India biotech policy out

www.biospectrumasia.com

BioSpectrum

the business of life sciences

Vol 3 | Issue 1 | January 15, 2008

ASIA EDITION

2008
Year of the Entrepreneur

Singapore's Enterprising 3

Technologies, trends & challenges

Forecast 2008

Taiwan
Ready for translational medicine age

Analysis
Eisai leaps to where action is

GVK Bio moves to collaborative business model: Mr Manni Kantipudi

Columns

Virtual R&D, Eli Lilly shows the way: **Mark Ravera**

Innovative regulator: **Dr Edison Liu**

Scientific community must not yield to the Luddites, this time: **Dr Shanthu Shantharam**

Interview

The objective is to identify and manage the risk: Dr Sue Meek Gene Technology Regulator, Australia

BioSpectrum is a CYBERMEDIA publication: MICA (P) 284/08/2007

Before delivery.

After delivery.

Wherever your destination, we will deliver your shipment in exactly the same condition it left.

As Cold Chain shipments face increased scrutiny from internal bodies and international agencies alike, strict adherence to temperature control is critical for compliance with international regulatory, manufacturing and safety standards.

With our proven track record in Cold Chain Management, World Courier is the only premium logistics provider that offers temperature-controlled transportation services 24 hours a day, 7 days a week, worldwide.

With our unique local insight, paired with our strong global network, we offer the expertise in handling temperature-controlled shipments to suit all our customers' needs.

World Courier is committed to provide every customer with the following:

- The assurance of strict temperature-maintenance throughout the transportation chain
- Distribution solutions that are customized to your needs and guarantee the highest standards of security and reliability
- On-time delivery of your shipment to the right place and the right person in the same condition it left

In addition to Cold Chain Management services, we conduct regular Cold Chain Awareness Courses that explore the latest handling techniques and equip you with effective strategies to optimize your cold chain distribution processes.

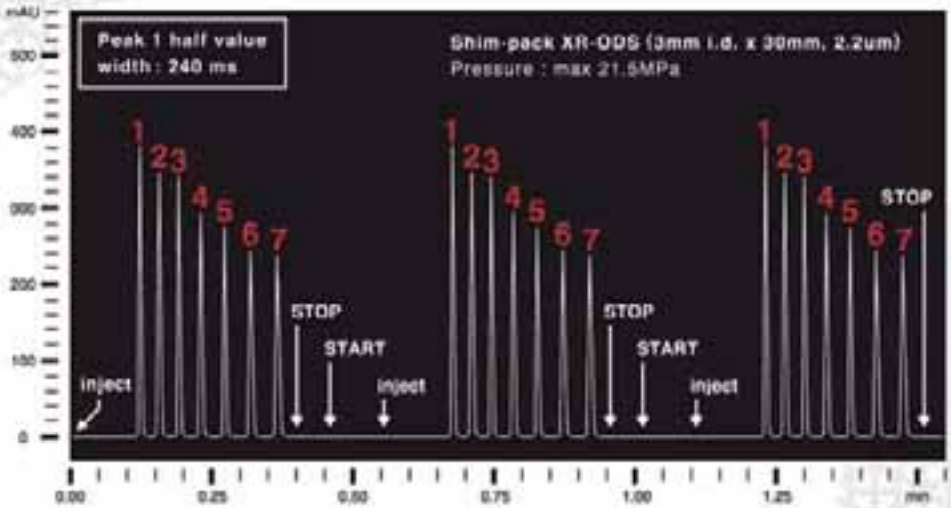
To find out more about our services or the Cold Chain Awareness Course, please visit **www.worldcourier.com**

WORLD COURIER
A SERVICE NO ONE ELSE CAN DELIVER

SHIMADZU

Fast HPLC Is More Than A Single Chromatogram

A SINGLE CHROMATOGRAM does not equate to Fast HPLC. When discussing Fast HPLC, the key is how many samples you can run per day, hour, or even minute. With Shimadzu's standard Prominence HPLC components and the NEW High-Speed Shim-Pack XR Series Columns, you can do more in one hour than most systems will do in a day. Since we are using standard components and not running at extreme pressures, there are no worries about ruggedness or component reliability.



Prominence LC-20AD UFLC Pump
Standard for LCMS analysis with excellent gradient formation due to the 3 nL/step pump motor resolution

Prominence SIL-20AHT UFLC Autosampler
10-second injection cycle time and virtually no carryover means less time between injections. Additionally, since no "inject ahead" routines are necessary, the system is not susceptible to sample loop carryover problems.

Prominence SPD-20A UFLC Detector
50Hz sampling rate for seeing even the narrowest peaks

Shimadzu

Prominence UFLC
ULTRA FAST LIQUID CHROMATOGRAPH

www.shimadzu.com

Vol 2; Issue 8; December 2007

Good to see India's success

Your coverage on the rise of biotechnology entrepreneurs in India was an eye opener. It's always good to see India coming up trumps in the biotechnology sector after its success in the IT sector and it is an indicator that India can be second to none in biotechnology arena. My best wishes to Indian entrepreneurs.

Dakshina Moorthy, Malaysia

Interesting read

Your interview with Dr Laszlo Kondor was quite an interesting read. With rising petroleum costs, depleting hydrocarbon resources and geopolitics that is revolving around oil, biofuels are the way forward. As Dr Kondor has indeed pointed out, Asia will be the hub for biodiesel production as rising income and economy propel more people to buy cars; it is Asia that will be an experimental ground for biofuels.

Jeremy Roberts, Singapore

We welcome your suggestions and valuable comments. Please e-mail us your views on the magazine at nanditas@cybermedia.co.in

2007 roundup was good

Every New Year brings in a new hope for patients across the world. 2007 was better in terms of introduction of safe and better drugs, diagnostics devices. Your coverage on the 2007 was good. May be a little more research should have thrown in better results that showed some cool products that either did not receive enough publicity or were highly undervalued.

Jason Chuang, Hong Kong

Good to know about Korean biotech

Although a strong player in automobile and electronics, Korea has started making forays into biotechnology sector and it heartens me to read what Youngguk Cho has to say about the country's vibrant biotech industry.

I don't see any reasons why Korea should lag behind others in biotech R&D. It has strong educational, industrial and governmental backing and this will only get stronger with time.

Kim, Singapore

FROM all indications, 2008 is poised to be the year in which the life sciences industry will thrive on collaborations. This is the dominant message that has come from various industry experts. And in this issue, some of them have outlined how collaborations are going to work in favor of life science companies in the region.

Pharma and biotech sectors are going to benefit the most from collaborations. As Mr Utkarsh Palnitkar, Ernst & Young's leading biotech analyst, pointed out, the Asia Pacific region is going to emerge as a major bio-manufacturing hub. And this is going to happen as leading biotech players transform from just leveraging low costs to become high value companies.

The global pipeline for new drugs is shrinking. But the coming years will see the emergence of collaborative research that will spur development of biologicals targeting autoimmune diseases, infectious diseases and neurological disorders. Of course, these will happen when drug developers are able to move to the level with incremental advances in current therapies.

2008: Year to work together

While technology developments will continue, the business side of pharma industry globally will continue to be moderate. Leading pharma consultants, IMS Health, expects the pharma industry to grow globally at six-seven percent in 2007 and this may drop slightly in 2008. This will be mainly due to the increasing pressure on companies to reduce prices to meet social obligations and demands for increasing access to health care. This in turn is leading to greater acceptance of generics even in the developed markets to help government and other big procurement NGOs. In fact, this development is a boon for Asia's generics players, who are no longer forced to rely only on patent challenges to gain marketing windows in the world's big pharma markets.

Overall, 2007 has been good for the life science industry in the region. Many countries have stepped up the efforts to woo life science companies to the region and also make conditions ideal for the development of domestic companies. One of the prominent developments is the announcement of India's first-ever National Biotech Policy that seeks to provide an ideal platform for the country's $2 billion biotech industry to build quickly on its strong foundation. A series of measures to help the industry has been announced. India is also revamping its regulatory systems to spur the growth of the industry.

Australia which has been a pioneer in putting in place a modern regulatory system for the biotech sector, is a country to which every one looks up to in this regard. In this issue of *BioSpectrum*, Australia's gene regulator, Dr Sue Meek, has outlined the efforts that went into making one of the world's best biotech regulatory system I am sure Dr Meek's experiences will come in handy for other regulators in the region.

BioSpectrum looks forward to the New Year with great hope. As is now *de rigueur* we will continue to bring you a ringside view of the developments that are going to shape the life sciences industry in Asia Pacific.

Narayanan Suresh

Chief Editor
sureshn@cybermedia.co.in

BioSpectrum the business of life sciences
ASIA EDITION
www.biospectrumasia.com

Publisher: Pradeep Gupta
Editor-in-Chief: Shyam Malhotra
Group Editor: E Abraham Mathew
Chief Editor: Narayanan Suresh
Associate Editor: Nandita Singh
Assistant Editor (Online): Sanjeev Jain
Designer: Sareeta Sajjan
Associate Vice President: Naveen Barsainya
Assistant Product Manager: Sanjeev K Mishra

Editorial & Marketing Offices

Singapore
Associate Editor: Narayan Kulkarni
(narayank@cybermedia.co.in)
Asst Manager Sales & Marketing: Paul Lim
Asst Manager Admin & Sales Support: Saradha Mani
1 North Bridge Road
#14-03 High Street Centre
Singapore 179094
Tel 65-63369142, Fax 65-63369145
Advertisement sales E-mail: paull@cybermedia.co.in
Editorial E-mail: nanditas@cybermedia.co.in

Bangalore
India Editorial Team: Srinivas Rao, Namratha Jagtap, Jahanara Parveen, Shalini Gupta
India Sales Team:
Aninda Sen (anindas@cybermedia.co.in);
Bangalore: Gurunath S A (gurunathsa@cybermedia.co.in);
Delhi: Vivek Verma (vivekv@cybermedia.co.in);
Mumbai: Imran Khan (imrank@cybermedia.co.in)
International sales:
Kavita Pote (kavitap@cybermedia.co.in)

CyberMedia (India) Ltd
401, 4th Floor, MBC
134, Infantry Road
Bangalore-560001 India
Tel: +91-80-22861511/22868238/22869872
Fax: +91-80-22862971

Australia
Media Representative: Mr Jim Stride
Adsales connect
Suite 103 Level 1
110 Pacific Highway
St. Leonard, Sydney 2065
Tel: +61-2-94399929
E-mail: jstride@adsalesconnect.com.au

Taiwan
Media Representative: Ms Anita Chen
Prisco Ind. Service Corp
2F, No. 85, Zhouzi Street
Neihu District, Taipei City 114, Taiwan
Tel: +886-2-8751-5162 ext 66; Fax: +886-2-8751-8861
E-mail: anita_chen@globalitmedia.com

USA
Media Representative: Ms Leslie Hallanan
Avani Media, Inc.
69a Liberty Ship Way
Sausalito, CA 94965, USA
Tel: + 1-415-331-2150; Fax: + 1-415-289-0402
E-mail: info@avanimedia.com
website: www.avanimedia.com

Europe
Media Representative: Mr Alain Schiff-François
Dipl-Ing
ASF labmarketing
Am Mühlebach 1
D-79219 Staufen, Germany
Tel:+49-7633-9234210
E-mail: asf@labmarketing.de
Website: www.labmarketing.de

Corporate Office
Cyber House
CyberMedia (India) Ltd
B-35, Institutional Area
Gurgaon, Haryana-122 002 India
Tel: + 91-124-2384816; Fax: +91-124-23841683
Website: www.cybermedia.co.in

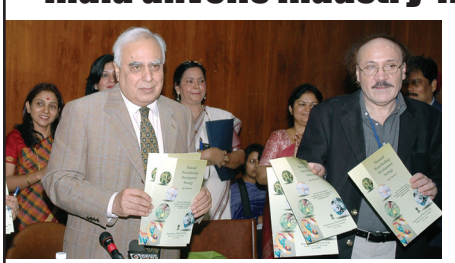
This issue is the digital version of the BioSpectrum Asia Print edition – Vol 3, Issue 1, Jan 2008

BioContent

The New global order

BioSpectrum brings you technologies, trends and challenges that are ahead for the industry in 2008

India unveils industry-friendly biotech policy



The policy had been in the works since 2005 and has been formulated after extensive consultations with a wide range of stakeholders of the biotechnology sector. The country has also announced the government's intention to set up a unified regulatory system, in the form of a National Biotechnology Regulatory Authority (NBRA), on the lines of the regulatory system that exists in Australia now

2008 Year of the Entrepreneur

Singapore's Enterprising 3

BioNews

Sanofi-aventis opens first Asian development center in India

GLOBAL pharma major Sanofi-aventis has opened its first Asian pharmaceutical development center in Goa, India.

Set up at an approximate cost of $25.54 million (Rs 100 crore) the Goa Development Centre (GDC) represents the group's single largest investment in India to date and is testament to Sanofi-aventis' strategy to expand its presence and accelerate growth both in India and in Asia.

Located close to Sanofi-aventis' state-of-the-art manufacturing facility in Goa, the 2,600 sq mt GDC will play a pivotal role in allowing the group to introduce new, quality medicines rapidly both in Asia Pacific and the global marketplace. The GDC will have the capacity to develop up to 12 pharmaceutical compounds per year.

Dow, AIBN join forces for new materials

THE University of Queensland's Australian Institute for Bioengineering and Nanotechnology (AIBN) and The Dow Chemical Company have announced an alliance that will combine AIBN's research expertise with Dow's market knowledge.

The alliance is expected to deliver new materials and processes capable of producing desired molecules from renewable resources in a cost effective manner achieving long-term benefits for the consumer.

Eisai leaps to where action is

Japan's pharma major Eisai has been expanding in Asia leveraging on local strengths. The company aims to become a global player by 2012

JAPAN'S top pharma company Eisai, has been on an overdrive of late. Recently, the Tokyo-headquartered company bought US-based cancer drug maker MGI Pharma, in an all-cash transaction, for a total consideration of approximately $3.9 billion.

Eisai has already strengthened its oncology research and development and marketing infrastructure in the US through the October 2006 acquisition of four oncology products and know-how from Ligand Pharmaceuticals. These acquisitions are part of its oncology business strategy as its bread-and-butter drug for Alzheimer's disease is set to lose patent soon.

In April 2007, it acquired Morphotek, a biopharmaceutical company that specialized in the development of protein and antibody gene evolution technology. Besides, Eisai is building a new oncology facility for manufacturing and formulation R&D at its North Carolina site, as part of its transformation strategy.

At the inauguration of Eisai Clinical Research Singapore (L-R) Dr Raymond Chua, Managing Director, Eisai Clinical Research Singapore, Mr Soichi Matsuno, Deputy President, Global Pharmaceutical Business, Eisai and Mr Kentaro Yoshimatsu, Senior Vice President, R&D at Eisai

Celebrating 40 YEARS
INTEGRITY · FOCUS · DEDICATION

BioTek

Hybrid

Microplate Reader Technology

The Next Big Breakthrough.

Flexibility of monochromator-based detection.
Sensitivity of filter-based detection. Together in Synergy™4.

Yes. You can have it all. By combining two powerful fluorescence detection systems into one, Hybrid Technology™ offers an extraordinary degree of flexibility and sensitivity for today's assays. And it doesn't stop there – Synergy 4 with Hybrid Technology also adapts to your future needs. With an outstanding feature to value ratio, the rewards are both immediate and boundless.

Patent Pending

The choice is yours.	Filter-based	Monochromator-based	Hybrid Technology
Spectral Scanning		√	√
Flexible wavelength selection		√	√
Convenience		√	√
High performance fluorescence polarization	√		√
High performance TRF / TR-FRET	√		√
High performance across spectrum	√		√
Ratiometric ion channel assays	√		√
Filtered luminescence (e.g. BRET)	√		√
AlphaScreen®	√		√

Uncover Hybrid Technology at www.biotek.com/hybridtechnology

BioTek
Get a Better Reaction.

BioTek Instruments, Inc.
Highland Park, P.O. Box 998, Winooski, Vermont 05404-0998, USA
Tel: 802-655-4040 • Toll-Free: 888-451-5171 • Outside the USA: 802-655-4740
www.biotek.com

DLReady htrf

BioNews

New Zealand, Korea embark on research program

THE Korea-New Zealand Joint Committee on Scientific and Technological Cooperation have selected two projects from six proposals at their first meeting held recently in Seoul. The projects include applications of frontier protein expression technologies, aiding drug discovery for infectious diseases.

Approximately $2.2 million will be invested in the projects over the next three years, half being funded by New Zealand's Foundation for Research, Science and Technology and the balance by Korea's Ministry of Science and Technology.

Phalanx Biotech expands US sales

PHALANX Biotech Group (Phalanx), a spin off from Industrial Technology Research Institute (ITRI) of Taiwan has reached a licensing agreement with Oxford Gene Technology (OGT). The agreement will allow Phalanx to expand its efforts in marketing and sales in the US of its DNA microarray products, Human and Mouse One Array.

Phalanx leveraged technologies are developed at ITRI to enable the mass-production of the DNA microarray at a price (less than $100) substantially lower than that of other competing technologies. Phalanx is also a founding member of a Consortium organized by ITRI to promote the business based on clinical applications of DNA microarrays.

Eisai, a pharmaceutical company with strong focus on prescription drugs that has pharmaceutical R&D, production, distribution and marketing and post marketing surveillance functions has adopted world headquarters strategy, the oncology business strategy, and the transformation strategy. These strategies were set out in the 'Dramatic Leap Plan (DLP)' that covers the six years to the fiscal year ending March 31, 2012. Through these strategies, it aims to achieve and grow as a global company.

In the thick of business in Asia, from the last four decades, Eisai now has operations in China, South Korea, Hong Kong, Thailand, Taiwan, Indonesia, Singapore, Malaysia, the Philippines, India and Australia. For Eisai, Asia holds the promise of a huge market and the company is focused on expanding in the region.

Invests $50 million in India

As part of its DLP, Eisai entered India and has commenced work on its $50 million manufacturing unit in the Southern Indian city of Vishakhapatnam in Andhra Pradesh. The company will begin making drugs and APIs from this facility by 2010 and will also house a research facility here.

Mr Soichi Matsuno, Deputy President, Global Pharmaceutical Business, Eisai said, "The actual validation of the facility will be done in summer 2009 and the aim is to start manufacturing activities by 2010. We already have 10 people working with us. On completion, this number will go up to 80-100."

The new facility for API and dosage form manufacturing and research will synergize the Eisai's global effort for its DLP goal, which is to achieve the net sales of over $8 billion (1 trillion yen) and 15 percent in cost-to-sales ratio in FY 2011.

Opens clinical research center in Singapore

Recognizing Singapore's fast-paced growth in the biomedical sciences

APAC potential

- South East Asia and China will play an increasing role in clinical research activities over the next 10 years at the expense of North America and Western Europe that are getting saturated.
- Asia Pacific region accounts for almost 56% of the world's population, 25% of the world's GNP and 22% of the world's international trade (specifically China, which will be the world's largest economy by 2050).
- With regard to the pharmaceutical market, China is already projected to be the No. 7 pharmaceutical market and Korea the 11th largest by 2010.
- A PwC survey showed that 55% of MNCs and 62% of domestic companies believe that the centre of gravity for global pharmaceutical market will be in Asia, with China, India, and Singapore being the key countries.

BioNews

Green Cross to commercialize Abraxane

ABRAXIS BioScience, a fully integrated biotechnology company, has granted an exclusive license to Green Cross Corporation for the commercialization of Abraxane (paclitaxel protein-bound particles for injectable suspension) (albumin-bound) in Korea.

Green Cross is responsible for the commercialization of Abraxane in Korea and will employ an exclusive sales force following regulatory and pricing approval.

Abraxane is currently co-promoted in the US with AstraZeneca. Abraxis is responsible for the clinical development and regulatory approval.

DuPont, BWK joint venture to discover agronomic traits

DUPONT and Beijing Weiming Kaituo Agriculture Biotechnology (BWK) have formed a joint venture to accelerate the discovery of genes for high value agronomic traits such as stress tolerance and efficient nutrient utilization to improve the performance of important crops for farmers in China and throughout the world.

For DuPont, this marks another step towards the globalization of its R&D capabilities to accelerate new product launches and drive business growth for its worldwide seed business, Pioneer Hi-Bred. The financial terms of the agreement were not disclosed.

industry over the last few years, primarily because of its stable and pro-business government, Eisai has opened its Regional Clinical Research Center in Singapore—Eisai Clinical Research Singapore.

Eisai Singapore will be working closely with the investigators and sites as well as its partners within this region, such as contract research organizations (CROs), and central laboratories, to establish a stronger relationship, build up its knowledge, skills, insights and capabilities in this region as well as ensure the timely, efficient execution and management of the clinical trials throughout Asia, Oceania, and the Middle East. Some of the clinical trials that will be initiated in the Asia Pacific region would include that of new oncology compounds for breast cancer, critical care compounds for severe sepsis, and neurology compounds for epilepsy and Parkinson's disease.

The establishment of clinical research center in Singapore and upcoming manufacturing facility in India are part of Eisai's transformation strategy

Eisai Singapore has taken the initial steps to strategically grow its clinical research operations in the Asia Pacific region in order to achieve greater efficiency in bringing products that are new into the region and global market. This will be in line with the Eisai's "Human Health Care" (HHC) philosophy to fulfill the unmet medical needs and increase benefits to the patients and their families.

Benefits of being in APAC region

- Increasing clinical trial opportunities with more conducive environment.
- Higher government support and funding for biomedical research.
- Reduced costs of conducting trials.
- Increasingly experienced research and clinical trial sites and investigators.
- Growing CRO industry.
- Better GCP regulatory harmonization coupled with higher quality data and accelerated timelines for INDs and NDAs.
- Enhanced clinical practice environment with larger patient pool, higher recruitment rate as well as better development and drug discovery efforts.

Dr Raymond Chua, Managing Director, Eisai Clinical Research Singapore said, "The Asia Pacific and Middle East countries will play an increasing role in clinical research activities over the next 10 years, with the fast maturing regulatory environment, increasingly experienced investigators, higher data quality yield and growing patient base in these regions."

"Being a global pharmaceutical company, Eisai acknowledges the need for more efficiency and flexibility in responding to markets in the region where there are multiple differences in the culture, disease structure and the regulations, unlike that of the US and EU. Having a clinical research hub located in Singapore will allow for an efficient development of new products, through which Eisai can make further contributions to increasing the benefits to the patients and their families in the region," he adds.

The establishment of clinical research center in Singapore and upcoming manufacturing facility in India are part of Eisai's transformation strategy to transfer some of its primary operation functions to the areas with high technologies standard aiming for reinforcement of its global flexibility to realize DLP and emerge as a truly global company.

Narayan Kulkarni BS

BioNews

Glenmark expands Nigeria operations

GLENMARK Pharmaceuticals Nigeria, a subsidiary of Mumbai-headquartered Glenmark Pharmaceuticals is expanding in Western Africa's largest economy Nigeria.

At present, Glenmark has 14 SKU registered in 12 months, and plans to have another six new products in Nigeria. In addition, Glenmark also has plans to substantially increase its team in Nigeria in the coming fiscal.

Glenmark started its Nigerian operations in April 2007 and has created a market for its products expecting sales of $1.3 million by the end of this fiscal.

In 2008, the Asian biotechnology sector is poised for faster growth as the region enters the new product patent regime. In the years to come, the focus will be on developing proprietary products, building global capacities for global markets, and increased cross-border partnering across the biotech value chain

The New global order

BioSpectrum brings you technologies, trends and challenges that are ahead for the industry in 2008

THE Asia Pacific biotech sector continues to grow aggressively. Fueled by an increased focus on the sector by regional governments and investors, and growing numbers of cross-border collaborations, biotech companies never had it so good. In spite of its impressive growth, however, the region faces considerable challenges as it tries to take its biotech sector to the next level.

The industry, at the end of 2007, is at crossroads. On one hand the region is being increasingly seen as a bio-manufacturing hub leveraging the advantages that accrue from operating in this geography. On the other hand, the domestic industries are rapidly scaling up to participate in the global opportunities. Asia's history of moving from a low-cost manufacturing hub to a high-value player in several industries provides some indication of the future evolution of its biotech sector.

Future forward
Forecast **2008**

THE NEW GLOBAL ORDER

Today's biotechnology industry is truly global. The trends in the global industry have had their repercussions in the Indo-China region, and have influenced the state of the industry in this region. Prominent among these trends is the growing cost of drug development and the ever-increasing pressures on containment of prices. India is playing a key role in today's integrated business environment, with companies and the government seeking to leverage the talent pool in the region, which is available at very competitive costs. With the alignment of intellectual property protection legislation and a growing focus on state-of-the-art infrastructure, the region is quickly emerging as a destination of choice.

BREAK THE CODE

It's Mission Possible with the Whatman® FTA® Elute

FTA Elute is an all-in-one device, for room-temperature collection, purification and archiving of DNA from biological samples. With its quick and easy 30 minute elution protocol, the Whatman FTA Elute enables researchers to rapidly "break the code". The device represents a highly flexible solution for a wide range of critical applications.

HOW TO BREAK THE CODE:

With the Whatman FTA Elute, breaking the code is quick and easy:

Asia Pacific
Whatman Asia Pacific Pte Ltd
Tel: 65 6534 0138
Fax: 65 6534 2166
Email: wap@whatman.com

Australia
Whatman Australia Liaison Office
Tel: 61 3 9787 7830
Fax: 61 3 9787 7092
Email: john.sestanovich@whatman.com

China
Hangzhou Whatman-Xinhua Filter Paper Co Ltd
Shanghai Liaison Office
Tel: +86-21-5150 5518, 51505516
Fax: +86-21-5150 5517
E-mail: Chinainfo@whatman.com

India
Whatman India Liaison Office
Tel: 91 22 2529 7035
Fax: 91 22 2529 7036
Email: indiainfo@whatman.com

Whatman®

To jump-start their growing biotech industry strengths, governments and companies in various Asian economies have concentrated on specific competitive niches. In some cases, these niches are areas where many western countries have been unable to invest because of political or other limitations—examples include stem cells, gene therapy, and traditional medicinal systems. For the most part, though, these areas of specialization are driven by another factor—cost competitiveness. The common thread across many of the niches emerging in the Asian biotech sector—from contract research and contract manufacturing, to vaccines, generics, and bioinformatics—is the ability of Asian companies to compete in these segments, in the west at a fraction of cost.

Future forward

Forecast **2008**

The emergence of China and India is also the biggest story in the Asian biotech sector. Increased outsourcing of research and development (R&D) to these two countries could have a revolutionary impact on the cost of drug development in the west. But these developments are also reshaping the domestic industries in both nations. While western drug companies are attracted to China and India because of the huge markets for their products as well as tapping the domestic advantages, they have long been frustrated by the issue of intellectual property (IP) protection. The arrival of stronger IP protection has changed the rules of the game. The question facing companies is on the enforcement side of the IP debate.

Driven by these changes, companies in the two countries, China and India, need to develop innovative pipelines. Encouraging signs are emerging, including a reverse brain-drain of western educated Chinese and Indian nationals who are building a new generation of biotech startups in their home country. But much of this activity is in its infancy, and bringing products to market will require patient investments and experienced venture capital.

Challenges

The three major challenges that can affect the Asian Biotech dream relate to manpower issues, counterfeits and early stage funding.

Manpower training in the biotech industry is emerging as a high investment cost issue and the following ways can be adopted by biotech companies and regional governments when dealing with the human resource issue:

- Educational institutions, when preparing their curricula and syllabi, can seek inputs from industries in their area and incorporate relevant courses or materials into their programs, wherever possible.

- A second approach would be to invite people from industry to lecture at institutions on specific topics, which are academically relevant, and of interest to the industry.

In recent years, investors have shown a clear preference for later-stage financing rounds. A slight improvement in early-stage financing might reflect the first returns from various government initiatives to motivate seed- and early-stage funding. Nevertheless, funding of early-stage startups remains a serious issue for the sustainable development of the industry. One source of capital that has been tried in some countries is from large industrial houses looking to diversify. A second source of funding is government money. To some extent, this is nothing new. Governments are actively helping grow the industry, getting involved in everything from developing human capital to providing essential infrastructure.

Outlook

Industry insiders consider a negation of the cost advantage within the next 10 to 15 years and are preparing for the next logical step in the evolutionary ladder: progression up the value curve. The enabling environment for innovation being put in place, with a proactive government doing its utmost to promote this sector and the sheer entrepreneurial spirit, has formed a unique spiraling effect.

In 2008, the Asian biotechnology sector is poised for faster growth as the region enters the new product patent regime. In the years to come, the focus will be on developing proprietary products, building global capacities for global markets, and increased cross-border partnering across the biotech value chain.

Utkarsh Palnitkar

(Mr Utkarsh Palnitkar is Industry Leader – Health Sciences at Ernst & Young. He is based out of Hyderabad in India)

Smaller companies will have a greater role to play

THE global life sciences industry has transitioned to a growth phase, and has started to deliver results. In the second and third quarter of 2007, the life science companies have registered a healthy growth. Business confidence is on the rise amongst life science companies as they have developed a strong product pipeline, which have very good market potential.

Trends for pharma industry in 2008

- Outsourcing & off-shoring to continue
- Global licensing
- Layoffs and lean operations
- Growing importance and dominance of generic companies
- Challenging times for wholesalers
- M&A / consolidation
- Eliminating hospital infections
- Prevention of medical errors
- Emergence of new global players
- Additional pressure, limelight and scrutiny of US Pharma industry due to elections

Source: www.pharmanewsanalysis.com

Future forward Forecast **2008**

The industry, it seems, has drawn a long-term strategy to make these products more user-friendly, develop combination therapies to enhance their effectiveness. In the changing scenario, the small companies have a greater role to play to bridge the gap in the discovery process by reducing time and cost in product development. There is a clear indication of growing partnership in terms of mergers and acquisitions across the globe between the big and small companies.

The scenario is changing in Asia as well. With the growing economy in the Asian countries the opportunities are opening up. At the same time the costs and wages are also increasing for skilled and talented work force in a high technology industry such as life sciences. Companies in the west are looking at smaller emerging and developing markets like Malaysia and Thailand for outsourcing activities. These developing markets will take an active participation in the knowledge-intensive life sciences industry.

THE CHALLENGES

Factors like long gestation period and no quick returns on investments are still coming in the way of venture capitalists to invest in life sciences companies. The companies need to showcase their unique and niche position with emphasis on product application and commercialization aspects.

The technologies that will make a difference.

During 2008-2010, biologics serving treatment of autoimmune diseases, infectious diseases, and neurological disorders will be in focus. However, this will be possible only through a series of incremental advances, such as the development of targeted therapies that match pharmaceuticals to genetically appropriate patients.

Mr Nitin Naik

(Mr Nitin Naik is Director of Healthcare Technologies & Life Sciences Consulting Practice, Asia Pacific at Frost & Sullivan, Singapore)

Phacilitate

VACCINE FORUM
WASHINGTON 2008

Phacilitate

CELL & GENE THERAPY
FORUM 2008

28th – 30th January 2008, Washington DC

2 industry-leading events.
1 unparalleled networking opportunity

The Washington Vaccine Forum and the Cell & Gene Therapy Forum take place in parallel over the same 3 days in the same hotel – The Grand Hyatt.

The Washington Vaccine Forum 2008 speaker panel includes:

Dr Carol Linden, Principal Deputy Director & Acting Director, BARDA, Office of the Assistant Secretary for Preparedness & Response (ASPR), US Department of Health & Human Services (HHS)

Rajiv De Silva, President, Novartis Vaccines USA

Carol A. Dahl, PhD, Chief of Staff, Global Health Program & Director, Global Health Technologies, Bill & Melinda Gates Foundation

Dr Allan P. Jarvis, Senior VP, Corporate Development, sanofi pasteur

Dr Gary J. Nabel, Director, Vaccine Research Center, NIAID, NIH

Dr Norman W. Baylor, Director, Office of Vaccines Research & Review, CBER, US FDA

Dr David C. Kaslow, VP, Infectious Diseases & Vaccines Franchise, Merck Research Laboratories

Dr Krishna Mohan, President, Bharat Biotech Intl Ltd

Anne Schuchat, MD, RADM, US Public Health Service, Assistant Surgeon General, Director, National Center for Immunization & Respiratory Diseases, CDC

Dr Luc Hessel, Chairman, Influenza Vaccine Supply International Task Force, Executive Director, Medical & Public Affairs, Europe, Sanofi Pasteur MSD

Dr Michael Pfleiderer, Head of Section: Viral Vaccines, Paul-Ehrlich-Institut

Frank Malinoski, MD, Senior VP, Medical & Scientific Affairs, MedImmune, Inc

Stephen M. Sammut, Senior Fellow, Wharton Health Care Systems & Venture Partner, Burrill & Company

Dr Peter Khoury, VP, Global Marketing, Baxter BioScience, Vaccines

Dr Douglas J. Pon, Assistant VP, Vaccine Licensing, Global Business Development, Wyeth Pharmaceuticals

For full program information and online registration facilities, visit www.phacilitate.co.uk/wv.

The Cell & Gene Therapy Forum 2008 speaker panel includes:

Earl M. Collier, Executive VP, Genzyme Corporation

Dr Akihiro Shimosaka, Director, EPS Co, Ltd

Dr Alan Sachs, VP, RNA Therapeutics, Merck Research Laboratories

Dr Karen Kozarsky, Head, Gene Therapy, Biopharmaceutical CEDD, GlaxoSmithKline

Professor Ryuichi Morishita, Professor, Department of Clinical Gene Therapy, Osaka University Graduate School of Medicine & Founder, Board Member, AnGes MG

Sudha Kadiyala, PhD, Worldwide Director, Business Development & Strategic Planning, Johnson & Johnson Regenerative Therapeutics, LLC

Daniel Takefman, PhD, Chief, Gene Therapy Branch, Division of Cellular & Gene Therapy, OCTGT/CBER, US FDA

Dr Mitchell H. Gold, President & CEO, Dendreon Corporation

Stephen Potter, Senior VP, Corporate Development, Genzyme Corporation

Dr Garheng Kong, General Partner, Intersouth Partners

Jeffrey M. Ostrove, PhD, President & CEO, Ceregene, Inc

Dr David Eckland, Director of R&D, Ark Therapeutics

Professor Klaus Cichutek, VP & Head, Division Medical Biotechnology, Paul-Ehrlich-Institut & Chair, EMEA Gene Therapy Working Party (GTWP)

Dr Madhusudan V. Peshwa, VP, R&D, Maxcyte, Inc

John LeGuyader, Director, Technology Center 1600, United States Patent & Trademark Office (USPTO)

Dr Peter Working, Senior VP, R&D, Cell Genesys

Dr Robert E. Sobol, Senior VP, Medical & Scientific Affairs, Introgen Therapeutics Inc

Linda Powers, Managing Director & Co-Founder, Toucan Capital Fund II & Chair, Maryland Stem Cell Commission

For full program information and online registration facilities, visit www.phacilitate.co.uk/cgtherapy

Whilst the two conferences remain separate, all networking activities are shared, taking place in the exhibit area directly in between the 2 plenary rooms. Over 500 senior level executives attended the '07 meeting, almost all of whom represented cell, gene and tissue therapy developers, and vaccine developers and manufacturers.

For information on the few remaining sponsorship and exhibition opportunities, **contact Nicola McCall at nicola@phacilitate.co.uk** (Tel: +44 (0)20 7839 6137).

Contact team@phacilitate.co.uk or call +44 (0)20 7839 6137 with any queries.

Collaborate for RoI

The pharmaceutical companies have to look at cost effective approaches to ensure return on investment (RoI) and become profitable. Collaboration will help in the objective, reports IMS Health

THE global pharma market will grow at five-to-six percent in 2008, says a forecast by IMS Health. Compare this figure with six-to-seven percent the pharma industry saw in 2007 and one concludes the pharma industry is going southwards. Besides, IMS also forecasts that in 2008 drug treatment costs will decline in several major therapy areas where leading products have lost or will lose patent protection, and generic drugs capture significant market share.

Future forward
Forecast **2008**

According to **Mr Murray Aitken, Senior Vice President, Healthcare Insight, 2008** is an important year for the global pharmaceutical market. In 2008, for the first time, the seven large markets will contribute just half of overall pharmaceutical market growth, while seven emerging markets will contribute nearly 25 percent of growth. And, as the impact of established pharmaceuticals losing patent protection accelerates, there will be a decline for the first time in the size of the $370-$380 billion audited market for primary care-driven drugs. In 2008, biopharmaceutical and generics companies will more aggressively adjust their business models to manage through these inflections, capturing new opportunities in this changing market environment.

Here is what market watchers forecast:

Dr M D Nair, Consultant to healthcare industry, India: The pharma industry like any other business segment will become a profit-driven industry. The large multinational pharmaceutical companies will invest in research and development for new drugs only in areas that ensure adequate return on investment. He further noted that many new diseases and epidemics will continue to emerge as the developing countries' problems will not be the area of interest to the big pharma companies.

Dr Chau Shi Ming, Technical Services Manager, Schering Plough, Singapore: There will be an increased reliance on outsourcing and contract services to overcome the burden of R&D costs. On the other hand to overcome the growing counterfeiting of drugs, companies are looking at technologies such as Radio-frequency identification (RFID). And to increase efficiency and effectiveness of the manufacturing process, companies are adapting new technologies such as Process Analytical Technology (PAT) and Quality by Design (QbD).

Dr Paul W S Heng, Associate Prof., Department of Pharmacy, National University of Singapore: Global regulatory frame work, economies of scale, attention to quality at source, fully integrated and monitored manufacturing processes, integrated in line inspection and product traceability to unit dose will play an important role in manufacturing of pharmaceutical products in the coming few years.

Challenges

Despite the growth of the pharma industry, the sector faces many challenges. According to Dr Nair, the challenges include credibility gap on its motives and social obligations, inability to contain prices to affordable levels, perceived scant respect to medical needs of the poor and high R&D cost.

Dr Prasad Kanneganti, Director, Quality Operations, Pfizer Asia Pacific, Singapore added that the

Next Issue: February 2008

BioSpectrum
the business of life sciences
ASIA EDITION

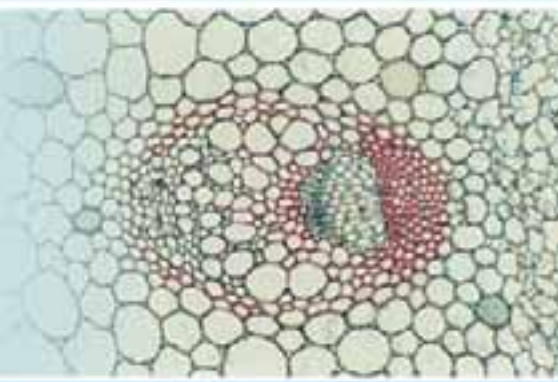
IT drives life sciences

IT tools development drives life science advancements...

Alternative Energy

Emerging global Biofuel market...

New insights into the Australian orthopedic application of stem cell



For advertisement enquiries:
bsasales@cybermedia.co.in

www.biospectrumasia.com

pharmaceutical industry is facing other challenges such as complexities of diseases requiring a therapy, patent expiry and loss of exclusivity, pressure to reduce drug costs, challenges to IP, counterfeiting and piracy, regulatory pressures and unprecedented need for change.

However, when it comes to manufacturing, the industry is facing the problems of under utilization, high cost of maintaining quality of the products, changing regulatory standards putting pressure on the manufacturers to upgrade the systems. These are ultimately adding to the overheads and not providing enough space for the companies to look at spending on innovation.

Solutions

To overcome the poor R&D productivity that has characterized the pharmaceutical industry over the last few years, companies are being forced to re-evaluate R&D strategies. Companies are using licensing and acquisitions along with better prioritized spending and more structured decision-making in an effort to deliver improved returns. Pharma companies turned to a range of inorganic growth strategies to give bottomlines a fillip.

This has allowed big pharma companies to expand their geographical presence, while enhancing the strength of their pipelines, frequently with the acquisition of small pharma and biotechs providing additional products and technologies. Markets such as India and China represent significant targets for growth because of their rapid economic expansion, but with the globalization of the industry, manufacturers are increasingly outsourcing and offshoring numerous functions there.

Though the pharma industry has many issues, growth opportunities abound. The future opportunities lie in developing new drugs pipeline sustainability and possibility for diverse portfolio of product pipeline and offering services to meet increased medical and market needs, ability to penetrate into new markets, making available drugs accessible and affordable to diverse populations. The companies should also move from blockbuster model to disease and population models by concentrating on diseases of aging, immune disorders, metabolic diseases, cancer and other lifestyle diseases as well as emerging new infections is imperative. Considering the opportunities the big pharmaceutical companies have adapted collaborative approach like merger and acquisition strategy or partnership approach to afford the high cost of R&D.

To overcome the challenges what could be the mandate for the pharmaceutical industry? Dr Nair suggested companies that are involved in drug discovery research adopt a collaborative mode to reduce costs; carry out extensive literature and patent search for the therapeutic field with respect to the chemical structure scaffold of the active and patented products, mechanism of action of the class and its current relevance; identify a project which will stay clear of the patents; carry out analog synthesis for new molecules and screen for biological activity, while developing the product further, and search for partners.

"We are in for a major change in the way pharmaceutical business will be conducted in the future. To succeed we need a change in mindset and approach. Moreover, as Edward De Bono once said, "To get something, you need to combine method and motivation. Motivation without method is ineffective. Method without motivation usually sits on the library shelf," quoted Dr Nair.

Narayan Kulkarni *in Singapore* BS

2008 will see new cost effective approaches for drug research

- **System-based**—alternate systems of medicine;
- **Therapeutics-based**—new indications for existing drugs through clinical research;
- **Product-based**—biotechnology, NDDS, chiral products;
- **Process-related**—non-infringing processes, bio-process catalysis and other eco-friendly and cost-effective processes.

Collaborative approach strategies

- In knowledge industries, to attract collaborators to at least complement, if not synergize core competencies of partners.
- Partnerships to be based on common values and objectives, strategic match, meeting of the minds and mutual benefits (win-win).
- Joint venture partnerships to be based on shared responsibilities, shared risks and shared benefits.

Future forward
Forecast **2008**

www.InterphexAsia.com

INTERPHEX ASIA 2008

Pharmaceutical Manufacturing, Processing & Technology

02-03 June 2008 • Suntec Singapore

Asia's dedicated platform for the Pharmaceutical Manufacturing industry

Organised by: Reed Exhibitions

Sponsoring Partner: ISPE

Official Conference: ISPE SINGAPORE CONFERENCE IN ASSOCIATION WITH INTERPHEX ASIA

Reply Slip – Please fax to +65 6588 3798

Please print

Please send me more information on : ○ Exhibiting ○ Visiting ○ ISPE Singapore Conference

Name _____ Job Title _____

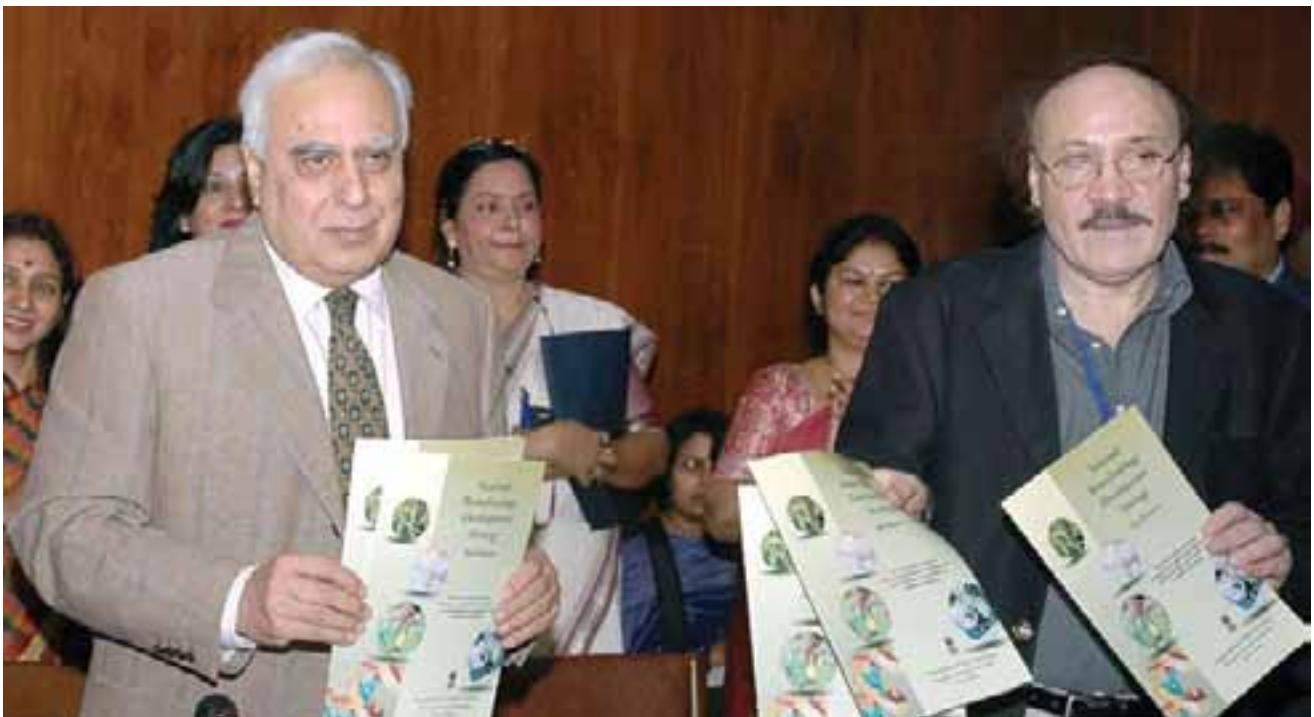
Company _____

Address _____

Nature of Business _____

Tel _____ Fax _____ Email _____

For more information, please contact **Ms Dayna CHUA** © **tel** : +65 6790 4697 **fax** : +65 6589 3798 **email** : dayna.chua@reedexpo.com.sg



India's Science & Technology Minister Mr Kapil Sibal and Dr MK Bhan, Secretary, Dept of Biotechnology announcing the country's biotech policy

India unveils Industry-friendly biotech policy

The policy had been in the works since 2005 and has been formulated after extensive consultations with a wide range of stakeholders of the biotechnology sector. The country has also announced the government's intention to set up a unified regulatory system, in the form of a National Biotechnology Regulatory Authority (NBRA), on the lines of the regulatory system that exists in Australia now

INDIA has unveiled an industry-friendly biotechnology policy that aims to make the country a hotbed for discovery and innovation, leverage the opportunities in manufacturing and services and develop novel technology platforms to stimulate long term benefits in agriculture, human and animal health, ensure environment security and promote sustainable economic growth.

"Biotechnology is a sunrise sector which requires focused attention and the government has accorded approval for the broad framework of this strategy and the sectors proposed therein," said India's Minister for Science & Technology, Mr Kapil Sibal, while announcing the policy.

The policy had been in the works since 2005 and has been formulated after extensive consultations with a wide range of stakeholders of the biotechnology sector.

A major highlight of the policy is the proposal to spend 30 percent of the government funds, earmarked for biotech activities, to promote the biotech industry in a big way. The funds will be used in public-private-partnership schemes in the following years.

"These schemes will promote innovation, pre-proof-of-concept re-

Grab the right talent

- Research Associate (Formulations)
- Regulatory Affairs Associate
- Clinical Research Manager
- Global / Regional Project Managers
- Intellectual Property Management

Post job

Industry Reaction

'A welcome move'

Mr M Ramasami, Chairman, Rasi Seeds, Athur, Tamil Nadu

I FEEL that the approval of the National Biotechnology Development Strategy by the Government of India is very welcome, particularly for the private industry that involves biotechnology in their R&D. This is very significant for the Indian agriculture and specifically for the seed industry, as the seed is the main carrier of technological inventions, including biotechnology.

It is very interesting to note that public-private partnerships are being encouraged through this strategy. This will facilitate the flow of technological inventions from public sector to private sector in an effective manner. It is important that strategic alliances between private and public research institutions are important. The research planning has to be from the conceptualization stage so that the research outputs will be very useful for all concerned. This agenda should be on national priority, taking into consideration of bridging the knowledge from basic life sciences to the applied sciences such that the research and development is useful to the agricultural community that includes farmers and consumers.

We suggest that private sector representation is allowed in all stages, programs and councils including in human resource development. I also feel that it will be useful and beneficial for involvement of private sector in "Research Resource Units", in addition to the academia. Further, private sector along with public sector can be involved in facilitating international partnerships. It is also important to create national facilities to cater to the needs of biotech research particularly for high throughput, cost-intensive technologies/ equipment for use by both public and private institutions. This can be in addition to the service labs in biotechnology at national level.

In general, the formation of the National Biotechnology Development Strategy is a welcome sign and will be a great opportunity for all of us to use the biotechnology strategies for the benefit and betterment of our people of India.

search, accelerate technology and product development in biotechnologies related to agriculture, human health, animal productivity, biomanufacturing and environment," Mr Sibal said.

The scheme is likely to get over $500 million to promote biotech industries in the next five years.

India's biotech industry is made up of nearly 250 companies in biopharma, bioindustrial, bioagri, bioinformatics and bioservices segments. According to the fifth BioSpectrum-ABLE Industry survey, the sector had revenues in excess of $2 billion in 2006 and is growing at an average of 32 percent. The national biotech policy estimates that the biotech industry will generate revenues over $7 billion by the year 2010.

Regulatory bottlenecks

India's regulatory system to handle clearance of biotech products have been simplified in the last three years and it involves four different ministries of health, environment, science and technology and chemicals and fertilizers. The policy has announced the government's intention to set up a unified regulatory system, in the form of a National Biotechnology Regulatory Authority (NBRA), on the lines of the regulatory system that exists in Australia now.

The country has invested over $1 billion in biotech research in the last 30 years. The benefits of publicly-funded research are not fully available to the industry for commercial use. To overcome this, India plans to formulate its own version of the US government's Bayh-Dole Act.

A Draft Bill, called "Public Funded R&D (Protection, Utilization and Regulation of Intellectual Property) Bill, 2007 has been prepared. India's parliament will debate the Bill soon.

Some of the other highlights of the policy are:

- ✓ A high-powered Inter-ministerial Committee is to be set up under the chairmanship of Secretary, DBT (Department of Biotechnology), to effectively coordinate the development of the sector by addressing cross cutting issues.
- ✓ 30 percent of DBT's budget to be spent on public-private partnership programs.
- ✓ A Biotechnology Industry Partnership Program (BIPP) for Advanced Technology would be launched.
- ✓ The existing Small Business Innovation Research In-

dustry (SBIRI) Scheme to promote innovation in SMEs has been a success. Approval has been accorded for the expansion of SBIRI in the next five years.

✓ A Biotechnology Industry Research Assistance Council (BIRAC) is to be launched to act as an interface between academic and private sector, particularly SMEs (Small and Medium Enterprises) and startups; nurture and catalyze R&D and innovation in biotechnology in the private sector and promote public-private partnerships.

HUMAN RESOURCES

To build world-class human capital, the strategy has focused on:

- Improved and expanded PhD and post-doctoral programs in order to reach the best levels in the Asian region.
- Enhanced quality of masters level and undergraduate level education.
- Promotion of life sciences and biotechnology at undergraduate and masters levels.
- Creation of a translational workforce of high quality to meet short- and mid-term requirements of the country.
- Promoting support to institutions for undergraduate education to achieve 'Star College' status.
- A new role visualized for autonomous institutions of DBT to promote excellence in R&D. Selected institutions will be financially empowered for promoting excellence in and translational R&D by supporting 'Research Resource Units' in universities and sister institutions through extramural funding.
- UNESCO Regional Centre for Science, Education and Innovation in Biotechnology being established at Faridabad, Haryana, by DBT as part of a Health Science and Technology Cluster.
- Innovative re-entry packages in terms of fellowships and R&D support will be offered to young and senior scientists of Indian origin to return to Indian laboratories and pursue research on national priorities.
- In order to create and strengthen world class institutional research capacity in biotechnology, 50 Centers of Excellence (CoEs) to be established during the 11th plan.

'A good step'

Dr Krishna Ella, CMD, Bharat Biotech, Hyderabad, Andhra Pradesh

THE proposal for a National Biotechnology Regulatory Authority, which would be set up as an independent, autonomous and professionally led body to provide a single window mechanism for biosafety clearance of genetically modified products and processes, is a good step.

The next step would be to quickly integrate or harmonize the Drugs and Cosmetics Rules and the health ministry's proposed independent Drugs Regulatory Authority like the FDA.

The biggest concern is the human resource. The courses do not promote skills needed by the industry. One of the ways that can be done is DBT increasing the number of PhDs, post doc, and lab technicians currently. This can be achieved if all the CSIR labs and universities increase their intake immediately. This would automatically improve the infrastructure. And DBT can give funds to increase PhDs.

Integrating CSIR, DST, ICAR, IVR, and DBT and making human resource as a national agenda for the life sciences can improve the situation.

Another important area that needs attention is support for patent filing. There is no funding for global patent. It costs $250,000 to file a patent. The government should provide some facilitation and have minimum rights kind of options. It will benefit a lot of scientists and small institutes. Further, having an innovation agenda will be very important.

In general the line is clear now and recommendations like cluster development, TDB (Technology Development Board) and SBIRI schemes are very encouraging.

'It is encouraging'

Dr Kiran Mazumdar-Shaw CMD, Biocon, Bangalore, Karnataka

IT IS for the first time that all the stakeholders were involved in writing the strategy, where we are really focused on some of the key issues of the sector such as talent development. It has been about investment in the biotech sector, how to incubate biotech companies and how do you foster the academia-industry linkage. It is of course, also about the regulatory issues that we constantly face in biotechnology. In fact, it has covered quite a lot of issues that we face in the industry.

To be a leader in biotechnology we should know the inadequacies in the policy systems and then arrive at what is it that we need to do to build the leadership.

There are certainly models that we need to emulate, one of the most powerful models is the US model where the academic institutes and research institutes are forming new companies—it is not happening on that scale in India. So, it encourages small entrepreneurs to form small companies.

We recognized that there was a huge shortcoming in pre-clinical activities and animal houses. So, we thought how does the government give an impetus. So, government is giving grants and soft loans to private sectors to develop animal houses.

We also recognize that clinical development is a huge opportunity for India so the government has been very proactive in making sure that our regulatory systems and regulatory agencies have the required expertise to promote clinical trials and allow the whole CRO business to develop very well. So, now the whole system is getting set up.

We have now really created an environment where biotech sector is a very attractive sector to be in.

- Keeping in view the requirements for translating scientific leads into useful products and processes, a new national initiative will be taken up to build capacity in technology transfer and intellectual property rights.

- Cluster development is a key strategy to promote innovation and accelerated technology and product development. This new approach has been given the green signal by the government. Four technology clusters are at an advanced stage of planning.

- Grand challenges of national relevance in the area of agriculture, health, energy and environment will be identified through national and international consultations. Programs will then be launched through multidisciplinary teams, involving public-private partnerships.

- DBT's proposal to establish new institutional structures, especially in areas very vital to India's progress but in which current strengths are suboptimal has been approved in principle by the government. The institutions, representing a new breed, will be designed with a strong bias for integrating science and translation, and for producing skilled personnel driven towards entrepreneurship.

New legislations

- A draft bill entitled 'Public Funded R&D (Protection, Utilization and Regulation of Intellectual Property) Bill, 2007' has been prepared through inter-ministerial consultation for promotion of innovation, and would be introduced in the Parliament after obtaining cabinet approval.

- DNA Profiling Bill to Augment and Transform Forensic Investigation and Criminal Justice Delivery System to be introduced in the Parliament after obtaining Cabinet approval.

- New Translational Initiatives for mass use technologies—DBT will give special emphasis on translational initiatives to promote mass use technologies.

- Leveraging international partnerships to achieve global best practices in our S&T efforts for joint IP generation, harmonization of regulatory processes, smooth trans-boundary movement of biological materials, and to access global markets for our products and processes.

Narayanan Suresh

(Inputs: Jahanara Parveen & Shalini Gupta)

India advantage

If global companies have to move forward, they must have an India strategy

A FEW days after announcing the new biotechnology policy, India's Science & Technology Minister, Mr Kapil Sibal, dwelt at length on India's advantages in R&D and innovation, at an event organized by the Federation of Indian Chamber of Commerce and Industry (FICCI) in New Delhi. Excerpts from interaction during the event:

Q *What are India's advantages in the global economic landscape?*

One of India's advantages is that it is a living and working democracy. It is perhaps because of this foundation that India's economy is growing at eight-nine percent in recent years that has given the opportunities for entrepreneurs and ordinary people to move ahead.

Mr Kapil Sibal, Science & Technology Minister, India

Q *How is it translating into promoting innovation?*

When I think of innovation and India advantage, there are two factors that come to my mind. The first advantage is that India today has a middle class population that is 300-million strong and the economic opportunities created by this segment are huge. The middle class lives in a relatively highly networked space and interconnects with the rest of the world very easily. So what you see in India now is the connectivity that is happening on the ground with companies, multinationals coming to India and connecting with the 300 million people and become the driver of products and process in India. That's advantage India.

That explains why 200 of the Fortune 500 companies are in India. These companies have some of their largest R&D bases in India. If global companies have to move forward, they must have an India strategy. That India strategy involves sourcing not just talent from India but sourcing the market in India to exploit the world market.

Q *What are India's advantages in the life sciences sector?*

If we look at the pharma sector, most of the big pharma MNCs have come to India. They have made investments and this is not only for doing contract research but some of them are involved in innovation with Indian companies. Indian pharma companies are now sharing the intellectual property rights with big multinationals. It's no longer feasible for MNCs to invest $3-4 billion to develop a new drug outside of India when the cost of manufacturing the drug is much lower in India. The innovation costs, HR costs and economic costs are much lower than elsewhere. Our pharma companies are now acquiring companies in Europe and the US. It's very difficult for a mid-sized pharma company to survive in the US because the costs are high and there is stiff competition. Indian companies are buying these companies along with their IP rights and then manufacturing the same drug in India at much lower cost making them competitive in the world market.

Shalini Gupta

APAC Biotech Policy Highlights

Japan	The Japanese government issued a strategic plan in 2002 to focus research and commercial efforts based on emerging bio-based technologies. The goal was to stimulate the economy while addressing two pressing concerns: an aging population and a depletion of natural resources. The plan concentrates on four areas of research capitalizing on Japan's strengths in genomics research and technological proficiencies: ➢ Pharmaceuticals ➢ Medical supplies & equipment ➢ Microbial and Bioprocess Engineering ➢ Functional foods
New Zealand	Released in May 2003, the New Zealand Biotech Strategy is based on three key objectives—promoting community understanding & connection, growth and effective regulation. As far as implementation goes, the Bioethics Council provides independent advice to the Government on biotechnological issues that have significant cultural, ethical and spiritual dimensions. Amendments to the Hazardous Substances and New Organisms Act (HSNO) strengthened the provisions for consideration of cultural, ethical and spiritual matters. The ministerial call-in powers have been extended to include these matters. Also, amendments to reflect better the Treaty of Waitangi include adding knowledge and experience of the Treaty and tikanga Maori to the knowledge and experience that the Minister for the Environment considers when appointing members of the Environmental Risk Management Authority (ERMA) Board.
China	In early 2006, China adopted a 15-year "Medium-to Long-Term Plan for the Development of Science and Technology" (MLP) with an aim to become an "innovation-oriented society" by the year 2020, and a world leader in science and technology (S&T) by 2050. The MLP is built around developing indigenous innovation capabilities in the new science-intensive industries. According to the plan, China will invest 2.5 percent of its increasing gross domestic product in R&D by 2020, up from 1.34 percent in 2005; raise the contributions to economic growth from technological advance to more than 60 percent; and limit its dependence on imported technology to no more than 30 percent.
Korea	In 1999 the "Long-range Science and Technology Development Vision Toward 2025" was established, with a goal of promoting science and technology competitiveness to the G7 level by 2025 in Korea. In 2001 the Science and Technology Basic Law was enacted. The Science and Technology Principle Plan (2002 - 2006) was enacted in conjunction with a five-year plan on science and technology reform that was already underway. In 2004, the headquarters of Science and Technology Innovation was established under the Ministry of Science and Technology. In 2006, Korea outlined its Bio-Vision 2016 Plan. In this plan the Ministry of Science and Technology of Korea proposed to invest $14.3 billion in biotechnology research and industrialization over the next 10 years to create a $60 billion market by 2016. This investment will drive Korean biotechnology industry to capture the seventh position in the world from its current position 14.
Australia	In 1999 the Government established Biotechnology Australia and the Commonwealth Biotechnology Ministerial Council to coordinate government biotechnology activity and to develop a national biotechnology strategy. The government also established the Biotechnology Consultative Group (BIOCOG), a panel of experts from industry and the scientific research community, to provide independent advice to government. The National Biotechnology Strategy addresses the six key themes: ➢Biotechnology in the community ➢Ensuring effective regulation ➢Biotechnology in the economy ➢Australian biotechnology in the global market ➢Resources for biotechnology ➢Maintaining momentum and coordination. Australia has put in place excellent regulatory infrastructure including the Office of the Gene Control Regulator (OGTR) to smoothen GMO approvals.

APAC Biotech Policy Highlights

Singapore

The Singapore Biomedical Sciences (BMS) initiative was launched in June 2000 to develop the Biomedical Sciences cluster as one of the key pillars of Singapore's economy, alongside Electronics, Engineering and Chemicals. To achieve its aim, the BMS initiative is led and coordinated both by a Steering Committee on Life Sciences, comprising the Ministers for Trade & Industry, Health and Education, and the BMS Executive Committee. The first phase of development (2000-2005) of the Biomedical Sciences (BMS) initiative was focused on establishing a firm foundation of basic biomedical research in Singapore. In the second phase (2006-2010), the focus is on deepening the basic research capabilities and strengthening translational and clinical research (TCR) to help realize the full potential of investments in the BMS initiative with the translation of laboratory discoveries to clinically useful and commercially viable applications. The country's biomedical policy came under heavy criticism by World Bank in early 2007 for resources being spread too thinly. However, the government's Agency for Science, Technology and Research (A*STAR) stated that there is no rethink or a change at the broad policy level.

Malaysia

"Malaysia's National Biotechnology Policy unveiled in 2005 encompasses nine thrusts that underline its commitment to the sector:

- To transform and enhance value creation of the agricultural sector through biotechnology. To capitalize on the strengths of biodiversity to commercialize discoveries in health-related natural products and bio-generic drugs.
- To leverage our strong manufacturing sector by increasing opportunities in bio-processing and biomanufacturing.
- To establish biotechnology centres of excellence in the country, where we bring together multi-disciplinary research teams in coordinated initiatives.
- To build the nation's human capital in biotechnology via education and training.
- To develop financial infrastructure to support biotechnology.
- To improve the country's innovation system by reviewing the country's legal and regulatory framework.
- To build international recognition for Malaysian biotechnology.
- To establish a dedicated and professional agency to spearhead the development of Malaysia's biotechnology sector."

Thailand

Thailand finalized the National Biotechnology Policy framework in 2005. The key strategies include: ➢ To construct/develop infrastructure such as a biotechnology park to attract both domestic and overseas investment, as well as using services in research and development. ➢ To set forth clear policy or management to settle some highly controversial issues, such as issuance of law on protection of bioresources and policy on the development of safe GMOs products. ➢ To create an environment and incentives for venture capital to be invested in biotechnology, which needs a longer period than other industrial technologies for the return of the investment. These include taxation privileges, in particular import duties, corporate tax and co-ownership of the rights to utilize bioresources where Thailand has a particular advantage. ➢ To promote investment in research, development and innovation, as well as cultivate capability for biotechnology research following the concept of cluster research, skill-based technology and innovation approaches ➢ To support the listing of biotechnology companies on the Stock Exchange of Thailand.

BS

AUSTRALIA is a trendsetter in setting up the unified regulatory structure for GMOs with its Gene Technology Act 2000, which is in force since June 2001. Managing the complexity of enforcing the regulation is the office of Gene Technology Regulator (OGTR) headed by Dr Sue Meek, who is an independent statutory office holder responsible for administering and enforcing the national regulatory system for the development and use of gene technology. With 25 years of experience behind her, Australia's scientist-turned Gene Technology Regulator is in charge since December 2001. Holding the office of the country's first Gene Regulator is a complex, tough task. Dr Meek shares with *BioSpectrum* how OGTR handles the complexity of the task.

'The objective is to identify and manage the risk'

Interview: Dr Sue Meek, Gene Technology Regulator, Australia

Q *Can you give a brief outline of the background of the Gene Technology Act 2000? What factors let to the formation of this Act and how has this helped the industry and public health initiative in Australia?*

The use of gene technology in Australia was previously governed by a voluntary system overseen by the Genetic Manipulation Advisory Committee. It was decided that a national scheme for regulating gene technology was necessary as the range of applications for gene technology was changing very rapidly and legally enforceable ways to audit or monitor the use of gene technology and penalise breaches were needed.

The development of the Gene Technology Bill 2000 (the Bill) involved extensive consultation with all Australian jurisdictions and was conducted in four stages:

- ✓ In 1998, a paper entitled "Regulation of Gene Technology" was circulated for limited public consultation, after which, a set of policy principles was agreed by the Commonwealth State Consultative Group on Gene Technology.
- ✓ In 1999, the discussion paper "Proposed national regulatory scheme for genetically modified organisms – How should it work?" was released for public consultation and invitations to attend targeted consultations were sent to approximately 1,000 individuals and organizations across Australia.
- ✓ A consultation draft of the Bill was prepared by the Commonwealth Office of Parliamentary Counsel.
- ✓ The draft Bill was released for public comment. Calls for submissions and invitations to public forums were published in newspapers in all jurisdictions and mailed directly to over 2,500 interested stakeholders.

In 2000, the Bill was referred to a Senate Committee Inquiry and subjected to extensive debate in the Australian Parliament. It was passed into law in December 2000 and commenced operation on June 21, 2001.

The Gene Technology Act 2000 (the Act) is the Australian Government's component of the nationally consistent regulatory scheme for gene technology. Under the Gene Technology Agreement 2001, all States and Territories have committed to maintaining corresponding legislation.

The object of the Act is to protect the health and safety of people, and to protect the environment, by identifying risks posed by or as a result of gene technology, and by managing those risks through regulating certain dealings with genetically modified organisms (GMOs). The Act regulates both intentional release of GMOs into the environment and research in contained laboratory facilities.

In drafting the gene technology legislation, Australian governments decided to confine the Regulator's powers to the consideration of risks to human health, safety and the environment. This was due in part to feedback received during the consultation process which identified strong community concerns that a requirement to consider economic issues, such as the market-

ability of GM crops, could compromise the regulatory system's focus upon the protection of people and the environment.

Q *How often the various committees meet. And what is the coordination process you follow while liaising with other agencies such as TGA?*

The Act established three advisory Committees: the Gene Technology Technical Advisory Committee (GTTAC), the Gene Technology Ethics Committee (GTEC) and the Gene Technology Community Consultative Committee (GTCCC). From January 1, 2008, GTEC and GTCCC will be replaced by the Gene Technology Ethics and Community Consultative Committee (GTECCC). The establishment of GTECCC was among a number of changes to the Act made by the Gene Technology Amendment Act 2007 that was passed in June 2007.

GTTAC meets three-to-four times a year on average, and is also consulted out-of-session. It is anticipated that GTECCC will meet two-to-three times per year.

The Act requires extensive consultation with key stakeholders and the public on applications to release GMOs into the Australian environment. The methods of communication used by the Regulator include sending letters or emails directly to relevant stakeholders and posting advertisements on the OGTR website and in national, state and regional newspapers.

The Regulator is required to seek advice and comment on the Risk Assessment and Risk Management Plans (RARMPs) prepared for each of these applications from a wide range of experts, agencies and authorities. Those consulted include the State and Territory Governments, the Australian Government Environment Minister, other Australian Government regulators prescribed in the legislation (Food Standards Australia New Zealand (FSANZ), the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Therapeutic Goods Administration, the National Industrial Chemical Notification and Assessment Scheme and the Australian Quarantine and Inspection Service), GTTAC, and relevant local councils. The Act also requires the Regulator to invite submissions on the RARMP from members of the public.

The Act forms part of the integrated regulatory framework for the development and use of GMOs in Australia. All Australian Government regulators, mentioned above are also required to consult the Gene Technology Regulator when considering GM products (i.e., not live and viable). The regulation of GM (and non-GM) food is the responsibility of FSANZ. The regulation of agricultural chemicals, including the use of herbicides on herbicide tolerant (GM or non-GM) crops, is principally the responsibility of the APVMA.

Q *How many applications come to your office every year and how many get cleared? What is the time frame that an application takes from filing to clearing?*

In 2006–07 the OGTR received 1474 applications and notifications as defined under the Act. Fluctuations in the timing and volume of application lodgement can be influenced by factors such as research grant funding cycles and seasonal agricultural factors.

Licences for DIRs issued in 2006–07 ranged from limited and controlled releases (field trials) to Australia-wide commercial releases of GMOs. Ten decisions on applications for DIR licences were made during the reporting period. All were made within the statutory 170 working day timeframe. Approvals do not necessarily occur in the same year as applications are received.

Q *India is planning to emulate Australia's unified regulatory structure. What would be your advice to India and other Asian countries that are looking at outlining a similar regulatory structure and implementing it?*

The object of the Act, which underpins the regulatory system, is to protect the health and safety of people and the environment. This is achieved by focusing on risk and ensuring that any risks to the health and safety of people and the environment posed by, or as a result of, gene technology are identified and managed.

The recent Review of the Act found that this object is being achieved and that Australia's regulatory framework is appropriate and being applied effectively.

Q *Learning from the Australian experience what are the implementation bottlenecks of putting in place such as structure that other countries can be forewarned about and thus be better prepared to handle it?*

The most time consuming aspect of developing the national regulatory framework for GMOs was the extensive public consultation conducted. However, this process was necessary to ensure a clear understanding of the differing positions of all interested parties, and to provide information to interested parties to improve understanding of the issues involved.

The development and implementation of the Act included transitional arrangements for approvals made under the former voluntary system.

Nandita Singh BS

Keep yourself updated with the latest news on life sciences

BioSpectrum
the business of life sciences
ASIA EDITION

A unique integrated B2B media platform for Asia Pacific life sciences industry

Get connected to

Pharma | Biotech | Medtech

Log on to

www.BioSpectrumAsia.com

for free subsciption

Print Edition

Online Portal

Digital Magazine

CYBER MEDIA

BioSpectrum the business of life sciences ASIA EDITION

Free Subscription

Asia's Leading Life Sciences Magazine

☐ YES I would like to recieve free subscription of:

Print Magazine (Monthly) | Digital Magazine (Fortnightly) | Newsletter (Daily update)

BUSINESS ADDRESS

Please attach business card

Mr☐ Ms☐ Dr☐ Name:

Designation: Company:

Address

City: State: Country:

Zip-code:

Telephone: Fax:

Website: E- Mail:

Fax this form to us at: (+65) 63369145 or register online at www.BioSpectrumAsia.com

SUBSCRIBERS INFORMATION :

Which of the following best describes your job function / Job title?

- ☐ Corporate Management
- ☐ Senior Management
- ☐ Scientific Research Management
- ☐ Middle Management
- ☐ Non - Managerial
- ☐ Others pls specify _____

Which of the following best describes your organization business?

- ☐ Biotechnology
- ☐ Pharma
- ☐ Medical Technology
- ☐ Bioinformatics
- ☐ Biologicals
- ☐ Distributor / Dealer / Supplier
- ☐ Research / Training / Education Institute
- ☐ Government
- ☐ Genetics
- ☐ Health Care
- ☐ Legal Services / Patent Services
- ☐ Media / Event Organisors
- ☐ Venture Capitalist / Investors
- ☐ Others please specify _____

How many people are there in your organization?

- ☐ Less than 50
- ☐ 50 -100
- ☐ 100-500
- ☐ 500-1000
- ☐ 1,000 and above

What is the total revenue of your entire organization? (In US$)

- ☐ Less than a Million
- ☐ 1-10 Million
- ☐ 10-50 Million
- ☐ 50-99 Million
- ☐ 100-500 Million
- ☐ 500 Million and above

If there are any colleagues in your company who you think should be receiving *BioSpectrum Asia* free, please fill out their name, job title and e-mail ID

Name | Name

Job title | Job title

E-Mail | E-Mail

Address | Address

Cyber Media Singapore PteLtd., 1 North Bridge Road; #14-03 High Street Centre; Singapore 179094
Tel: Tel 65-63369142 **Fax: 65-63369145** Website: www.BioSpectrumAsia.com

'We've people, projects, money and infrastructure'

Interview

Dr Chungcheng Liu, Director General, Biomedical Engineering Research Laboratories, Taiwan

FOUNDED in 1973, the Industrial Technology Research Institute (ITRI) is a primary R&D center for industry in Taiwan. Back then, there were very few high-tech industries in Taiwan. Today, Taiwan is known for its ICT industries. ITRI has played a significant role in this transformation. In an e-mail interview with *BioSpectrum* Dr Chung-Cheng Liu, who recently took charge as the Vice President and General Director of Biomedical Engineering Research Laboratories (BEL), shares his views about the initiatives taken by ITRI in promoting and supporting the upcoming biotech industry in Taiwan.

Q *What initiatives ITRI has taken to promote biotechnology in Taiwan?*

ITRI's key strength is its capability in various engineering disciplines such as electronics, chemical and material science, machinery and automation. Since its inception in 1999, Biomedical Engineering Center (split into Biomedical Engineering Research Lab and Medical Electronics & Device Technology Center in 2005) has positioned itself in leveraging these capabilities to develop biomedical innovations. Examples are medical devices from electronics, bioinformatics for genomics applications, and chemical and materials for drug development and drug delivery technologies. Over the past eight years, several advancements such as gene chip arraying technology, proteomics and genomics, novel scaffold for protein therapeutics & applications, novel delivery technology have been made, besides moving two herbal derived chemicals into US FDA IND process. A framework also has been established to integrate distributive care in community-based healthcare that could promote the development of home-care medical devices. All these advancements will be further integrated into innovations for the expected arrival of new health care paradigm—a perspective health care system.

Q *What strengths of Taiwan in biotechnology space make it different from other Asia Pacific countries as far as attracting investors is concerned?*

There are four major elements of achieving success in biotechnology business: project, people, money, and infrastructure/culture. People and project are considered most important. We also know that it takes good people to select or develop a good project. Good people are the single most important element if one follows the above argument. One of the key strengths of Taiwan is people, especially the skilled ones who have worked in major Western pharmaceutical and biotech organizations. Taiwan also has abundant capital though the deployment is not adequate. However, Taiwan enjoys strong governmental support in the biotech sector to compensate the lack of private sector participation. Very few places in the world have these kinds of advantages. What Taiwan needs is clearly articulated ambition among all the things it can do yet with relatively little resource when compared to its western rivals.

Q *ITRI has opened offices in Russia, Japan, Germany and the US. Considering the market potential and opportunity in countries like Australia, Singapore, India and China do you have any plans of opening any offices in these or any other countries which you feel make a difference for Taiwan?*

ITRI is in R&D business. We operate offices in Russia, Japan, Germany and the US because those areas provided abundant sources for technological innovations for us to leverage in the past. As the world evolves, there will be new centers of technological innovations established. We will continue to look for new places that provide invaluable innovations that we can leverage to make advancement and to make a difference for Taiwan.

Q *Taiwan is known for its manufacturing IT hardware. What are the initiatives or projects initiated by ITRI to establish a linkage between this sector with that of the biotechnology?*

Areas of biotechnology where IT hardware can link up more easily are medical device and bio-informatics. Pharmaceutical manufacturing is another area that can leverage IT innovation but Taiwan does not have a strong base for pharma manufacturing at present. Not surprisingly, ITRI's strong initiatives are in the medical devices developments and bio-informatics. The early results consist of our concerted efforts in establishing the biochip industry in Taiwan and progress in genomics, proteomics and micro RNA research. The framework to establish distributive care model in a community-based healthcare system which could promote the development of home-care medical devices could provide a hot-bed for local IT hardware manufacturing firms to move into the biotech business easily. For examples, ITRI has cooperated with Mackay Memorial Hospital and Farglory Realty to build the platform for telehealth care and home-care. In addition, ITRI has also focused on human-machine interactive interfaces by using the concept of "enjoyable technology" in order to provide a user-friendly devices in an aging society.

Q *In biomedical technology space, one of the six identified areas of research initiatives of ITRI, how much investments have been made so far in different projects?*

We all know that biotechnology is a very capital intensive and high risk business but with high return—if it is successful. On the other hand, its success cannot be guaranteed with large sum of money because of its complexity and unpredictability. At ITRI, we spend roughly 10 percent of our resources in biotech sector and will increase over time. The allocation of resource to different areas of biotech research is kept in a more dynamic fashion depending on progress in risk reduction and is reviewed frequently to make sure needed resource is provided timely. We think the resource allocation process needs to be different from the previously used model in ITRI's earlier efforts to establish Taiwan's IT manufacturing industry since we can use the budget in a flexible way compared with traditional IT industry. We don't know what the perfect model is and are learning it as we go along.

In addition to real budget, ITRI has also promoted a new idea that any employee can use 10 percent of their working hours to do some innovative projects after permission by the committee.

Q *How does ITRI plan to promote biotechnology in Taiwan and in the global market?*

Because of its demand for large capital, all countries in the world developing biotech business have global market as the target and Taiwan is no exception. As mentioned, the biotech sector in Taiwan enjoys strong support from government, has good supply of seasoned professional, good IT hardware manufacturing base, but is lacking a clearly articulated ambition. With good vision and planning in the beginning and hard work of its people coupled with strong support from Ministry of Economic affairs over the past eight years, ITRI has targeted several specific projects/technologies that will change the way healthcare is done or practiced in the future if they are successful. These include a novel platform where an antibody drug can be re-engineered to provide a better one, a world leading content of small RNA sequences where new potential drugs and biology can be discovered as well as providing the tools to discover them, and a framework to integrate distributive care in a community-based health care system which could promote the development of home-care medical devices after it is fully integrated with the clinical environment and living community in Taiwan. We are not there yet, but we are very excited about the future we are creating.

"As the world evolves, there will be new centers of technological innovations established. We will continue to look for new places that provide invaluable innovations that we can leverage to make advancement and to make a difference for Taiwan"

Narayan Kulkarni BS

Dr Shanthu Shantharam is the President of Biologistics International (www.biologistics.us), a US-based biotech management and consulting company. He has over 25 years of experience as a scientist, has served as a Branch Chief of the USDA office of Biotechnology Regulatory Services in Washington DC for over 14 years, and worked as a visiting biotechnology advisor to the World Bank in the mid 1990s. Dr Shantharam also contributes in the capacity of a resource person at various biotechnology management and biosafety courses around the world.

Dr Shanthu Shantharam

Scientific community must not yield to the Luddites, this time

Nanobiotechnology & Synthetic Biology

"DNA neither cares nor knows. DNA just is. And, we dance to its music."
—Richard Dawkins

It seems it is always the anti-technology activists who are first to cast their stone at any new technology, and scientists come later. Ottawa-based ETC has fired the first salvo demanding stringent regulatory restrictions on the development of nanobiotechnology and synthetic biology. Undoing PR damage is always a hopeless effort afterwards as we have learnt from the GM crops example. As the anti-GMO campaign rages on in India and around the world, the same Luddites are starting to open a new battlefront to stop newer technologies like nanobiotechnolgy and synthetic biology.

Potential of newer technologies

Synthetic biology is a pioneering field of new biology in which sub-cellular components and molecules can be assembled to create designer life forms for useful purposes. In one sense, synthetic biology is as old as synthetic chemistry. In fact, chemists who started understanding the structure and function of biomolecules started synthetic biology. Dr Hargobind Khorana got his Nobel Prize precisely for synthesizing polynucleotides (DNA) in a test tube, which paved the way for a flourishing nucleic acid synthesis industry. Scientists have been synthesizing or semi-synthesizing many macromolecules like proteins, carbohydrates and antibiotics for along, and these processes have helped enormously to bring down the costs of chemicals and drugs. Synthetic biology promises to do the same. Dr Craig Venter, a pioneer in this field recently appeared on several TV talk shows in the US and "Hard Talk" on BBC explaining synthetic biology and its potential uses. Smart TV talk show hosts grilled him with questions about environmental, public health impacts, and ethical concerns of synthetic biology and he gave convincing answers to lay those concerns to rest. His new book, *A life Decoded; My Genome; My Life* is a wonderful read for all interested in future of modern biology. Craig Venter is not just interested in understanding how life works, but he is trying to make it work for human beings. To a criticism that scientists are playing God, Dr Venter said a brilliant thing. He said he would like to excel God in playing God as the benevolent God we all know has made some horrible mistakes in creating life forms,

and he would like to correct them. Asking hard-nosed questions about the safety, utility, risks, benefits, and being concerned about socio-economic impacts are all normal, and everyone should collaborate in such an exercise, and find appropriate grounds for benefiting from this technology. However, demanding total stoppage of the technological development is clearly out of place. The more sinister thing is to scare the public without any basic understanding of the technology just to kill technological development on some political agenda as if techno-imperialism is a crime against humanity. Science and technology waits for none. If India is held back because of anti-technology activism, it is only the Indians who are going to suffer, but not the urban Luddites who have carved out a nice life for them anyways.

Nanobiotechnology & Synthetic Biology

Nanobiotechnology and synthetic biology have so much of potential benefits to offer, and can solve many of the intransigent problems of our society. It is not unimaginable to synthesize organisms that can remove excess carbon dioxide from the atmosphere, clean up pollutants in soil and water much more efficiently than hitherto before. The biggest hope for synthetic biology is to design organisms for bioenergy production in a cost effective and efficient manner. These may sound like dreams, but remember GMO was also a dream not too long ago. Science and technology development should not be stopped because of political demagogues.

Need for initiatives by scientists

Nanotechnology is once again not a brand new science that has not been seen before. It is just a new fancy name for methods and processes that are carried out at sub-micron level. It goes further than that and can get very sophisticated. Application of nanotechnology can be endless. Nanotechnology combines physics, mathematics, chemistry, and biology to find applications in medicine and agriculture and environmental protection. Dr Anita Goel, a 34-year-old MIT scientist of Indian origin is making headlines in the US in the field of nanobiotechnolgy and it is wonderful to see such brilliant young minds achieve such laurels, and they can all be helpful to India's growth in modern technologies. She is already helping Himachal Pradesh to set up a biotech park in Solan. India needs to create and nurture such young minds in a creative atmosphere for the benefit of its people. May her tribe flourish.

UK's Royal Society has taken the lead by releasing a report on nanotechnology in which it asked for a science-based assessment, which is the right thing to do. Every stakeholder must take part in a comprehensive assessment, and then decide priorities for proper technological development. No one technology is a panacea for all our problems, but there is no doubt that all of them when used appropriately can benefit the society. If the scientific community in developing countries does not take this matter seriously, the Luddites will have a free reign again, and there is no telling where this will all end up.

Whenever scientists have spoken in strong terms, the controversies have subsided quite fast. The best example of that in India was when a paper by Kranti et al in *Current Science* on differential expression of Bt gene in Bt cotton was erroneously bandied about as the best scientific evidence for alleged Bt cotton failures in the country. Mercifully, the scientist Kranti took effective steps by writing in *The Hindu* to put an end the scientific nonsense that the Luddites were propagating. It is another thing that Bt cotton is a hands down winner in India, and has overtaken China in GM cotton area. However, the shameless Luddites will concede an inch on this score. The Indian scientific community must develop a stake in India's science and technology development, and never let scientific ignoramuses, and wanton "mischief makers" with scientific credentials to hijack the science and technology agenda. India needs all the science and technology it can muster for its development and more, and not endless controversies, and debates by the Luddites.

Scientists must take the initiative to reach out to the public through media and build confidence in science and technology. Even though, nanotechnology and synthetic biology are seemingly young and promising, they should not be allowed to become a victim of the Luddite shenanigans. India has so many scientific academies and scientific associations and societies. They all have to come out with a white paper on all emerging technologies, scientific pursuit, and advise the government, courts, and the media to place the proper facts before the public. Otherwise, who knows how many more cattle, sheep, donkeys, pigs, and chickens will die because of nanotechnology and synthetic biology? If only the Agricultural Sciences Academy of India or the Indian National Science Academy had filed a friend of the court brief against all the nonsensical court cases against GM crops, those cases could have been dismissed out of hand.

(*You can e-mail Dr Shanthu Shantharam at: sshantharam@biologistics.us*) BS

Bilcare to invest $22 mn in Wales facility

BILCARE, an Indian pharmaceutical packaging-to-clinical research company, will invest $22.27 million (£ 11 million) in setting up a new clinical supplies facility in Wales, in the UK.

The investment will enable Bilcare to expand its presence in Wales and cater to the needs of its customers in Western Europe and some parts of Eastern Europe. With University research excellence, good availability of key skills—from laboratory staff through to PhDs—superior infrastructure and a network that links companies, academics and government together, Wales, just two hours drive from London, is an ideal location for Bilcare to service the European market at a competitive cost.

Mr Mohan Bhandari, CEO of Bilcare said, "We have aggressive plans for Europe and Wales is a good base from which to operate in Europe. We acquired DHP, a clinical supplier, last fiscal and now with our new facility will employ around 200 people in Wales. With the support of the Welsh Government and International Business Wales, we have been able to expedite the process of servicing the European market."

Novartis in $1b antibody deal

NOVARTIS has expanded its collaboration with the German biotechnology company MorphoSys to create an alliance focused on the discovery and development of antibody-based biologic therapies.

The treatments will be based on monoclonal antibodies and are used to treat diseases that, in some cases, have been more challenging with "small molecule" approaches based on chemical substances.

Under this new decade long agreement, which may be extended by Novartis for an additional two years, Novartis and MorphoSys will jointly discover and optimize antibodies against a significant number of molecular targets in a wide range of diseases.

In addition, Novartis will have virtually exclusive access to MorphoSys' human antibody libraries and any future improvements made during the collaboration. MorphoSys will also fully transfer a copy of its antibody libraries and technologies to Novartis research sites.

MorphoSys has developed HuCAL (Human Combinatorial Antibody Library), a technology for the rapid and automated production of specific antibodies that involves more than 12 billion functional and distinct fully human antibodies.

Eisai to buy MGI Pharma for $4 bn

JAPANESE pharma major Eisai is buying American pharma company MGI Pharma for approximately $3.9 billion. The acquisition is expected to conclude during the first quarter of 2008.

Eisai has strengthened its oncology research and development and marketing infrastructure in the US through the October 2006 acquisition of four oncology products and specialists' know-how from Ligand Pharmaceuticals and the April 2007 acquisition of Morphotek, a biopharmaceutical company specializing in the development of protein and antibody gene evolution technology. In addition, Eisai is building a new oncology facility for manufacturing and formulation R&D at its North Carolina site.

Sequoia Capital invests over $25 mn in GVK Bio

SEQUOIA Capital has invested $25.21 (Rs 100 crore) million in GVK Biosciences, a leading pharma and biotech R&D outsourcing company based in Hyderabad, India and has nominated Mr Sandeep Singhal to the Board of GVK Bio.

Mr Sandeep Singhal, Managing Director, Sequoia Capital India said, "The rapid growth of GVK Bio in the last few years has made it a global leader in the CRO market. With the strength of its management and leadership, we believe that the company is on its way to become a dominant force in the life science industry."

GVK Bio will use the funds to: expand capacity in drug discovery services, build a state-of-the-art campus in Hyderabad on a 25-acre site, provide new service offerings in pre-clinical and clinical space and pursue growth opportunities through mergers and acquisitions.

BS

Singapore builds clinical capability

PROVIDING a critical bridge between basic science and clinical medicine to strengthen Singapore's overall translational and clinical research capabilities as part of phase II of the Biomedical Sciences Initiative, the Institute of Medical Biology (IMB) was declared open.

Taking a disease-centric approach, IMB focuses on strategic research in critical human disease areas such as heart disease, cancer, genetic diseases, regeneration after tissue damage, and degenerative diseases like parkinson's and diabetes. The institute undertakes basic research directed towards clinical problems to open the way for doctors to explore and apply new therapeutic strategies or cures for diseases. Conversely, it brings disease-oriented problems from the bedside upstream onto the bench in order to gain a better understanding of the diseases and discover possible ways to treat them.

With the opening of IMB, A*STAR now has seven biomedical research institutes and five research consortia that provide both the basic scientific capabilities and the translational and research capabilities to bring research from "bench to bedside" to impact public health and grow the biomedical sector.

Arana ART621 in phase II trials

FOLLOWING successful completion of a phase I study of ART621 (anti-TNF domain-based antibody), Arana Therapeutics, an Australian biotechnology company will conduct a three-month phase IIa dose-finding study in psoriasis patients ahead of a phase II study in rheumatoid arthritis.

The psoriasis study, to be conducted in Australia, is expected to commence in first quarter of 2008 and the phase II rheumatoid arthritis program is planned to start in third quarter 2008.

Arana has also completed pharmacokinetic analysis of data from the phase I trial of ART621. The data indicate that ART621 has a half-life of approximately 14 days in volunteers following subcutaneous administration. These data suggest that, although ART621 is approximately half the size of conventional antibodies, it remains in the blood stream for at least as long as currently marketed anti-TNF antibody products.

Sosei begins SD118 phase I study

SOSEI, a Japanese biopharmaceutical company, announced its collaborative project SD118, which is under development for the treatment of neuropathic pain, has commenced a multiple dose ascending phase I study and the initial single ascending dose phase I study to explore higher doses has been extended.

SD118 is being jointly developed with NeuroDiscovery and its subsidiary NeuroSolutions under collaboration. The latest study is a double blind, placebo controlled, multiple dose, sequential group, dose escalation trial in healthy male volunteers to assess the safety, tolerability and pharmacokinetic profile of SD118 administered as an oral capsule. The study, involving some 36 subjects in 4 cohorts, is being conducted in a single center in the UK under a CTA (Clinical Trial Authorization) regulatory approval.

Biota phase II trials for flu drug begins

MELBOURNE based Biota Holdings Limited, responsible for the development of zanamivir (Relenza), has announced the commencement of phase II clinical trials of a new treatment for influenza. Japanese drug giant Daiichi Sankyo, which co-owns the drug, is carrying out the trials in the northern hemisphere influenza season.

The compound, CS8958, is an inhaled long acting neuraminidase inhibitor (LANI). Neuraminidase enables influenza viruses to spread from infected cells, but LANI drugs block its activity and so stop the infection from spreading.

CS8958 offers higher potency and a lower dose than currently available products. It also has consumer advantages over existing inhaled and oral therapies, with the potential for once-only treatment and once weekly doses to provide protection from influenza. This compares with twice-daily treatments required by existing therapies.

Two trials, one in Japan and the other elsewhere in Asia, will test the effectiveness of the new drug in adult patients who have naturally acquired influenza A or B. Double blind trials will examine the safety and efficacy of CS8958 and assist in selecting the best doses for treating influenza.

BS

'Collaborative business model is the next level'

GVK Bio, one of India's leading CRO, is making aggressive plans to move to the next level and emerge as a global player. On the anvil are plans to acquire businesses to add competencies, and an organization-wide cultural shift that is needed to push the company to next level

Interview
Mr Manni Kantipudi, President, GVK Bio

HYDERABAD-headquartered GVK Biosciences figures in the top tier of contract services providers in India. Offering a highly integrated platform of research services across pharma R&D value chain, the company counts 15 of the top 20 global pharma majors among its customers and there is no let-up in its fast paced growth. Set up in 2001, GVK Bio had a strong last quarter and has been growing rapidly in FY 2006-07. Moving ahead, the company aims to be a one-stop-shop to all large pharma and biotech outsourcing.

The company is now building on its strengths, to emerge as a global player. On the anvil are plans to acquire businesses to add competencies, and an organization-wide cultural shift that is needed to push the company to next level. Led by its President, Mr Manni Kantipudi, who took charge in mid-2007, the company is forging ahead towards the new goal. In an exclusive interview with *BioSpectrum*, Kantipudi shares how it is all coming together for GVK Bio and what the company is doing to make the most of opportunities that the market is throwing-up.

Q *What are the strengths of GVK Bio?*

GVK Bio is a part of the $1 billion GVK group, known for its diversified interests in infrastructure, services and manufacturing. Founded by Mr Sanjay Reddy the company has been built on a solid foundation. Today, we offer the whole gamut of integrated services for drug discovery and development value chain with about 1,300 people spread across three locations in India—Hyderabad, Chennai and Gurgaon. However, we have no intention of striking it out on our own, even when we have the infrastructure that allows us to do that. We have a clear focus. We are a services company with an integrated service offering for large pharma and biotech outsourcing.

GVK Bio as a company is financially strong. Mr Reddy is a great entrepreneur. He has been building a great foundation for the company from day one. Our Chairman Mr D S Brar brings in 30 years of industry and Ranbaxy experience to GVK. I bring the experience of setting up Intel India, which has demonstrated scale. All put together we have great experience in IT, generics and business acumen between the three of us. And that is a strength we will be building upon. I intend to integrate a lot more IT in the business at GVK.

The company has five main divisions—informatics, chemistry, biology, clinical research and clinical pharmacology. Though chemistry is our biggest division employing 900 people we have strengths that we are leveraging across all divisions. In the next five years, GVK Bio will emerge as a globally recognized leader in life sciences.

Q *How has the business model evolved since inception?*

We are maturing with the industry. We have an exclusive relationship with Wyeth Pharmaceuticals where we have set up a dedicated facility with 200 people for Wyeth. The nature of the relationship is collaborative. The next level for us is collaborative customer-relationships. We have all the components of drug discovery chain and are ready for partnership/ collaborative discovery model.

Our relationship with Wyeth where we got the contract after competing with 100 CROs globally; our joint venture with INC Research which materialized in 2007; and the manufacturing scale up capabilities at our sister concern Innogent are all geared towards coming together to provide value to customer. We know—how to scale up. We are currently talking to five companies to get into collaborative research with them.

Our position is very clear. We want to excel in the services and that is how we want to create customer satisfaction. We are willing to help companies produce a drug. These days, companies are under tremendous pressure and are getting into collaborative drug development to shorten development cycle time. While the mechanics of the deal will vary from case-to-case but the point is we have the infrastructure and resources, and we can take their work forward. We can add a certain risk component of our own and work out a win-win deal. We intend to manage this risk through a portfolio approach by capping it at a certain percentage.

Q *What would be high growth areas for you?*

Chemistry, of course, is a high growth area. It is also our largest operation. With 900 people it generates about 70 percent of the revenue. It is a high growth area because it is fairly easy to outsource chemistry as it is labor intensive and the cost savings are clearly visible.

However, all the areas of the company are doing well and we expect our clinical pharmacology business to take-off in a big way in the near future. This service is tailored for the generics companies. There is a huge business opportunities in this area between 2008-2010. A number of domestic generics players are competing in the space, globally. All this bodes well for us.

Q *What are the competencies you are looking at adding to the company?*

I am not satisfied growing organically. So, we are certainly looking at acquisitions in the US or Europe. The strategy is to add pre-clinical toxicology and safety studies offering to our value chain.

Also, my vision is to set up a "virtual team". It will be a small team. This will be assembled on the basis of projects that we have. And these teams will come together and get disbanded as and when needed depending on the projects.

Another paradigm shift that I am working towards in the company is—product thinking. Though collaborative research is a service but the thinking behind it has to be outcome-based, product-based.

Year 2008 will also see us consolidate our operations. The company has grown so fast that a number of inefficiencies have crept in the system. These are being addressed by consolidating operations. The recent infusion of over $25 million (Rs 100 crore) by Sequoia Capital will help us execute this consolidation, integrating our operations.

"Companies are under tremendous pressure and are getting into collaborative drug development to shorten development cycle time. While the mechanics of the deal will vary from case-to-case but the point is we have the infrastructure and resources and we can take their work forward"

The Sequoia Capital infusion brought a lot to the table. They have tremendous experience in the pharma outsourcing corridor between US and India. They are well networked in the industry and bring with them the skill to hedge against currency fluctuations and so on. This will help the company in being competitive and give it an edge leading to a systematic scale up to market demands that we will have to face when we go public. We do plan to go for an IPO in a three-to-four year horizon.

Q *Any industry issues that you would like to highlight?*

There is a need to have a strong industry body to represent CRO-industry related issues to the government in the country. Industry players should come together on that and I am thinking about taking an initiative on that front.

Nandita Singh *in Hyderabad* BS

SGS Life Science Services is a contract service organization offering clinical research and quality control services. It owns over 30 laboratories and offices as well as three clinical research units in Europe, Asia and the Americas. SGS has been providing integrated solutions from preclinical activities to phase I-IV trials, bioanalytical and QC testing for 30 years. It has state-of-the-art facilities including three phase-I units with 162 beds, four bioanalytical labs, and phase II-IV clinical trial management offices.

Mr Beat In-Albon, Executive Vice President, SGS Life Science Services, on his recent visit to Singapore, elaborates on the opportunities for the company in the Asia Pacific region. Some excerpts:

'We see huge potential for QC and testing in Asian market'

Interview

Mr Beat In-Albon, Executive VP, SGS Life Science Services

Q *According to you, which of the two SGS Life Science's focus areas–clinical research and testing and quality control services – has more potential for the company in Asia Pacific region?*

We want to play a role in both the areas. In fact, I see these two bases as completely different bases with same mindset. In the area of quality control, we are more global with labs set up all over the world. And in clinical research area, we are more or less active in Europe – in late stage clinical trials, BA activities. Nevertheless, both areas are a big interest for SGS. We think we can develop these two areas in the region.

Q *With established players already present in the Asian market, do you see competition for SGS Life Sciences in the clinical research space?*

If you speak about the Asian market, I think the clinical research market will develop tremendously in future. Despite the fact that we are not yet active today, it doesn't mean that we shouldn't become active very soon. You know, I joined the organization very recently. We are working on organizational set up of the QC and CR business. The next step will be on the strategy work. In the area of clinical research, we will become more active in the Asian market because this is the market where growth is taking place.

Q *What about the opportunities in testing and quality control, there are only a few global players in the area, in Asian market?*

I think there are a lot of small players active in Asian market. Again, we are present in India, China, Singapore, Thailand, Taiwan and Hong Kong. We have been present in these countries only for a while. We did invest in these markets and created potential for future growth. We are in the process of ramping up the business for future growth. We see huge potential in the Asian market, especially in the local market such as Singapore with all biopharmaceutical companies that are expanding their operations. This has bright future and I am sure that we have better market opportunities.

Q *For SGS, what is the focus area in quality control and testing?*

We are testing vitamins, food supplements and even cosmetics as well. However, pharmaceuticals will be our focus area. At the same time, we shouldn't forget the other areas as well and wish to grab the other business options.

Q *How is the market for quality control and testing growing in the Asia Pacific region?*

It is difficult to answer. However, I can only say that the market for quality control and testing is certainly growing. In Singapore, all the big pharmaceutical companies are increasing their presence. This will tremendously support the growth of QC and testing in future. The market is also growing in China and India particularly in APIs and manufacturing of pharmaceutical drugs. This gives an indication for definite growth for the sector in the future. However, it is difficult to say as it depends on the behavior of the pharmaceutical companies' outsourcing their activities. If you have contacts with the global pharmas you can act upon them to increase their outsourcing activities. We are aiming for a growth rate of 20-25 percent from the region.

Narayan Kulkarni BS

Executive Director of the Genome Institute of Singapore, Dr Edison T Liu, is a physician-scientist who trained with Nobel Laureate, J Michael Bishop. Dr Liu has authored over 220 papers, reviews and book chapters. He sits on a number of scientific boards for biotechnology and pharmaceutical entities and is also the Executive Director for the Singapore Cancer Syndicate — a funding agency, the Singapore Tissue Network — the national tissue repository, and is Chairman of the Health Sciences Authority of Singapore, the country's FDA equivalent.

Dr Edison T Liu

Innovative regulator

The Health Sciences Authority of Singapore

TALKING about government regulatory agencies is as interesting as watching grass grow. On face value, the topic is considered by most rational human beings as bland. So, when I say that one of the most important institutions in Singapore's advance in biomedicine is in the organization that regulates its blood supply and the availability and safety of drugs here, I expect eyes to roll with the exhaled sighs of disbelief. But indeed, this is true.

The institute I will be discussing, and for which I am the Chairman of Board, is the Health Sciences Authority (HSA)—the statutory board of Singapore's Ministry of Health formed in April 2001 that manages a collection of important health regulatory roles (*http://www.hsa.gov.sg/publish/hsaportal/en/home.html*). The HSA is charged with regulating which drugs and devices are allowed to be sold in Singapore (health product regulation), it runs the national blood bank and transfusion medicine services for the country, and it is the expert center for analyzing biological samples at crime scenes (forensic or national crime laboratory). So, HSA houses under one roof the equivalents of what are normally several agencies in other countries. In the US, the HSA would be equivalent to the Food & Drug Administration agency (FDA), the Red Cross (blood banking), and the Crime Scene Investigations (CSI) or the FBI crime laboratories.

The mission of the HSA is to wisely regulate health products, serve the administration of justice and secure the nation's blood supply, all towards the fundamental aim of safeguarding public health.

So why is this agency such a lynchpin for good public health and of biomedical innovation? A related question is why are quality regulatory agencies essential for the public good and national wealth? The answer is easily found in the economic sector where the regulation of the monetary and financial system is essential for advanced and competitive economies. The critical role of the Monetary Authority of Singapore, the Bank of China, the Federal Bank and the Securities Exchange Commission of the US to national prosperity and economic growth is uncontested. A more dire example is the recently reported disasters involving the Chinese drug regulatory agency the SFDA whose corrupt practices jeopardized the health of Chinese citizens and caused global product recalls costing billions of dollars. Some would say, equally problematic is over-regulation as has been seen in the Japanese Ministry of Health's ban on birth control pills until 1999. Over-regulation blocks access to key drugs, sometimes life saving medicines. Any process involving human transactions needs a fair set of rules and good referees. The alternative is distrust and chaos: progress stops.

Challenges of regulation

To be a government regulator is one of the most difficult jobs because there is no clear metric to determine success. Unlike business where positive cash flow is a simple single measure of success, or academia where the publication record is paramount, no one can specify simple performance targets for a regulator. How many products approved or rejected, or measuring the number of recalls are clearly inappropriate measures of goodness. Instead, a good regulator should be judged by three characteristics: efficiency, transparency or clarity, and righteousness. The first characteristic can easily be measured: what is the turn-around time for products to receive a de-

cision (not time to be approved). Transparency can be measured by: how clear a regulator's guidances are and the brevity of the rules book (the shorter the better). Righteousness is the hardest to measure, but is found in the respect of one's own governmental peers in the regulatory institution. For example, the US Supreme Court receives very high ratings from other governmental agencies.

The Singapore government has given the HSA a major legislative tool recently in the new Health Products Act. The Act's modular approach and mechanism to activate relevant clauses means that instead of a one-size-fits-all approach, the regulatory requirements can be tailored according to the degree of risk

In this fast moving environment spurred by heightened expectations by Singapore's citizens and government, the HSA has recognized that it cannot function in a business-as-usual or traditional mode. The challenge for the HSA is how to regulate the same number of products that another sovereign nation like the US regulates but with 1/100th the human resources of the US FDA. So, what are some of the solutions?

The Health Sciences Authority of Singapore

First, one must regulate with intelligence. This means that whenever possible, for drugs already examined carefully in key index regulatory agencies (like the US FDA, the Australian TGA, and the European Union's EMEA) HSA will expedite its review and not reinvent the wheel. The HSA concentrates on those drugs that have no regulatory history, and those with unique properties such as medicines with significantly different effects across ethnic groups.

Though these may be difficult aims to achieve given that HSA is and will always be a small agency when compared to large agencies like the US FDA. But these can be achieved if there is (a) clarity about HSA's regulatory philosophy and operations, (b) international networking and benchmarking to add value in fundamental regulatory activities, (c) organizational innovation with a focus on efficiency, and (d) intelligent and appropriate resourcing in manpower and financing.

Regulatory innovation

While HSA must adhere to international regulatory standards, it cannot simply follow the operational and organizational plans used in larger countries. Instead, HSA seeks to take advantage of the compactness of Singapore and the presence of mature networking systems to enhance its surveillance and enforcement capabilities.

The Singapore government has given the HSA a major legislative tool recently in the new Health Products Act (*http://statutes.agc.gov.sg/non_version/cgi-bin/cgi_legdisp.pl?actno=2007-ACT-15-N&doctitle=HEALTH%20PRODUCTS%20ACT%202007%0A&date=latest&method=part&sl=1*). The Act's modular approach and mechanism to activate relevant clauses means that instead of a one-size-fits-all approach, the regulatory requirements can be tailored according to the degree of risk. At the same time, the Act provides the necessary flexibility making it simpler to fine-tune the regulatory regime for different products over time. This is important in order to accommodate new discoveries that will come into the market in future.

In another on-going example, the National Healthcare Group (NHG) which covers almost one-half of the country's public health care delivery has a system that automatically prompts physicians to input information on unusual side effects of drugs (or commonly called adverse drug effects), but then passes this information to HSA's Pharmacovigilance Unit. This effectively means that HSA is able to receive 100 percent of adverse event records from NHG institutions in a secure manner. In this manner, HSA can pick up key adverse events more efficiently and effectively than its developed country counterparts.

At the end of the day, there is no perfect model for a health regulator to adopt. But the HSA aims to be innovative and flexible, always acting with integrity and continually seeking efficiency. In so doing, it has a high likelihood of making a positive impact not only on the health and safety of Singaporeans but also, as a model of an effective regulator, on world public health.

BS

2008
Year of the Entrepreneur

INSPIRED by the opportunities that exist in the life sciences industry at this point of time *BioSpectrum* has named year 2008 as "Year of the Entrepreneur". Beginning with the first issue of the year we will bring you a series profiling prominent entrepreneurs from the Asia Pacific region. The first in the series has three hot and happening companies from Singapore. We talk to the CEOs of MerLion Pharmaceuticals, S*BIO and CordLife to find out where they are leading their organizations in 2008 and beyond

Singapore's Enterprising 3

(*L-R*) Steven Fang, CEO, CordLife, Dr Tony Buss, President and CEO, MerLion Pharmaceuticals, Dr Jan-Anders Karlsson, CEO, S*BIO

2008 Year of the Entrepreneur

On course to become APAC's largest cord blood banking facility

MR STEVEN Fang, CEO, CordLife has to his credit negotiating the merger with Cytomatrix that led to establishing of CordLife Limited (previously known as CyGenics). His work experience includes stints at Sterling Withthrop, Baxter and Becton Dickinson, with business development assignments in Malaysia, Korea, Taiwan, Singapore, Vietnam and the Philippines. He shares with *BioSpectrum* the journey so far and what he is looking ahead to. Over to Mr Fang:

Mr Steven Fang, CEO, CordLife

ACHIEVEMENTS

The first and foremost is relocating the Singapore facility to the new and larger facility. Second important milestone for us is regional expansion, with the launch of Jakarta facility. On financial front, the cord blood banking business revenue saw year-on-year increase including revenues from the client's annual storage fees. By end of September 2007, we had more than 11,000 cord blood units stored in our banks. The other major achievement is restructuring of CordLife Limited. After restructuring, Cytomatrix, which holds the patented technologies, is now a wholly owned subsidiary of CordLife.

The company

CordLife, a division of CordLife Limited, a healthcare company listed in Australia collects, processes and stores cord blood stem cells, which may later become potential source material for life saving treatments. Its laboratory in Singapore where the company stores cord blood units is the first and only AABB (American Association of Blood Banks) accredited private cord blood banking facility in South and Southeast Asia. The Ministry of Health in Singapore also licensed it.

LOOKING AHEAD

You will see significant amount of investments in brand building and creating awareness programs for the services, we provide in the coming months in India and Indonesia.

India and Indonesia will take our major focus in the coming years—particularly India market. The facility in India is set to be operational early this year. It will be the most advanced facility of its kind in India and one of the largest facilities in Asia. We have plans to open up 30 offices spread across India. We are opening up collection centers in Indonesia as well. These undertakings require huge investments and management bandwidth. At present, the company has about 100 people. We are looking at doubling the headcount by next year.

Australia is relatively small market in terms of awareness and is highly price sensitive. The market is limited as the competition level is high. We are looking at consolidation of business opportunities in Australia. At the same time, a strong branding exercise is underway to position us well in the medical community there in Australia.

We are consolidating business opportunities in Australia and exploring options in Malaysia, Vietnam and China. Our Singapore and Hong Kong operations are profitable. We want to build the company to be the largest cord blood banking facility in the region.

FUNDING GROWTH

If we look backwards, we have raised quite a good amount of funds. The company has strong cash reserve in excess of $ 8.5 million (AUS $10 million). As on date, we have invested in the range of $20-$25 million (AUS $25-30 million) in setting up facilities in the region. The revenue for the year ending June 30, 2007 from cord blood banking services was $4,749,812.29 (AUS $5,517,000) as compared to $3,098,767.95 (AUS $3,597,000). This is an increase of 53 percent.

The business model of the company provides not only the upfront revenue but also regular annual revenue. It is also important to note that, we have zero percent defaults year-on-year. We expect a significant growth in the coming three-to-five year span in volumes as well as revenue.

2008
Year of the Entrepreneur

Natural product-based drug discovery leader

DR TONY Buss is the President and CEO of MerLion Pharmaceuticals. He has held senior research and management positions with major pharmaceutical and agrochemical firms, including a seven-year stint with Pfizer, six years with Schering AG (both in the UK and Germany) and 13 years with GlaxoSmith-Kline. He joined the Center for Natural Product Research, Singapore, in 2000 as the head of center, before its incorporation as MerLion Pharmaceuticals in 2002. In a chat with *BioSpectrum* Dr Buss shares the company's achievements and plans for 2008. Over to Dr Buss:

ACHIEVEMENTS

One of the key achievements in 2007 was completing the integration of two companies that we acquired in 2006. We acquired Combinature Biopharm, a Berlin-based company, primarily driven by the fact that they had drug development expertise, we were interested in and to augment our discovery capabilities as we were beginning to move from discovery to clinics processes. In addition, we acquired a Swiss company called Athelas. We worked with that company in a collaborative discovery partnership. Their normal screening technology interested us. Instead of conventional approach to discover antibiotics to kill pathogenic organisms, Athelas has the technology targeted at bacterial variance to disarm the pathogens. We acquired them essentially to get the technology.

Between 2006 and 2007, we transferred that technology—that was already proven in vivo and in proof of concept—to Singapore. The acquisition of both the companies was completed in 2007.

Also, in 2007, we successfully applied to the Swiss authorities to commence clinical evaluation of antibiotics called Finafloxacin that was in licensed from Bayer. It belongs to the fluoroquinolone class of antibiotics and it is different from other marketed quinolones.

The important thing for us is that we gained regulatory approval to commence phase I clinical valuation for our antibiotic in August 2007 and those trials are almost complete with final dose of multiple dosing arm in healthy volunteers. The trials are going very well. We are planning to start clinical evaluation on patients on two indications in 2008.

Dr Tony Buss, President & CEO, MerLion Pharmaceuticals

LOOKING AHEAD

In 2008, we are planning for phase II trials with Finafloxicin in patients with dyspepsia initially and we will test for Finafloxicin's efficacy. As it belongs to fluoroquinolone class, it can be used for other infections as well. It is systematically available and has activity in other broad spectrum of positive and gram negative organisms.

The unique feature of this is that unlike any other marketed fluoroquinolone, its activity gets better at lower pH. Most quinolones are best in certain alkalines in nature. However, our quinolone works better in acidic conditions that may be the reason, why it is most effective in animal model. We want to explore the efficacy of Finafloxicin in treating patients with urinary tract infection (UTI) next year.

FUNDING GROWTH

In 2006, we raised $30 million in Series B funding as a private venture financing round. Now, we are planning to raise a similar amount of money in 2008. We have just begun preparing towards that. The number of existing investors indicated their interest in participating in the new C series of funding as well. However, we are also keen to attract at least one new investor.

The company

MerLion Pharmaceuticals is a privately held international drug discovery and development company headquartered in Singapore. MerLion's activities are focused on the clinical development of its portfolio of novel antibiotics and the discovery of new drug candidates from the world's most diverse natural products sample collection.

Dr Jan Anders Karlsson, CEO, S*BIO

The making of a fully-integrated oncology focused company

DR JAN-Anders Karlsson, who joined S*Bio as the CEO in January 2005, has extensive experience in the pharmaceutical industry, especially in the drug discovery area. Before joining S*BIO, Dr Karlsson was the Executive Vice President, Global Research of Bayer Pharma, where he was a member of the executive management committee and responsible for the company's global drug discovery organization. He shares with *BioSpectrum*, S*Bio's achievements in 2007 and plans for 2008. Over to Dr Karlsson:

2008 Year of the Entrepreneur

ACHIEVEMENTS

Our most important achievements include identifying two proprietary compounds developed in our labs about which we are very excited. Now, the first compound SB939 is in clinical trials. We are currently conducting phase I clinical trials for SB939 in Canada and Singapore.

We are also delighted about our Flt3-CDK inhibitor, SB1317. The data clearly demonstrates the strength and diversity of S*BIO's pipeline and validate our target-driven approach in developing "best-in-class" and "first-in-class" drugs."

The setting up of the USA operation in 2007 was a deliberate strategy to establish an excellent access to key opinion leaders in the US. At present it is a small operation. In the next couple of years, we will have at least 10 people working there in the clinical development side. However, much depends on the progress of the compounds, which entered the clinical trials. This will also give us a platform to further develop our operations and presence in the US market. The Bay area is good for us since it is a major hub for biotech and has excellent academic and clinical centers.

LOOKING AHEAD

We hope to take the compound—SB939 to phase II clinical trials by second half of the next year. We are planning to start phase I studies for SB1518 in the first half of next year. At the same time, we are also working on other compounds like mTOR and PDK1. We have not yet identified the final candidates. We hope there will be excitement in 2008 too.

We are looking at working with partners. Since oncology is very niche area, we might need the help of big players for marketing, once our products hit the market. A lot of discussions are on.

FUNDING GROWTH

We are looking at raising $30 million in the B round of funding. This will close by the end of Q1 2008. We hope to add new foreign venture capital investors. We raised in excess of $50 million in the first round of financing that we used, since the establishment of the company in 2000. Since, this was the first biotech company in Singapore; we invested a quite a lot in setting up buildings, infrastructure and buying equipments.

Narayan Kulkarni *in Singapore* BS

The company

Established in 2000 as a joint venture between the Singapore Economic Development Board Investments and Chiron Corporation, S*BIO is Singapore's first fully integrated drug discovery company.

This privately-held biotech company focused on the research and clinical development of novel targeted small molecule drugs for the treatment of cancer with leading programs around histone deacetylases (HDAC) and kinases. S*BIO's lead candidate, SB939, has entered the clinic in Q2 of 2007 and is currently conducting a dose-escalation phase I clinical study to evaluate the safety and tolerability of SB939 in patients with either solid or hematological tumors. It recently announced that a second compound, SB1518, would enter the clinic in H1 of 2008 and a third compound, SB1317, is in pre-clinical development.

The company also opened its office in Mountain View, California, to expand clinical development capabilities and competencies.

Mark Ravera is a principal of Strategic Pharma Consulting Group, which provides advisory services to both emerging market and western biopharmaceutical companies. This work makes him a frequent visitor to Asia. His industry experience of more than 20 years includes large pharmaceutical R&D, biotechnology start-ups, and Wall Street investment analysis.

Mark Ravera

Virtual R&D, Eli Lilly shows the way

Is Eli Lilly changing from being a fully-integrated pharmaceutical company into a company with virtual R&D? More importantly, is Lilly leading the way for other global pharmaceutical companies to follow, and what are the implications for Asian life sciences companies?

THE global pharmaceutical companies continue to face the dual challenges of patent expirations and an apparent lack of new blockbuster drugs in the pipeline (at least, a lack of blockbusters that don't get recalled or have onerous warning labels added after launch). Their investors are pushing the companies to improve both their near-term operational performances and their longer-term growth potentials. We can be confident that pressure is building in boardrooms across the industry.

Many companies have been looking to Asia to cut costs and possibly improve productivity. But perhaps none of the global pharmaceutical companies have been as aggressive as Eli Lilly in this regard.

Over the past two years, Lilly has struck no fewer than nine deals with Asian companies for drug target discovery, lead identification & optimization, drug development, API production and new molecule in-licensing. In terms of investment, all of these deals (should they be successful over several years) could cost Lilly hundreds of millions of dollars in upfront and milestone payments; but the financial and commercial upsides resulting from such success would be worth the price.

Lilly is certainly not alone among big pharmaceutical companies, as all of them have shifted portions of their R&D operations to Asia over the past several years. But it is important to note that many of these efforts remain within the "legal walls" of the parent company. Novartis, GlaxoSmithKline and AstraZeneca are setting up or expanding wholly-owned drug discovery and development centers in Asia. In contrast, Lilly is outsourcing much of its Asian R&D efforts.

At first glance, it is easy to assume that Lilly is outsourcing this work to cut costs and improve operating margins – that certainly was my first thought. But the company is not cutting costs on the R&D line of their income statement. Their overall R&D budget, which stands at just over $3 billion for 2007, has grown over 40 percent since 2001. The company is also proud of the fact that, at over 20 percent of corporate revenues, it is spending a larger percentage of sales on R&D than any of its global pharmaceutical competitors. No, this is certainly not a pure cost cutting effort.

Like most other multinational pharmaceutical companies, Lilly is under considerable pressure to replace revenues from current products that will be going off patent. Starting in 2011, major drugs including Zyprexa, Humalog, Gemzar and Cymbalta will lose their patents, which means that Lilly needs new products to replace over half of their current revenue in a relatively short time span. The recent clinical setback for prasugrel, a potential blockbuster cardiovascular drug, only added to the pressure.

It appears that Lilly's Asian strategy is less about cost

Eli Lilly: Asian Deals

Partner	Deal Size & Comments
India	
Suven/ August 2006	Details not disclosed; Lilly to pay up-front and milestone payments. **Comment:** Pre-clinical studies to identify oral molecules that will modulate G-protein coupled receptors for CNS indications. Initial agreement for 18 months.
Jubilant Organosys/ May 2006	Details not disclosed, but Jubilant eligible for milestones. **Comment:** Five-year drug discovery agreement.
Tata Consultancy Services/ November 2006	Estimated at $30 – 35 million. **Comment:** Clinical Data Management, Statistical Analysis and Medical Writing Services.
Nicholas Piramal/ January 2007	Successful development triggers call-back payment from Lilly, up to $100 million in milestones and sales royalties. **Comment:** Nicholas responsible for development of group of Lilly molecules through phase II.
Glenmark/ October 2007	$45 million upfront and $215 million in development and sales milestones; also sales royalties. Additional milestones of up to $90 million for other indications. **Comment:** License of drug portfolio with lead compound in early phase II development. Glenmark has co-promotion in the US and marketing rights in RoW countries.
China	
Hutchison MediPharma/ August 2007	Upfront payment; annual R&D support fees; milestones of $20-$30 million per drug candidate; sales royalties. **Comment:** Drug discovery and development in oncology and inflammation, using Hutchison's library of herbal compounds. Hutchinson has the right to any drug candidates that Lilly declines.
Hisun/ August 2005	Terms not disclosed **Comment:** API production of capreomycin.
ChemExplore/ October 2007	Terms not disclosed **Comment:** ChemExplore has an exclusive agreement to provide synthetic chemistry services to Lilly.
BioVeda China	Lilly has made a $10 million investment through their Asian venture investment group. **Comment:** BioVeda China makes venture investments in Chinese life sciences companies.

cutting than it is about risk cutting. Through a combination of in-licensing, outsourcing, venture investing and partnering, Lilly is attempting to make the best of their R&D budget while looking at as broad a cross-section of potential new drug sources as possible.

Eli Lilly may be the leader among the multinational pharmaceutical companies in a new wave of R&D virtualization. If other companies follow Lilly's lead, then there are several implications for Asian life science companies:

- There will be an increased demand by the big pharmaceutical companies for partners who can add value to the drug development process in a timely, high-quality and cost-effective way.
- This increased demand will result in increased demands by the Asian partners for highly-skilled, experienced people. As such people are already in short supply in Asia, increased demand will result in higher salary demands and therefore greater costs for Asian partner companies.
- Partners will be "encouraged" to share in more of the risk. While Lilly has some agreements that are fee-for-service deals, a closer look at their drug discovery/development deals show that the partners are making sizable investments themselves in these programs. The financial rewards (which could be quite large) will come only after successful development. These partners, including their investors, must be willing to accept this high risk/reward scenario.

So is Lilly fundamentally different from its peers in regard to outsourcing significant amounts of R&D to Asian companies, or is it simply ahead of the curve? Big pharma is notoriously conservative in their business practices, which has not served the industry well in recent years. One only has to look at the difficult changes that Merck's R&D went through when it became apparent that their "we can do it all in-house" strategy was not working. I think that the answer to this question will take some time to become apparent. Lilly's efforts are different from outsourcing manufacturing, for which one can quickly and easily see a long-term financial benefit. Lilly is not outsourcing manufacturing, it is outsourcing risk – and by its very nature, risk is difficult to quantify. Unfortunately, we may need to wait 10 years to get a clear verdict on their strategy.

BS

Ready for translational medicine age

The National Taiwan University College of Medicine tackles the challenge of expeditiously moving basic research findings from bench to bedside

Mr TERRY Guo, 57, founder of Hon Hai Precision and the world's 142nd richest person with a personal fortune of $5.5 billion, recently donated $454.54 million to his alma mater National Taiwan University (NTU). Though the donation itself made big news for being the single largest donation to a university medical school ever, what was even bigger was his concern for people suffering from cancer and the need for early detection. He lost his wife to breast cancer in 2005 and earlier this year his brother died of Leukemia.

Guo's donation will be used to construct a cancer hospital, and advanced medical facilities such as a proton therapy center and other biomedical engineering projects.

Some background

In 1945, when Taiwan was returned to Mainland China after Japan—its occupier—lost the World War II, the local government took over the former Taihoku (Taipei) Imperial University and reorganized it into six faculties. One of the faculties was Faculty of Medicine. However, when Taiwan split from the Communist China in 1945, the former Japanese teaching system was replaced with the system set by the local government. To raise the standard of medical education, the one-year pre-medical course was increased to two years in 1949. Thus, the medical course, leading to the degree of Doctor of Medicine (Bachelor of Medicine before 1991), was started.

During the war, the buildings of the College of Medicine and its teaching hospital (National Taiwan University Hospital) were either completely or partly damaged by air raids. Most of the facilities were out of order. In 1951, the United States Aid Missions to China began donating funds for the rehabilitation and reconstruction. Even other agencies such as The China Medical Board of New York, The American Bureau for Medical Advancements in China, and The World Health Organization extended their assistance to the college.

With substantial improvement of the laboratory and library facilities, and with the recommendations of the American consultants, the curriculum for medical students was reorganized, and the teaching methods were changed. The number of hours for lectures was reduced, while the time allotted to laboratory exercises and bed-side teaching was increased. The so-called "Block System" and "Clerkship" were adopted in 1945. To meet the urgent needs of Taiwan, the schools of allied health sciences were established. These schools have been sharing most of the teaching staff and facilities of the college.

Present scenario

The National Taiwan University College of Medicine (NTUCM) now has seven schools. The School of Medicine that consists of 28 departments, offers a seven-year medical program; it includes two years of pre-medical courses, two years of basic medicine,

two years of clinical medicine and one year of rotating internship. The School of Dentistry offers a six-year course. The courses of the School of Pharmacy, Nursing, Clinical Laboratory Sciences and Medical Biotechnology, Physical Therapy and Occupational Therapy are all of four-year duration and lead to a Bachelor's degree.

Prof Pan-Chyr Yang, Dean, College of Medicine, National Taiwan University informs that the university has 367 full-time faculty members, including three

academician member of the Academia Sinica. There are about 1,900 undergraduate students and 1,300 graduate students.

The School of Medicine has 10 graduate institutes—Anatomy and Cell Biology, Biochemistry and Molecular Biology, Microbiology, Immunology, Physiology, Pharmacology, Pathology, Toxicology, Molecular Medicine, and Clinical Medicine—which accept graduate students and confer Masters and PhD degrees. The school curriculum is arranged to provide students with necessary opportunities for acquiring knowledge of basic medical sciences, clinical medicine and psychosocial medicine.

According to Prof Yang, the NTUCM has established the Office for Medical Research and Development in 1996 in order to integrate and make efficient use of research resources among the College of Medicine, National Taiwan University Hospital and the College of Public Health. The office has come up with guidelines to share instruments and resources, to integrate basic and clinical medical researches, to support junior researchers, to supervise research activities, to encourage research publications and to administer all research related affairs. The NTUCM has established four research centers to help students.

The NTUCM has added Medical Informatics course to the core curriculum for medical students in 1994. It also has Laboratory Animal Center (LAC). Besides providing laboratory animals to the NTU and other universities, colleges, schools, and research organizations in Taiwan, the LAC provides information on rearing and breeding of animals, rears various types of laboratory animals, assists in various experiments, disease diagnosis of laboratory animals, health monitoring, microbiologic monitoring of water and feeds, environmental microbiologic monitoring and development of animal experiment techniques. It hopes to advance laboratory animal research and establish laboratory animal science data storage in the future.

The NTUCM will focus on disease-oriented genomic translation, with an emphasis on identifying mechanisms and genetic bases for diseases common in Taiwan including cancer and infectious diseases

The NTUCM proposes to set up "total resources service" incubation centers, to collaborate R&D centers, and industrial R&D centers. "With the participation and investments from private enterprises, we will build a first rate biomedical and biotechnology industrial cluster in Asia," states Prof Yang.

"The 21st century will be the age of translational medicine. Researchers and physicians will be expected to expeditiously move basic research findings from the bench to the bedside. The NTUCM seeks to provide support for research scientists, post-doctoral fellows, graduate students and laboratory space required for studies in biotechnology. Additional shared resources will be created," he adds.

The NTUCM will focus on disease-oriented genomic translation, with an emphasis on identifying mechanisms and genetic bases for diseases common in Taiwan including cancer and infectious diseases.

Narayan Kulkarni *recently in Taiwan* BS

Youngguk Cho has over 20 years of experience in the biotechnology industry. Currently, he works as Vice President of Korea Integrated Services (KIS). Founded in 2003, KIS (www.kis-co.com) is a Korean investment firm specialized in comprehensive financial and technology consulting and technology transfer in North America, East Asia and Israel. Mr Cho also contributes in the capacity of advisor to multiple government projects in the biotech industry in Korea.

Youngguk Cho

Korean companies

Ready to take-off

In the last three years Korean stock market saw a huge boom in the life sciences segment, including pharmaceutical and bio venture companies. In time, fruitful achievements will flow out of these companies

KOREAN bio industry is still in its take-off stage so there are not many companies showcasing sustained profitability. However, the entire industry has reached a market size of $4 billion-a-year and is growing at a constant year-on-year rate.

In the last three-four years in Korean stock market, there was a huge boom among the life science companies including pharmaceutical and bio venture companies.

There are several trends behind the current bio boom in Korea. One, of all bio companies listed in the country 50 percent were listed within last three-four years; two, the rise of the newly-listed bio companies brought re-appraisal of the undervalued pharmaceutical companies in the Korean stock market; three, government also initiated various support plans for bio companies, and four, global attention to stem cell, cell therapy, and anti-cancer drugs became a big issue in Korean bio industry as well and quite a few Korean companies got product approvals on these new type of drugs.

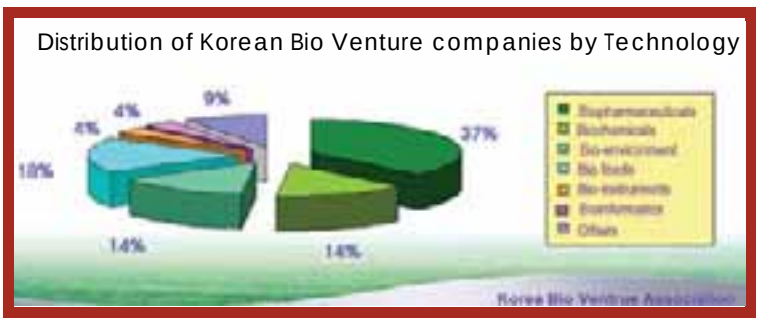
However, there are some challenges for Korean bio companies. Small to medium pharmaceutical companies have limitations on its marketing ability and product lineup while most bio venture companies don't have competitive core technologies such as genetic modification technology, fermentation process, chemical separation and purification technology, cell culture technology, stem cell separation and culture technology. Therefore, market competitiveness of Korean companies is weaker compared to the companies of advanced countries.

Korean bio industry has its strength in manufacturing and core technologies while it lags behind in new material development. According to the world biotech competitiveness analysis, Korea scored over 90 percent in manufacturing technologies such as fermentation, and 70 to 85 percent in core technologies such as gene regeneration, cell culture, and protein engineering. On the other hand, in new material development technologies such as new material screening technology and safety evaluation technology, Korea scored only 25 percent representing poor new drug development environment of Korea.

In other advanced countries, large pharmaceutical companies generally lead the bio industry. However, Korean bio industry is rather led by the bio venture boom that resulted in mushrooming of bio venture companies in the fields of new drug development, stem-cell research, cell therapy, gene therapy, bio diagnosis, and agri-bio. This venture boom successfully drew large companies' attention to the bio industry. Large companies started to step into the bio business by investing some amount of money in the bio venture companies, making partnership agreements with the venture companies, and even creating bio department within the corporation.

Bio venture companies can be further categorized into new drug development, bio food, medical device, bio infrastructure, diagnostics manufacturing, and agri-

Figure 1



bio segments. (See Figure 1)

Many Korean bio companies have been concentrating on new drug development. However, due to the relatively small investment scale, most of the companies have only progressed from the stage of preliminary study, preclinical, to phase one. While stem cell business including gene therapy, cell therapy, and cord blood stem cell takes a huge part of the Korean bio industry with 40 plus companies in related businesses.

Crystal Genomics is one of the leading companies in new drug development. The company focuses on efficient and accurate determination of chemical and protein structure, and rapid generation and optimization of novel drug leads, enabling efficient and productive discovery of novel leads and drug development candidates. The company uses the lock and key model of drug action structure (structural-based drug development method).

Several companies are in cell therapy business including Binex and Creagen using dendritic cells and NK bio using natural killer cells. Viromed is in gene therapy business and RNL bio is in stem cell research and natural material screening business. Sewon Cellontech is focusing on regenerative medical practices providing Cartilage Cell Implantation. Quite a few of aforementioned companies have gained the first market approval of their products after finishing phase two clinical trial and started selling their products in the market this year. The market size will rapidly grow with more products coming out next year. Cell therapy has several advantages in Korean bio market. Korean cell therapy technology is competitive as compared to any other leading country, there is less clinical trial time requested, cell therapy arouse little side effect, and market entry is relatively low because most indications of cell therapy fall into the category of first market approval with a condition to sell the product while processing phase three clinical trial.

In medical diagnostics reagents field, there are gene diagnosis and protein diagnosis companies. For example, a Kosdaq listed company SD is specialized in use of immunoassay. Seegene has a lot of good items in genetic diagnostics based on their noble platform technology. Seegene's technology has a great potential to advance as a world-class technology in the near future.

Agri-bio business was formerly focused in the fertilizer additive, veterinarian medicine, and microorganism fertilizer and feed. Nowadays, the focus has moved to the organic business such as prevention of epidemics using natural enemies. Though agri-bio business is still not mature in Korea, there is a huge potential to grow if the government is determined to expand Agri-bio business and local governments nourish new business opportunities in the field.

Many companies were founded in bio-infrastructure business including reagent, device, and gene. However, only one of each category supports and leads the field. Daesung has been producing antibiotics, antibacterials, anthelminthics, nutrition, and feed additives, Bioneer provides total genomic research solutions ranging from reagents to instruments used in molecular biology, Macrogen provides gene creation and analysis services, Seolinbio provides research tools, and Orientbio supplies guinea pigs for trial sites. Bio infrastructure business has not got much profitability. However, the business has a very independent character because those products and services are essential to most of the bio companies ranging from pharmaceutical, bio-food, to agri-bio field.

Bio-food business forms a huge segment of the Korean bio industry. Over half of the bio-food companies are in research and development of new drug. The R&D of new drug development takes too long with no profit. Therefore, those companies sell health-food related products based on their core technologies and items in order to sustain the business while developing new drugs. CellBiotech, for example, develops lactic acid bacteria and anti-microbial peptides to be used as ingredients for major food companies and BT-Gin supplies the highest quality Saponin of Ginseng to health food companies by enzyme engineering the regular Saponin.

Most Korean bio companies are in the initial stages. In time, there will be some fruitful achievements from these new-drug developing companies, and the bio food companies will soon start to develop new drugs based on their accumulated technology and production know-how.

BS

Siemens launches next gen Interventional Imaging Systems

SIEMENS Medical Solutions, the medical solutions part of Germany's diversified Siemens group, has unveiled its next generation of interventional imaging systems that offer versatility, enhanced image quality and streamline workflow across an array of clinical environments, from body and neurointerventional radiology suites to operating rooms and hybrid rooms.

The versatility of the Artis zee family is exemplified by the new Artis zee-go, which features a multi-axis C-arm that employs robotic technology to extend imaging capabilities through virtually unrestricted C-arm positioning. This results in advanced cross-sectional imaging via its positioning flexibility, which is not achievable with traditional C-arm systems. The Artis zeego makes it possible for the position of the isocenter to be adjusted according to the procedural needs or the height of the physician, which is particularly beneficial to a physician during lengthy procedures while wearing a heavy lead-shielded apron.

Ran Tamsulosin approved in Canada

INDIA-based pharma major Ranbaxy Laboratories has received Canadian approval to manufacture and market Tamsulosin Hydrochloride Capsules.

This product is used for the treatment of Benign Prostatic Hyperplasia (BPH). The total market for both generic and brand Tamsulosin Hydrochloride Capsules in Canada is over $20 million.

Bio-Rad introduces in2it A1C analyzer in the market

BIO-RAD Laboratories, a manufacturer and distributor of life science research and clinical diagnostic products, announced the launch of the in2it analyzer for the "point-of-care" market. The in2it analyzer measures A1C, a well-established indicator of a diabetic patient's glucose control, and offers healthcare professionals greater efficiency and convenience by providing laboratory-accurate A1C test results—while the patient waits.

Designed for simplicity, convenience, and speed in near-patient testing, the in2it A1C analyzer is small, portable, and fully automated, delivering results in minutes from a patient sample.

Luminex FlexmiR Select enhances miRNA analysis

LUMINEX has launched FlexmiR Select, a new microRNA (miRNA) assay designed to allow researchers to further advance understanding and enhance the analysis of miRNAs. The latest addition to Luminex's FlexmiR line of products, FlexmiR Select allows researchers to create customized miRNA panels for more efficient and focused miRNA analysis.

Until now, miRNA expression studies have been conducted on a global scale resulting in unnecessary data overload. Extensive expression studies have repeatedly shown that miRNA expression is specific to various experimental systems including tissues and cellular pathways. Application-specific subsets of miRNAs, which usually consist of fewer than 50 miRNAs, can be used to analyze larger numbers of samples to further investigate or validate potential miRNA markers.

The FlexmiR Human and FlexmiR Mouse/Rat panels give researchers the ability to measure the expression of miRNA sequences from the public miRBase database. FlexmiR Select allows researchers to configure customized miRNA panels for their specific needs. FlexmiR Select provides the flexibility to mix and match upto 50 different miRNA probes in a single well.

BS

'In Asia Pacific we expect a

JAPAN'S leading manufacturer of analytical instruments and medical equipments, Shimadzu's analytical and measuring instrument division is its largest in terms of revenues. The sector accounts for 57 percent of its business followed by aircraft and industrial equipment, which accounts for 22 percent and medical systems account for 19 percent. Its chromatographs and mass spectrometers have received good response from the customers. On the sidelines of "Asia Pharma Summit" organized by Shimadzu Asia Pacific in Singapore, *BioSpectrum* spoke to Mr Prem Anand, Business Manager, Shimadzu Asia Pacific, Mr Senya Imamichi, Deputy Managing Director, Shimadzu Analytical India and Mr Tsuguo Kishida, Managing Director, Shimadzu Asia Pacific, about the opportunities and their plans of growth in life sciences in Asia Pacific region. Excerpts from the interview:

(From L-R): Mr Senya Imamichi, Deputy Managing Director, Shimadzu Analytical India, Mr Tsuguo Kishida, MD & Mr Prem Anand, Business Manager, Shimadzu APAC, Singapore

Interview
Shimadzu APAC team

Q *What factors led to Shimadzu's success in life sciences space in the Asia Pacific region?*

Mr Prem Anand: Shimadzu is an innovative technology provider. We have a long history and experience of understanding and fulfilling the requirements of the industry in analytical instrumentations space. I think in chromatography we are one of the first to release the GC with integrator, which is widely accepted by industries even today.

We have sold more than 15,000 systems of Prominence HPLC since its launch in late 2004. Shimadzu is the first to launch the truly integrated HPLC – LC-2010 systems for the pharma industry, and now it has become an industry standard. And in the Asia Pacific region, I would say Shimadzu safely is one of the top three suppliers' of analytical instrumentations to the pharmaceutical and life sciences and other related industries. If you ask the factors for success of Shimadzu, it's the long history of Shimadzu as we have been in the business since 1875. Our experience in analytical instrumentations has been accumulated over many years.

From the market point of view, we should not forget that Asia has emerged as the new epicenter for

BioNews

Rockeby Pepp to sell in Hong Kong, Macau

SINGAPORE-based Rockeby Biomed announced that it has signed a memorandum of understanding with DKSH Hong Kong for the latter to market and sell Pepp in China's Special Administrative Regions of Hong Kong and Macau.

DKSH will be Rockeby's exclusive sales and marketing partner for Pepp in the two SARs for an initial period of three years with an extension option for three years pending an ongoing market survey.

Directors say DKSH will use its marketing muscle and local market knowledge to promote and sell Pepp in the most appropriate channels. Rockeby will support DKSH by providing product training to the sales and support staff, literature and materials and product samples.

Pepp is a natural enzyme-based health supplement containing alcohol dehydrogenase, manufactured from a bio-fermentation process. It has been clinically proven to be able to reduce alcohol levels and hangover symptoms.

growth rate of 15 percent'

drug development and manufacturing with excellent opportunities and possibilities. Strong government back-up and maturing analytical technologies are making more companies cross regional barriers and become world players in the pharma market. This is another factor that contributes to our life science success in the region.

Q *As a front runner in offering need-based products to customers, what next the researchers in life sciences can look forward to from Shimadzu in the near future?*

Mr Senya Imamichi: Shimadzu is a leading manufacturer not only of analytical instruments but also of medical equipment. The new life science technology created by combining the technologies of medical instruments and analytical instruments will enable the development of new drugs and new clinical test methods that were impossible earlier.

As a manufacturer of diagnostic PET scanners in Japan we have developed a small- animal –PET scanner that supports drug discovery and already started selling in Japan. In future, these scanners can play a major role in pharmacology, pharmacokinetics and the evaluation of receptor occupancy.

In addition to providing the basic instruments used in the life sciences areas, we are continually striving to provide more effective up-to-date analytical technologies. The MALDI-TOFMS, microchip electrophoresis, ultra fast LC, and MS microscope technologies are expected to fulfill important roles in the respective fields of protein analysis, DNA and RNA analysis, the ultrahigh-speed analysis of pharmaceutical products, and molecular imaging.

Q *How do you perceive life sciences industry in growth potential as compared to the other industries you cater to? Can you share the growth plans for life sciences division?*

Mr Tsuguo Kishida: The growth of the life science sector is more compared to any other industries. In the Asia Pacific region we are looking at a growth rate of over 15 percent in the next three years. Currently, the Asia Pacific region's total revenue is about $100 million and we are looking at increasing this number to $150 million in the coming three years. The pharma and life science sectors contribute to about 50 percent of our total turnover. To achieve this growth we will integrate different operations. At the same time we also employ more professionals with life sciences background to work with our distributors and customers.

> "Currently, the Asia Pacific region's total revenue is about $100 million and we are looking at increasing this number to $150 million in the coming three years"

Q *Considering the growing activities in life sciences space in Asia Pacific region, which countries according to you provide a better market of growth for Shimadzu?*

Mr Tsuguo Kishida: India provides a lot of opportunities for us to grow in life sciences area followed by Singapore and Vietnam.

Narayan Kulkarni BS

Millipore, Novozymes team-up for CellPrime

MILLIPORE Corporation and Novozymes have announced an agreement to develop, market, and sell new, animal-free cell culture supplements for biopharmaceutical manufacturing.

The new products, to be marketed under the brand name CellPrime, will be manufactured by Novozymes and sold through Millipore's sales organization. The alliance expands the existing relationship between Millipore and Novozymes and will initially focus on developing recombinant human albumin and recombinant human transferrin.

According to the company, the CellPrime products are designed to reduce risk and ease regulatory concerns for biopharmaceutical manufacturers. Additionally, these products will help to improve the consistency and productivity of customers' industrial cell culture processes.

Mr Peter Rosholm, Vice President of Novozymes Biopharma said, "The collaboration leverages the strengths of both companies."

BioNews

Integrating research, policy & practice

The George Institute of International Health

IN DECEMBER 2007, the George Institute of International Health expanded its Asia Pacific operations. Following close on the heels of the launch of its China office, earlier in May 2007, Sydney-headquartered not-for-profit health research organization, the George Institute, launched its India operations in Hyderabad.

A scientific evaluation of the disease burden, the risk factors and health interventions can go a long way in improving population health in the country.

—Prof Lalit Dandona
Senior Director, George Institute, India

According to Prof Lalit Dandona, Senior Director of the Institute who is heading the institute's India operations, the George Institute's objective in India is to identify solutions to major health problems through research, translation of research findings into policy and practice, and capacity building.

Given the scope of the project that the George Institute is tasked with globallly, in India, for George Institute there couldn't have been a partner better than ICMR. "It is a good start," said Prof Robyn Norton, Principal Director of the George Institute of International Health. Beginning from here, the institute will forge partnerships at various levels spanning academic institutions, non-govenmental organizations and international multi-lateral agencies to fulfill its commitment to bring long-term health benefits in India.

Moving ahead with this three-point agenda the institute has already delineated and rolled out various projects spanning a number of disease areas such as

Positive impact in China

Prof Yangfeng Wu, Director, Center for Evidence Based Medicine, Peking University Health Science Center

THE George Institute though officially launched in China in May 2007 has had operations in the country since 2004. Director of The George Institute, China, Prof Yangfeng Wu is also the Director of Center for Evidence Based Medicine at Peking University Health Science Center. A cardiovascular specialist, Prof. Wu is responsible for the scientific program in China, which includes all areas of non-communicable disease and injury. He elaborates on the successes the George Institute operations have had in China so far.

Q *What kind of impact the George Institute programs have had in China so far?*

So far, the programs conducted in The George Institute, China include population health research projects such as China Seatbelt Intervention, APCSC, Obesity in Asia Collaboration, clinical research projects such as ADVANCE, CSSS, SHIFT, and health system research projects such as CPACS, China QUEST, Health Policy Roundtables, and capacity building projects such as China Clinical Control of Dyslipidemia: Goal Attainment Initiative (CCCD: GAI).

All these projects have had great impact in China in each of their corresponding areas. For example, China Seatbelt Intervention increased drivers using seatbelt by about 14 percent after one year of intervention in Guangzhou, one of the biggest city in China and

cardiovascular, diabetes, malaria and tuberculosis. The institute that is affiliated to the University of Sydney also inked a Memorandum of Understanding (MoU) with India's apex policy-making body for public health—the Indian Council of Medical Research (ICMR). This tripartite agreement was signed by the representatives of the George Institute, University of Sydney and ICMR. The agreement is build around collaboration on key areas, apart from bringing in expertise and funds.

Evidence-based Population Health Models Project is one of the major projects initiated by the institute in India. The aim of this project is to provide answers to questions such as: how to improve population health and health systems in India. It is quite a shock to realize that the country with a billion-strong population hardly has any credible research on which it can model its health policy and health systems. "It is this health-planning gap that the George Institute is aiming to close. The impact that a project like this can have is not difficult to imagine—a scientific evaluation of the disease burden, the risk factors and health interventions can go a long way in improving population health in the country," elaborated Prof Dandona.

Currently, the institute has a ground presence of 150 people in India while globally the George Institute operates across 40 countries and is networked with over 400 hospitals.

Nandita Singh *in Hyderabad* BS

The George Institute of International Health

Originally known as The Institute of Internatinonal Health, the George Institute was established in 1999 in Sydney, Australia, in response to the growing worldwide burden of non-communicable diseases and injury, particularly in the Asia Pacific region. It was rechristened The George Institute for International Health in early 2004.

The Institute is a legally independent, not-for-profit institution. With operations in Australia, China, and now India the Institute has over 180 staff working on projects in over 40 countries with the collaboration of more than 400 hospitals and universities worldwide. It seeks to improve global health through undertaking high quality research, and applying this research to health policy and practice.

The institute has seven distinct research divisions including cardiovascular, critical care & trauma, health policy, injury & musculoskeletal, neurological & mental health, nutrition & lifestyle and renal. These divisions oversee large-scale international and regional projects supported by a diverse range of public and private funding.

the results and the measures of intervention used in the project have been highly promoted in China by the Ministry of Public Security. China Salt Substitute Study (CSSS) used randomized double-blind trial design and clearly demonstrated that systolic blood pressure was reduced by 5.4 mmHg on average in 600 rural cardiovascular high risk patients after one-year intervention. As a low cost, easy use, public health measure for prevention and control of hypertension and its related diseases, the study results have been published in *Journal of Hypertension* and presented in international and national conferences.

CPACS collected clinical data on diagnosis, treatment and prognosis of over 3,000 acute coronary syndrome patients from more than 50 hospitals in China and demonstrated an urgent need for intervention to promote the evidence-based clinical practice in China. The second phase of the project has been launched in this October 2007 to promote the use of the ACS guidelines by implementing clinical pathways and involves 74 hospitals. The Health Policy Roundtables brought together international and national expertise to discuss with Chinese government on the current major health policy issues including healthcare services, health insurance, drug regulations among others. CCCD: GAI is trying to identify the gaps between clinical practice and guidelines in the area of control of dyslipidemia and promoting the use of Chinese Guidelines on Prevention and Control of Dyslipidemia by training the doctors nationwide with the guidelines and solutions suggested by the expert committee.

Q *What kind of influence can this have on public health policies in China?*

These research projects have influence on public health policies in China in many ways. They generate high quality scientific evidences that can be used as a strong base for forming the public health policies; They promote the evidence-based policy making in China; They introduced international intellectual brains on policy making; and They also demonstrated the modern ways of how to promote public health policy making.

SciGen, NasVax onto intranasal Hep B vaccine

SINGAPORE'S SciGen has tied up with Israel's NasVax to jointly develop and commercialize a prophylactic intranasal Hepatitis B vaccine.

The companies said the product is under development, and will combine antigens for immunization against Hepatitis B produced by SciGen with Nasvax unique adjuvant technology, and it will be directed towards intranasal delivery.

NasVax has also granted SciGen an option to obtain a non-exclusive license—to be utilized within 12 months—to use NasVax technology to develop an intramuscular prophylactic Hepatitis B vaccine under conditions to be mutually determined in the future.

GSK, Oncomed to develop, market antibody therapeutics for cancer

BRITISH pharma giant GlaxoSmithKline (GSK) and OncoMed Pharmaceuticals will together discover, develop and market novel antibody therapeutics to target cancer stem cells that are believed to play a key role in the establishment, metastasis and recurrence of cancer. The alliance with GSK will be conducted through its Center of Excellence for External Drug Discovery (CEEDD).

The alliance leverages California, US-based OncoMed's expertise in the discovery and development of cancer stem cell antibody therapeutics and provides GSK with an option to license four product candidates directed at multiple cancer stem cell targets from OncoMed's broad library of monoclonal antibodies.

OncoMed has established a diverse pipeline of monoclonal antibodies to target multiple pathways important in the activity of cancer stem cells. The alliance with GSK includes OncoMed's lead antibody product candidate, OMP-21M18, a monoclonal antibody that is scheduled to enter the clinic in 2008.

S*BIO announces data on SB1518

S*BIO, a privately-held biotech company from Singapore has stated that its novel and selective JAK2 inhibitor SB1518 highlighted the therapeutic potential of SB1518 for the treatment of myeloproliferative disorders.

Dr Jan-Anders Karlsson, CEO of S*BIO said, "We are pleased to announce data for the first time on our JAK2 inhibitor, SB1518, and its potential treatment of myeloproliferative disorders, an area of great unmet medical need. We are currently conducting phase I clinical trials for SB939 in Canada and Singapore, and expect the initiation of phase I trials in various centers in the US. We are also delighted to report data on our Flt3-CDK inhibitor, SB1317. The data presented clearly demonstrates the strength and diversity of S*BIO's pipeline and validates our target-driven approach in developing "best-in-class" and "first-in-class" drugs."

End of human embryonic experimentation in sight

THERE is good news for stem cell researchers. A recent significant breakthrough in stem cell research using adult skin cells could end the use of live human embryos as research subjects.

Scientists from the University of Wisconsin announced that they have identified four genes that, when manipulated, can force a skin cell back to the embryonic stage, creating a potentially unlimited supply of stem cells without having to destroy human embryonic life. The discovery was made simultaneously with independent researchers in Japan.

In the wake of this discovery, the famed cloner of "Dolly the Sheep," Prof. Ian Wilmut, has abandoned and denounced the life-destructive therapeutic cloning in favor of the more ethical production of human stem cells through the use of adult skin cells, signaling the possible end to academic acceptance of live human embryonic experimentation.

BS

Dr Alastair Riddell is the new StemCell CEO

STEMCELL Sciences, a biotechnology company focused on the commercialization of stem cells and stem cell technologies in research and cell-based therapies has appointed Dr Alastair James Riddell as the CEO.

Dr Riddell has over a decade of experience at board level in building companies, raising funds and negotiating deals for both public and private companies. He replaces the company's founder, Dr Peter Mountford, who has taken the role of Chief Technology Officer while retaining the Executive Directorship.

Dr Jubo Liu joins Immtech China

IMMTECH Pharmaceuticals, a developer of drugs to treat infectious diseases, has hired Dr Jubo Liu as the Development Liaison for Clinical Trials in China. Dr Liu will coordinate and manage Immtech's clinical development program in China that currently includes the phase III clinical trial for pneumocystis pneumonia (PCP).

Dr Liu left Vertex Pharmaceuticals to join Immtech. A specialist in formulation strategies and drug discovery, he also worked as director of marketing and regulatory registration at Beijing Zhenlingxin Health Consulting in Beijing, and has coordinated clinical trials for both domestic and imported drugs in China.

Immtech has advanced clinical programs that include new treatments for Pneumocystis pneumonia (PCP), malaria, and trypanosomiasis (African sleeping sickness), and a well defined, expanding library of compounds targeting Hepatitis C, fungal infections, and bacterial infections.

Dr Stewart joins IMB, Singapore

Dr COLIN Stewart, from the National Cancer Institute (NCI) at Frederick, US, has joined the Institute of Medical Biology (IMB) under the Agency for Science, Technology and Research (A*STAR) as a Principal Investigator.

Dr Stewart, previously Chief of Laboratory for Cancer and Developmental Biology at the NCI, is a well-known cell and developmental biologist. At IMB, Dr Stewart will be heading a new Developmental and Regenerative Biology group and will study the molecular mechanisms underlying multiple tissue failure in genetic disorders caused by mutations in lamins and related proteins of the nuclear envelope. He will also be investigating how the organization of the cell nucleus plays a role in aging, obesity, and other degenerative diseases. In addition, his group will be deeply involved in studying the importance of nuclear architecture for embryonic and adult stem cell functions.

Dr Simon Parry & Dr Roberts receive HRC, NZ fellowships

THE Health Research Council of New Zealand has awarded Sir Charles Hercus Health Research Fellowships to Dr Simon Parry of the University of Auckland and Dr Rebecca Roberts of the University of Otago. They both get fellowships worth $0.5 million each to complete doctoral studies.

Dr Roberts

Dr Parry is investigating adiponectin, a hormone secreted by fat cells that is involved in the control of fat metabolism and insulin sensitivity while Dr Roberts' research is focused on the genetics of inflammatory bowel disease (IBD), specifically how genes may be able to predict both the risk of developing IBD and the response to drugs used to manage IBD.

The Sir Charles Hercus Health Research Fellowship was established by the HRC in 2002 as an advanced postdoctoral award that would enable outstanding emerging researchers to establish or re-establish their career in New Zealand. The award is named after Sir Charles Hercus in recognition of the contributions he made to biomedical, clinical and public health research during a distinguished 36-year career at the University of Otago, and his dedicated service to the Medical Research Council, now the HRC.

BS

India joins nano race

Bangalore Nano inauguration

The audience at the event

Bangalore Nano @ Bangalore, India

HAVING been at the forefront of information technology and biotechnology for more than a decade in India, Bangalore will now get the tag of being India's nanotechnology hub.

To begin with, Bangalore will house the country's first Nanotechnology Institute by 2009. This announcement was made when recently, the country's biotech and IT hub, Bangalore, recently played host to the first ever event on nanotechnology 'Bangalore Nano.'

The event was to highlight Bangalore as a Nanotechnology hub, much the same way as the annual Bangalore IT promotes Bangalore as an information technology hub and Bangalore Bio showcases Bangalore's prowess as a biotechnology powerhouse.

Speaking at the inaugural, Mr Rameshwar Thakur, the Governor of the State of Karnataka of which Bangalore is the capital said, "The state government has taken a lead in exploring priority areas of nanoscientific research and technology. A modest beginning was made last year and in the current fiscal (2007-08), budgetary support has been allocated to promote the nanotechnology."

Dr Patrice Millet, Program Officer, European Commission participating in the event as a country partner said, "Public funding in Europe has become the largest global investor into nanoscience and nanotechnology. International co-operation is increasing in this field for the development of nanotechnology worldwide. The funding from the European Commission is also going to increase for the research and development in the field of nanosciences and nanotechnology.

The event saw Prof C N R Rao, Chairman, Science Advisory Council to the Prime Minister and honorary president of the Jawaharlal Nehru Center for Advanced Scientific Research (JNCASR), being conferred the first Bangalore Nano National Award, in recognition of his achievements in the field of nanotechnology.

Prof Rao said, "We have not yet missed the nano bus, but must hurry. If we do not do it in two-to-three years, it might be too late. However, as of now, we can still join the nano race. Though India lags behind countries such as the US, China and Japan in nano science, the country could fuel this field by pumping enough investments and manpower."

Nanotechnology had already become an important scientific and research activity all over the world with applications in almost everything around us such as—physics, chemistry, healthcare, biotechnology, drug delivery systems and materials industry. The event was positioned as an event for researchers, students, policy makers and industrialists to interact and explore the possibilities of using nanotechnology.

There were sessions such as Research to Reality, ICT-Electronics and Lifestyle Products, Nano Process and Nano Engineering, Chemicals and Nano Materials, Nano biotechnology and Nano Medicines besides a RICH (Research Industry Collaboration Hub) session.

About 500 people—including scientists, industrialists, students and policy makers from within India and elsewhere participated in the event.

Sanjeev Jain *in Bangalore* BS

2nd International Conference in Cellular and Molecular Biology
January 05-07, 2008
New Delhi, India
URL: **http://www.jnu.ac.in/conference/SLSConf.pdf**

Utilizing Biomarkers to Determine Optimal Dose
January 14-15, 2008
The Inn At Penn, Philadelphia, PA
URL: **http://www.exlpharma.com**

Asia-Pacific Bioinformatics Conference 2008
January 14–17, 2008
Kyoto, Japan
URL: **http://sunflower.kuicr.kyoto-u.ac.jp/apbc2008/**

1st Pharm Tech IAPST International Conference
January 19-20, 2008
Kolkata, India
URL: **http://www.expresspharmaonline.com/20070930/market06.shtml**

Bangkok International Conference on Avian Influenza 2008: Integration from Knowledge to Control
January 23-25, 2008
The Dusit Thani, Bangkok, Thailand
Email: **AIconf2008@biotec.or.th**
URL: **www.biotec.or.th/AIconf2008**

Lab Automation 2008
January 27-30, 2008
Palms Spring Convention Center California
URL: **www.labautomation.org**

Arab Health 2008
January 28-31, 2008
Dubai, UAE
URL: **http://www.arabhealthonline.com/arab_health/Arab_Health_Congress.html**

BioAsia 2008
January 28–29, 2008
Tokyo, Japan
Email: **bioasia@bio.org**
URL: **http://bioasia.bio.org/opencms/bioasia/2008/**

Strategic Management of Clinical Research Hubs
January 29-30
Singapore
URL: **http://www.iqpc.com/sg/clinicalresearch**

Snapshot @ Bangalore Nano, India

Bangalore Nano, the first ever event on Nanotechnology in India was held from December 6-7, 2007 in Bangalore. About 500 people—including scientists, industrialists, students and policy makers from within India and elsewhere participated in the two-day event. The event had sessions such as Research to Reality, ICT, Electronics and Lifestyle Products, Nano Process and Nano Engineering, Chemicals and Nano materials, and Nano Biotechnology and Nano Medicine. The highlight of the event was announcement that Bangalore by 2009 will be home to India's first Nanotechnology Institute.

International Conference on Biotechnology 2008
February 6-8, 2008
Chennai, India
URL: http://www.vit.ac.in/incob2008.asp
BioAsia 2008
February 7–9, 2008
Hyderabad, India
URL: **http://www.bioasia.in**

BIO CEO & Investor Conference 2008
February 11–13, 2008
New York City, New York
URL: **http://ceo.bio.org/opencms/ceo/2008/index.jsp**

Nano Bio Expo 2008
February 13–15, 2008
Tokyo Big Sight, Japan
URL: **http://www.ics-inc.co.jp/nanobio/en/**

Tokyo Health Industry Show
February 27–29, 2008
Tokyo Big Sight, Japan
URL: **http://www.this.ne.jp/en/inner_yellow.html**

MEDICAL 2008
February, 27-29, 2008
Shanghai, China
Email: **topreput@hkabc.net**
URL: **www.toprepute.com.hk**

5th IFPMA Asian Regulatory Conference
March 11–13, 2008
Kuala Lumpur, Malaysia
URL: **http://www.ifpma.org/arc-2008/**

HospiMedica India 2008
March 14–16, 2008
Mumbai, India
URL: **http://www.messe-duesseldorf.de/uptodate/cipp/uptodate/pub/md_events,menu,main.ww_events.2006/lang,e**

MedChem India
March 18–19, 2008
Bangalore, India
Email: **paul.raggett@selectbiosciences.com**
URL: **http://www.selectbiosciences.com/conferences/MCI2008/**

BS

Cloned cats glow in dark

CATS have eyes that glow in the dark, but can an entire cat glow? South Korean scientists have made it possible by displaying two genetically modified cats that glow in the dark when exposed to ultraviolet light.

A team of scientists at Gyeongsang National University cloned the cats after manipulating a fluorescent protein gene to change the color of their skin. The two Turkish Angora cats—born in January and February— glow red when exposed to ultraviolet light.

According to the South Korean Science and Technology Ministry, it is the first that cats with RFP genes have been cloned. It said the cloning is significant because the technology could be used for treating human genetic diseases and could help reproduce rare animals such as cheetahs, leopards and tigers.

To clone the cats, Korean scientist Kong Il-Keun's team used skin cells of the mother and modified its genes to make them fluorescent using a virus, which was transplanted into the ova. The ova were then implanted into the womb of the cat. Four kittens were born but two died during birth.

The team that cloned the cats said this technology would help them decode mysteries of over 250 genetic diseases that affect humans and animals

Asia faces $1 trillion tuberculosis burden

$1 TRILLION, yes that's the burden that 11 Asian countries could end up taking over the next decade if they don't work on their anti-TB strategy, a World Bank study says.

The study also said that 22 countries with the world's highest numbers of TB cases could earn significantly more than they spend on TB diagnosis and treatment if they signed onto a global plan to sharply reduce the numbers of TB-related deaths. Highly affected African countries could gain up to nine times their investments in TB control. The study also warns about the need to step-up TB control worldwide with the growing emergence of multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) in Southern Africa, Eastern Europe and Central Asia.

Did you know?

Global ethanol fuel production more than doubled between 2002 and 2007, which is more than 90 percent of the total biofuel production, and in the same period biodiesel capacity also quadrupled, globally.

(*source: www.allafrica.com*)

FIGURE FACTS

Novartis is slashing 3,750 jobs to save **$1.6 billion** in annual costs by 2010.

Chinese pharmaceutical market will grow anywhere between 12-13 percent year-on-year to hit **$90 billion** in 2008. Beijing, Guangzhou and Shanghai accounted for 21 percent of pharma sales in China. (*Xinhua*)

India's stem cell market is growing at the rate of 15 percent annually and will be worth **$540 million** by the end of the decade, while the global stem cell market is expected to touch $20 billion mark.

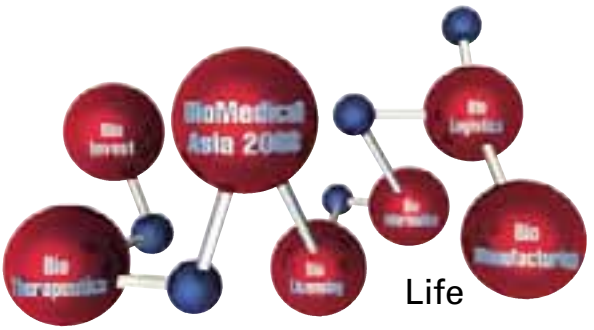
World Health Organization has **193** member countries.

British aid organization Oxfam says globally **2 billion** people lack access to essential medicines, and most of them live in poor countries.

BS

The largest and most comprehensive event of its kind where science meets business, investors meet new projects and start-ups, buyers meet sellers

BioMedical Asia 2008 SINGAPORE



14 – 17 April 2008, Suntec Singapore International Convention & Exhibition Centre

Asia's #1 premier biomedical industry convention

Diamond sponsor

invitrogen

Platinum sponsors

Exploit Technologies

sartorius stedim biotech

Gold sponsor

WORLD COURIER
A SERVICE NO ONE ELSE CAN DELIVER

Silver sponsors

ceva

NXP founded by Philips

QUINTILES

SIEMENS

Supported by

Agency for Science, Technology and Research

BioOne

EDB Singapore

Singapore Exhibition & Convention Bureau

Supported by

Uniquely Singapore
visitsingapore.com

KEYNOTE SPEAKER

Gordon Binder
Managing Director
Coastview Capital, USA
Founder & former CEO
Amgen Inc, USA

KEYNOTE SPEAKER

Philippe Kourilsky
Chair of Molecular Immunology
College de France, France
Former Director General,
Pasteur Institute, France

KEYNOTE SPEAKER

Ansbert Gadicke
Founder & General Partner
MPM Group, USA

In-Chull Kim
Chief Executive Officer
LG Life Sciences, Korea

Thomas Okarma
President and
Chief Executive Officer
Geron, USA

Melanie Lee
Executive Vice
President, R&D
UCB group, UK

Silviu Itseu
Founder and
Chief Scientific Advisor
Mesoblast Limited, Australia

Zhi Yang
Managing Partner
BioVeda China, China

BioMedical Asia 2008 **Fax (65) 6226 3264**

- ☐ I am interested in sponsorship opportunities. Please contact me.
- ☐ I wish to register for the conference. Please contact me.
- ☐ Please send me the conference brochure.

Media partner: BioSpectrum

Name: _____

Designation: _____

Organisation: _____

Address: _____

Tel: _____ Fax: _____ E-mail: _____

Created & delivered by:

terrapinn
B2B media

www.biomedicalasia.com