

Bangalore India Bio – June 02-04, 2010

S.NO	ARTICLE	Date	PUBLICATION
1	Biotech Investment Pays off	03-June-2010	The Times of India
2	Bangalore India Bio Kicks off	03-June-2010	Deccan Herald
3	Biotech Flexes its muscle	03-June-2010	DNA
4	Biotech sector likely to pierce \$5billion mark by fiscal end	03-June-2010	Financial Express
5	Biotech sector set to grow 20% to \$5bn	03-June-2010	Mint
6	Biotech swings past slump, eyes \$5bn-mark	03-June-2010	DNA
7	Clinical trials beckons India with a \$26 billion purse	03-June-2010	DNA
8	'It's not just a business, but a chance to help the poor'	03-June-2010	DNA
9	When will biotechnology in India be properly regulated?	03-June-2010	DNA
10	Quick diagnostics key to control pandemic	04-June-2010	DNA
11	Biosimilars hold big opportunity bigger hurdles	04-June-2010	DNA
12	Biosimilars to be next growth area for BT firms	04-June-2010	Business Standard
13	Lab-on-a-chip concept catching on	04-June-2010	The Times of India
14	Shift in parenting trends brings R&D tie-ups to the fore	04-June-2010	DNA

India's vaccine draws world attention

TIMES NEWS NETWORK

Bangalore: India's vaccine production and its vaccine innovation pipeline is drawing major global attention.

Pune-based Serum Institute's swine flu vaccine will hit the market in the next couple of weeks. According to Dr S D Ravetkar, senior director, Serum Institute of India, the future for innovations looks bright as more and products are manufactured in India and sold in the outside world. "India's entire landscape for vaccines and drugs is changing. The country is gearing to manufacture not just affordable medicines, but the best quality ones," he said.

Delhi-based biotech major Panacea Biotech is coming out with a vaccine for dengue and Japanese encephalitis in the next 5-6 years. "These are the vaccines with which India can enter the developed world including the US and Europe. The vaccines industry is now buoyant," said Rajesh Jain, joint MD, Panacea Biotech.

Last year the company had received a Rs 1,067 crore (about \$222.37 million) UNICEF contract for the supply of its Easy-Five (pentavalent vaccine). EasyFive is a liquid pentavalent vaccine that immunizes children against five dreadful diseases — diphtheria, tetanus, wholecell pertussis, hepatitis B and hemophilus influenza Type b — of early childhood.

Biotech investments pay off

Rashmi Shrikant & Anshul Dhamija | TNN

Bangalore: With India's biotechnology sector scaling the \$3 billion mark on a standalone basis and the \$4 billion mark including ancillary industries (data management and equipment manufacturing), the industry is in a buoyant mood. Hopes are that by the end of this financial year the industry would have crossed \$5 billion in revenues.

Though the years of 30% growth seem to be over for the industry, the fact that the sector successfully emerged out of the global economic turmoil has boosted the confidence of industry players.

"The biotech industry holds a lot of promise. As the pipeline of drugs of multinational companies is drying up, they are looking at India as the new Mecca for cash," says Viloo Morawala



An exhibitor explains the disposable bio-reactor system to visitors at Bangalore India Bio 2010

Patell, founder and MD of Avesthagen.

The industry rammed into speed breakers in 2007-08, when growth came down to 21% from the previous five years' average growth of over 30%. The trend continued in 2008-09, when it grew 18%, with revenues of Rs 12,137 crore. But 2009-10 saw the growth rates bounce back over 20%, and is expected to continue in this range over the next few years, say industry experts.

Public-private partnerships, industry-academia collaborations and government support are expected to steer the industry on to a steady and strong growth path. Global partnerships between Indian and foreign companies is said



Chief minister B S Yeddyurappa along with Katta Subramanya Naidu, minister of IT & BT, and Kiran Mazumdar-Shaw, chairperson of Karnataka Vision Group on Biotechnology, at the inauguration of Bangalore India Bio 2010 on Wednesday

Karnataka's 2009-10 scorecard

- ▶ The state saw 11 BT firms set up shop over the last one year, while the rest of India added 32 firms.
- ▶ The state attracted investments of Rs 1,500 crore in the last one year, including Rs 250 crore by Kemwell Biopharma, Rs 550 crore by Hindustan Petroleum for a proposed green R&D centre for clean energy, Rs 250 crore from Bangalore Helix and Rs 200 crore by Biocon.
- ▶ State to set up the Nutraceutical Park in Mysore.

Future road map

- ▶ Sector-specific biotechnology parks to be set up at Mysore, Mangalore, Dharwad and Bidar.
- ▶ A bio IT centre to be set up, which will help to cut the drug development process time by 30%.
- ▶ Government plans to set up a \$10-million bio venture fund.
- ▶ 10 biotech finishing schools to be set up. Letters of intent to have 2 finishing schools were handed to the Manipal Life Sciences Centre and Dayanand Sagar Institutions on Wednesday

to be another key growth driver. Some 800 odd bio-partnering meetings are taking place between Indian and foreign companies over the

three-day event India Bio.

Says Kiran Mazumdar-Shaw, CMD, Biocon, and chairperson of the Vision Group on Biotechnology in Karnataka, "I think the current mood is very positive and there is enough work coming India's way. Besides, the gestation period is over, and the investment the industry made in the past decade is beginning to pay off."

CHALLENGES

But the industry still has big challenges. "Our industry is very fragmented. We need to group together to bring a breakthrough drug to market," says Patell.

An investment banker with a biotech focused PE fund adds, "Indian companies still don't have the muscle and money to discover a drug and take it to market at a global level. That's why we are seeing buyouts happen like that of Piramal. It will take some more time for Indian companies to reach that scale."

Shaw sees finding employable and industry-ready manpower a challenge. The country's regulatory framework is a bone of contention. Says Shaw, "Today the patent rulings always favour the imitator. They don't protect the innovators enough. So today any company can say I'm going to copy this drug and I don't care about patents because our country needs cheap drugs."

IS IT STILL ADVANTAGE BANGALORE?

Though the biotech sector in Bangalore saw investments worth Rs 1,500 crore in the last 12 months, neighboring cities like Pune and Hyderabad are attracting biotech funding from global companies.

"Karnataka today is becoming extremely key in the emerging trends that we see in the biotech world globally," claimed Shaw in her inaugural address at India Bio, adding that the state has become a global hub for clinical data management. However some in the industry feel that Bangalore is slowly losing its hold on the biotech space. This despite the fact that the state's exports in the sector stood at Rs 3,650 crore in 2009-10 and is expected to cross the \$1 billion mark by the end of 2010-11.

Says Patell, "In Andhra Pradesh, the government gives you land and says 'go get on with it'. Their approach is more business orientated, which is not quite the case in Bangalore."

Biotechnology conclave: Karnataka rolls out red carpet B'lore India Bio kicks off

BANGALORE: The tenth edition of Bangalore Bio, annual biotech conference in India, Bangalore India Bio 2010, was inaugurated by Chief Minister B S Yeddyurappa here, on Tuesday.

Yeddyurappa said "The year 2010 is very significant for the conference as we are celebrating the 10th anniversary of Bangalore Bio. The event has pan-India significance and the new name 'Bangalore India Bio' itself indicates the same."

Further, he said, the biotech sector in Karnataka enjoys comfortable position in terms of growth and revenues. The government has already announced several fiscal incentives and concessions for the sector in the 'Millennium Biotech Policy.' "We have also proposed a Bio-Venture fund of \$10 million and also plan to start 10 BT finishing schools to groom the industry ready biotech professionals."

The State government would set up biotech parks in Mysore, Mangalore, Dharwad and Bidar. Bio-cluster part of Bangalore Biotech Park would be developed in the PPP (Public Private Partnership) mode and the process of selecting the developer is in the final stage, he added.

Karnataka had added 11 BT firms over the 12 months while rest of India added 32 firms. The state attracted investments of Rs 1,500 crore in the last one year. The chief minister also handed over letter of intent to Manipal Institute of Life Science and Dayanada Sagar Institute to start Biotech finishing school.

Steady growth

Biocon CMD Kiran Mazumdar Shaw said the country's biotech industry is on its growth trajectory. In the financial year 2010 the revenue from biotech sector

was around \$3 billion and the ancillary industries registered revenue of around \$1 billion. She said the overall revenue from the sector was about Rs 18,500 crore which is about \$4 billion and expect to cross the \$5 billion mark soon.

Further, she said, climate change and clean energy were turning out to be huge opportunities for the sector. Karnataka constitutes 50 per cent of BT firms in India. Out of 380 BT companies in India, 198 are in Karnataka, she added.

DH News Service

C-DAC developing new technologies

Centre for Development of Advanced Computing (C-DAC) R&D organisation of Department of Information Technology (DIT), sees high end computing cutting drug discovery time, reports *DHNS* from Bangalore.

The bioinformatics group in C-DAC is developing technologies and applications that can reduce drug discovery time. The centre is also developing software which can help the data intensive clinical research work much simpler. CDAC Group Coordinator for Bioinformatics Rajendra Joshi said "We develop technologies to speed up genome analysis and molecular studies, primarily focused on Indian health issues." The bioinformatics division of CDAC has developed Genome Grid solution for sharing bioinformatics data from different sites to help in combining data at a single location.



SALUTING SUCCESS: Chief Minister B S Yeddyurappa presenting a memento to Karnataka Vision Group on Biotechnology Chairperson Kiran Mazumdar Shaw in Bangalore on Wednesday. Chief Secretary S V Ranganath is also present. *DH PHOTO*

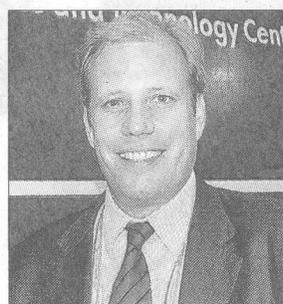
EU sets up €20 m business centre in India to boost ties

Cethan Kumar

BANGALORE: In an effort to help business and research houses, specially small and medium enterprises from European Union (EU) to enter India, the EU has set up a European Business & Technology Centre (EBTC) with an initial investment of €20 million.

The Centre will focus on developing new technologies in the areas of biotechnology, transport, energy and environment. Director Poul V Jensen told *Deccan Herald* that EBTC is an initiative which helps SMEs connect with local partners in India and overcome challenges they face in expanding into Indian markets.

"We are helping companies overcome market access issues



Poul V Jensen. *DH PHOTO*

and are particularly focused on business and research. Our task is to connect European firms with partners in India. Ultimately, EBTC - which has 16 consortium partners - will be self-sustainable," he added.

Besides trade facilitation, the centre is also an intelligence hub, producing reports and pro-

viding information to companies and is already in the process of developing sector-wise reports, he said.

Stating SMEs wanting to come to India need hand-holding he said EBTC helps by providing office space, contacts and information on the market, adding this can help lower the cost of market entry - which can be a barrier to SMEs expanding into India.

The centre has close-knit ties to EU member-state organisations and missions and is in the process of establishing formal partnerships with organisations like CII, Ficci and others in India. He said once the centre finds success in India the EU plans to replicate the project in other countries.

DH News Service

Biotech flexes its muscle

The three-day Bangalore India Bio 2010 began on Wednesday evoking a response surpassing the expectations of the organisers. The event was launched in a celebratory mood as the Indian biotech industry is on track to achieve a decade-old dream of crossing the \$5 billion mark in 2010-11

At least 750 delegates from 20 countries are participating in 20 programmes crammed into three days of the event. The biotech industry is on track to touch \$5 billion in 2010-11, a decade-old dream

The biotechnology sector records a revenue growth of \$4 billion (Rs18,500 crore) in 2009-10 — 52% revenue growth over the previous fiscal, says Kiran Mazumdar-Shaw, chairperson of Karnataka's vision group on biotechnology

Out of the 380 biotech firms in India, 198 are located in Karnataka, and 191 in Bangalore which accounts for 27% or \$810 million (Rs.3,888 crore), contributing \$750 million (Rs3,650 crore) in exports

With focus on biopharma, Bangalore India Bio 2010 receives 2,300 business requests on the first of the three-day mega event. This is 1,100 more than Bangalore Bio 2009



SMILES TO GO: Biocon chairperson Kiran Mazumdar-Shaw and British deputy high commissioner Richard Hyde (second right) inaugurate the Bangalore India Bio 2010, India's premier biotech event, in the city on Wednesday. The event will be on till Friday

Biotech sector likely to pierce \$5-billion mark by fiscal-end

fe Bureau

Bangalore, Jun 2: The domestic biotechnology sector, viewed as one of the top five biotech destinations globally, is likely to touch \$5-billion mark at the fiscal-end owing to robust growth in ancillary segments such as data and equipment management, said Kiran Mazumdar-Shaw, chairperson of the Vision Group for Biotechnology (Karnataka).

Inaugurating the Bangalore-India Bio 2010, Mazumdar-Shaw said that the industry had seen growth

at the rate of 20% in the fiscal 2009-10 to reach \$3 billion, while exponential growth in ancillary industries added to the figure to take it past \$4 billion.

"As against a decline to 18% in 2008-09, the bio-tech industry has grown remarkably well in 2009-10. You take into account clinical trial, data management, equipment management and other ancillary segments, the biotech sector touched \$4 billion over the past year and I would say that puts us well on track to achieve the target of reaching \$5 billion this year," said

Mazumdar-Shaw who is also the CMD of India's biggest biotech firm Biocon.

During 2008-09, the global financial crisis restricted the sector's growth to 18% as against a 34% year-on-year growth in 2007-08.

Ancillary segments had grown at close to 40% during the fiscal, while biotech segments like bio-pharma continued to be a major driver, followed by services and agri-biotech, which was expected to grow as a major contributor this year as well.

With a steady growth mo-

mentum gathering in biotech sector, Mazumdar-Shaw said that the industry was optimistic of doubling its stature in the coming years, aiming at reaching \$10 billion by the year 2020.

While bio-manufacturing, clinical development and service based offerings were seen as some of the key segments to drive growth, climate change and clean energy were also being viewed as huge opportunities for the Indian biotech sector, which presented great cost and man power advantages.

Biotech sector set to grow 20% to \$5 bn

By K. RAGHU

raghu.k@livemint.com

BANGALORE

India's biotechnology industry is expected to grow 20% this fiscal to \$5 billion (Rs23,600 crore) as the country becomes a low-cost research hub for global agricultural and pharmaceutical firms.

The nation's 380 biotechnology firms reported revenue of \$4 billion for fiscal 2010, said Kiran Mazumdar-Shaw, chairperson of the vision group on biotechnology for Karnataka. Of this, around \$1 billion was contributed by the equipment and ancillary segment of the industry.

Bangalore is home to half the biotechnology companies in the country.

"Having come a long way, now is the time to shift from western-centric models. India and China can play a lead role in the world in the areas of food security and healthcare," said Mazumdar-Shaw at the inaugural of the 10th edition of Bangalore India Bio, the annual biotechnology event of the state.

"New challenges, such as global warming, energy, health and food security offer huge opportunities for the biotech industry," she said.

Of the 32 new foreign firms that have invested in India in the past year, 11 are located in Bangalore, with an investment of Rs1,500 crore.

They include a Rs500 crore research unit for clean energy and biofuels from **Hindustan Petroleum Corp. Ltd** and a Rs250 crore contract manufacturing unit to make enzymes, proteins and DNA

vaccines by **Kemwell Pvt. Ltd** in collaboration with **Boehringer Ingelheim Pharmaceuticals Inc.**

"Our plant will be operational by next year," said Anurag Bagaria, vice-president at Kemwell.

Biocon Ltd, of which Mazumdar-Shaw is the chairperson and managing director, is investing Rs200 crore in a new facility to make drugs.

Clinical data management, drug discovery and low-cost product manufacturing are the advantages Indian firms enjoy in the global market.

"India has shown its competitiveness in the past two decades and now it is time to work towards R&D (research and development) leadership. We can achieve this by removing hierarchical bureaucratic and academic structures. From next year, India will produce about a million engineers and if we deploy them in the R&D projects even for few months, we can do wonders," said Samir Brahmachari, director general of Council of Scientific and Industrial Research (CSIR).

Of CSIR's 37 laboratories, India's largest public-funded research agency, about 10 are dedicated to biotechnology research.

CSIR has developed an enhanced *aswagandha*, the equivalent of Chinese ginseng, for farmers in six states, Brahmachari said, adding that biotechnology can play a key role in promoting inclusive growth.

Karnataka plans to set up sector-specific biotechnology parks in Mysore, Dharwad, Mangalore and Bidar, chief minister B.S. Yeddyurappa said.

BANGALORE INDIA BIO-2010 OFF TO A COLOURFUL START AS THE VERTICAL RECOUPS FROM THE 18% TUMBLE IN FY2008-09 TO POST 52% Y-O-Y IN THE PREVIOUS FISCAL

Biotech swings past slump, eyes \$5-bn mark



Maitreyee Boruah. BANGALORE

The celebratory mood was quite palpable at the 10th edition of Bangalore India Bio-2010, India's premier Biotech event, inaugurated on Wednesday, on achieving the growth rate dreamt ten years ago.

It seems global economic recession could not have any effect on biotechnology sector, as it recorded an estimated revenue growth of \$4 billion (Rs18,500 crore) in 2009-10, announced Kiran Mazumdar-Shaw, chairperson of Karnataka's Vision Group on Biotechnology at the inaugural session.

The revenue growth is a whopping 52% over the previous fiscal year.

"As against a decline of 18% in 2008-09, the biotech industry has grown remarkably well in 2009-10 and we are on track to achieve \$5 billion this fiscal (2010-11)," said Shaw, also the chairman and managing director of India's leading biotech firm Biocon.

While bio-pharma and agri-biotech, accounted for \$3 billion (Rs14,400 crore), the equipment and ancillary segments contributed about \$1 billion.

"Ten years back, we had dreamt of achieving a \$5 billion industry size, which we'll achieve by 2010-11," Shaw said.

"India has emerged as an attractive market for the global pharma sector, as evident from increasing investment flow into the country. We offer huge cost advantages with high value of services. Several countries want to build long lasting partnership with us," she added.

Around 700 delegates from 20 countries,

TIME TO WORK TOWARDS R&D LEADERSHIP

Elaborating on India's scientific achievements, Prof Samir K Brahmachari, director general of Council of Scientific and Industrial Research said India had shown her competitiveness in the past two decades and now it is time to work towards R&D leadership. "We can achieve this by removing hierarchical

bureaucratic and academic structures. From next year, India will produce about a million engineers and if we deploy them in the R&D projects even for a few months, we can do wonders," added Brahmachari, who is also the secretary, Department of Scientific and Industrial Research.

who are part of the three-day event, are hopeful of creating several business deals with the host country. The visiting delegates are mostly looking at fostering partnership with various Indian companies in biotech sector.

The event has been organised by the Department of Information Technology, Biotechnology and Science & Technology, Government of Karnataka, Vision Group on Biotechnology and MM Activ Sci-Tech Communications Co.

The focal theme of this year's biotech event is *Biotech For a Better Tomorrow*.

Inaugurating the three-day event, chief minister BS Yeddyurappa said the state was helping in the growth of the industry.

"The state government is continuously working towards the industry's needs. The Millennium Biotechnology Policy of 2001 has given many incentives and concessions. As a result, the state has accounted for \$810 million (26%) of India's biotech market of \$3 billion," said Yeddyurappa.

In order to produce employable and

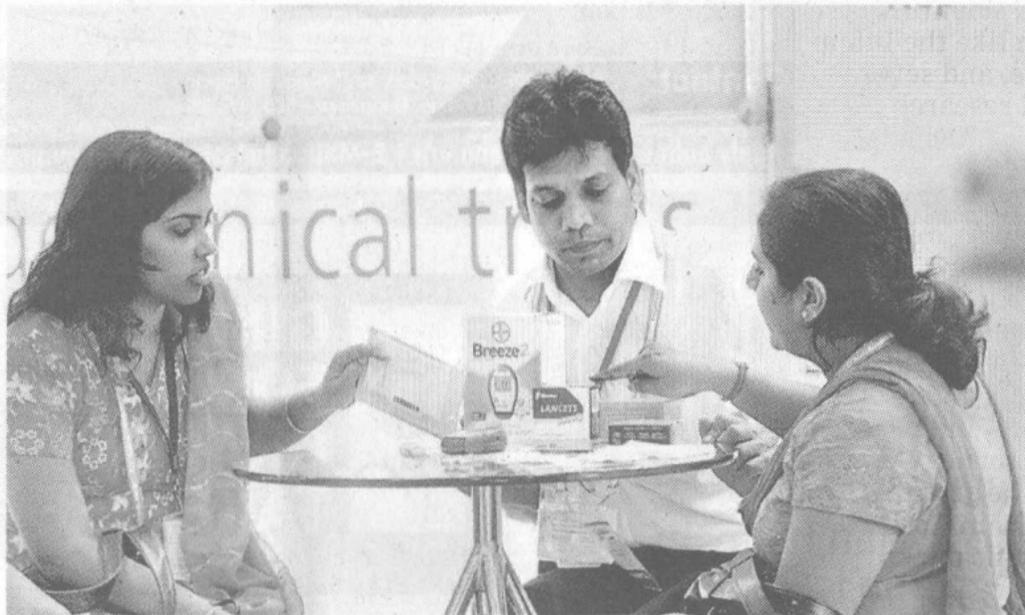
skilled manpower to the industry, the state government is encouraging biotech finishing schools, of which ten will come up this year. Government has also proposed to set up bio-venture fund of \$10 million. Sector specific Biotech Parks would be set up in Mysore, Mangalore, Dharwad and Bidar.

Over the years, Bangalore has truly emerged as the hub of biotech sector in the country. Out of the 380 biotech firms in India, 198 are located in Karnataka, and 191 in Bangalore, which accounted for 27% or \$810 million (Rs3,888 crore), with exports to the tune of \$750 million (Rs3,650 crore).

Richard Hyde, British Deputy Commissioner, said the UK was a very important partner for India, as it accounted for 20% of the biotech medicines of the world.

"Acting in accordance with the edition's theme of *Biotech For A Better Tomorrow*, the UK has signed for a \$160 million vaccine development scheme with India," said Hyde.

Clinical trials beckon India with a \$26 billion purse



MATTER OF CONCERN: Experts expressed their concern over the lack of research culture in Indian medical colleges and hospitals. They called for an interface between the academia and industry

THE NUMBER OF CLINICAL INVESTIGATORS IN INDIA IS TOO SMALL WHEN COMPARED TO OTHERS

Hemanth Kumar. BANGALORE

Experts and investors at the Bangalore India Bio-2010 on Wednesday made a strong plea for a strong interface between the academia and industry to enable the country to grab huge opportunities in Biotechnology research, especially in clinical trials.

Dr Moni Abraham Kuriakose from Narayana Hrudayalaya, participating in a panel discussion on the issue, said, "India has highly trained work force, world-class health facilities, 221 medical colleges and a huge cost advantage in clinical trials. But still, the potential has

not been fully utilised."

India has 50% to 75% cost advantage in clinical trials and "we have a great opportunity to bag a huge share of the \$26 billion clinical trials market in the world. India has just about 500 to 1,000 clinical investigators and it is too small, when compared with countries like the USA which has 50,000 of them. India is training about 1,000 clinical investigators each year and it should be ramped up to at least 10,000," he said.

Dr Kuriakose wanted the government and private sector to initiate measures to develop research culture in medical colleges and hospitals, and encourage research as a career.

Dr Ravi Kumar Banda, managing director of Xcyton Diagnostics Ltd, said "There are large gaps between the industry, academia and investor that need to be bridged. Institutes and research facilities should develop technology platforms or

proof of concept for a product to showcase to the industry. Most collaborations fail because of the way the academia approach the industry. Some of the academic institutions like the Indian Institute of Science have good infrastructure. But not even 20% of its potential is being used for research and development."

Prof Gayatri Saberwal, scientific officer, Institute of Bioinformatics and Applied Biotechnology (IBAB), said "75% of the students passed out from IBAB have been placed in premier organisations such as Biocon, BrickWood, IBM, etc. IBAB is a novel private academic institute of the Govt of Karnataka and ICICI Bank. One of the challenges faced by the institute is the funding scheme of the Central government."

Dr SR Rao, adviser, Department of Biotechnology under the Central government, said, "There is very little institutionalised relationship between indus-

try and universities and only about 1,500 projects have been funded so far. The barriers in linkages and partnership are lack of mutual trust and appreciation, lack of financial gains, lack of infrastructure facilities, lack of frame work and different norms of evaluation."

Dr Sunny Sharma, senior managing director (Asia), OrbiMed Advisors, India Pvt., Ltd., said, "The role of venture capital in life sciences is very much needed. Access of capital is important for research and development. What OrbiMed looks for are novel products and technology, technological breakthrough, strong management team, and growing market. Investors like OrbiMed can help in certain areas such as providing a long-term, value-added, strategic source of capital helping management achieve strategic, financial and operational objectives via participation at the board level."

TOP

k_hemanth@dnaindia.net



STRAIGHT TALK: If there is no inclusive growth, there is no meaning to the great achievements on the technology front

'It's not just biz, but a chance to help the poor'

Maitreyee Boruah. BANGALORE

For eminent Indian scientist Prof Samir K Brahmachari, Biotechnology is not only about business, but an opportunity to help 800 million poor people of the country.

"Biotechnology is not about business, but an opportunity to help poor population of the country by bringing them affordable healthcare facilities, sustainable energy and food security," said Brahmachari, director-general of Council of Scientific and Industrial Research (CSIR) on the first day of Bangalore India Bio-2010 on Wednesday.

Strongly espousing the cause of underprivileged section of the society, Brahmachari said that there was an urgent need to solve the problem of hunger and health-related issues.

"If people are healthy, and we can solve the problem of hunger the world over, bigger issues like terrorism would be take care of on its own. Biotechnology has the potential to solve these pertinent issues," added Brahmachari, who is also the secretary, Department of Scientific and Industrial Research (DSIR).

Out of its 37 laboratories, CSIR has 10 laboratories dedicated to biotechnology. These laboratories work to focus on CSIR 800, a programme focusing on the issues of 800 million people at the bottom of the pyramid in the country.

"If there is no inclusive growth, there is no meaning to the great achievements on the technology front," said the veteran scientist.

"CSIR has given an enhanced *Aswagandha* to the farmers of six Indian states. The biotech sector has lots of such opportunities to participate in India's inclusive growth."

Brahmachari's who has extensively worked in DNA and its structure, felt that India's young talent pool should be used effectively in the scientific field.

"From next year, India will produce about a million engineers and if we deploy them in the R&D projects even for a few months, we can do wonders. We need to empower the youths. We can achieve this by removing hierarchical bureaucratic and academic structures," said the scientist who has to his credit discovering two genes linked to bipolar disorder and schizophrenia.

When will biotechnology in India be properly regulated?

THE MINISTRIES OF HEALTH, S&T AND AGRICULTURE HAVE BEEN UNABLE TO REACH AN AGREEMENT ON NORMS

SELVAPRAKASH L



NEED OF THE HOUR: India produces 8% of the world's medicines. Experts feel there is need for uniform regulations in Europe and India

Nirad Mudur. BANGALORE

Who regulates research in biotechnology in India? Who takes care of discrepancies in drug pricing, genetic engineering in plants, or the safety of clinical trials? The answer, at present, is: Nobody. Different ministries at the Centre have still not arrived at a consensus on the nature of regulations needed in the area, and the functions that will fall within the jurisdiction of the proposed National Biotech Regulatory Authority (NBRA). A draft bill on the regulatory body lies in cold storage.

The delay affects bio-safety and a slew of other issues, many too complicated for a lay person to even understand. At the Bangalore India Bio-2010, discussions occurred around, significantly, the need for a fool-proof regulation of the emerging industry of 'biosimilars'.

The biosimilar is a term used to describe officially-approved new versions of innovator biopharmaceutical products after the patent of a similar older product has expired. Simply put, these are pharma products developed using the latest technology, including gene therapy. They speed up and

mimic a drug discovery method, to faster achieve a better, but similar, drug. "There have been differences between various union ministries and agencies concerned with health, science and technology, food and agriculture," an expert privy to the government's efforts to set up the authority, who also participated in the session, told *DNA* on condition of anonymity.

KK Tripathi, adviser and member-secretary of the review committee on genetic manipulation, union department of biotechnology, under the ministry of science and technology, admitted to *DNA* that fast-progressing technology had remained outside regulatory cover. The sheer pace of developments made legislation quickly obsolete, leaving it in a constant state of contention between different players.

The pace of technological advancement in the field also comes as a stumbling block in the formulation of guidelines for the regulatory authority. The absence of a regulatory authority, however, could pose problems that cannot even be properly anticipated, as legal loopholes could be abused and new and insufficiently researched pharma products could be introduced in the market.

IT'S A LONG PROCESS, ONE STILL TO BEGIN

SELVAPRAKASH L

So when can we expect to have a national-level biotech regulatory authority? KK Tripathi, adviser and member-secretary of the review committee on genetic manipulation, under the ministry of science and technology, did not know quite how long the setting up of the NBRA would take. "First, there needs to be a consensus. Then, we have to formulate the guidelines. After that, the bill will have to be put through discussion in Parliament. Public opinion on it should be sought too. All that takes a long time," he said.

At the meet on Wednesday, Martin Cox, a business development manager and faculty member in medical science at the Newcastle University, UK, in his presentation at the session on 'Regulatory issues for biopharma industry' highlighted the problems faced by regulatory bodies in his country, on account of the rapid advances in



technology. Tripathi said that India should learn from such experiences elsewhere in the world.

TOP

ONE OF THE PRIMARY GOALS FOR FUTURE IS TAILORING DRUG TREATMENT TO A PERSON'S GENETIC PROFILE, SUCH PERSONALISED MEDICINE HOLDS HOPES FOR CANCER PATIENTS

Quick diagnostics key to control pandemic

SELVAPRAKASH L



Soumita Majumdar and Maitreyee Boruah
BANGALORE

The year 2009 will be remembered for the deadly disease swine flu Influenza A (H1N1) which took the entire world by storm. India, including its tech hub Bangalore, too was not immune to the deadly virus, resulting in thousands of deaths.

Taking a closer look to deal with pandemic like H1N1 virus, experts across the country brainstormed at the ongoing three-day 10th edition of Bangalore India Bio-2010, India's premier Biotech event, on Thursday.

A more advanced diagnostic kit for H1N1 is on its way to the market. Defence Research and Development Organisation (DRDO) has developed the simplest kit for swine flu screening and the kit is now awaiting approval from Indian Council of Medical Research (ICMR).

"This kit will enable naked eye visualisation and identification of H1N1 virus. Trials have been done on this kit with samples sourced from centres including NIMHANS, Bangalore, SMS Medical College, Jaipur, and Post Graduate Institute of Medical Education and Research (PGI), Chandigarh. It has been inferred that diagnosis through this kit can be highly specific, simple, rapid and effective," said Dr PVL Rao, joint director and head, division of virology and bioprocess scale-up facility, Gwalior.

"ICMR has already appreciated this kit and soon after getting clearance from ICMR and the government, this kit will be introduced to the hospitals," he said.

DELEGATES EYE DEALS AS MEET ENDS TODAY

The three-day event will end on Friday. About 700 delegates from 20 countries, who are participating in the event, are hopeful of creating several business deals with the host country. The event has been organised by the department of information technology,

biotechnology and science and technology, Government of Karnataka, Vision Group on Biotechnology and MM Activ Sci-Tech Communications Co. The focal theme of this year's grand event is 'Biotech for a better tomorrow'.

The session titled 'Future of Diagnostics' looked deep into issues like how pandemic diseases could be managed by using quick, affordable and easy-to-use diagnostic solutions.

"The current system of diagnosis is time-consuming. The problem is that the time taken to move from presumptive/provisional stage to final diagnosis is quite long," said Chandrasekhar B Nair, founder director of Bigtec Private Limited, Bangalore.

"This is especially true for infectious diseases where there is a special need to diagnose quickly. For instance in H1N1 scenario, point of care (POC) diagnosis is required. The challenge lies in making laboratories go to the patient. An affordable and easy-to-use solution is the need of the hour," he said.

Talking about the solutions to deal with pandemic diseases, Nair said special solutions like lab-on-chip were the best way to tackle H1N1 virus.

"Such products need to be mass pro-

duced to make them affordable. They should be portable and faster but should be reliable," he said.

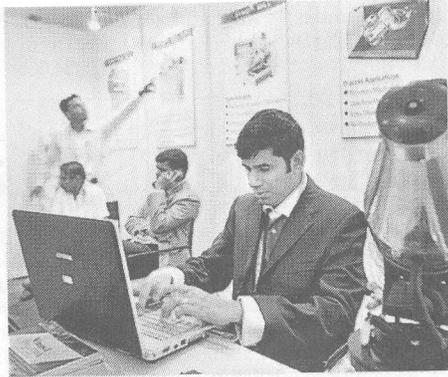
The session was chaired by Dr Shama Bhat, founder, chairman & MD, Bhat Bio-Tech India (P) Ltd, Bangalore.

Elaborating on the importance of pharmacogenomics, Shama Prasada K, of division of biotechnology, Manipal Life Sciences Centre, Manipal University, said it deals with identifying drug response on the genetic make-up of individuals to achieve a personalised treatment.

"One of the primary goals for future is to have personalised medicines. With pharmacogenomics, we are working on developing personalised medicines for ovarian, cervical, breast and oral cancer," he said.

Prof AQ Contractor of IIT Bombay spoke on the platform for low-cost electronic diagnostic systems. The issues discussed at length had direct and immediate implications to common people, who are mostly deprived of medical aid in time during the spread of pandemic diseases.

Publication	DNA
Edition	Bangalore
Date	June 03, 2010 p.04



NEW THEME: The focal theme of this year's event is 'Biotech for a better tomorrow'

Biosimilars hold big opportunity, bigger hurdles

Team DNA. BANGALORE

While biosimilars hold big opportunity amid hurdles, its competitive advantages will hinge on quality, cost, timelines, and regulated market access, an expert said.

'Biosimilars' is a term used to describe officially approved new versions of innovator biopharmaceutical products, following patent expiry.

Participating in a discussion on 'Successfully Negotiating the Biosimilars Landscape' at Bio India-2010, Dr KV Subramaniam, president and CEO, Reliance Life Sciences, said: "The global biosimilars opportunity is significant, valued at \$ 70 billion covering 25 products. An integrated biosimilars initiative requires several competencies working seamlessly across the value chain. Hence, competencies are required. Competitive advantages in biosimilars will hinge on quality, cost, timelines, and regulated market access."

"The technology hurdles, significant costs and regularity pathway in development markets are major challenges we face. The right talent and partnership play a key role in addressing challenges in biosimilars," he said.

"Reliance life science is building a research-led, diverse and integrated biotechnology business. They have five biosimilars in the semi-regulated market and 17 biosimilars under development. The biosimilars landscape is attractive but marked by several formidable challenges," he added.

Dr KK Tripathi, member secretary of the Review Committee on Genetic Manipulation, said: "Biopharmaceutical term can be used widely and is hardly defined by users over 4 million entries on Google, involves use of biotechnology and pharmaceutical compared to drugs. Biopharma is complex on how we think of, define, name and regulate these products. Biopharma industry is more than 25 years old and has 350 products in the market."

Dr Eric Grund, senior director, Biopharma Applications, GE Life Sciences, said: "As the regulatory pathway for biosimilars in Europe and US becomes clearer, manufacturing of these products still remain challenging. There is a pressure in increasing the efficiency and there are market uncertainties," he said.

Discoverer, 9th Floor
Te

d
Road, Bangalore – 560 066
30-2841 8780

TOP



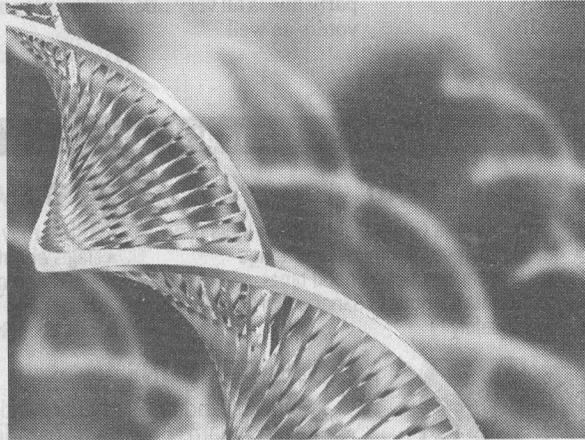
Publication	Business Standard
Edition	Bangalore
Date	June 04, 2010, p.07

Biosimilars to be next growth area for BT firms

DEBASIS MOHAPATRA
Bangalore, 3 June

Notwithstanding the regulatory hurdles for biosimilar drugs, these generic products in the biotechnology space are the next growth areas for biopharma companies in India. Biosimilars are copy cat products of patented biotechnology drugs with different process of development.

"Though peptides are driving the growth of our company as of now, biosimilars are definitely the next growth area for our company in near future," K V Subramaniam, president and CEO, Reliance Life Sciences, said. Reliance Life



The revenue loss to the pharma industry will be around \$78 billion due to a 'patent cliff' during 2009-14 period which will throw up new opportunities for biotechnology companies in the biosimilar space

Sciences, a subsidiary of Mukesh Ambani-led Reliance Group, has already launched four biosimilar drugs in the semi-regulated market.

"We will soon launch our fifth biosimilar with another 17 products being under development," he added. Biosimilars, otherwise the generic version of patented biotechnology drugs, will have a market size of \$70 billion by 2013. This space is set to expand with a number of biopharma products going off-patent by 2014.

"The revenue loss to the pharma industry will be around \$78 billion due to a 'patent cliff' during 2009-14 period which will throw up new opportunities for biotechnology com-

panies in the biosimilar space," Neelima Khairatkar-Joshi, senior vice-president of Glenmark Research Centre, said.

Glenmark, which has a sound pipeline of new molecules, is also bullish on the biosimilar vertical, she added. Other companies like Biocon and Auregene are expanding their present portfolio in this segment.

In a bid to enhance its biosimilar portfolio, Biocon, recently, bought back the 51 per cent stake from its Cuban partner, CIMAB to boost biosimilar manufacturing facility. The Bangalore-based biopharma company has insulin and monoclonal antibodies' development programme in this segment.

Similarly, Aurigene Discovery Technologies Ltd, an independent subsidiary of Dr Reddy's Laboratories, is also betting big on this segment.

"Biosimilars pose both challenges and opportunities for Indian companies. In terms of challenges, there is a lack of regulatory clarity, market access issues and such others. However, keeping in view the cost arbitrage, talent pool in India, the opportunities are more than challenges," C S N Murthy, CEO of Aurigene, said.

Presently, the market size of biosimilars in India stands at Rs 750 crore and is around Rs 4,500 crore in the emerging economies and semi-regulated markets

TOP

Avesthagen Limited.

Discoverer, 9th Floor, Unit 3, International Tech Park, White Field Road, Bangalore – 560 066
Tel: +91-80-2841 1665 / 2770 / 2308, Fax: +91-80-2841 8780

Publication	The Times of India
Edition	Bangalore
Date	June 04, 2010, p.21

Lab-on-a-chip concept catching on

Rashmi Shrikant | TNN

Bangalore: India in the last decade saw rapid developments in the field of digital diagnostics, as low-cost medical imaging equipments including portable ECG machines hit the market.

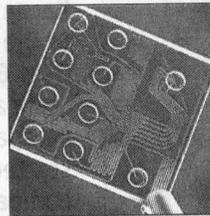
The next 10 years could see the country making rapid strides in molecular diagnostics, making pathology lab tests more affordable and portable. The result could be that a pregnancy test, which now costs anywhere between Rs 60-80 in a lab could come down to Rs 4, or a malaria test could be made available at one-tenth of the current cost.

Significant research and development is happening in the field of molecular diagnostics and India is on the verge of new-age diagnostics based on genetic and protein markers. Several small and medium diagnostic companies, which have developed indigenous test kits, are now investing into marketing their products.

Bangalore-based Bhat Biotech, for instance, is planning to invest Rs 3 crore

this year to develop and market its DNA-based and protein-based test kits. Last year, it developed the country's first

Chikungunya kit, which is a rapid test for the detection of antibodies to Chikungunya virus. The company has recently developed a swine-flu kit.



Molecular diagnostic kits typically analyse key DNA or protein as against the old technique of mixing up some reagents. "The results are amazing as the device, that integrates one or several laboratory functions on a single chip, can detect up to 100 cases," said Dr Shama Bhat, CMD of Bhat Biotech. The company has entered into partnership with IIT, Bombay and has set up a firm, Polymeric Sensors. The new firm is working on biosensor based diagnostic kits in several disease areas, he said.

The lab-on-a-chip concept, integrating biology, chemistry, electronics, optics, micro fluids and software in a single chip,



BANGALORE
INDIA BIO
02-04 JUNE, 2010
India's Biggest Biotech Show

is fast catching up, as another city-based diagnostic company Bigtec is working on marketing its hand-held di-

agnostic device that can diagnose a pathogen in 10-12 minutes. The device was developed a year ago with a grant of Rs 6 crore from the New Millennium Indian Technology Leadership Initiative (NMITLI) of the Council of Scientific and Industrial Research (CSIR). The product will hit the market in a year, said Chandrasekhar Nair, Bigtec's founder director. "We are in talks with a few funding companies and also have our own go-to-market strategy," he said. Bigtec's kit is useful in testing a wide range of diseases including malaria, dengue, hepatitis A and hepatitis C.

New-age diagnostics track disease progression and drug response, and are designed to customize therapy in a differentiated manner, as they are DNA and protein-based. However, funding remains a major challenge for the companies to translate lab results into a commercial product, Bhat said.

TOP



Publication	DNA
Edition	Bangalore
Date	June 04, 2010, p.04

Shift in partnering trends brings R&D tie-ups to the fore

WEST IS PLANNING TO ENGAGE INDIAN COMPANIES WITH PARTNERSHIPS HIGHER UP THE VALUE CHAIN

SELVAPRAKASH L



BIG DRAW: About 700 delegates from 20 countries are participating in the event which will conclude on Friday

Team DNA. Bangalore

Partnerships in global biotechnology industry are moving away from outsourcing research and development partnering models as the latest trend in this sector.

This is what has emerged on the second day of the three-day Bangalore India Bio 2010, which began on Wednesday.

Experts speaking at a session on biopartnering at the event said this change in the trend was mainly due to the ability of the partners to address serious issues like data security and perfection of intellectual properties.

Earlier, outsourcing to India was confined only to functional areas. But now, companies in the West are planning to engage Indian companies with partnerships higher up the value chain, they said.

"Jubilant-Astra Zeneca collaboration project (JAZ) is a strategic research collaboration and a classic ex-

ample for externalisation of R&D. Pharma industry is moving away from highly internalised R&D to a network model. The service provider's role of emerging markets like India is changing to effective innovation management partnerships based on relationships rather than transactions," said Sri Mosur, CEO and president, global discovery and development, Jubilant Biosys, while citing the example of a successful partnership between Astra Zeneca and Jubilant Biosys.

Jit Patel, director, strategic planning, business and development, Astra Zeneca R&D, US, said: "Biopartnering helped our company to grow from only two products with \$ 2.5 billion R&D spending in 1999 to 10 products with \$4.4 billion R&D spending in 2009. R&D partnerships facilitate speed, control on cost and quality and finally establish new delivery standards."

Chairing the session, Robert Lee Kilpatrick, partner, Technology Vi-

sion Group, US, said, "Local presence and global reach-out are the two buzz words in working out biopartnerships between companies belonging to two different geographies and cultures. Conference networking, partner networking and experts networking are the important routes that will eventually facilitate global partnerships in R&D."

Experts also highlighted the importance of international partnerships for key drug discovery and R&D.

Neelima Khairatkar Joshi, senior vice-president, biological research, Glenmark Research Centre, said: "Partnership is needed in all stages of drug discovery and there is a lot of partnership available. Several partnership models are being used successfully in India. In the global biotech industry, Indian pharma companies are on the way to be recognised. The strategy should be flexible and there are no short cuts in this process of drug discovery."

FLEXIBILITY IS THE KEY TO SUCCESS

Dr Scott J Grossman, vice-president, scientific director, BBRC, Bristol-Myers Squibb Company, says: "Innovation in pharmaceutical research is alive and well, which is one of the major factors to succeed. In the earlier days, companies were built with self-suf-



ficiency and partnerships were built internally to overcome all adversity. The new-age concept is to build not only partnerships externally. It also needs versatility and flexibility to succeed in today's biotech industry.

"Today's partnership is about transactional, co-operative, shared and co-created products. BBRC partnered with Biocon and has about 660 scientists. This partnership makes a tangible difference in the industry. In a recent research conducted, it was found that the API delivery time in 2010 just took one month. This is possible due to the combined efforts through partnerships."

TOP

Avesthagen Limited.

Discoverer, 9th Floor, Unit 3, International Tech Park, White Field Road, Bangalore – 560 066
Tel: +91-80-2841 1665 / 2770 / 2308, Fax: +91-80-2841 8780