingredients, processing machinery, packaging machinery, and equipments. The objective of the exhibition will be to bring together the manufacturers and suppliers of process plant and equipment, for this growing industry, all under one roof.
	Contact Details	Krista Media Pratama PT Krista Exhibitions, Jln.Blandongan 28 DG, Jakarta, Indonesia Tel:+(62)-(21)-6345861; Fax:+(62)-(21)-6340140

9	Event	Busan Health & Food Expo 2009
	Date	Nov 05-08, 2009
	Venue	Busan Exhibition & Convention Centre, Busan, Korea
	Highlights	Busan Health & Food Expo 2009 is a leading trade fair for the medical & agro industry. It focuses on fast tracking growing innovations within the health industry to enhance quality product and service delivery to meet international standards and to contribute efficiently to national development projects on health.
10	Event	Body & Health Expo
	Date	Nov 06-08, 2009
	Venue	Messe Essen, Norbertstrasse D, Essen, Germany
	Highlights	Organised by Messe Essen GmbH at Messe Essen, Nordrhein-Westfalen, Germany, the Body & Health Expo, the Body & Health Expo is a leading consumer fair. It is 3 days event which will be attended by trainer, cosmeticians, hotel owners, physiotherapists etc. from around the globe.
	Contact Details	Messe Essen GmbH. Postfach, 100165, Essen, Germany Tel:+(49)-(201)-72440; Fax:+(49)-(201)-7244248
11	Event	The Natural Health Fair
	Date	Nov 11-13, 2009
	Venue	Hong Kong Convention & Exhibition Centre, Wan Chai, China
	Highlights	The Natural Health Fair has confirmed its position as the leading international marketplace for the natural health industry in the region. The Natural Health Fair - now announcing its fourth edition - leads the trends, connecting the Asian and the global markets with a glittering and qualified exhibition, constantly growing from year to year, and with a targeted and insightful programme of professional seminars and workshops.
	Contact Details	CMP Asia Limited. 17/F, China Resources Building, 26 Harbour, Wanchai, China (Hong Kong S.A.R.). Tel:+(852)-(2827)-6211; Fax:+(852)-(2827)-7831/28029934