



Inside the Issue

- In Focus: "CRAMS opportunity in India".
- News Brief
- Product Focus - Glucose Monitoring Device
- Stock Scan
- Regulatory Issues
- Upcoming Events



In Focus: "CRAMS Opportunity in India"

Introduction:

The pharma industry is flourishing and that one of the most significant contributors in this giant industry is Contract Research and Manufacturing Services (CRAMS). India's pharmaceutical industry is well positioned for sustainable growth and expansion. Over the last couple of years, the pharmaceuticals industry has grown at approximately 1.5-1.6 times the growth of economy.

Market

With a number of block buster drugs getting off patent in the coming years and increasing R&D costs the major pharmaceutical companies' world wide are finding it difficult to maintain their bottom lines. They have taken recourse to outsourcing part of their research and manufacturing activities to lower cost countries there by saving costs and time, this has led to evolution of Contract Research and Manufacturing Services. Indian pharma industry, particularly small and medium size drug units, is increasingly looking at contract manufacturing as one of the best survival options in the product patent regime. Several MNCs are also exploring the possibility of outsourcing drugs at various stages of production, including the finished dosages. The CRAMS can be split in to three major business segments:

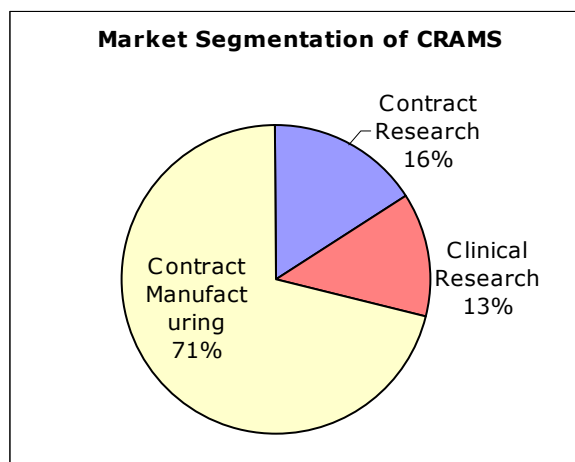
1. Contract Research
2. Contract manufacturing
3. Clinical Research

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Global:

The global pharmaceutical outsourcing market was worth USD52 billion in 2006. It is expected to reach USD76 billion by 2010 at a CAGR of 10% for 2006-10 period. In 2006, Contract Manufacturing activity accounted to the major share approx 67.3% of the total global outsourcing market. The global Contract Manufacturing Outsourcing (CMO) market in 2006 was USD35 billion and it is expected to reach USD48 billion by 2010 at a CAGR of 8.2% during 2006-10.



Source: Frost and Sullivan; Cygnus Research

India

The Indian outsourcing market is valued at USD929 million in 2006. It is expected to reach USD3.33 billion by 2010. Industry estimates put that the clinical trials market in India will be USD200 million by 2007 and USD1 billion by 2010. Consequently, India's contribution to the global pharmaceutical outsourcing market is expected to increase from 1.8% in 2006 to 4.4% in 2010. The Indian CMO market stood at USD620 million in 2006 and is expected to reach USD2.5 billion by 2010 with a CAGR of 41.7%.

Global Players

The major players include GSK, Pfizer, Astra Zeneca, Novartis and Amgen

Major Indian Players:

Biocon, Bharat Biotech, Biological E, Serum Institute, Nicholas Piramal, Shasun Chemicals, Suven Life Sciences, Strides Arcolabs, Jubilant Organosys, Orchid Pharmaceuticals, Ranbaxy, Cipla, Matrix, Wockhardt and Shantha Biotechnics are few major players.

Recent Collaborations in CRAMS Sector in India

- Wockhardt has a contract-manufacturing relationship with Amylin and many other leading pharmaceutical companies, such as Aventis and AstraZeneca.
- Jubilant Organosys has signed a multi-million dollar long-term agreement with Syngenta for the supply of pyridines.
- Pune based Serum Institute entered into a Development and Manufacturing Agreement (DMA) with the Lipoxen PLC, a UK-based biopharmaceutical company for the complete process of fermentation, purification and manufacture of polysialic acid.

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Advantages offered by India in CRAMS and Clinical trials domain

1. Cost saving

Today, the cost of hiring a medicinal chemist in the US is very high, approximately USD250,000-300,000 per year. The US pharma industry employs roughly 50,000 chemists. According to industry sources, Indian discovery research outfits charge global pharma companies around USD60,000 per chemist which is roughly one-fifth of what the pharma companies pay abroad. Beside, the Indian company is also reimbursed the costs of all consumables. So, it is a win-win situation the overseas pharma saves about 50% cost and the Indian company makes it about 50% margin.

2. Improved skills to face international competition

The future in this space belongs to the one who will not only grab the opportunity with both hands, but also play the game well. Like the IT and the software wave, and the earlier generic pharma wave, Indian discovery services companies have the opportunity to make it to the global scheme of things. Time will tell which of the niche players will consolidate to become fully integrated discovery companies and which of the Indian companies, if any, will become global players. Indian scientists are exposed to the outsourcing environments, improved confidence to face international challenges. This directly attracts international players to the Indian market.

3. Already existing strong manufacturing base

India's manufacturing clout has become a massive threat to the Western generic firms. The freedom to manufacture generic versions of patent protected drugs using non-infringing processes has also given them a head start in developing new methods of production and getting them to the market very rapidly.

4. Strong marketing and distribution network

Many of the Indian mid sized pharmaceutical companies have extensive marketing and distribution network facilitating the business of contract research and manufacturing services.

5. Rich biodiversity

The huge patient population offers vast genetic diversity, making the country an ideal site for clinical trials. Low clinical trial costs and easy availability of patients for clinical trials will encourage the global pharma players to conduct clinical trials in India.

Outlook

The 'India Advantage' makes it a preferred destination for outsourced services, the industry will see participants offering a gamut of services for sponsors to choose from and partnerships between service providers will exist in an effort to offer sponsors one-stop solutions. Making APIs and oral solid formulations will continue to be the major source of revenue for India's contract manufacturing industry in coming years. India with its inherent competitive advantages, stands as one of the most preferred outsourcing destinations for a range of activities and is now becoming a critical part of manufacturing and drug development value chain of various global innovator pharma companies.



News Briefs

INTERNATIONAL

AMERICAS

Alpharma Inc, a global specialty pharmaceutical company, announced that a New Drug Application (NDA) has been submitted for EMBEDA(TM), a pharmacological abuse-deterrent, extended-release morphine product candidate. Corporate peoples believe that EMBEDA(TM), if approved by the FDA, would be the first opioid medicine to incorporate an abuse-deterrent feature while effectively treating patients with chronic pain. In clinical trials when EMBEDA(TM) was taken as directed, it provided pain relief and the naltrexone remained sequestered in the pellet core while passing through the gastrointestinal tract without significant absorption.

USA: Sagent Pharmaceuticals Launches Cefazolin for Injection, USP

Sagent Pharmaceuticals, Inc. has launched Cefazolin for injection, USP, an essential antibiotic used to treat serious infections. Sagent's Cefazolin for injection will be available in 1g single dose vials and 10g pharmacy bulk package vials. The launch of Cefazolin for injection introduces for the first full-line of latex-free, multi-source prefilled, ready-to-use, 6mg and 12mg and adenosine syringes in the market. According to CEO of the company, the first product to emerge from extensive anti-infective pipeline, marks further progress toward Sagent's ultimate goal of becoming a leader in the injectables marketplace.

USA: NanoBio's cold sores drug meets study endpoints

NanoBio's uniquely formulated lotion has reportedly resulted in faster healing of herpes labialis - cold sores, at a rate faster than any topical product. Moreover, NB-001 demonstrated an excellent safety profile, with no serious adverse events. Researchers have confirmed through this trial, that the NB-001 achieves the efficacy of leading systemic treatments without presenting safety, drug interaction or toxicity risks.

USA: 18 states sue drug companies for blocking generic competition

18 states including Maine have sued Abbott Laboratories in federal court, alleging the drug maker blocked generic competition for a popular cholesterol medication. The antitrust lawsuit against Abbott and French Drug Company Fournier Industrie et Sante and Laboratories Fournier, S.A. charges the companies sought to block competition for a cheaper, generic version of the prescription drug, TriCor. Complaint also alleges about Abbott and Fournier obtained patents protecting TriCor from competition by deceiving the U.S. Patent Office with incomplete and misleading data.

USA: Oncothyreon obtains patent for small molecule compound

Oncothyreon has stated that the US patent and trademark office has issued a patent for PX-867, a small molecule compound currently in preclinical development. The newly issued patent includes claims covering both composition of matter of PX-867 and pharmaceutical preparations containing PX-867. According to CEO of Oncothyreon, the company plans to seek a partner to develop PX-867 in non-oncology indications, particularly in cardiovascular applications, while focusing on internal development efforts of PX-866 in oncology.

USA: Biothera's drug enhances Avastin's efficacy

Biothera has reported the preclinical trials increase the effectiveness of Avastin, a monoclonal antibody approved for the treatment of metastatic colorectal, breast and non-small cell lung cancer. Researchers at the University of Louisville studied the synergistic effects of Imprime PGG in

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combination with Avastin in a xenograft mouse model, human ovarian cancer cells were implanted into the mice. These results are consistent with previous research with Imprime PGG and various monoclonal antibodies in numerous cancer indications.

USA: FluoroPharma initiates Phase I trial of myocardial imaging tracer

Fluoropharma has started Phase I clinical trials of BEPET, a PET blood flow imaging agent, for use in classic 'rest-stress' cardiac testing. The Phase I trial is a study designed to evaluate safety, distribution and dosimetry of BFPEP as a PET tracer for myocardial perfusion imaging in healthy subjects, according to the study led by researchers of Massachusetts General Hospital. The FluoroPharma president stated that BFPEP's progress follows on the tail of CardioPET, an agent for the detection of metabolic integrity of the heart, recently completed a Phase I safety evaluation in normal healthy volunteers and cardiac patients.

USA: Vaccination could treat hypertension

Immunisation against angiotensin II could provide an alternative treatment for hypertension. Angiotensin is a hormone secreted by the body to cause vasoconstriction, which increases blood pressure. By actively immunizing against angiotensin II, researchers hope to lower patient's blood pressure while providing a treatment patients are more likely to adhere. By combining these factors, this sort of a treatment could eventually replace traditional medications in the treatment of hypertension. The results of this new biotherapy for hypertension are intriguing and promising, and vaccination for hypertension may turn out to be very useful in many patients.

USA: New method boosts cardiac arrest survival

Researchers of American Medical Association analysed the cardiac arrest outside of the hospital can quickly turn deadly, but a new method of restarting stalled hearts might boost people's chances of survival. Current guidelines call for people with cardiac arrest to receive an electric shock and periodic chest compressions to get their heart beating again. MIRC's (minimally interrupted cardiac resuscitation) innovation is that it emphasizes near-constant chest compression. This technique minimizes all the interruption of chest compression, and maximizes the time when chest compressions are being given, patients get pre-shock and post-shock chest depression, and also the drug called epinephrine.

Europe

Germany: Hikal to Supply Bulk Drugs to Bayer CropScience

Chemicals and Pharmaceuticals maker Hikal Ltd signed a long-term deal with Bayer CropScience, a unit of Germany's Bayer, for supplying bulk drugs to make crop protection products. The financial details were not disclosed. Hikal will start supplying from the second half of 2008, the company reported. Also, Hikal signed a deal with the U.S.-based Pfizer Inc for supply of bulk drugs. It also supplies bulk drugs for a veterinary product to another U.S. drug maker Alpharma.

Italy: New aspirin-like substances safer for fighting heart disease

Researchers at Italy have developed a new group of aspirin with safe conventional to fighting heart disease. It has long been known that daily low-doses of aspirin reduce the risk of developing heart attacks and stroke in some people. However, prolonged use of the anti-inflammatory drug can also have side effects. It can damage the stomach lining, causing bleeding and ulcers that can be life-threatening. Researchers have developed a new form of aspirin by attaching a special chemical structure called a nitrooxy-acyl group that allows the drug to resist breakdown by stomach acidity while promoting its absorption by the blood.

England: 98% of child drug trials lack independent safety checks

Study finds 98% of child drug trials lack independent safety checks. The research highlights the adverse effects of tests and lack of monitoring committees. A study stated that, only a tiny minority of drug trials on children have an independent safety monitoring committee to pick up potentially dangerous side-effects. Researchers of Nottingham University stated that fewer than 2% of the 739 international drug trials published between 1996 and 2002 had such committees of independent experts to scrutinise data and warn, which is unsafe to progress.

UK: GlaxoSmithKline to pay Pharmacopeia USD5m

Pharmacopeia Inc will receive USD5m from GlaxoSmithKline PLC from the companies' ongoing collaboration to develop drugs. GlaxoSmithKline stated that the two companies together have made significant progress with their discoveries and advancement of molecular therapy. Pharmacopeia is developing small-molecule treatments for high blood pressure, diabetic nephropathy, muscle wasting, inflammation and respiratory disease.

UK: Uncertainty over drug pricing casts fear on pharma investments

The Department of Health has announced that it would be re-negotiating the pharmaceutical price regulation scheme (PPRS), even though the current five-year agreement had only been in place for two-and-a-half years and included a 7% across-the-board price cut. The unscheduled renegotiation of PPRS deal has shocked the pharmacy industry as it expected the deal to last to the end of 2009. Industry leaders warned the government that the uncertainty in the UK drug pricing is taking a toll on the investment prospects of the pharmaceutical industry.

Sweden: Magnesium may lower risk for some strokes in male smokers

Researchers at the Karolinska Institute analysed the diets and other health/lifestyle habits and characteristics of male smokers who never had a stroke. They stated the age and cardiovascular risk factors and concluded that men who consumed the most magnesium (589 milligrams per day) had a 15% lower risk for cerebral infarction. The association was stronger in men younger than 60. Recent studies have suggested that high blood pressure is a risk factor for stroke, and changes in diet may lower blood pressure, and it may reduce stroke risk.

Middle East**Israel: Samaritan acquires rights to Abiogen's cancer drug**

Samaritan Pharmaceuticals has acquired the rights from Abiogen Pharma of Italy to distribute and sell the specialty pharmaceutical, Abioklad in Greece, Cyprus, and Turkey. Abioklad is used for the treatment of cancer malignancy-associated hypercalcemia, the inhibition of osteolysis, and the decrease of bone pain associated with cancer. Samaritan Pharmaceuticals CEO stated that commercialising branded approved prescription products in Greece and Eastern Europe is a priority within Samaritan's strategy to generate revenue to cover the rate and become cash-flow positive.

Asia Pacific**Japan: Bachem Production Facilities Licensed for the Manufacture of APIs**

Bachem announced the Japanese Ministry of Health that Labour and Welfare (MHLW) has granted the company a manufacturing license in conformity with the new regulations. The license is granted for the manufacture of active pharmaceutical ingredients (APIs) for the Japanese market at Bachem's production facilities both in Bubendorf, Switzerland and in Torrance, California, USA. Bachem is further reinforcing its already well-established position in the Japanese market, and will be able to supply pharmaceutical and biotech companies in Japan with the necessary quantities of APIs ranging from small quantities for development projects to bulk deliveries for successfully marketed products.

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China-made heparin scare spreads beyond US

The made-in-China heparin scare has now spread beyond the US, with Germany and Japan both recalling the drug. Although the product in question was manufactured locally in Germany, the drug's active pharmaceutical ingredient (API) has been associated with two Chinese suppliers.

After the drug reported severe allergic reactions by the patients, the country's drug regulators have since asked all the German heparin producers to check if their drug's API is sourced from China. The action has been prompted by a heparin health scare that has been going on in the US for the past couple of weeks involving a product sold by Baxter, where the API was sourced in China.

Japan: Fighting bacteria produce new antibiotic

Researchers have provoked a soil dwelling bacteria into producing a potent antibiotic by pitting it against another bacteria. By comparing the bacteria's DNA with the genome of other bacteria, the researchers noticed, that the Rhodococcus shared many genes that are known to contribute to the production of antibiotic chemicals, dubbed rhodostreptomycin. The mystery lies in the fact that the Rhodococcus genome did not appear to contain the right genes to produce the rhodostreptomycin antibiotic. Rhodostreptomycin is an amino glyceride antibiotic, but the Rhodococcus genome appeared better suited to producing two other classes of antibiotics - PKS and NRPS.

China: Vietnam military to test bird flu vaccine on humans

Vietnam Military Medical Officer stated that one of the countries hardest-hit by bird flu will start a human vaccine trial. The academy had been licensed by the Ministry of Health to conduct the trial but it still required permission from the Ministry of Defence. The World Health Organisation has recorded 51 deaths in Vietnam since late 2003 out of 235 people killed among 372 known cases globally. The vaccine and biological production company called Vabiotech indicated the vaccine which is used for poultry would be 1.5 microgram per dose, or one tenth the dose for humans.

Australia: Phosphagenics granted approval to initiate Phase II diabetes trial

Phosphagenics has received ethics approval to commence treating patients with type 1 diabetes in a Phase II clinical trial using its patented transdermal insulin delivery system, TPM/Insulin. The trial is a randomised, single-blinded trial aims to assess the efficacy of TPM/Insulin. The results of this trial will be used to assist in obtaining an IND from the FDA. This will enable Phosphagenics to commence the next phase of its clinical development program for TPM/Insulin at the Joslin Diabetes Centre. Researchers of Phosphagenics indicated that clinical trials conducted and demonstrated the TPM/Insulin formulation can safely penetrate through human skin and deliver insulin into the blood stream over a sustained period of time without any adverse events.

Africa

High heart disease rates expected for Africa

Researchers estimated that within the next 20 years, about 1.3m people per year will be affected by heart disease in Africa. It is vitally important that the full African-specific forms of heart diseases are fully researched with the intention of developing effective treatments and healthcare programmes. The major findings from comprehensive study of heart disease in Africa indicated that most patients had multiple risk factors commonly associated with affluent heart disease. The findings suggested that the phenomenon is due to combinations of lack of awareness of this condition, paucity and quality of primary care facilities.

Uganda: Weak health systems affect child birth

Health systems deficient in basic facilities is to blame for the country's problem of maternal mortality. Statistics from the Uganda Demographic and Health Survey conducted by the Ministry of

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Health indicate there are 435 deaths per every 100,000 live births among Ugandan women. Health department officer at Uganda stated that high fertility and population growth rate, poor maternal and infant child indices are some of the challenges of reproductive health

National

NIPER Hyderabad set to enter academic collaboration with industry

The National Institute of Pharmaceutical Education and Research (NIPER), Hyderabad, is looking to enter academic collaborations with leading pharmaceutical companies in the state. The Institute is in discussions with the pharmaceutical companies and all of them have agreed to collaborate with the Institute in principle. As per planned collaboration, the students will be able to access the companies for their project work. The centre, which has been created as a centre of excellence for higher education, research and development in pharmaceutical sciences, offers post graduate degrees in Medicinal Chemistry, Pharmacology & Toxicology and Pharmaceutical Analysis. As per the institute, the number of programmes would be increased and PhD programmes would also be commenced in the future.

ISPE partners with US university to provide biotechnology training

The International Society for Pharmaceutical Engineering (ISPE), a global not-for-profit association of 25,000 pharmaceutical science and manufacturing professionals, is partnering with a major American university for the first time to provide comprehensive, hands-on biotechnology training from 12-14 May 2008 at North Carolina State University's Golden LEAF Biomanufacturing Training and Education Centre (BTEC) in Raleigh, North Carolina, USA. The training programme would offer four three-day courses that include lectures, problem-solving workshops, and hands-on activities at BTEC's state-of-the-art cGMP pilot plant facility. Developed for professionals in the pharmaceutical manufacturing and biotechnology industries to help increase knowledge in their respective fields, the training will focus on current issues, including process validation for biotechnology manufacturing, biopharmaceutical manufacturing facilities, disposables in biomanufacturing,

Nycomed Transfer Bulk Drugs to Cadila JV

Cadila Healthcare Ltd reported the joint venture partner 'Nycomed' of its plans to transfer bulk drug manufacturing from its Austrian and German units to their venture Zydus Nycomed Healthcare Pvt Ltd. This would result in equal joint venture manufacturing 18 active pharmaceutical ingredients (API) or bulk drugs for four years. The joint venture currently manufactures raw materials for the drug to treat heart burn, pantoprazole, and supplies it exclusively to Nycomed. Pantoprazole supplies contributed an estimated 20% to Cadila's net profit in 2006/07. Zydus Nycomed will have to invest INR500m to put up an additional unit and expand the existing unit to handle the additional products. These products are expected to start contributing to revenue by 2010-end.

Duty Cut on Six Life-Saving, Bulk Drugs

The Finance Minister, Mr P. Chidambaram, announced a slew of initiatives for the pharmaceutical and healthcare sectors. Customs duty on six specified drugs and bulk drugs used in treating cancer, diabetes, asthma and hepatitis B has been halved from 10% to 5% in order. Customs duty on specified raw materials for manufacture of ELISA kits has been reduced from 10% and 7.5% to 5%. Enzyme-Linked Immuno Sorbent Assay, or ELISA, is a biochemical technique used mainly in immunology to detect the presence of an antibody or an antigen in a sample. The Finance Minister has removed the excise duty on anti-AIDS drug Atazanavir and bulk drugs in order to enable local manufacturing.

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Alembic Buys Bulk Drug Unit for INR175m

Alembic Ltd has acquired the bulk drug manufacturing unit of Nirayu Pvt Ltd for INR175m. The acquired unit is expected to add about INR200m in revenue for 2008/09. The objective is not to increase the topline immediately but to enable more filings that will add to the topline in 2-3 years. The unit, which has the U.S. Food and Drug Administration's approval to export bulk drugs to the United States, will start contributing INR200-250m per year from 2008/09. Alembic already has two bulk drug making plants in Gujarat, one that is FDA-approved in Panelav and the other in Vadodara catering to the domestic market.

NPPA to Rein in Bulk Drug Prices

The drug price regulator National Pharmaceutical Pricing Authority (NPPA) plans to turn its attention to bulk drug prices. Bulk drugs account typically for over 70% of the cost of a formulation. NPPA will begin analysing pricing trends of 74 bulk drugs that come under the government-notified price-controlled list every quarter. The authority's comparison will be based on major parameters including the notified or approved prices of these bulk drugs, the landed cost of the imported bulk drugs and the prices quoted in the trade journals. NPPA's price intervention, based on the market surveillance, is known to have been very effective between 2005 and 2007. According to an official analysis, instances of drug companies raising prices of price-controlled medicines have come down considerably during this period.

Vitabiotics to launch three OTC brands

UK's well known vitamins and health supplements company Vitabiotica will launch three of its top over-the counter brands Wellman, Wellwoman and Perfectil in India. The company brands are from UK market leaders, as lifestyle products for young and health conscious Indians.

Pfizer plans to develop India-specific drugs

The world's largest spender on research to create new drugs, Pfizer Inc, plans to develop a range of India-specific drugs and also conduct trials for its new kidney cancer drug Sutent, to explore its usage for the treatment of other forms of cancer. Sutent was launched in India; a small study in the US reported a disproportionately high number of heart failures among its users.

Sun Pharma granted FDA approval to market generic Demadex tablets

Sun Pharmaceuticals has reported that the FDA has granted final approval for the new drug application to its generic version of Hoffman la Roche's Demadex, torsemide tablets. These generic torsemide tablets are therapeutic equivalents of Roche's Demadex tablets. Torsemide is a diuretic, indicated for the treatment of edema associated with congestive heart failure, renal disease, or hepatic disease. Torsemide is also indicated for the treatment of hypertension alone or in combination with other antihypertensive agents.

NRDL initiates Phase I trial of metabolic drug

NPIL Research & Development, recently demerged from Nicholas Piramal India, has commenced Phase I studies on new molecule for metabolic disorders in Netherlands. The company had submitted the clinical trial application to the Central Committee on Research Involving Human Subjects (CCMO), the regulatory authority of the Netherlands, and the Independent Ethics Committee of the foundation Evaluation of Ethics in Biomedical Research (BEBO). Both these bodies have approved the application to initiate the Phase I study of P1201-07. Director of NPIL claimed this is fourth new drug to enter the clinic and the first from research collaboration with Eli Lilly.

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Nicholas joins hands with DBT in drug discovery

NPIL Research & Development Ltd (NRDL) has signed an agreement with the Department of Biotechnology (DBT), New Delhi, on screening for bio-molecules from microbial diversity collected from different ecological niches, thereby initiating in drug discovery. This is the first project in the country in which industry and academia will work together to screen such a large number of bacterial isolates. The purpose of this study is to exploit the biodiversity of microbes. This will help in identifying specific therapeutic properties that may be further used to identify novel molecules and passed on to the drug development phase.

India and the US join hands for healthcare safety

India and the US have agreed to set up committee that will work together in establishing a regulatory body to check the quality and safety of food, drugs and other medical products. This was jointly announced by the Indian Union Minister of Health and the US Secretary of Health in a press conference of Indo-US Life Sciences. They would propose a network to evolve a compatible regulatory system, which enables all to access drugs and medical products. The two countries are providing the bridge for categorisation of medicines. This hope of cooperation will also help manufacturing units to achieve global standards.

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Product Focus – Glucose Monitoring Device

Introduction

A glucose metre (or glucometre) is a medical device for determining the approximate concentration of glucose in the blood. It is a key element of home blood glucose monitoring (HBGM) by people with diabetes mellitus or with proneness to hypoglycemia. A small drop of blood obtained by pricking the skin with a lancet is placed on a disposable test strip, which the metre reads and uses to calculate the blood glucose level. A number of blood glucose metres, or monitors, have been developed to help people test their blood glucose, using a drop of blood. Computer capability features and data management are available in glucose monitor devices, contain enough memory for several hundred test results. Most new models contain a data port that allows the metre to be hooked to a computer so that stored readings can be graphed and analysed at home.



Glucose Monitor

Glucose monitors

Brand Name	Company Name	Description	Range (mg/dl)
Accu-Chek Voicemate	Roche Diagnostics	Incorporates voice guide for visually impaired	10-600
Assure	MEDgenesis	Extensive data management; 180-test memory; large touch-screen display	30-550
AtLast	Amira Medical	All-in-one metre and sampling system, eliminates fingersticks, uses samples from less sensitive sites	40-400
ExacTech R-S-G	Abbott, MediSense	Easy to use, 3-step testing; economical test strips	40-450
Glucometre Encore	Bayer Diagnostics	Automatically shuts off after 3 min; 10-test memory; kit includes case, control solution, test strips and lancets	10-600
One Touch Ultra	LifeScan, J&J	Uses tiny sample (1 microliter) from forearm; 150-test memory; data management, downloading features	20-600
Prestige LX	Home Diagnostics	Easy, 3-step test; large display; 365-test memory	25-600

Blood Glucose Monitor

A continuous blood glucose monitor determines blood glucose levels on a continuous basis. A typical system consists of a disposable glucose sensor placed just under the skin, which is worn for a few days until replacement, a link from the sensor to a non-implanted transmitter which communicates to a radio receiver, and an electronic receiver worn like a pager (or insulin pump) that displays blood glucose levels on a practically continuous manner, as well as monitors rising and falling trends in glycemic excursions. Some current and future continuous glucose monitoring products include:

- The Freestyle Navigator
- Real Time Continuous Glucose Monitor
- The Guardian
- Dexcom S7S
- GlucoDay S
- GlucoWatch

Accuracy

Accuracy of glucose metres is a common clinical concern; the error grid is a common way of analysing and displaying accuracy of readings related to management consequences.

Indian Diabetic Scenario

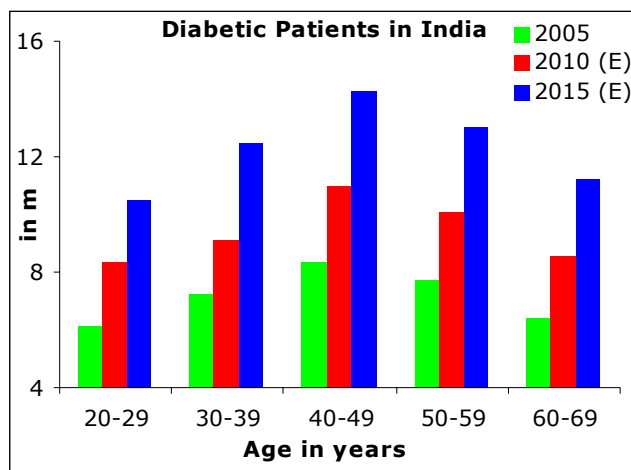
There are more than 150m diabetic patients worldwide, with approximately 90% suffering from type 2 diabetes. Of the estimated 30m diabetic patients are in India with 95% suffering from type 2 diabetes. Accordingly age wise, at the age of 40-49 the diabetic patient's prevalence was more in India, about 8.3m in 2005. The total diabetic population in India uses glucose monitoring devices to check their blood glucose. Moreover, there is a need for proper control of blood sugar.

Outlook

Due to constant change of lifestyle, work pressure, irregular food intake, and lack of physical exercise force many people to fall into the diabetes trap. Diabetic patients in India are estimated to be more than 10m at the age of 40-49 by 2010; and more than 14m at the age of 40-49 by 2015. Consequently, diabetic patients need to check their blood glucose regularly, hence glucose monitoring device is going to lead in sales in coming years.

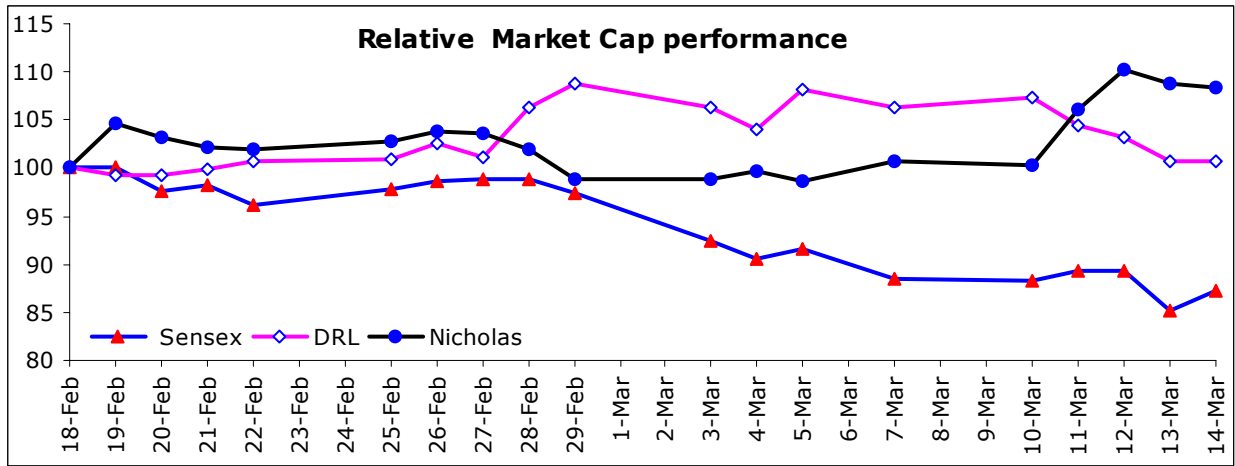
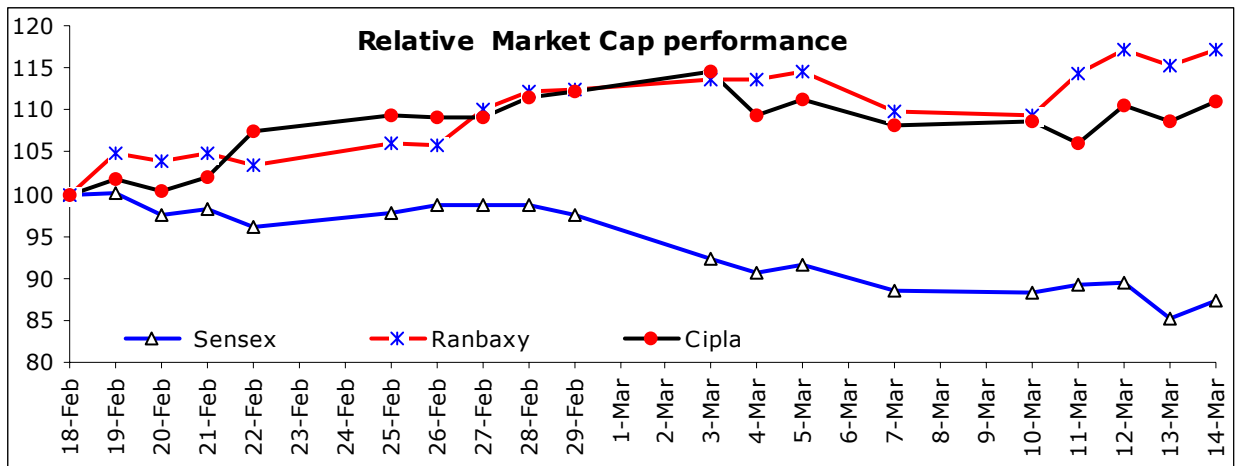
Major Players	
➤	Abbott Diagnostics
➤	Bayer Diagnostics
➤	Cardinal Health Inc
➤	Roche Diagnostics
➤	LifeScan, J&J
➤	Home Diagnostics

Accuracy factors	
➤	Calibration of metre
➤	Ambient temperature
➤	Pressure use to wipe off strip
➤	Size of blood sample
➤	High levels of certain drugs in blood
➤	Hematocrit
➤	Dirt on metre
➤	Humidity
➤	Aging of test strips



Source: Indiastat; Cygnus Research

Stock Scan



Source: BSE; Cygnus Research

	17 Feb - 23 Feb	24 Feb - 01 Mar	02 Mar - 08 Mar	09 Mar - 15 mar
BSE Sensex	Uncertainty in global markets and rising crude oil prices were responsible for the negative sentiment in the markets. During this period Sensex lost 766.18 points that is 4.2%.	The Sensex posted gains for 3 out of 5 days. The Sensex rose 155.62 points on 26th February 2008 after Railway Minister provided thrust on modernising rail infrastructure in the Railway Budget 2008-09. The Sensex gained 229.65 points that is 1.3%, closed at 17578.72 points.	The US recession and the global market meltdown made the Sensex lose 1,603.20 points that is 9.1%, and closed at 15975.52 points.	The deepening of the US recession concerns dampened the investor sentiments and made Sensex lose 215 points that is 1.34%, closed at 15760.52 points.

Ranbaxy	The share price increased by 3.46%, as the company is creating an independent pathway for NDDR with enhanced forces for long term growth, leading to rise in confidence.	Increase in volumes of shares trading resulted in the jump in the stock price from INR420 to INR445.75, by 6.13%.	Lack of demand made share prices to fall by 3.46% during this period.	The index moved by 7.11% driven by positive sentiments of its investors.
Cipla	The share price increased by 7.47% as major players performed well during this period.	The share price increased by 2.60% as bullish sentiments prevailed in the market.	The share price dropped by 5.53% as it moved in tandem with the BSE sensex.	Increased trading volumes gave necessary thrust to the share prices by 2.22%.
DRL	Dr Reddy's allotment of 37,094 equity shares, under Employees Stock Option Scheme, led to rise confidence on the investors.	Increase in volumes of shares trading resulted in the jump in the stock price from INR540.65 to INR582.65 by 7.77%.	The stock price remained flat.	The share price declined by 6.24% as it moved in tandem with the BSE Sensex
Nicholas	The index moved up by 1.98%, driven by rising consumer confidence.	The share price declined by 3.86% even though the company's R&D arm started phase I trials on metabolic disorders compound from Eli Lilly & Co. This however did not go well with the investors sentiments.	Positive results from the company made its shares to move up by 1.99%.	The share price increased by 8.18%, as the company's planning to go for acquisition in the US and Europe for expanding the customer base and technology in its contract manufacturing business, showed rising confidence on the investors.

Regulatory Issues

FDA makes progress in plans for China presence

The US Food Drug Administration plans to establish its presence in China. China is a major supplier of foreign-made drug products entering the US. The country's 714 drug-producing establishments made up 22% of all foreign facilities eligible for FDA inspection in 2007. Of which the agency conducted only 13 inspections in China that year. The agency lacks the resources to inspect a meaningful proportion of all products when they arrive at the US port. The Memoranda of Agreement is signed with two FDA counterpart Chinese agencies, stated to fill permanent FDA positions in China towards ensuring access to safe food, drugs, and medical devices in the global market.

FDA Finds Hazardous Levels of Selenium in Samples of "Total Body Formula" and "Total Body Mega Formula"

The U.S. Food and Drug Administration announced today that it has found hazardous levels of selenium in samples of certain flavors of the dietary supplement products "Total Body Formula" and "Total Body Mega Formula." The FDA has received 43 reports of persons from nine states from Alabama, Florida, Georgia, Kentucky, Michigan, New Jersey, North Carolina, Tennessee, and Texas, who experienced serious adverse reactions using these products. Selenium, a naturally occurring mineral, is needed only in very small amounts for good health. Selenium can boost the immune system. Generally, normal consumption of food and water provides adequate selenium to support good health. Excessive intake of selenium is known to cause symptoms to include significant hair loss, muscle cramps, diarrhea, joint pain, fatigue, loss of finger nails and blistering skin.

India: Standards for accreditation of wellness centres to be ready in six months

The Quality Council of India (QCI), the autonomous body of the Central government for national accreditation programme, is all set to frame a set of new standards for 'wellness centres' in India. The Indian wellness market segment, relatively new and unorganised, is growing by double digit, which is expected to touch INR. 18 million in another two years time. The QCI is governed by a council of 31 members with equal representation from the government, industry and consumers. It is responsible for formulating strategies, general policy, constitution and monitoring of various components of QCI including the accreditation boards with objective to ensure transparent and credible accreditation system

Upcoming Events

1.	Event	World Vaccine Congress Washington 2008
	Date	Apr 21-24, 2008
	Venue	Hyatt Regency Crystal City, Arlington, Virginia, USA
	Highlights	World Vaccine Congress Washington is the biggest, fastest, up-to-date vaccine event in North America. This is an opportunity to meet the industry shapers, hear the leading case studies and latest developments and trends.
	Contact Details	Gina Geldenhuys Tel: 0044 (0) 207 827 5997; Fax: 0044 (0) 207 242 1508 Email: gina.geldenhuys@terrapinn.com; Web : www.terrapinn.com
2.	Event	Pharmacy/Pharmtech
	Date	Apr 23-26, 2008
	Venue	Uzexpocentre, Tashkent, Tashkent City, Uzbekistan
	Highlights	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. The exhibition will provide an excellent platform for service providers to showcase their products and services to decision makers from leading pharmaceutical manufacturers.
	Contact Details	The Organising Secretary, ITE Group Plc 105, Salusbury Road, London, United Kingdom. Tel: +(44)-(207)-5965000, Fax: +(44)-(207)-75965111 Website: www.ite-exhibitions.com
3.	Event	Comparability, Immunogenicity and Biosimilars
	Date	Apr 28-29, 2008
	Venue	Dubai International Exhibition Centre, Dubai
	Highlights	Application of analytical methods during comparability studies <ul style="list-style-type: none"> • Strategies for dealing with glycosylation of biopharmaceutical • Successful design and validation of screening and confirmatory assays • To what extent can immunogenicity be predicted? • Essential considerations of biosimilar drugs for a safe introduction
	Contact details	Kirianne Hanlon, Commercial Director, Sponsorship, Tel and Fax: +44 (0) 20 7017 7129, Web:www.iir-events.com; Email: simon.lau@informa.com
4.	Event	The 8th International Healthcare Exhibition and Conference
	Date	May 04-06, 2008
	Venue	Cairo International Conference Center, Nasr City, Cairo, Egypt.
	Highlights	The event is the gateway to medical business in Africa and the Middle East. A wide range of top-level distinct products and solutions are provided from medical equipment, hospital, laboratory, pharmaceuticals, dental to orthopaedic are displayed to satisfy the demand of Egypt, African countries and the Middle East.
	Contact Details	Organiser: SGI INC, , 4847 Hopyard Rd #4227, Pleasanton, California, USA Tel: 1800-274-3448; Fax: 510-770-0740 Email: ino@sgitrade.com; Web: www.sgitrade.com

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

16

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4th & 5th Floors, Astral Heights, Road No.1, Banjara Hills, Hyderabad-500034
Tel: +91-40-23430203-07, Fax: +91-40-23430201,
Email: info@cygnusindia.com; Website: www.cygnusindia.com

5	Event	Drug Discovery-Japan
	Date	May 07-09, 2008
	Venue	Tower Hall Funabori, Tokyo, Japan
	Highlights	The event will be focus on the following areas, International Partnering and Alliances, Emerging Impact of Asian Markets, Innovative R&D and Regulatory Strategies, Japan's Regulatory and R&D Landscape, Fundraising in Japan compared to US/Europe.
	Contact Details	The Organising Secretary, IBC USA Conferences Inc. One Research Drive, Suite 400 A, P. O. Box 5195, Westborough, United States of America., Tel: +(1)-(508)-6165550, Fax: +(1)-(508)-6165533 Email: custserv@ibcusa.com, Web site: www.ibclifesciences.com
6	Event	1st Intl. Conference on Healthcare Transformation: Primary Care Focus
	Date	May 9–11, 2008
	Venue	Suntec International Convention & Exhibition Centre, Singapore
	Highlights	<ul style="list-style-type: none"> To understand the perspectives of healthcare transformation is taking in developed countries and the increasingly important role of Primary Care. To understand the various models of primary care currently practises. To learn new quality strategies in primary healthcare
	Contact Details	6 Commonwealth Lane, #06-01, GMTI Building, Singapore 149547. Phone: +65 6496 6843 Fax: +65 6496 6853, Website: www.pca.sg.com
7	Event	Adaptive Designs for Clinical Development
	Date	May 12-15, 2008
	Venue	Melia White House, London
	Highlights	Adaptive clinical trial designs appear to offer a great deal in terms of cost and time saving and potential ethical advantages <ul style="list-style-type: none"> Adaptive designs in late stages Seamless phase II/III studies The regulatory perspective
	Contact Details	The Organising Secretary, Melia White House, London, United Kingdom Tel: +44 (0) 20 7017 7165, Email: simon.lau@informa.com
8	Event	Integrative Medicine for Health Care Organizations Conference
	Date	May 15-17, 2008
	Venue	Phoenix, Arizona, USA
	Highlights	This three-day program will offer strategic discussions and in-depth case studies, skill-building workshops, a visit to a successful integrative medicine centre, an interactive exhibit forum and poster board presentations, and ample time for networking.
	Contact Details	Organiser, Health Forum, North Franklin, Chicago Tel: 312-893-6897; Fax: 312-422-4600 Email: clang@healthfoum.com; Web: www.healthforum.com;

9	Event	KIHE / DRUGSTORE
	Date	May 14-17, 2008
	Venue	Atakent International Exhibition Centre, Almaty [City], Kazakhstan
	Highlights	KIHE is the premier medical event in Kazakhstan. It is an annual event organised by the GIMA International Exhibition Group. The Ministry of Healthcare of Kazakhstan supports this trade show.
	Contact Details	The Organising Secretary, ITE Group Plc, 105, Salusbury Road, London, United Kingdom., Tel: +(44)-(207)-5965000, Fax: +(44)-(207)-75965111 Website: www.ite-exhibitions.com
10	Event	Interphex China 2008
	Date	May 20 - 22, 2008
	Venue	Dalian World Expo Center, Xinghai Bay, Dalian, China
	Highlights	Overview of China National Pharmaceutical Market Trends in the World Pharmaceutical Ingredients Market Policy Advices on Centralized Drug Purchase by Tender Developing & Implementing 'Effluent Standards of Pollutants from Pharmaceutical Industries' Intellectual Property Protection of New Drug in China Focus on Drug Price Administration in China
	Contact Details	The Organising Secretary, Reed Exhibitions China Unit 4-5, Level 12, Office Tower E1, The Towers, Oriental Plaza, No.1, East Chang An Ave, Dong Cheng District, Beijing 100738, China Tel: +86 10 8518 9070, Fax: +86 10 8518 9060 Email: zhen.tan@reedsinopharm.com, Website: www.interphexchina.com
11	Event	Interphex India
	Date	May 29-31, 2008
	Venue	Bombay Exhibition Centre - NSE Exhibition Complex, Mumbai, India
	Highlights	Interphex India is internationally renowned for bringing together the pharmaceutical sectors' most innovative technologies, equipment, products and services, and the highest level of education and insights into international standards, practices and regulation.
	Contact Details	The Organising Secretary, Reed Exhibitions India, 11th Floor, Building No. 9-A, DLF Cyber City, Phase - III, Sector 25-A, Gurgaon, India. Tel: +(91)-(124)-4686300 Fax: +(91)-(124)-4686309 Email: india@reedexpo.co.uk, Website: www.reedexpo.in

12	Event	Biotech China 2008
	Date	May 28 - 30, 2008
	Venue	Intex Shanghai, 88 Loushanguan Rd, Shanghai 20036, China
	Highlights	The event is the only international exhibition in China that focuses on biomedicine, gene-technology and life science. It has become the well-known and highly professional expo in this particular field with widely acknowledged fame in both China and the whole Asia region. Serving as an international fair which facilitates technology discussion, trade negotiation and business cooperation, it has been a not-to-be-missed purchasing platform for manufacturers, suppliers and end-user.
	Contact details	The Organizing Secretary, SMIE - World Expo (Group) Shanghai Modern International Exhibition Co., Ltd., Ms. Maggie Lau Tel: (+86) 21 6238 8899, Fax: (+86) 21 6374 9188 E-mail: info@biotech-china.com, Website: www.biotech-china.com
13	Event	Organic Process Research & Development
	Date	June 23-26, 2008
	Venue	Montréal, Canada
	Highlights	Presenting important and detailed case studies Learn to design for efficiency and optimise your development objectives Discover the strategies are evolving to meet the challenges Current developments, future trends and meet and network with key people working in the chemical and pharmaceutical industries
	Contact Details	Contact: Kate Laird, Scientific Update LLP, Maycroft Place, Stone Cross, Mayfield, TN20 6EW, UK Tel. +44 (0)1435 873062; Fax: +44 (0)1435 872734 Website: http://www.scientificupdate.co.uk E-mail: sciup@scientificupdate.co.uk
14	Event	Cardiology Update in Primary Care Medicine:
	Date	Jun 23-27, 2008
	Venue	Hyatt Sarasota, Florida, USA
	Highlights	This presentation will teach both medical device therapies for such common patient complaints as CHF, HTN, Tachy and Brady arrhythmias. It will also teach the skills of ECG "first-read" and management options that are most needed in the settings of rural office and emergency rooms, as well as after-hours interpretation in any clinic or urgent care settings.
	Contact Details	Organiser, American Medical Seminars, Inc. P.O. Box 49947, Sarasota, Florida Tel: 1-941-388-1766; Fax: 1-941-365-7073 Email: mail@ams4cme.com; Web: www.ams4cme.com