

The Year of Consolidation & Collaboration

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The year 2011, is slated to be a year of consolidation and collaboration for the biotech industry. Mergers and acquisitions, strategic alliances and partnerships would be a continuing trend in 2011. Most of them will be inbound and like 2010, we will see valuations of domestic companies reach sky rocketing heights. However, we will witness more strategic alliances between MNCs and domestic firms more on the lines of the Pfizer-Biocon deal (\$350 million, with \$200 million upfront payment). Industry experts also predict that domestic companies will now turn to investing in novel molecules rather than plain low cost generics and follow on biologics.

Keeping their focus intact, Indian biotechs are foreseeing the underlying opportunities and are optimistic about their growth in 2011. Besides expanding their employee base, companies are looking forward to significant investments in terms of R&D and on the commercial front. Further, companies in the services sector look to strengthen their existing capabilities and work on new business models that are rapidly emerging in the contract research industry.

The dawn of the New Year is also expected to see the launch of newer vaccines and biopharma products. Making vaccines affordable and within the reach of poor and needy seems to be on the priority list of the vaccine companies. While, Public Private partnerships are burgeoning in the agri biotech sector, the companies in this space are betting big on genetically-modified crops and improving hybrid varieties of different crops. Although the moratorium on Bt brinjal continues, these companies are hopeful that the government will review the situation in the New Year. They are also optimistic that Bt brinjal will soon win the confidence of farmers and consumers alike and will set the ball rolling for other food crops, such as the Bt rice and Bt maize and Bt tomato.

In 2011, one can expect domestic companies to come up with indigenous Bt genes. Bangalore-based Metahelix Life Sciences is one of the forerunners, with its cry1c gene receiving approval from GEAC for its use in two Bt cotton hybrids, MH5125 Bt and MH5174 Bt. India could also see the launch of Bt rice in the coming year, with DuPont receiving GEAC

approval for field trials of its Bt rice. Tata Chemicals' subsidiary, Rallis India acquiring majority stake of 53.5 percent in Metahelix for over \$20 million (₹99.5 crore) is seen as another important event in this sector.

There is no holding back for Bioindustrial companies too. While keeping their focus on developing new products, these companies are also majorly looking at exports. Diagnostic companies will look to leverage the breadth of their portfolios to bring quality in vitro diagnostics into the market. Industry associations like the CII, ABLE, FICCI and ASSOCHAM are also looking forward to further catalyze the growth of biotech industry by bringing together different stakeholders for deliberation.

Even the Government of India is keen on supporting R&D activities for developing novel molecules. In this regard it is planning to set up a new venture fund to promote drug discovery in India, with a start up capital of close to \$45 million (₹200 crore). This could bolster drug discovery activities which till date, has been reeling under paucity of funds and capital. Further, the Department of Biotechnology (DBT), has been spending around \$300 million-a-year (₹1,300 crore) to support research, development and innovation. India plans to spend over \$150 million (₹700 crore) in the next two years to boost production at biopharmaceutical firms, even as the local industry gears up for a global boom. The government will focus on developing infrastructure in the sector that makes drugs using biotechnology on increased demand for funding. DBT for the year 2010-11, had allocated an amount of about \$260 million (₹1,200 crore) as plan expenditure and \$12 million (₹22 crore) as non-plan expenditure.

Experts across all segments unanimously agree that the regulatory environment in India, come 2011, would become all the more stringent and well-defined. This would be applicable in avenues like biosimilars, stem cell therapies, clinical trials and pharmaceuticals. This will be a big boost for India because in the past, global heads of many MNCs were hesitant to invest in the country due to lack of a well defined regulatory structure. Clearly, experts are optimistic that it will be the pharma, biopharmaceutical and bioservices sectors, which will be the primary driving forces for industry growth. Companies are fully aware of the roadblocks that have been hindering the progress of the sectors so far, and are confident about consolidating their positions. Hence, 2011 will truly be a year of consolidation and collaboration!

In the ensuing pages, *BioSpectrum* brings you some interesting insights from the industry observers and leaders for the year 2011.

Biosimilars to drive growth

More biosimilars would be launched in India, thereby strengthening the country's position in the global market. The regulatory environment in India would get progressively stringent on quality of biosimilars.

Indian regulators can also be expected to subject imported biosimilars to the same level of scrutiny and approval as with biosimilars developed and manufactured in India.

2011 can witness more partnerships between Indian biotech and pharma companies. There would be more stem cell therapies and tissue engineered products in the Indian market. Regulations for stem cell therapies would get better defined. India would begin to make a mark in developing novel biotherapeutics as well.

Company Outlook: Reliance Life Sciences (RLS) would continue to focus on developing and bringing in a range of biosimilars, including several monoclonal antibodies, to the Indian market as well as take them to other semi-regulated markets. RLS would be progressing its pipeline of specialty pharma products in oncology, steroids, hormones and peptides range. We are also looking to commercialize stem cell therapies and tissue engineered products in India.

- Mr KV Subramaniam, president,
Reliance Life Sciences

Understand the trend or 'perish'

India will gradually move towards an integrated and robust healthcare financing system, ushering in the dawn of a new paradigm, provided doctors should no longer remain the sole decision-makers for the drugs they prescribe to the patients and the way they treat the common diseases. Healthcare providers and medical insurance companies will start playing a key role in these areas by providing to the doctors well thought out treatment and prescription guidelines.

For a significant proportion of the products that the pharmaceutical companies will sell, tough price negotiations is inevitable.

Health Technology Assessment (HTA) or 'outcome-based pricing' model will play an important role in pricing healthcare products.

A shift from just 'brand marketing' to marketing of a bundle of value-added comprehensive disease management processes

along with the brand, will gradually be the order of the day.

Over the counter medicines, especially originated from natural products for common and less serious illness, will carve out a larger share as appropriate regulations are put in place. Regulatory environment within the pharmaceutical industry will be much more stringent.

Contrary to the expectations of many, valuation of the domestic pharmaceutical companies will continue to remain high, which, however, will not pose any serious impediment to the consolidation process in the industry.

With these emerging trends, required wherewithal in the ball game of the Indian pharmaceutical industry will be quite different. In the evolving scenario, it may not be easy for the domestic players to adapt to all these changes fast and compete with the global players on equal footing. Companies which are already global players in their own rights, would be able to understand the nuances and implement them better in the new paradigm. These players, I reckon, would offer a tough competition to the global players, especially, in their own turf.

However, for the smaller local players, the new environment could prove to be quite challenging, which in turn, could further accelerate the consolidation process in the Indian pharmaceutical industry. Thus, the 'writing on the wall' appears to be - 'understand the trend and start preparing from now on or 'perish'.

- **Mr Tapan Ray**, director general,
Organisation of Pharmaceutical Producers of India (OPPI)

Reverse innovation to take center stage

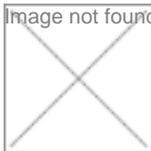


Biotech industry will witness more strategic alliances in terms of CMOs and CROs. Reverse innovation will be setting in with more focus on vaccines, mAbs, and biopharmaceuticals. If government takes initiatives with more incentives and tax holidays backed by proper infrastructure, more overseas biotech companies will set up their facilities for manufacturing in India.

Company Outlook: Serum Institute of India will launch some new affordable quality vaccines and biopharmaceuticals in line with the philosophy of founder Chairman, Dr C S Poonawalla.

- **Dr SD Ravetkar** senior director,
Serum Institute of India

Biotech to boost agri production



Last year's moratorium on Bt Brinjal has spurred the industry to play a more active role. People who value the importance of growth in agriculture believe that biotechnology will play a dominant role irrespective of temporary set back. Our policymakers are well aware of the potential of biotechnology, both genetic-engineering based or genome-based. I believe, they are going to extend full support for the development and application of biotechnology in agriculture. I believe, the increasing public-private and private-private partnerships will help finding solution to issues that are threatening the food and economic security of farmers. Many of these have evaded solution through conventional breedings. Bt cotton was success and North Zone was again flourishing with cotton trade. India rose to the position of the second biggest producer and largest exporter. If we do not harness biotechnology to find solution to this problem in time, we will be back to square one. We see a continued support to research, both to institutes and industry, so a synergy is created to accelerate growth in agricultural sector. I am optimistic that release of Bt Brinjal as first food crop is imminent and it will win the confidence of farmers and consumers alike.

Company Outlook: We are better determined to disseminate the varieties and hybrids that have been improved, using GMO and Non GMO approach. Being a group committed to serve farmers and people, we are planning to partner with public and private sector in application of biotechnology. Our target is to invest more than three fold of what we have already done for biotechnology segment

- **Dr Govind Garg**, head,
R&D, Krishidhan Seeds

CROs to see big boom



decade, rising pressure to reduce costs and time-to-market has led to a rapid expansion of the global contract research organization market. Pharma and biotech company spend on CRO services has shown double digit growth in the past years highlighting the importance of this fast growing market.

CROs today are critical contributors to the drug development programs of pharma and biotech companies often resulting in substantial time and cost saving. Many CROs and pharmaceutical companies are turning to strategic partnerships to gain a competitive edge in the global business environment. Various business models are being employed to forge long-term relationships.

Consolidation of businesses has turned from a trend to reality today. The CRO market, which is highly fragmented today, will

see further consolidation in 2011 where small as well as large CROs will continue to merge.

Company Outlook: While Dabur Research Foundation (DRF) already has the required infrastructure and competence to take a new molecule from early discovery to advanced preclinical stage of development, as a CRO our focus in 2011 will be in the following critical areas –

(i) develop and offer in vitro alternatives to animal testing to drug companies, especially those developing dermatological and skin care products.

(ii) offer state-of-art screening strategies in oncology to companies developing drugs to treat cancer.

(iii) help reduce attrition rates in drug development and thereby reduce costs by offering special drug screening modules that DRF has developed over several years of painstaking research.

- **Dr Manu Jaggi**, CEO,
Dabur Research Foundation

M&A, sell-offs to linger till 2012

In 2011, I expect mergers and acquisitions in the Indian clinical research industry and consolidations between Indian CROs. There are also possibilities of smaller Indian CROs selling-off their business interests to larger CROs, as the spate of consolidation is expected to continue till 2012.

Company Outlook: We are looking to build upon existing capabilities in India and the US, and expand our capabilities in the UK office to allow sponsors the advantage of running studies through our UK office in both Western and Eastern Europe.

- **Mr SK Mukherjee**, director,
CliniRx Research

India is in-sync with global trend

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at companies to acquire or partner with Indian companies. There will be an increase in genomic spending by academia. The industry is very much in tune with global trends. The number of clinical trials in India will increase, and better regulations for the industry are also expected.

Company Outlook: We will be moving into our new GLP campus to increase services. Besides, we will further enhance and release the full blown RaaS (research as a service) platform to open up for collaborations. In the New Year, we will also invest in diagnostics and kits.

- **Ms Anuradha Acharya**,
chief executive officer and co-founder,
Ocimum Biosolutions

R&D to be the top priority

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pharmaceutical industry has shown some very remarkable developments. Like Indian IT space, Indian pharma companies are now considered key for entire global development. We have lot to catch up in other biotechnology segments. But due to some critical developments, India and Indian biotech companies are being looked up now. Some very good work has also been done by several biotech companies including Advanced Enzymes.

Research and development must be encouraged for next 10 years for Indian companies to emerge as next destination for biotechnology. This is indeed a –knowledge industry– and agriculture with industrial biotechnology can help India proceed at a faster pace of growth. Our agriculture is key for national growth with green technologies. Many crop productivity is still quite low.

Company Outlook: Advanced Enzymes aims to become a global company with manufacturing presence in all key economies. We plan to merge our America operations and expect to grow our exports at rapid pace. We foresee lot of opportunities there and we are optimistic about our growth. In tune with that, we are setting up an 100 percent EOU in Indore SEZ with massive capacity expansion plans - seven times bigger than our present plant in two steps. Our first plant with double capacity is expected to become operational by mid-2011. If every thing goes well, we expect to cross our exports alone over \$20 million (1 billion) in 2011+2. (In billion) in 2011+2. ~~2.5€?~~

- **Dr CL Rathi**, managing director,
Advanced Enzymes

Non-urban demand for healthcare rises

Image not found demand and availability in non-urban areas will go up considerably. The increasing educated patient population is posing huge demand for improved health services, and a more focused approach to personalized healthcare.

Company Outlook: We will leverage the breadth of our portfolio and market leadership to bring quality in in-vitro diagnostics, personalized healthcare. We are also looking at bringing new technologies, such as, sequencing and microarray into diagnostic arena.

- **Dr Bhwnesh Agrawal**, managing director,
Roche Diagnostics

It's the time to expand operations

Image not found **Outlook:** We are looking to expand coverage of our foot & mouth disease program from 64 districts to 121 districts, a significant increase from \$25 million (₹10 crore) to \$50 million (₹220 crore).

We are also doubling milk production by spending lot more on nutraceuticals. Currently we have 15 percent share of the 2,000 crore health market.

We are working on NDTB and have also partnered with Indian Vaccine research Institute. We also expect 60-70 percent share in the cattle and sheep vaccine industry. so looking at bringing new technologies, such as, sequencing and microarray into diagnostic arena.

- **Mr KV Balasubramaniam**, managing director,
Indian Immunologicals

A mix of innovation and right policies

Image not found **Outlook:** India is well positioned to become a leading global biotechnology centre. India's success in biotechnology will depend largely on how it implements policies for biopharmaceutical products that balance innovation and competition, and make patient safety and product quality paramount considerations.

Company Outlook: We are committed to improving the lives of patients by transforming scientific discovery into health care guides. In 2011, our focus would be to increase awareness about Multiple Sclerosis (MS) in India, be an integral part of the health care system in treatment of MS and enable neurologists to provide meaningful solutions to their patients.

Our goal is to expand the Biogen Idec drug portfolio in India and launch more products for Indian patients; we currently have AVONEX and Tysabri for the treatment of MS.

We have made significant investments in India, both on the R&D as well as on the commercial front. We have already integrated our India operations into our global drug development strategy and investments and plan to continue to enhance that in the coming months and years. Our high caliber India team is well-poised to make significant contributions in developing and growing this exciting field of biotechnology in India.

— **Dr Alpana Seth**, chairman and managing director,
Biogen Idec

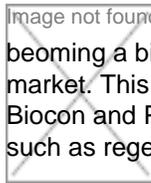
Innovation to play a major role

Image not found **Outlook:** The biotech industry is dependent on extraordinarily high investments and long incubation times. For the industry to sustain and become globally competitive in the future, the focus will be on rapid innovation and effective R&D management, collaboration and to explore opportunity for contract manufacturing. Value creation through generation of strong pipelines leading to robust intellectual property portfolios will be a big play in the future. There will be increased spend on R&D and innovation, as more Indian companies undertake new product development, increase in M&A activity and more importantly product/franchise acquisitions by MNCs in India.

Company Outlook: Bharat Biotech's focus is to consistently innovate, bring out new molecules and vaccines to serve the 5.8 billion emerging market. Our immediate goal is to bring out at least one 'made in India' molecule. Bharat Biotech has delivered over one billion doses of its vaccines. Our aim is to double the number in the next five-to-six years. We are also investing substantially in R&D, clinical trials and to add new facilities, including expansion of our existing facility to meet the growing demand for our range of products. In our new product pipeline, we have made significant advancements in the

— **Dr Krishna Ella**, chairman and managing director,
Bharat Biotech

Investors increase biotech focus

 economy recovers from downturn, the investor community will increase its focus on biotechnology. India is becoming a big market for pharma/biotech products, Indian biotech firms are also looking beyond borders to expand their market. This will lead to more partnerships between Indian and international players, similar to the one we saw between Biocon and Pfizer recently. Growth is predicted in agri-biotech, biopharma, oncology products, vaccines and new therapies such as regenerative medicine (stem cells). Systems and predictive biology segment is poised to grow in India too.

Association Focus: The prime motivation of ABLE is to play a catalytic role for the growth of the Indian biotechnology industry. We will continue to be the platform for all the the stakeholders, (industry, government, academia) of this sector to interact, connect, deliberate and partner. One of our main focus will be to intensely engage with the government to streamline regulation be in biopharma, bioagri, diagnostics & devices, improve access to early stage funding schemes and continue the dialogue on various issues that affect the industry.

— **Dr Satya Dash**, chief operating officer, ABLE

Nayantara Som & Rahul Koul