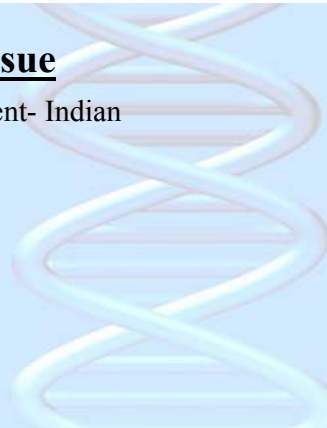




**Inside the Issue**

- In Focus: Clinical Data Management- Indian
- News Brief
- Product Focus: Rosuvastatin
- Stock Scan
- Regulatory Issues
- Upcoming Events



**In Focus: Clinical Data Management-Indian**

In the recent past, the Indian pharmaceutical industry has witnessed a phenomenal rise in the number of clinical trials being conducted within the country. India has developed into a superpower for IT skills and has become a major hub for pharmaceutical and biotech manufacturing, and contract research. The outsourcing business in various other segments is also promising. Clinical trial data management and statistical analysis is one such area, which is growing rapidly, accompanied by a wide range of players entering into different models of this business.

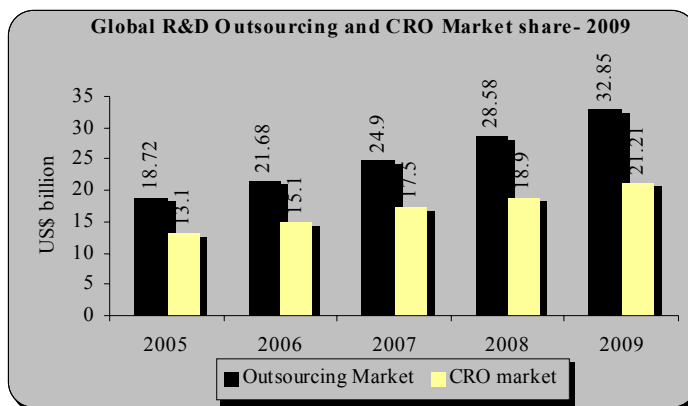
**Market**

Global pharmaceutical companies invest billions of dollars in R&D with the annual spending of the top 15 pharmaceutical companies being around US\$72 billion. A pharmaceutical company spends around US\$1 billion for introducing a new drug, of which around US\$250 million goes into clinical trials alone. And of that, around US\$15-20 million is spent on CDM activities.

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## Global Market

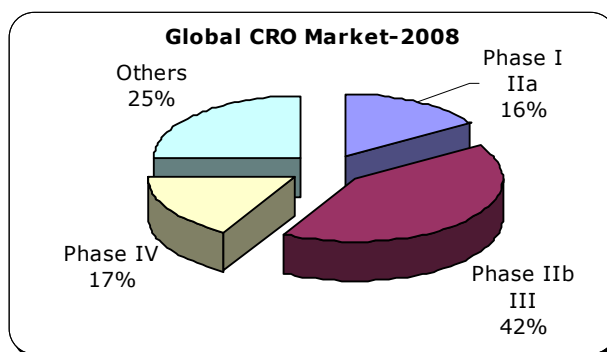
The international CDM market has created new business opportunities, both for project developers as well as technology suppliers. Custom manufacturing for innovator companies stands out as the most attractive outsourcing opportunity for pharmaceutical companies. This market is estimated to cross the US\$31.58 billion mark in 2012 from an estimated US\$22.48 billion in 2009. The largest number of FDA-approved plants are in the US. India follows the US with the potential of capturing 10% of this opportunity. There is a steady progress in the global R&D outsourcing; it's estimated to reach US\$32.85 billion in 2009 from US\$18.72 billion in 2005, growing at a CAGR of 15.10%.



Source: Cygnus Research

The global CRO market in 2009 was US\$19 billion, increasing at a CAGR of 13% from 2005-2008. The options that sponsors are considering while outsourcing clinical trials and data management are as follows:

- Strategic long-term needs Vs Tactical short-term requirements
- Use of global CRO Vs Regional / Local CRO
- Full service contract Vs Functional outsourcing



Source: Cygnus Research

## Indian Market

Global pharmaceutical and biotechnology companies are beginning to see the potential of India's R&D resources, and are exploring alternative engagement models to effectively collaborate with Indian entities and add value to their internal R&D efforts. At a broad level, global companies can access Indian R&D under two wide-ranging models:

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- Licensing or purchasing rights to innovative products or IP (product strategy)
- Contracting specific research services from India (services strategy)

Accordingly, Indian companies have adopted congruent business models, that focus on innovation and

IP for licensing (product strategy), or being a pure services provider, leveraging India's high-quality, low-cost workforce to bring value to global customers (services strategy). According to Cygnus estimates, CDM market in India was about 20% (US\$ 54 million) of the clinical trial market in 2008. Indian clinical trials market in 2008 was US\$ 268.95 million and has been growing at a CAGR of 29% for the last five years. The industry is likely to scale up to US\$320.21 million by 2009 and US\$1 billion by 2014.

Projected figures for revenue, human power and patient load for clinical research in India		
	2008	2010
<b>Value (USD m)</b>	200	1000
<b>Revenue (INR cr)</b>	300	875
<b>Full-time staff requirement</b>	4000	20,000
<b>Site-staff requirement</b>	6000	30,000
<b>Patient load</b>	50,000	300,000
<i>Source: McKinsey report</i>		

### Global Players

Major global players include Pfizer, GSK, Astra Zeneca, Novartis, Merck, Chiltern International, Clintec International, Kendle, Quintiles, Omnicare Clinical Research, Abbott, Elly Lilly and Roche.

### Indian Players

The major players in the CDM market are Asian Clinical Trials, Clinigene, Clininvent Research, GVK Biosciences, iGATE Clinical Research International, Manipal AcuNova, Veeda Clinical Research, Siro Clinpharm, Ocimum Biosolutions, Omnicare Clinical Research, Quintiles Research (India) and Reliance Clinical Research Services.

### Growth Drivers for CDM Market in India

#### Availability of infrastructure

The accessibility to various infrastructures like hospitals, animal houses, established biotechnology laboratories and facilities provided by government for clinical trials and support provided by the local governments is one of the important growth drivers.

#### Availability of patients

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India has diversity of patients for various types of clinical trials, thus possessing large potential for CRO market, which is attracting the global sponsors and other MNCs to establish their presence in India.

### **Rich talent pool**

The expertise of IT providers is a crucial factor in influencing the growth of IT investments, and availability of such skilled personnel is abundant in India. Reaching global locations and process orientation along with expertise in specialised areas like CDM in pharma value chain is an important growth driver.

### **Creditable quality**

India has developed into a superpower for IT skills and has become a major hub for pharmaceutical and biotech manufacturing, and contract research. The outsourcing business in various other segments is also promising.

### **Cost effectiveness**

India's domestic CDM players can excellently develop software for data management on par with global standards and at costs lower by almost 50-75% of the existing costs. India has the advantage of low-cost clinical trials; it is increasingly accepted by reputed global regulators like FDA and the European authorities, besides having lower R&D expenditure among others.

### **Outlook**

With India emerging as an IT superpower and clinical trial hub, outsourcing to India for clinical data management is more obvious than predicted. Indian industry, which previously relied on its cost effectiveness to attract customers, is now moving towards an entirely different direction with good infrastructure and rich expertise. As per Cygnus estimates, the Indian clinical research business will reach US\$ 1 billion by 2014; according to the organisation, even if 20% of trials adopt EDC by 2014, it is a huge market of US\$200-300 million. Hence, India is expected to witness rapid growth in EDC trials.



## News Briefs

### MARKETING

#### Americas

##### **Deerfield: Takeda Pharma to market Kapidex under new product name as DEXILANT**

Takeda Pharmaceuticals North America Inc announced Kapidex will be marketed in the United States under the new product trade name DEXILANT (dexlansoprazole). The product is indicated for heartburn associated with symptomatic non-erosive gastroesophageal reflux disease, the healing of erosive esophagitis (EE) and the maintenance of healed EE. After receiving reports of dispensing errors between KAPIDEX and the products Casodex® (bicalutamide) and Kadian® (morphine sulfate extended-release), Takeda, in coordination with the US Food and Drug Administration (FDA), determined that, in the interest of patient safety, a name change would be the best way to minimise future medication errors with KAPIDEX. It is important to stress that the formulation, indication and approved dosages of DEXILANT will remain the same as KAPIDEX.

##### **New York: ECR Pharma to promote Urocit-K 15mEq tablets to primary care physicians**

Hi-Tech Pharmacal Co Inc announced that its branded marketing subsidiary, ECR Pharmaceuticals will promote Urocit-K 15mEq, and potassium citrate extended release tablets to primary care physicians beginning in April, 2010. Hi-Tech has a license agreement with Mission Pharmacal Company, which will promote the product to Urologists. Indicated for the treatment of kidney stones, UroCit-K 15mEq is the maximum strength potassium citrate product available, and provides convenient twice-a-day dosing. Urocit-K 15 mEq offers kidney stone sufferers the only twice-daily treatment at this dosage strength. The new formulation provides patients with 50% more of the active ingredient, potassium citrate, than Urocit-K 10 mEq.

##### **US: QHN expands to the Western Colorado communities of Aspen and Montrose**

Quality Health Network (QHN) and Axolotl Corp announced QHN's successful expansion to the Western Colorado communities of Aspen and Montrose. The addition of the two communities initiates the next stage of QHN's overall expansion effort to allow more than 20 hospitals and attendant physicians in the 40,000 square miles of Western Colorado to securely share clinical information, improve patient outcomes, and reduce costs. During a recent visit to Grand Junction and town hall meeting conducted by President Obama, QHN is identified as a model for quality improvement and cost efficiency.

##### **US: Diabetes Association announces 2010 schedule for free community health events**

In an age of soaring health care costs and staggering diabetes prevalence, the American Diabetes Association announced its 2010 schedule for free community health events throughout the country—the American Diabetes Association EXPO. By attending EXPO, people will be able to join the Association's new movement Stop Diabetes (SM) and learn how to live healthy, be active, and change the future of the disease. EXPO is one way the American Diabetes Association helps combat this disease on a community level. By providing free access to diabetes information, educational presentations and screenings for things like blood pressure, blood glucose and cholesterol.

##### **US: isoft to showcase interoperability innovative health it solutions at himss**

iSOFT Group Limited will showcase its suite of innovative solutions that focus on interoperability at the HIMSS health IT conference in Atlanta in the US from March 1-4, 2010. iSOFT, which last year entered the important US market through its acquisition of Boston-based technology developer BridgeForward Software, will at HIMSS demonstrate its solutions that are designed to address the requirements for 'Meaningful Use' under the US Government's US\$34 billion health IT stimulus package. A key

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differentiator of iSOFT in the US market is that it ranks among the few global health IT companies whose existing portfolio of solutions meets the requirements for interoperability across the full spectrum of complex healthcare environments. iSOFT has 20 years of expertise and direct engagement with healthcare organizations in some 40 countries and has cemented its global reputation as an important agent of change as national healthcare systems around the world undergo transformation.

#### **Canada: Semafore Pharma gets US patent for novel PI3K/mTOR pathway inhibitor**

Semafore Pharmaceuticals announced that the United States Patent and Trademark Office (PTO) has issued United States Patent Number 7,662,977 entitled "PI-3 Kinase Inhibitor Prodrugs. This composition of matter patent covers a genus of novel compounds that includes SF1126, Semafore's clinical stage, small molecule inhibitor of phosphoinositide-3-kinase (PI3K) and mammalian target of rapamycin (mTOR), two key members of the PI3K signaling pathway that is vital to several essential biological processes, such as cell proliferation and survival. PI3K is commonly altered in human cancers, making inhibition of the target attractive for cancer therapy. Semafore Pharmaceuticals believes that the issuance of US patent recognises the novelty and inventiveness of its approach to create product candidates, such as SF1126, that are designed to deliver more active drug to the tumour while sparing normal tissue. The issuance of the new U.S. patent is a significant milestone for the Company and greatly enhances the intellectual property portfolio around its lead clinical agent, SF1126, according to Joseph Garlich, Ph.D., Semafore's Chief Scientific Officer.

#### **Colorado: Ceragenix and BexPharm enter pact to commercialize EpiCeram in South Korea**

Ceragenix Pharmaceuticals, Inc. (OTC Bulletin Board: CGXP) has entered an exclusive distribution and supply agreement with BexPharm Pharmaceuticals, Inc. to commercialise EpiCeram. EpiCeram is a prescription topical cream which treats atopic dermatitis and other dry skin conditions in South Korea. The agreement grants BexPharm exclusivity in the Territory for the distribution and marketing of EpiCeram while Ceragenix will be responsible for the manufacturing and supply of the product. BexPharm will be responsible for receiving regulatory approval to market EpiCeram in South Korea.

#### **Europe**

##### **UK: Siemens present the latest in diagnostic imaging**

Siemens present the latest in diagnostic imaging, the Ultrasound innovations the company has created to provide consultants with greater detail in diagnostic information. The future of ultrasound lies in Acoustic Radiation Force Imaging (ARFI) and elasticity imaging techniques which will dramatically change diagnostic imaging

##### **Hungary: Egis cooperates with Celltrion on distribution of biopharma products**

Egis, the Hungarian drug manufacturer, has signed an agreement with the South Korean Celltrion Group for distribution of biopharmaceutical products developed and manufactured by Celltrion. Under the agreement, Egis will include eight new biosimilar drugs in the areas of oncology, autoimmune and inflammatory diseases in its product portfolio and will become their exclusive distributor in five countries of the Commonwealth of Independent States (CIS), including Russia. In turn, Celltrion will use the distribution network of Egis in 12 additional countries of the Central and Eastern Europe (CEE) and CIS. The new products are expected to be launched between 2012 and 2018. The first biosimilar drug is planned to be distributed by the beginning of 2013 and it is expected to bring €30m in revenues to Egis over the first year.

#### **Asia Pacific**

##### **Japan: Daiichi Sankyo & Ranbaxy announce establishment of Daiichi Sankyo Espha**

Daiichi Sankyo Company Limited and Ranbaxy Laboratories Limited announced that Daiichi Sankyo will establish Daiichi Sankyo Espha Co Ltd on April 1<sup>st</sup>, 2010. Daiichi Sankyo Espha will market generic drugs, as well as Daiichi Sankyo's products which have gained a well-established reputation in the market. "Daiichi Sankyo is dedicated to meeting the universal desire of patients to improve their health and better balance their lives," said President & CEO of Daiichi Sankyo. "We believe that our understanding of the Japanese market and local presence united with the global expertise of Ranbaxy in the generic arena will enable us to achieve efficient and immediate entry into the generic market."

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**India: Bafna Pharma gets site approval for clarithromycin 250 mg in UK**

Bafna Pharmaceuticals, which is engaged in the business of manufacturing pharmaceutical formulations of betalactum and non-betalactum products in India and other international market, announced that its product clarithromycin 250 mg, has got site approval from Medicines and Health Care Products Regulatory Agency UK. The company offers its products in various therapeutic areas, including anti-bacterials, anti-pyretics, anticonvulsants, anxiolytics, pain management, anthelmintics, anti-fungal, appetite stimulants, anti-diarrhoeals, antiemetics, hypnotics, antacids and anti-ulcerants, vitamin and dietary preparations, cough and cold preparations, anti-asthmatics, calcium preparations, anti-hypertensives, and anti-diabetics.

**India: New India Assurance plans low-premium mediclaim cover**

New India Assurance Company, the market leader in the general insurance sector, plans to launch by the end of 2010-11 a low-premium health insurance policy for the masses. The proposed mediclaim policy, expected to be one of the lowest priced in the market, would cover a selected number of diseases and also restrict the number of hospitals from which the policyholders can avail themselves of the medical services. The whole idea is to bring down the premium rates by restricting the choices to the insured. It also planned to launch a new motor insurance policy in 2010-11 and would look at revising upwards the prices of some of its existing health insurance products.

**India: AP CM inaugurates new facility at cancer centre**

The Chief Minister of Andhra Pradesh inaugurate a new Arogyasri block along with advanced treatment facilities for cancer patients at the Indo-American Cancer Institute and Research Centre assuring Government support to the healthcare sector. The newly set up 2PET-CT GE Discovery equipment helps in detecting metabolic activity of the cancer cells in the body. The institute now into the tenth year of its operation has upgraded its equipment in the new block to include high-end machines that can perform stereotactic radio surgery and host of other facilities

**INVESTMENTS****Americas****California: Transcept receives US patent covering Intermezzo formulation**

Transcept Pharmaceuticals, Inc announced that the first patent covering the composition and method of use of Intermezzo (zolpidem tartrate sublingual tablet), the lead Transcept product candidate, has been issued by the United States Patent and Trademark Office. Transcept announced the issuance of a Notice of Allowance for claims under the application for this patent, U.S. Patent Application Serial No. 11/060,641, on December 14, 2009. The newly issued patent, U.S. Patent No. 7,658,945, titled "Compositions for Delivering Hypnotic Agents Across the Oral Mucosa and Methods of Use Thereof," will expire no earlier than February 2025.

**US: Obama's budget to boost Medicaid funding, broaden global health approach**

President Obama's budget proposal tops US\$3.8 trillion, and would draw a US\$1.3 trillion shortfall in 2011 despite efforts to freeze and cut spending and channel an extra US\$100 billion to immediately attack the high unemployment rate. The 2011 blueprint repeats many of Obama's grandest ambitions from his first budget, including an expensive overhaul of the nation's health-care system. The White House will include an additional US\$25 billion in Medicaid funding for states in the federal budget.

**Canada: YM BioSciences granted two additional US patent for AeroLEF**

YM BioSciences Inc announced that it has been granted two additional patents in the US for AeroLEF, the company's proprietary, inhaled-delivery composition of free and liposome-encapsulated fentanyl in development for the treatment of moderate to severe acute pain. US patent numbers 7,648,981 and 7,648,982 extend the life of YM's AeroLEF patent estate in the US to 2024. The company also announced that AeroLEF's patent estate has expanded to include other territories with the issuance of European patent number 1,603,533 and several patent allowances in China, India, Mexico and other

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territories. These patents strengthen and extend the patent protection for AeroLEF in the US, and expand the global market for this unique and potentially first in class product, according to CEO of YM BioSciences.

#### **Massachusetts: Formatech issued Patent Entitled "Methods of Enhancing Solubility of Agents"**

Formatech, Inc announced the issuance of US patent 7,659,310, entitled "Methods of Enhancing Solubility of Agents" which covers novel formulation methods to enhance the solubility of certain hydrophobic compounds. The patented nanoparticle technology effectively solubilises pharmaceutical compounds in fatty acids and/or fatty alcohols. The formulation achieves aqueous form after dilution with equimolar of protonating agent, thereby keeping the drug in the micelle of the fatty acid salt. Furthermore, the technology addresses many excipient related safety issues, results in significantly higher maximum tolerated doses, provides a better PK profile and delivers drug formulations compatible with parenteral, oral, pulmonary and topical administration. "This nanoparticle technology is ideal for application to commercially successful drugs that call for a safer, more effective drug product formulation, including: Lapachone, Digoxin, N-Acetylsalicylic Acid, Taxotere, Taxol, Diprivan and Cyclosporin...", said CEO of Formatech, Inc. s

#### **US patent for Avanir Pharma's low-dose quinidine formulations of Zeniva**

Avanir Pharmaceuticals, Inc announced that the United States Patent and Trademark Office has issued the company a new patent for its lead drug candidate Zenvia (dextromethorphan/quinidine), extending the period of patent protection in the United States into late 2025. US patent number 7,659,282 titled "Pharmaceutical Compositions Comprising Dextromethorphan and Quinidine for the Treatment of Neurological Disorders" was issued on February 9, 2010. The new patent will provide Avanir with patent protection for low-dose quinidine formulations of Zenvia used to treat pseudobulbar affect (PBA).

#### **Canada: Paladin Labs agrees to amend R&D pact with Isotechnika Pharma**

Paladin Labs Inc, a leading Canadian specialty pharmaceutical company, has agreed to amendments to its existing agreements with Isotechnika Pharma Inc that will give Paladin the full share of future net profits of the Isodiagnostika line of diagnostic products in exchange for an undisclosed lump sum payable over the next twelve months. "Our experience with the Isodiagnostika business over the last several months suggests that, in addition to providing an established base and capabilities from which to sell diagnostic products in Canada, the business, particularly the Helikit 13C-Urea Breath Test for helicobacter pylori, has untapped growth potential in Ontario and Quebec," stated president & CEO of Paladin Labs Inc. "The Helikit line of products holds further potential for export sales", president & CEO also noted.

#### **California: Avrio Receives Drug Manufacturing License**

Avrio Biopharmaceuticals received approval to manufacture and ship pharmaceutical products by the California Department of Public Health, Food and Drug Branch (Cal FDB), completing the organisation's portfolio of product development services in support of its pharmaceutical, biopharmaceutical, and medical device clients. Avrio's newly built, 20,000 square foot, state-of-the-art, aseptic fill-and-finish facility includes three aseptic suites and five production suites with each suite having its own dedicated air handling system. With great confidence in the newly built infrastructure, strategic manufacturing-process flow, state-of-the-art equipment, and experienced staff, Avrio boasts its level of quality by offering clients live video viewing of production (along with on-site viewing access). In addition to a production area designed to provide clients flexibility and scalability, Avrio also includes laboratory space for quality control, microbiology, formulation, and a pilot suite.

#### **Europe**

##### **UK: GSK forms new specialist unit to develop & market medicines for rare diseases**

GSK announced the formation of a new standalone unit specialising in the development and commercialization of medicines for rare diseases. Over 5,500 rare diseases have been identified of which less than 10% currently being treated, presenting a significant unmet medical need. Despite the rarity of each condition, the number of diseases means that between 6-8% of the population may be affected by a

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rare disease. Many are genetic in origin, start in childhood and cause lifelong debility and premature death. Operating under a lean structure, Marc Dunoyer, GSK's President of Asia Pacific and Chairman of Japan, will lead this new operation, working closely with Patrick Vallance, GSK's Senior Vice President of Drug Discovery. The new unit will seek to leverage existing capabilities and partnerships and establish further in-licensing opportunities.

#### **UK Trade body to lead delegations to India focusing biotech industry**

The UK Trade and Investment (UKTI), a government investment services organisation, will focus on promoting trade and investment relation between the biopharmaceutical industry in the UK and India by arranging business meetings in next month or two. The organisation's Bangalore, India, which unit helps businesses locate in the UK and grow internationally, is planning to lead a 10-member business delegation of biotech firms from Britain to India, from March 15, 2010. The delegation, consisting of small and medium-sized biopharma companies would visit biotherapeutic firms in Mumbai, Hyderabad and Bangalore on consecutive days in order to understand the strengths of the Indian industry, According to an official from the UKTI.

#### **Asia-Pacific**

##### **India: Pharma cos hope R&D sops will boost investment**

Indian drugmakers could see excise duty on drugs restored to 8 percent from the present 4 percent, but they are hopeful research & development could attract some tax sops in the Union budget. Industry Players and analysts expect tax sops for R&D to push investments in the sector. The government might restore the excise duty on drugs to 8% from the present 4% offered as part of the first economy stimulus package in December 2008, to ease the effects of a debilitating global financial crisis, according to chief financial officer, Aurobindo Pharma. Indian Drug Manufacturers' Association (IDMA), an industry lobby, however is pressing for the excise duty on drugs to be held at 4% to make Indian goods competitive globally.

#### **Africa**

##### **Nigeria offers huge incentives to attract Indian investments**

Nigeria is the second largest trade and investment destination in Africa for India companies with a trade exchange of more than US\$10 billion. However, with the Nigerian Government offering incentives for investors, the quantum of trade would increase, according to Engr Mustafa Bello, Executive Secretary & Chief Executive Officer, Nigeria Investment Promotion Commission (NIPC). Bello, informed that the Nigerian Government offers a 100% guarantee to all the investments in the country. "Nigeria also offers a five year corporate tax holiday and the country also has a very low VAT regime as compared to other countries. Apart from incentives such as capital allowance, the government also provides subsidies for investors on infrastructure and industries, which utilises local raw material," he told industry representatives.

##### **India: Bharat Bio to pump in Rs25m for vaccine facility expansion**

Hyderabad based vaccine major Bharat Biotech International Limited will invest Rs2.5bn to take its range of vaccines like rotavirus, typhoid, malaria Japanese encephalitis, chikungunya and seasonal influenza for clinical trials. Expansion slated Rs750 million for setting up a new manufacturing facility for these vaccines.

##### **India: Technosoft solution for healthcare**

Technosoft Corporation, the US-based software company with offshore development centres in Chennai and Bangalore has declared the "availability of its healthcare IT compliance services to address the needs of clients wanting to address the Healthcare Compliance planning, implementation and execution challenges. Practitioners can leverage Technosoft toolkits and cost-effective resources to meet the US Department of Health and Human Services mandated compliance deadlines and achieve efficient and effective data-driven Healthcare IT. The company's offering enables improved performance for clients with data-driven decision making for Case Management, Disease Management, Utilisation Management, Insured Population Management and Revenue Cycle Management.

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**India: Healthcare industry looking for intensive care**

The combined public-private spending on healthcare should be at least about 7% of the GDP. To tackle affordability or accessibility concerns on healthcare, it needs to bring in dramatic reforms, besides increase it's spending. The Centre has drawn flak from several quarters in the past on its low spending on healthcare, a little over 1%. If gaps between the need for healthcare and the existing infrastructure are not bridged, if the shortfall in next-generation healthcare and medical manpower is not addressed, people in the healthcare industry worry that the country is sitting on a huge health challenge. The Industry estimates that by 2025 an estimated 189 million people in the country will be more than 60 years, needing higher healthcare spends. The Centre needs to drive efficiencies in the system through public-private partnerships even, if necessary, he observes.

**MERGERS AND ACQUISITION****America****Louisiana: Albemarle enters manufacturing alliance with Pharma Core**

Albemarle Corporation, will partner with PharmaCore to provide manufacturing capabilities for customers with projects that require high volume capacity. This alliance allows a seamless technology transfer from PharmaCore to Albemarle, offering PharmaCore customers long term, higher volume capacity for their pharmaceutical projects. Albemarle's custom manufacturing capabilities include a network of manufacturing assets in South Haven, Michigan, Tyrone, Pennsylvania and Orangeburg, South Carolina, providing Active Pharmaceutical Ingredients (API) and advanced pharmaceutical intermediate production in a broad range of scale and chemistries.

**Switzerland: Debiopharm grants exclusive licence for development of alisporivir to Novartis**

Debiopharm Group, focus on the development of prescription drugs that target unmet medical needs, announced the signature of an exclusive licence agreement with Novartis for the development, manufacture and commercialisation of Debio 025 (alisporivir), a selective, first-in-class cyclophilin (Cyp) inhibitor with a potent anti-hepatitis C virus (HCV) effect. The product is currently in phase 2b clinical development for the treatment of hepatitis C. Debiopharm granted Novartis worldwide commercialisation rights to Debio 025 except for Japan.

**San Diego: Euthymics Bioscience to acquire DOV Pharma for US\$2m**

Euthymics Bioscience, Inc has signed a non-binding Letter of Intent to merge into and acquire DOV Pharmaceutical, Inc. (DOV), a Delaware corporation currently traded on the pink sheets for US\$2 million in cash plus payment of certain of DOV's expenses. DOV believes that the contemplated \$2.0 million cash payment to shareholders represents approximately \$0.015 per share of DOV common stock. If the transaction is consummated, it is anticipated that DOV will be renamed Euthymics Bioscience, Inc.

**US: Aetna, Grove City Medical Center sign a three-year agreement**

Aetna announced that it has signed a three-year agreement with Grove City Medical Center, expanding network access for its members in Western Pennsylvania's Mercer County. Under this new agreement, which takes effect Feb. 15, Aetna members will be able to receive covered services, at in-network rates, from Grove City Medical Center Aetna provides health benefits to more than 1 million people in Pennsylvania. In Western Pennsylvania, members have access to a network that includes 75 contracted hospitals and more than 8,500 primary care physicians and specialists.

**California: Regulus, GSK announce new collaboration on microRNA therapeutics**

Regulus Therapeutics Inc announced the establishment of a new collaboration with GlaxoSmithKline (GSK) to develop and commercialise microRNA therapeutics targeting microRNA-122 in all fields with Hepatitis C Viral infection (HCV) as the lead indication. Under the terms of the new collaboration, Regulus will receive additional upfront and early-stage milestone payments with the potential to earn more than US\$150 million in miR-122-related combined payments, and tiered royalties up to double digits on worldwide sales of products. The collaboration provides GSK with access to Regulus' comprehensive and robust intellectual property estate. Regulus exclusively controls patent rights covering miR-122 antagonists and their use as HCV therapeutics in the United States, Europe, and Japan, including but not limited to the patent families.

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**Philadelphia: TenX enx Biopharma Licenses zanolimumab from genmab**

TenX Biopharma Inc. announced it has signed a licensing agreement to acquire exclusive worldwide rights to develop and commercialise zanolimumab HuMax-CD4 from Genmab A/S (OMX: GEN). Under the terms of the agreement, Genmab will receive an up-front license fee of US\$4.5 million and will be entitled to milestones and royalties on sales of zanolimumab. TenX will be responsible for all future costs of developing, manufacturing and commercialising zanolimumab.

**California: BioMarin to acquire LEAD Therapeutics, Inc for US\$18m**

BioMarin Pharmaceutical Inc announced that it has entered into a stock purchase agreement to acquire LEAD Therapeutics Inc. (LEAD), a small private drug discovery and early stage Development Company with key compound LT-673, an orally available poly (ADP-ribose) polymerase (PARP) inhibitor for the treatment of patients with rare, genetically defined cancers. "The acquisition of LEAD Therapeutics will augment our development pipeline of orphan therapeutics. With LT-673 we see a tremendous opportunity to apply our expertise in developing therapeutics for genetic diseases to the field of oncology by targeting cancers with defined genetic mutations that make them susceptible to treatment with agents such as LT-673..." said Chief Executive Officer of BioMarin. Under the terms of the stock purchase agreement, BioMarin will pay to the stockholders of LEAD US\$18 million upfront and will pay an additional US\$11 million upon acceptance of the IND filing (filing expected by the end of 2010), and up to US\$68 million for development and launch milestones for LT-673.

**Europe****London: AstraZeneca sign worldwide licensing pact to commercialise fostamatinib disodium**

AstraZeneca and Rigel Pharmaceuticals have an exclusive worldwide license agreement for the global development and commercialisation of fostamatinib disodium (R788), Rigel's late-stage investigational product for Rheumatoid Arthritis (RA) and additional indications. Fostamatinib disodium, which has completed a comprehensive phase-II programme, is the furthest developed oral Spleen Tyrosine Kinase (Syk) inhibitor being evaluated for RA. Inhibiting Syk is thought to block the intracellular signalling of various immune cells implicated in the destruction of bone and cartilage which is characteristic of RA.

**UK: Biocartis acquires Philips technology platform**

The molecular diagnostics company, Biocartis, have purchased the Philips' technology platform for rapid fully-automated DNA/RNA molecular diagnostic testing. The platform has been designed for applications in a wide range of patient sample testing and Biocartis plan to develop and commercialise the platform, together with a menu of tests, through strategic partnerships. Biocartis will benefit from close access to the multi-disciplinary R&D facilities and services of Philips Corporate Technologies. This agreement is transformational for Biocartis as it accelerates our plans to bring innovative and cost-effective molecular diagnostic solutions that can turn personalised medicine into practice.

**Basel: Basilea enters co-development & co-promotion pact with Astellas on isavuconazole**

Basilea Pharmaceutica International Ltd announced that it has entered into a license, co-development and co-promotion agreement with Astellas Pharma Inc for Basilea's azole antifungal agent isavuconazole in phase-III clinical development for the treatment of life-threatening invasive fungal infections on a worldwide basis, including an option for Japan. Under the terms of the agreement, Basilea will receive an upfront payment of CHF 75 million and will be eligible to receive up to CHF 478 million in additional payments on achievement of pre-specified development and sales milestones. Basilea will also receive significant double-digit tiered royalties on sales. Astellas is granted an exclusive right to commercialise isavuconazole whereas Basilea retains an option to co-promote the product in the United States, Canada, major European countries and the People's Republic of China. Basilea and Astellas will jointly participate in the development of isavuconazole

**Asia-Pacific****China: 3SBio, Panacor Bioscience enter into collaboration and license agreement**

3SBio Inc., focused on researching, developing, manufacturing and marketing biopharmaceutical products, announced collaboration and license agreement with Panacor Bioscience Ltd., to develop and commercialise its Nephoxil pharmaceutical product for the treatment of hyperphosphatemia in China. Nephoxil is a differentiated, iron-based phosphate binder for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with End Stage Renal Disease (ESRD).

**India: Dishman Pharma enters strategic alliance with Codexis**

The Ahmedabad based Contract Research and Manufacturing Services (CRAMS) company, Dishman Pharmaceuticals and Chemicals, has entered strategic alliance with a California based biotech company, Codexis, Inc. The Rs10 billion company announced recently that the 5 year alliance would let the Ahmedabad based company use Codexis' proprietary enzymatic bio-catalysis technology in order to manufacture building blocks and intermediates. With this alliance, the company is looking forward to the reduction of chiral compounds in the APIs and the provision of low-cost, cleaner and greener processes of manufacturing.

**India: Bulk drug exports hit by govt's 15% value-addition directive**

Domestic bulk drug exporters has complained the value-added re-exports of common medicines like penicillin and erythromycin, are in trouble due to a recent government directive. The government has fixed 15% value addition as the minimum requirement for duty-free import of raw materials. Exporters say the manufacture of such medicines is highly dependent on the import of crucial ingredients from countries like China. The companies convert imported ingredients into bulk drugs and re-export them. Since there are no packaging costs involved, the maximum value-addition occurs during the process is 3-4%.

**Singapore: Merck to buyout Millipore for US\$7.2bn**

Pharmaceutical and chemical giant Merck is acquiring Millipore Corporation, a leading provider of technologies, tools, and services for bioscience research and biopharmaceutical manufacturing, for approximately US\$7.2 billion. The companies have entered into a definitive agreement under which Merck will acquire all outstanding shares of common stock of Millipore, for US\$107 per share in cash, or a total transaction value, including net debt, of approximately US\$7.2 billion. Millipore and Merck will create a US\$ 2.9 billion world-class partner for the life science sector, achieving significant scale in high-margin specialty products with an attractive growth profile.

**India: SIRO Clinpharm forms alliance with Korean CRO DreamCIS**

SIRO Clinpharm, a Contract Research Organisation (CRO) with a presence in India, Western and Central Eastern Europe, and the United States announced its alliance with DreamCIS Inc., a leading CRO based in Seoul, South Korea. Their services includes Clinical trial management, Pharma covigilance, Post Marketing Surveillance, Data management, Biostatistics and Quality Assurance services. "This pact will help us on one hand to build a strong competitive advantage in the Asia Pacific region, while on the other hand it will create a sustainable value for our existing as well as potential customers," said Ajit Nair, Ph.D., President, India. He further added that, "Our goal is to offer a wider platform of patient recruitment capabilities from the Asia Pac region for our global client base."

**Dishman Pharma signs strategic alliance with Codexis**

Dishman Pharmaceuticals and Chemicals Ltd. Said it has entered into a strategic alliance with Codexis, Inc, a California based Biotechnology Company. Under this alliance, Dishman will use Codexis' proprietary enzymatic biocatalysis technology for the manufacture of building blocks, intermediates and API's for innovator pharmaceutical companies.

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## RESEARCH AND DEVELOPMENT

### America

#### **Melbourne: Starpharma and Eli Lilly ink drug delivery collaboration in human pharmaceuticals**

Melbourne-based Starpharma Holdings has signed a new drug delivery collaboration agreement with Eli Lilly and Company for human pharmaceuticals. Indianapolis-based Eli Lilly is the 10th largest pharmaceutical company in the world. Lilly has a US\$40 billion market capitalisation. Starpharma's dendrimer drug delivery technology will be applied to enhance compounds in Lilly's human pharmaceutical portfolio. Lilly will fund a collaborative research and development program with the aim of creating improved drugs incorporating SPL's proprietary delivery technology, to be commercialised by Lilly. It was agreed that Starpharma and Elanco (Lilly's animal health division) would work together to develop new animal health products with enhanced properties.

#### **Canada: Alexza ties up with Biovail to develop & commercialize Staccato loxapine in US**

Alexza Pharmaceuticals Inc. announced that it has established a collaboration with Biovail Laboratories International SRL, a subsidiary of Biovail Corp., to develop and commercialize AZ-004, or Staccato loxapine in the US and Canada. As per the terms of the collaboration, Alexza is entitled to receive an upfront cash payment of \$40 million, up to \$90 million in potential milestone payments contingent on the successful approval of the first AZ-004 NDA, successful commercial manufacturing scale-up, and the successful completion of additional clinical trials, regulatory submission (if required) and approval of an sNDA (if required) in the outpatient setting for patients with schizophrenia or bipolar disorder. Biovail will make tiered, royalty payments of 10% to 25% on net commercial sales of AZ-004.

#### **California: Cytokine tics reveals phase-I multiple dose trial of CK - 2017357**

Cytokinetics, Incorporated announced results from its phase-I, randomised, double-blind, placebo-controlled, multiple-dose clinical trial of oral CK-2017357. The primary objective of this clinical trial was to determine the safety and tolerability of CK-2017357 after multiple oral doses to steady state in healthy male volunteers. The secondary objective was to evaluate the pharmacokinetic profile of CK-2017357 after multiple oral doses to steady state.

#### **New York: EpiCept gets orphan drug designation for EpiCept NP-1 in US**

EpiCept Corporation announced that EpiCept™ NP-1 has been granted orphan drug designation by the US Food and Drug Administration for the treatment of post-herpetic neuralgia. NP-1 is a prescription topical analgesic cream designed to provide long-term relief from the pain of peripheral neuropathies.

### Middle East

#### **Israel: Compugen finds protein for treatment of autoimmune disorders**

Compugen Ltd has announced the discovery and experimental validation of CGEN-15001 for the treatment of autoimmune disorders. CGEN-15001 is the extra cellular region of a previously unknown membrane protein in the B7/CD28 family. The existence and potential utility of the newly discovered parent protein from which CGEN-15001 is derived was predicted in silico utilizing Compugen's LEADS Platform and other proprietary algorithms. Autoimmune diseases develop when defects in the immune system lead the body to attack its own cells, tissues, and organs and include more than 80 chronic, and often disabling, illnesses.

### Europe

#### **France: Vivalis grants duck embryonic stem cell research licence to Kyoto Biken**

Vivalis, a biopharmaceutical company that provides the pharmaceutical industry with innovative cell-based solutions for the manufacture of vaccines and proteins and develops drugs to prevent and treat human diseases, announced that it has granted KYOTO BIKEN rights to the duck embryonic stem cell derived EB66(R) cell line to evaluate EB66(R) cell line for the production viral vaccines. Vivalis is pleased to enter in this agreement to support R&D efforts of Kyoto Biken, one of the largest animal vaccine manufacturers in Japan, for the development of veterinary vaccines produced on EB66 cell line. With more and more EB66 users in Japan, and in the rest of the World, this cell line is becoming a worldwide standard platform for viral vaccines manufacture on the Human and veterinary field.

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**UK: CellCentric licenses epigenetic discovery programmed to Takeda**

From its broad portfolio of novel targets in epigenetics, CellCentric has out-licensed exclusively the development and commercialisation of an important programme focused on cancer. Under the terms of the new agreement, CellCentric will receive from Takeda Pharmaceutical Company Limited an upfront payment and pre-clinical and clinical milestones, in addition to royalties. Based on the royalties and milestones defined, the overall deal could be worth in excess of US\$200 million to CellCentric over the course of the agreement. This is a pioneering deal for the emerging area of epigenetics, demonstrating the commercial interest in novel epigenetic targets beyond HDACs (histone deacetylases) and DNMTs (DNA methyltransferases). Therapeutic research will be initiated by Takeda's Research Group. Development of molecules stemming from this agreement will be completed by Millennium: The Takeda Oncology Company, which is responsible for Takeda's global oncology development strategy.

**Germany: Evotec extends research agreement with Cubist Pharma**

Evotec AG announced that it has extended its research agreement with Cubist Pharmaceuticals, Inc. to the end of 2010. Under the contract extension, Evotec will provide additional fragment-based drug discovery expertise using its proprietary platform, EVolution, which includes fragment screening, structural biology and protein crystallography, to discover and profile novel compounds against additional antibacterial targets selected by Cubist. Evotec and Cubist have collaborated since July 2009, successfully progressing drug discovery programmes. Over the course of 2010, Evotec will continue and expand its support of Cubist's discovery activities. A key benefit of Evotec's fragment-based drug discovery platform is versatility, combining biochemical and biophysical techniques including nuclear magnetic resonance surface plasmon resonance and x-ray crystallography, thus allowing the design of target-specific strategies.

**FDA APPROVAL****Abbott laboratories receives U.S. FDA approval for heat-stable ritonavir tablets**

Abbott announced that the U.S.FDA has granted approval of a new tablet formulation of the company's antiretroviral medication Norvir (ritonavir). The new Norvir tablets can be stored at room temperature and do not require refrigeration, making it more convenient for patients. The Norvir tablets and the Norvir soft-gelatin capsules both contain 100 mg of ritonavir. Norvir is used in combination with other antiretroviral medications to treat HIV. All forms of Norvir, including the soft-gel capsule and liquid form, remain available in the United States. Abbott has been dedicated to finding new and more convenient ways for patients to manage HIV through the development of novel diagnostics testing methods and medications for more than twenty years.

**Labopharm receives US FDA approves for Oleptro to treat depressive disorder**

Labopharm Inc announced the U.S. Food and Drug Administration (FDA) has approved Oleptro (trazodone hydrochloride) Extended Release Tablets, a novel once-daily formulation of the antidepressant trazodone, for the treatment of major depressive disorder in adults. Oleptro utilises Contramid, Labopharm's clinically validated technology controls the release of active substances within oral medications. MDD is a common mental illness often characterised by a combination of social and somatic symptoms. It affects more than 14 million adults in the US and is the leading cause of disability globally. Oleptro will offer physicians another therapeutic alternative for MDD patients.

**Strides Arcolab gets US FDA approval for Labetalol injection**

Strides Arcolab announced that it received ANDA approval for Labetalol Hydrochloride or HCl injection of USP 100 mg/20 mL and 200 mg/40 mL strengths. Labetalol is the third product launched by the company in partnership with Sagent Pharmaceuticals. Under the partnership, both the companies are jointly developing, supplying and marketing more than 25 injectable products for the US market. Labetalol HCl injection is the generic equivalent of Prometheus Laboratories' Trandate injection. Labetalol HCl Injection is an adrenergic receptor blocking agent that has both selective alpha1-adrenergic and non-selective beta-adrenergic receptor blocking actions that is used to control blood pressure in severe hypertension.

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### US FDA accepts Javelin Pharmaceuticals' Dyloject NDA for formal review

Javelin Pharmaceuticals, Inc. (NYSE Amex: JAV), a leading developer and marketer of specialty pharmaceutical products for pain management, announced that its New Drug Application (NDA) submitted on December 2, 2009 to the US Food and Drug Administration (FDA) for its investigational product candidate, Dyloject™ (diclofenac sodium) Injection, has been accepted for formal review. The Company expects to learn the Dyloject NDA's PDUFA date from the FDA in the next few weeks. The NDA is in support of US marketing approval and registration of Dyloject for the management of acute moderate-to-severe pain in adults. If approved, Dyloject will be the first IV non-steroidal anti-inflammatory drug (NSAID) marketed in the United States as a single agent for the management of acute moderate-to-severe pain in adults since ketorolac in 1990.

### Allergan announces US FDA approval of Juvederm XC dermal filler formulated with lidocaine

Allergan Inc announced the US Food and Drug Administration's approval of Juvederm XC, a new formulation of the currently US FDA-approved Juvederm dermal filler and the latest advancement in hyaluronic acid dermal fillers. Allergan's new Juvederm formulation contains the local anaesthetic lidocaine to provide patients with enhanced comfort during treatment of moderate to severe facial wrinkles and folds, such as the nasolabial folds appear around the nose and mouth. Allergan's new JUVEDERM is the first and only hyaluronic acid dermal filler approved by the US FDA to last up to one year from initial treatment and number-one selling hyaluronic acid dermal filler.

### Arena Pharmaceuticals Announces FDA Acceptance of Lorcaserin NDA for Filing

Arena Pharmaceuticals, Inc announced that its New Drug Application (NDA) for lorcaserin, Arena's internally discovered and developed drug candidate for weight management, including weight loss and maintenance of weight loss drug, has been accepted for filing by the US Food and Drug Administration (FDA). Arena submitted the lorcaserin NDA on December 22, 2009, and expects to learn the Prescription Drug User Fee Act (PDUFA) date in the next few weeks. The US FDA's acceptance of the lorcaserin NDA is a significant milestone towards Arena Pharmaceuticals goal of providing physicians and their patients with a new mechanistic approach to achieve sustainable weight loss in a well-tolerated manner, according to Arena's President and Chief Executive Officer.

### Tibotec gets US FDA nod for labelling update for Prezista tabs

Tibotec Therapeutics announced that the US Food and Drug Administration has approved a labelling update for Prezista (darunavir) tablets to include 96-week data from the ARTEMIS and TITAN studies. Both ARTEMIS and TITAN evaluated the efficacy and safety of Prezista with ritonavir vs. Lopinavir in combination with other antiretrovirals (ARVs) for the treatment of human immunodeficiency virus (HIV-1) in treatment-naïve and treatment-experienced adult patients, respectively. Based on the ARTEMIS results, the United States Department of Health & Human Services (DHHS) Guidelines for HIV recommended once daily Prezista, in combination with tenofovir/emtricitabine, as one of two preferred protease inhibitors (PIs) for patients starting therapy for the first time, in a December 2009 guidelines update.

### GSK's TYKERB® receives approval for treatment of HER2+/ErbB2+ metastatic breast cancer

GlaxoSmithKline announced that the US Food and Drug Administration has granted accelerated approval for a new combination regimen using TYKERB (lapatinib) as a first-line, all-oral treatment for women with metastatic breast cancer. TYKERB is now indicated in combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for hormonal therapy is indicated. TYKERB in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.

### Tibotec gets US FDA approves for labelling update for Prezista tabs

Tibotec Therapeutics announced that the US Food and Drug Administration (FDA) has approved a labelling update for PREZISTA (darunavir) tablets to include 96-week data from the ARTEMIS and TITAN studies. Both ARTEMIS and TITAN evaluated the efficacy and safety of Prezista with ritonavir

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vs. lopinavir in combination with other antiretroviral ARVs for the treatment of human immunodeficiency virus (HIV-1) in treatment-naive and treatment-experienced adult patients, respectively. Based on the ARTEMIS results the United States Department of Health & Human Services (DHHS) Guidelines for HIV recommended once daily Prezista, in combination with tenofovir/emtricitabine as one of two preferred protease inhibitors (PIs) for patients starting therapy for the first time. Prezista developed by Tibotec Pharmaceuticals and is marketed in the US by Tibotec Therapeutics, a division of Centocor Ortho Biotech Products.

#### **Massachusetts: Formatech receives US patent covering novel drug formulation methods**

Formatech Inc the issuance of US patent 7,659,310 entitled 'Methods of Enhancing Solubility of Agents' covers novel formulation methods to enhance the solubility of certain hydrophobic compounds. The patented nanoparticle technology effectively solubilises pharmaceutical compounds in fatty acids and fatty alcohols. The formulation achieves aqueous form after dilution with equivocal of protonating agent, keeping the drug in the micelle of the fatty acid salt. Furthermore the technology addresses many excipient related safety issues, results in significantly higher maximum tolerated doses, provides a better PK profile and delivers drug formulations compatible with parenteral, oral, pulmonary and topical administration. This nanoparticle technology is ideal for application to commercially successful drugs that call for a safer, more effective drug product formulation, including: Lapachone, Digoxin, N-Acetylsalicylic Acid, Taxotere, Taxol, Diprivan and Cyclosporin.

#### **Asia-Pacific**

##### **China: Simcere receives Chinese approval to manufacture and sell Zanamivir**

Simcere Pharmaceutical Group ("Simcere" or the "Company") (NYSE: SCR), a leading pharmaceutical company specializing in the development, manufacturing, and marketing of branded generic and proprietary pharmaceuticals in China, today announced that one of its subsidiaries, Nanjing Simcere Dongyuan Pharmaceutical Co. Ltd., has received new drug registration approval from the State Food and Drug Administration ("SFDA") to manufacture and sell Zanamivir, a neuraminidase inhibitor inhalant used in the prevention and treatment of Influenza A and Influenza B. Zanamivir is marketed globally by GlaxoSmithKline under the trade name Relenza. Zanamivir is one of only two WHO approved drugs to which the new H1N1 strain of influenza A has been shown to be susceptible

## **OPERATIONS**

#### **America**

##### **US: Mountain View Hospital extends the use of SRS hybrid EMR**

SRS, the leader in hybrid EMRs, announced that Mountain View Hospital, an SRS client based in Idaho, is extending its use of the SRS hybrid EMR throughout its diverse range of highly dedicated physicians and staff. The hospital has grown by 40% with its recent expansion. Mountain View Hospital has experienced success and is deploying SRS enterprise-wide. The SRS hybrid EMR is ideal for dynamic hospital environments.

##### **US: Premier healthcare alliance releases new value analysis solution for hospitals**

The Premier healthcare alliance has introduced a new value analysis solution to help hospitals effectively evaluate product and treatment options to improve quality and safety while reducing costs. The company has "ValueAdvisor" which transparently connects the supply chain, finance and clinical healthcare staff by providing the means to effectively communicate as a team on product, service and care delivery decisions. ValueConnect™ offers Premier's 2,300 hospital members the opportunity to standardize an approach to value analysis across the entire alliance. It supports the value analysis process through automated workflow management, tracking and measuring results, peer-to-peer collaboration and knowledge sharing.

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## Europe

### UK: Exploring the possibilities of multi-modality imaging solutions

Royal Philips Electronics have joined forces with VU University Medical Centre to research new multi-modality imaging solutions. By combining data from different imaging modalities, clinicians will be able to determine the presence and extent of many diseases at an earlier stage, which in turn can contribute to improved treatment success rates. Initial projects on medical imaging procedures will focus on nuclear imaging, especially Positron Emission Tomography (PET), and optical imaging techniques. For these modalities, the joint research projects will explore novel imaging agents (disease-specific contrast agents and tracers) and design new software for quantitative image analysis and user-friendly data presentation. Research programs for other imaging modalities are currently being prepared.

## Africa

### Africa: UN Secretary-General focuses on MDGs during African Union Summit

In the 14th African Union (AU) Summit, the UN Secretary-General, Ban Ki-moon called for African countries to maintain their commitment to the Millennium development Goals (MDGs), which include reducing poverty, disease and child mortality, ahead of their target date of 2015. The global recession, energy crisis, food insecurity and climate change have all made development more difficult and more urgent told more than 50 heads of state and government attending the three-day AU meeting.

## Asia-pacific

### India: High-end medical devices likely to get 30% cheaper

The cost of latest versions of medical devices like ultrasound systems, cardiac diagnostics could fall by 25 to 30% compared to their imported counterparts in the domestic market, once the recently launched Trivitron Medical Technology Park in Chennai starts manufacturing and rolling out products. Trivitron Healthcare has roped in five specialised global medical technology players and is in talks to finalise tie-ups with another five. Initially the products would be launched in the domestic market but eventually Velu plans to tap the emerging markets business by exporting at competitive prices to countries in Africa and West Asia.

### India: Healthcare seeks IIFCL funding

The healthcare sector has sought for India Infrastructure Finance Company Limited (IIFCL) funding for large-scale projects on a long-term debts basis. Besides, it has also mooted a healthcare upgrade and new investment fund or a health development fund with an initial Rs10,000m corpus. The overall healthcare infrastructure in India is very poor when compared with other developing countries. There exists a huge gap between healthcare infrastructure facilities available and their demand in the country. Currently, the sector contributes about 6.1% to the GDP of the country of which the government's contribution is 1.1%. Given its potential for growth and employment generation, the sector will contribute to increase in GDP by 2-3%. The sector would provide direct employment opportunities for at least two million people. In order to catalyse quality infrastructure development, the government needs to enable and facilitate the environment by incentivising the healthcare sector.

### India: Extend rural health mission to tea sector

The West Bengal Government is expected extend the scope of the National Rural Health Mission (NRHM) to cover the larger section of the community in tea estates of the State as had been done by the Assam Government with certain modifications to the scheme. The Assam Government, pointed out, in partial modification to NRHM scheme, had been providing assistance, both financial and others, by way of public private partnership model to cover not only tea garden workers but the entire tea estate population covering permanent employees and workers and their families, seasonal workers and other residents of tea estates. It is also appealed to the West Bengal Government for continuation of exemption from education and rural cess for at least another two years.

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**NIPER Ahmedabad to introduce PG diploma course for medical devices sector in July, 2010**

The National Institute of Pharmaceutical Education and Research (NIPER), Ahmedabad, is all set to launch India's first dedicated course in medical devices segment from the new academic year starting from July, 2010. The institute is currently in talks with some of the major educational institutes conducting similar courses in the country. The NIPER Ahmedabad, housed in the reputed institute B V Patel Pharmaceutical Education and Research Development (PERD) Centre, will offer a post graduate diploma course on the medical devices segment from the academic year 2010-11, focusing on multidisciplinary curriculum covering mechanics, engineering, pharmacology and medical aspects of the segment

**Centre approves proposal to upgrade state govt medical colleges**

The Central government has approved a proposal from union health ministry on strengthening and upgradation of state government medical colleges for starting new Post Graduate disciplines and increasing PG seats by central funding during XI Plan period. The Cabinet Committee, approved the proposals for funding the state government medical colleges by way of a one-time grant of Rs 1350 crore under a new centrally sponsored scheme with funding pattern of 75% by central government and 25% by state government for starting new Post Graduate disciplines and increasing PG seats.

**Health Min goes slow on proposal for rural MBBS course as opposition mounts**

The Health Ministry proposal to introduce a short-term rural medical course to tide over the shortage of doctors in the rural areas has hit a roadblock with the Indian Medical Association opposing the plan and the government asking Medical Council of India to consult all stake-holders and take note of concerns from different quarters.

## Product Focus – Rosuvastatin

### Rosuvastatin - Introduction

Rosuvastatin is a member of the drug class of statins, used to treat high cholesterol and related conditions, and to prevent cardiovascular disease. Shionogi developed the product and the pharmaceutical company AstraZeneca markets it as Crestor.



### Action of Rosuvastatin

Rosuvastatin is a competitive inhibitor of the enzyme HMG-CoA reductase, having a mechanism of action similar to other statins. Rosuvastatin's approximate elimination half life is 19 hours and its time to peak plasma concentration is reached in 3–5 hours following oral administration. Putative beneficial effects of rosuvastatin therapy on chronic heart failure may be negated by increases in collagen turnover markers as well as a reduction in plasma Coenzyme Q10 (CoQ10) levels in patients with chronic heart failure.

### Drug Interactions

Isoenzymes of the CYP system do not extensively metabolise rosuvastatin, and CYP isoenzyme inhibitors, including erythromycin, itraconazole, and ketoconazole, do not substantially affect it. Erythromycin plus rosuvastatin resulted in decreases of 20% and 31%, respectively, in the AUC and Cmax for rosuvastatin 40 mg. Itraconazole coadministration resulted in 28% and 39% increases in AUC after oral administration of 10 and 80 mg, respectively. These changes in AUC and Cmax were not considered clinically significant..

### Dosage

The recommended starting dose for most people with high cholesterol is rosuvastatin 10 mg once a day (although a starting dose of 20 mg daily can be used if the person has very high cholesterol). Healthcare provider may recommend a lower rosuvastatin dosage (5 or 10 mg per day, depending on the circumstances) if you:

- Are 65 years of age or older
- Are of Asian decent
- Take gemfibrozil (Lopid)
- Take cyclosporine (Gengraf®, Neoral®, Sandimmune)
- Take protease inhibitor medications for HIV
- Have severe kidney disease.

### Storage

It is Stored at room temperature away from light and moisture. The manufacturer of U.S. products recommends storage at room temperature between 68-77 degrees F (20-25 degrees C). The manufacturer of Canadian products recommends storage at room temperature between 59-86 degrees F (15-30 degrees C).

### Uses

Rosuvastatin is an enzyme blocker (HMG-CoA reductase inhibitor), also known as a statin. It is used along with a proper diet to help lower fats (triglycerides) and cholesterol in the blood. This drug is usually prescribed after non-drug treatment options have not been fully successful at lowering cholesterol (e.g., diet change, increase in exercise, weight loss if overweight). Reducing cholesterol and triglycerides help prevent strokes and heart attacks.

#### Classification

<b>Brand Name</b>	Crestor
<b>Generic Name</b>	Rosuvastatin
<b>Therapeutic Segment</b>	Anticholesterol
<b>Manufacturer</b>	Astrazeneca
<i>Source: Wikipedia; Cygnus Research</i>	

#### Side Effects

- Weakness, dizziness
- Mild nausea
- Constipation
- Diarrhea
- Sore throat
- Runny or stuffy nose
- Memory loss
- Headache

#### Adverse Side Effects

- Muscle damage
- Yellowing eyes and skin
- Dark urine
- Stomach/abdominal pain
- Severe nausea
- Fatigue
- Itching

## Precautions

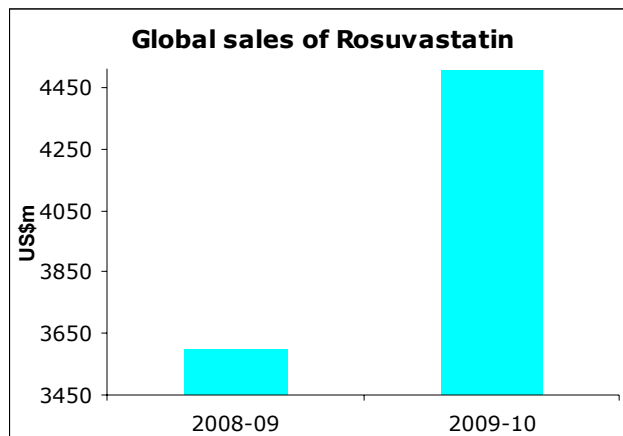
Before taking rosuvastatin, tell your doctor if you have

- Kidney disease
- Underactive thyroid
- Muscle disorder
- Epilepsy or other seizure disorder
- Electrolyte imbalance (such as high or low potassium levels in your blood)
- Severe infection or illness or
- Recent surgery or medical emergency

Major Players	
Company Name	Brand Name
Pfizer	Lipitor
Merck& Co	Vytirin
Wikipedia, Cygnus Research	

## Global sales of Rosuvastatin

US sales for Crestor for the full year increased by 25% to US\$2,100 million. Rosuvastatin sales in the Rest of World were up 28% to US\$705 million in the fourth quarter. Rosuvastatin volume growth continues to run well ahead of the statin market growth in both Established and Emerging Markets. There was strong growth in Western Europe (up 23 %), Canada (up 23%), Japan ( up 60%) and Australia ( up 50%). Sales in Emerging Markets were up 16%. Rosuvastatin sales in the Rest of World were up 33% to US\$2,402 million for 2009.



Source: Company Sources; Cygnus Research

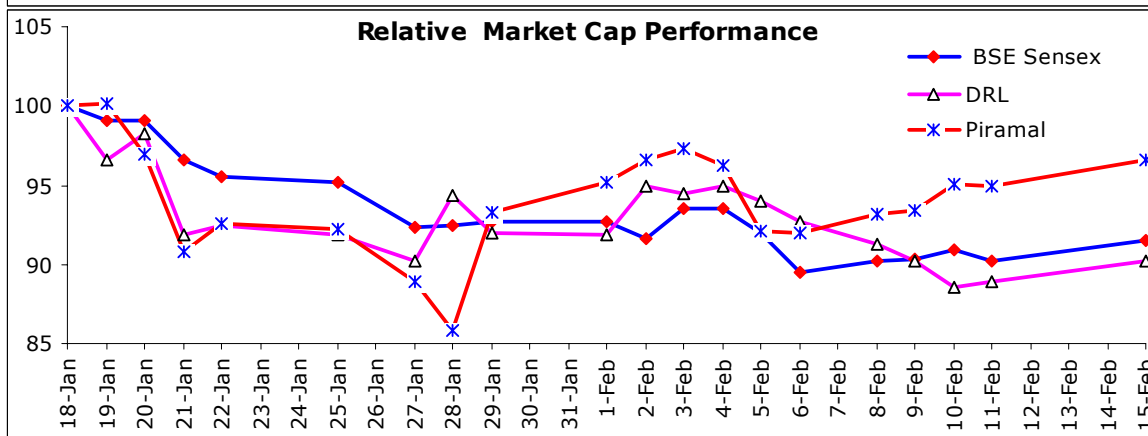
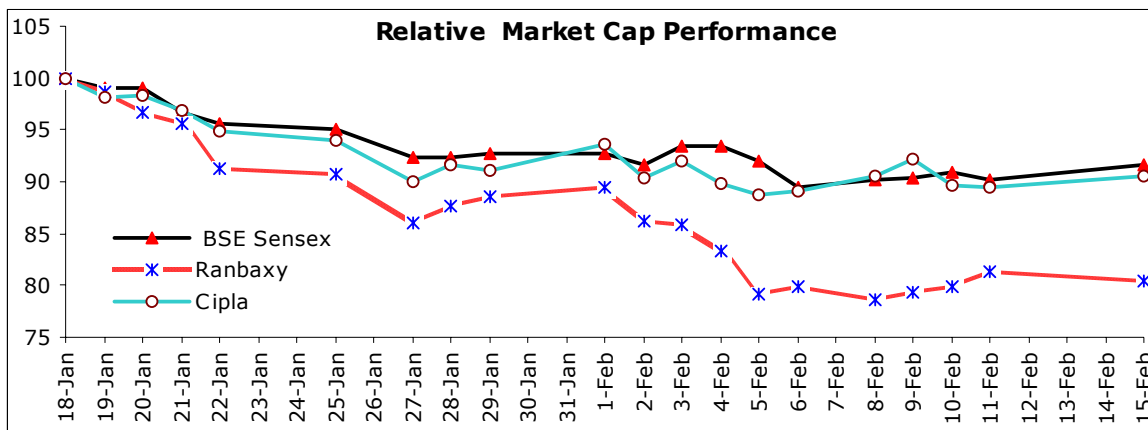
## India Scenario

Indian cholesterol-lowering drugs in India, presently estimated over Rs10 billion, is controlled by domestic players. Rosuvastatin in India achieves greater significance at this point of time because the cardiovascular disease occurrence in the sub-continent is peaking to an all time high with the increasing population of rich urban middle-class. Biocon, India's largest and USFDA qualified producer and exporter of cholesterol-lowering drugs, is the market leader. Other prominent players in this market include Ranbaxy, Lupin, Themis Medicare, RPG Life Sciences, Claris Lifesciences, Intas Pharma, Medley, Sun Pharma, USV, Concord Biotech, Emcure, Zydus Cadila, Torrent, Cadila Pharma, Carsyon, a division of Micro Labs and Cipla.

## Outlook

According to some analysts, Rosuvastatin revenue could rise to as much as US\$8 billion and 18% of the global statin market in 2014. Estimates suggest that by the year 2020 India will have the largest cardiovascular disease burden in the world and account for one third of all deaths, with one fifth of the deaths in India resulting from coronary heart disease. Heart disease in India occurs 8 to 10 years earlier than in the West. Even women are prone to the risk as one in four women in urban India and every eighth woman in rural India is suffering from high cholesterol. This is mainly due to the changing food habits and lack of physical exercise, particularly in urban areas. This disorder is directly proportional to the sales of Rosuvastatin in India.

## Stock Scan



Source: BSE India; Cygnus Research

	16 Jan-23 Jan	24 Jan-30 Jan	31 Jan- 06 Feb	07 Feb-15 Feb
<b>SENSEX</b>	This week, the Sensex declined by 4% to 16859 points, due to the sharp decline in capital goods, PSU, health care and metals indices.	The announcement of RBI credit policy where monetary tightening measures are expected to be taken. Interest rate hardening affected the market to move in to red during this week.	Weak global markets encouraged investors to lock in profits which made sensex to further fall by 3% to 15915 points during the week.	The market breadth has turned marginally positive due to the recovery made by telecom, auto and metal stocks during the week.
<b>Ranbaxy</b>	The share price decreased by 8.80% from Rs511.30 to Rs466.30	The share price decreased by 2.33% from Rs463.95 to Rs453.15.	The share price decreased by 10.63% from Rs457.15 to Rs408.55.	The share price increased by 2.27% from Rs401.70 to Rs410.80 due to the launch of new drugs.

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<b>Cipla</b>	The share price decreased by 5.20% from Rs348.40 to Rs330.30	The share price decreased by 3% from Rs327.10 to Rs317.30.	The share price decreased by 4.85% from Rs326.05 to Rs310.25.	The share price increased by 0.02% from Rs315.70 to Rs315.75.
<b>DRL</b>	The share price decreased by 7.60% from Rs1222.85 to Rs1129.90	The share price increased by 0.23% from Rs1122.70 to Rs1125.25.	The share price increased by 0.93% from Rs1123.60 to Rs1134.10	The share price decreased by 1.12% from Rs1116.35 to Rs1103.80.
<b>Piramal</b>	The share price decreased by 7.48% from Rs391.25 to Rs362.00 due to decline in Q3 sales.	The share price increased by 1.21% from Rs360.70 to Rs365.05.	The share price decreased by 3.32% from Rs372.40 to Rs360.05.	The share price increased by 3.69% from Rs364.60 to Rs378.05.

## Regulatory Issues

### International

#### FDA Approves Drug to Treat Condition That Causes Elevated Ammonia Levels

The U.S. Food and Drug Administration approved Carbaglu (carglumic acid) Tablets to treat a condition that results in too much ammonia in the blood. The condition, N-acetylglutamate synthase or NAGS deficiency, is an extremely rare, genetic disorder that can be present in babies soon after birth. NAGS deficiency and the resulting elevated levels of ammonia (hyperammonemia) can be fatal if it is not detected and treated rapidly. DNA testing can confirm the diagnosis of NAGS. The Side effects experienced by those using Carbaglu included vomiting, abdominal pain, fever, tonsillitis, anemia, ear infection, diarrhea, inflammation of the nose and throat, and headache. As with all FDA-approved products, the agency will continue to monitor Carbaglu as it is used to treat hyperammonemia.

#### FDA Approves First Totally Implanted Hearing System

The U.S. Food and Drug Administration approved an implanted hearing system used to treat moderate to severe sensorineural hearing loss, a type of permanent hearing loss. Sensorineural hearing loss is usually caused by genetic factors or damage to the inner ear resulting from noise, viral infections, or aging. The results are reductions in perception of sounds and in the ability to understand speech. This differs from conductive hearing loss, which occurs when sound waves cannot transmit well through the outer or middle ear or both. Medical or surgical treatment can often restore hearing in people with a conductive hearing loss, which can be caused by earwax, fluid in the middle ear space, or a punctured eardrum

### NATIONAL

#### India: NPPA eases norms for imported drugs

The National Pharmaceutical Pricing Authority (NPPA) has eased norms for pricing of imported drugs, allowing companies to seek approval once in six months. Earlier, pharmaceutical companies had to submit report to the NPPA on every imported consignment of drugs and seek approval for pricing them in the domestic market. With a single approval for six months, firms can import any number of consignments and sell it to the country without seeking fresh approvals. Through these changes, procedural delays associated with pricing of imported medicines in the country have been reduced. The eased norm is applicable to bulk drugs and other intermediate chemicals. Some of the most commonly imported drugs in India are for treatment of cancer, diabetes, respiratory and kidney related ailments, mainly by multinational drug firms.

#### India: Prices of antibiotics may flare up 50%

A Government proposal to slap anti-dumping duties on Chinese and Mexican imports of two key pharma ingredients will push up the prices of common antibiotics like Mox, Augmentin and Sporicid by almost 50%. The plan for an anti-dumping duty of over US\$16-18 per kg on 6-APA imported from Chinese and Mexican companies. For Pen G, the proposed levy is over US\$3.3-3.8 per Billion of Unit (BOU). Currently, local drugmakers buy 6-APA and Pen G at US \$25 per kg and at US\$7.5 per BOU. The government plan to implement the levies is to protect the businesses of local drugmakers who make the same ingredients.

## Upcoming Events

<b>1</b>	<b>Event</b>	<b>Medicall-Hyderabad</b>
	<b>Date</b>	Feb 19-21, 2010
	<b>Venue</b>	TBA, Hyderabad, India
	<b>Highlights</b>	Medicall-Hyderabad is one of the prestigious events in India for medical & pharmaceutical industry. The exhibition attracts many visitors from different parts of the world. The fair is considered as the hospital needs supermarket where producers, dealers, buyers, suppliers etc. capitalise emerging opportunities of the pharma world.
	<b>Contact Details</b>	Medexpert Isha Homes, Np 74 1st Avenue, Indranagar, Adyar, Chennai, India. Tel:+(91)-(44)-32516661
<b>2</b>	<b>Event</b>	<b>World Generic Medicines Congress Europe</b>
	<b>Date</b>	Feb 23-26, 2010
	<b>Venue</b>	TBA, London, United Kingdom
	<b>Highlights</b>	World Generic Medicines Congress Europe is World's leading generic medicines strategy conference & expo. World Generic Medicines Congress Europe Speaker panel included representation. It is World's most compelling and influential scientific and strategic leaders, facilitating education, debate and business. Machinery & Materials, Lab Equipment, Analytical Instruments will be targeting Venture Capitalists, Investment Banks, CSOs, Equipment Providers, Delivery technology manufacturers.
	<b>Contact Details</b>	Terrapinn Pte Limited 12, Prince Edward Road, 03-01 Podium A, Bestway, Singapore, Singapore. Tel:+(65)-(65)-62228550; Fax:+(65)-(65)-62263264
<b>3</b>	<b>Event</b>	<b>Meditec Clinika 2010</b>
	<b>Date</b>	Feb 26-28, 2010
	<b>Venue</b>	Chennai Trade Centre, Chennai, India
	<b>Highlights</b>	Meditec Clinika 2010 presents an opportunity in South Asia as the largest platform for the Medical Equipment and Technology industry. We envision Meditec Clinika to act as a catalyst to bring together a varied genre of medical professionals under one roof to interact, promote and transact business in this industry which will eventually lead to better healthcare for the common man in this densely populated region.
	<b>Contact Details</b>	Orbitz Exhibitions Private Limited 202, Navyug Industrial Estate, T J Road, Sewree, Mumbai, India. Tel:+(91)-(22)-24102801; Fax:+(91)-(22)-24102805
<b>4</b>	<b>Event</b>	<b>Body Mind Life Expo 2010</b>
	<b>Date</b>	Feb 27-28, 2010
	<b>Venue</b>	Minneapolis Convention Centre, Minneapolis, United States of America
	<b>Highlights</b>	The Body Mind Life Expo 2010 is the areas original, largest & most respected health and natural products expo. This trusted show features natural products, personal coaches, mainstream health care consultants, nutritional products, financial services, holistic health providers, fashion and beauty advice. The expo will be held on 07-08 March 2009 at Minneapolis Convention Centre.
	<b>Contact Details</b>	Mid-America Events & Expos, Inc. 350 W. Burnsville Parkway, Burnsville, United States of America. Tel:+(1)-(612)-7987256

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<b>5</b>	<b>Event</b>	<b>Medical Device</b>
	<b>Date</b>	Mar 04-05, 2010
	<b>Venue</b>	Puerto Rico Convention Centre, San Juan, United States of America
	<b>Highlights</b>	Medical Device is the island's most trusted source for education, innovation, and collaborative opportunities in the field of high-tech precision medical device manufacturing.
	<b>Event</b>	<b>Medical Device</b>
<b>6</b>	<b>Event</b>	<b>IndiaMART India International Pharma Show</b>
	<b>Date</b>	March 05-07, 2010
	<b>Venue</b>	Hyderabad International Trade Exposition Centre(HITEX), Hyderabad
	<b>Highlights</b>	This exposition attracts a 100% B2B audience. Pharma Show brings together the best of global and local technology and manufacturing, thus giving Indian manufacturers an opportunity to reach local customers and global buyers, while offering international players unlimited access to the south Indian market. IndiaMART India International Pharma Show-2010, Showcase the most Advanced technologies affecting the global manufacturing and cover the full spectrum of drug manufacturing products and services.
	<b>Contact Details</b>	Hyderabad International Trade Expositions Limited First Floor, Trade Fair Office Building, Hitex Exhibition Centre, Izzat Nagar, Hyderabad - 500 001. India. Tel: +(91)-(40)-23112121; Fax: +(91)-(40)-23112124
<b>7</b>	<b>Event</b>	<b>Dubai Pharmaceutical &amp; Technologies Exhibition</b>
	<b>Date</b>	Mar 15-17, 2010
	<b>Venue</b>	Dubai International Convention & Exhibition CentreDubai, UAE
	<b>Highlights</b>	It has entered into its 15th edition and is emerged out as a viable annual event for pharma industry of both domestic and international arena. It is a pivotal event which helps in finding out new business avenues in pharmaceutical industry of throughout the world. It is 3 days event which is attended by over 299 exhibitors from all over the globe.
	<b>Contact Details</b>	INDEX Conferences & Exhibitions Organisation Est. Dubai Health Care City, Block B Office 203, 2nd Floor, Dubai - 13636, United Arab Emirates. Tel: +(971)-(4)-3624717; Fax: +(971)-(4)-3624718
<b>8</b>	<b>Event</b>	<b>Tokyo Health Industry Show</b>
	<b>Date</b>	Mar 17-19, 2010
	<b>Venue</b>	Tokyo International Exhibition Centre (Tokyo Big Sight), Tokyo, Japan
	<b>Highlights</b>	Tokyo Health Industry Show (2010) is by far the largest and most important exhibition and conference serving this rapidly growing market and attracts a huge audience of buyers and health industry professionals.
	<b>Contact Details</b>	CMP Japan Company Limited. Kanda 91 Building, 1-8-3, Kaji-Cho, Chiyoda-Ku, Tokyo, Japan. Tel:+(81)-(3)-52961020; Fax:+(81)-(3)-52961010

<b>9</b>	<b>Event</b>	<b>World Pharma Trials Asia Expo</b>
	<b>Date</b>	Mar 16-19, 2010
	<b>Venue</b>	Raffles City Convention Centre, Singapore, Singapore
	<b>Highlights</b>	It is the exhibition for drug development offshoring and outsourcing opportunity for pharmas and biotech industry. The event will be taking place between 16 and 19 March 2010 at the Raffles City Convention Centre. For four days the expo is being organised by Terrapinn Pte Limited.
	<b>Event</b>	<b>World Pharma Trials Asia Expo</b>
<b>10</b>	<b>Event</b>	<b>Belarus Medica</b>
	<b>Date</b>	Mar 23-26, 2010
	<b>Venue</b>	Roofed Soccer Arena, Minsk, Belarus
	<b>Highlights</b>	Belarus Medica 2010 is the largest medical exhibition in Belarus featuring all major branches of the medicine. The main objectives of the Exhibition are to demonstrate the latest achievements of the leading foreign and domestic manufacturers of medical preparations, cosmetics, optics, laboratory and diagnostic equipment, dental hardware, disposable materials and products.
	<b>Contact Details</b>	Technics And Communications, P. O. Box 34, Horki, Belarus. Tel:+(375)-(17)-3060606