BioSpectrum the business of Bio & Health Sciences

Outlook promising for BioPharma in 2013

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BioPharma industry leaders share their valuable thoughts for the year 2013.

> I would expect 2013 to be a continuation of some of the trends we started seeing in 2012. In domestic pharma market National List of Essential Medicines (NLEM) will be a significant factor as also a focus by companies on building brands/improved sales force effectiveness. Increased co-marketing and licensing deals in the domestic market [both for prescription (Rx)and over-the-counter (OTC)]. In international generics space, there will be increased focus on value-over-volume for regulated markets and increasing relevance of emerging markets. R&D effectiveness will be crucial. Novel Drug Delivery Systems (NDDS) and niche technologies will continue to be a focus area. With increase in drug development costs, big pharma will return as clients for custom manufacturing and clinical research organizations (CRO). There will be growth in Contract Research and Manufacturing Services (CRAMS).
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> - Mr Ajit Mahadevan, partner, Life Sciences, Business Advisory Services, Ernst & Young

Globally, 2013 is a critical year that will indicate the impact of Euro-zone debt and the so-called US "fiscal cliff." Both these events are likely to have two significant impacts on government budgets. First, they are likely to reduce public spending on healthcare [growth of healthcare costs is higher than growth in gross domestic product (GDP) in most the Organization for Economic Co-operation and Development (OECD countries] and increase the pressure for new healthcare products to differentiate and show comparative benefits. Second, the impact on budgets could also reduce government spending on medical research (for example, budgets in premier biomedical research institutes such as the National Institutes of Health in the United States have been relatively flat); this could have a long-lasting impact on innovative biomedical research and ultimately new products and services in healthcare.

Indian healthcare, which is different from most OECD countries, is driven primarily by out-of-pocket expenses and private expenditure. In fact, India GDP growth has not been matched by growth in public healthcare spending (a paltry 1.2 percent of GDP); increases have been primarily in out-of-pocket, private spending. High out-of-pocket expenses, a primary reason that causes patients to fall into debt and poverty, are an important political issue both at the national level and in a global forum such as the United Nations. In order to ameliorate this situation, various groups are looking at universal healthcare coverage as critical to improving healthcare outcomes in India.

In a recent academic article, some leading researchers have estimated that the cost of such an initiative could be quite affordable at less than $40 per person per year (approx INR1700). Additionally, the government intends to increase public spending up to 2.5 percent of GDP by the end of the 12th plan to increase the available healthcare infrastructure. One of the bills winding its way through the political system is the National Health Bill. In addition to this, the Food Security Act, which could improve nutrition, is also critical to reduce high levels of Indian childhood malnutrition (a key correlate of poor healthcare outcomes). Apart from these, political activities in the field of public health, the new National Vaccine policy is an important document that outlines improved access to vaccines for the Indian public to reach global standards of prevention. An increasing trend in these activities of the government is also the change in its role from being a provider to a payer. If done with the right spirit and intent, one expects these various actions to increase equity in access to healthcare.

An important Indian public health success of 2012 has been the lack of incidence of polio for more than a year. This will help the government move from oral polio vaccine to an injectible polio vaccine over the coming years. The polio end-game needs to be worked out carefully with various stakeholders in mind. Shantha Biotech expects to play an important role as an important supplier of this injectible vaccine in this end-game of significant national importance.

In 2013, Shantha continues on our long term mission of providing affordable vaccines and medicines to the developing world. We will continue to provide vaccines to Indian government for public health. From an innovation perspective, Shantha continues to focus on simplification of vaccination by focusing on development of multivalent "one-shot" combination vaccines which will increase compliance and reduce programatic costs. Also, in focusing on women's health in a developing country, we are developing a novel, affordable, universal HPV vaccine that could significantly broaden coverage against the dreaded cancer caused by this virus.

- Dr Harish Iyer, CEO, Shantha Biotechnics

The year ahead holds immense promise for the Indian biotech sector, which is at an inflection point. The industry has leveraged the entrepreneurial spirit to build a strong foundation which has enabled the industry to grow at a CAGR of 20 percent for over a decade, growing to a size of $ 4 billion in 2011.The next year will see innovation taking center stage, driving significant progress in the areas of biosimilars and diagnostics for affordable healthcare, integrated traditional medicine, biomedical informatics, biofuels for less dependence on petroleum, bioremediation for environmental recovery, enhanced agricultural productivity and improved nutritional attributes.

BioPharma and the healthcare sector are the largest component of the Indian biotech industry and the most promising. It has the potential to carve out a large portion of the global biosimilars opportunity estimated to assume a size of $ 2.5 billion by 2015. The coming year will see collaborative trends gaining momentum with more co-development and marketing partnerships - between multinationals and the Indian companies as they seek to accelerate their growth by leveraging emerging markets.

We will see a surge in both biomanufacturing and bioservices partnerships which will enable innovative solutions for the world coming out of India. The increasing focus on genomics and proteomics in pharmaceutical research augers well for bioinformatics where India can position itself as a key hub of knowledge and expertise. With the excellent foundation, improved infrastructure, good quality talent and enabling regulatory environment, biotech has the potential to be the next technology beacon for the nation.

As for Biocon we are truly committed to provide affordable high quality biopharmaceuticals for chronic diseases particularly diabetes, cancer and autoimmune diseases. We are on track to bring our second novel molecule, Itolizumab, an anti CD6 monoclonal antibody, to the market in India next year. For 2013, that will be the most significant achievement for Biocon and a great boon for Indian patients struggling to manage Psoriasis. We will also continue to focus on expanding our Insulin market in several emerging markets in Asia, Middle East North Africa, LATAM and Eastern Europe.

- Dr Kiran Mazumdar Shaw, chairperson and managing director, Biocon

The outlook for BiopPharma sector for 2013 looks quite promising even though approvals of biologicals were on decline in 2012. The biopharma sector contributes about 60 percent of the Indian biotechnology industry and has witnessed compounded annual growth rate of 21.63 percent which is quite impressive. The vaccine story in which India has become major hub for vaccine manufacturer in the world producing vaccines at affordable cost is proof of capabilities of Indian companies in BioPharma sector.

Serum Institute of India is world's no.1 manufacturer of vaccines like tetanus, diphtheria, pertussis, HIB, BCG, hepatitis B, measles, mumps, and rubella. Key focus in the coming year will be enhancing further capacities of the above vaccines for which state-of-the-art plants are under various stages of completion. Development of critical mass in terms of knowledge to further strengthen quality systems is major thrust area in coming years. With robust pipeline of various newer vaccines in offing structured program is carried to reduce the time-to-market. Products on the horizon are many like rota and pnemococcus and HPV vaccines. This in itself is a gigantic task of putting new R&D incubators and going through entire process of germination of idea till commercialization.

The acquisition of Bilthoven Biologicals in Netherlands will be used as spring board for the launch of Serum vaccines in developed world. One of major focus areas in years to come will be efforts to make injectable polio vaccine at affordable cost.

- Dr SD Ravetkar, executive director, Serum Institute of India

The biotechnology industry in India continued to see strong growth in the year 2012; on the strength of biosimilars, in terms of their domestic market growth, exports, product/clinical development, new product launches and product-based partnerships. This trend is expected to strengthen further in the year 2013. At the same time, the industry has had to face several challenges in 2012, particularly with price erosion, greater competition, constraints in capital markets, currency depreciation and more stringent regulations for biotherapeutics. The industry would continue to face these challenges in the year 2013.

The biotechnology industry in India has the potential to grow at 20 to 25 percent per annum. This is contingent on a partnership between industry and government, which recognizes opportunities for the Indian biotech industry to be a global leader, particularly in vaccines, biosimilars and regenerative medicine, and institutionalises policies that enable faster market entry at lower costs, without compromising product quality, safety and efficacy.

Reliance Life Sciences looks forward to 2013 with expectations of higher growth and profitability, on the basis of the depth of its product pipeline and diversity of its market participation.

- Mr KV Subramaniam, president and CEO, Reliance Life Sciences

BioSciences industry will continue to grow with more ME-TOO products coming in and jostling for space. More and more companies will go for OTC-like branded products. Merger and acquisition will continue. Innovation will take a back seat as the focus on generating earlier revenues and lack of adequate financing will continue. However, the public-private innovation model will take a positive start as more and more products will be taking root under the BIRAP type opportunities.

The CRO model in India is yet to take off. China continues to be the preferred desitination for both clinical and discovery R&D. Large MNCs are shying away from opening up R&D centers in India on a large scale. The patent regime continues to be an over-riding factor. Even Indian firms like Avesthagen have been rudely surprised by arbitarary decisions made by the Ministry of Commerce and Industry, Government of India on a patent granted by the Indian Patent office for its diabetes product. Flimsy grounds, no discussion with the company on what is called the "rarest of rare" laws. Is this a joke? On one hand the government tries to promote science on traditional medicine and then revokes it when a company actually delivers. It's a shame and will not allow anyone to take risks in R&D in the future.

The BioAgri industry stagnates as the focus is only on Bt brinjal or Bt cotton, and always linked to MNCs. This is not the way forward. One needs to bring in and support SMEs and research products to get into the market.

Avesthagen will work towards the commercialization of its assets of products and patents in the areas of science and innovation, BioPharma, BioAgri andc BioNutrition world wide through licensing, royalties, spin outs and joint ventures.

- Dr Villoo Morawala-Patell, chairperson and managing director, Avesthagen

We ranked 134 out of 187 countries in the Human Development Index. We are facing an increase in both chronic diseases such as cancer and diabetes and infectious diseases such as tuberculosis (TB) and malaria. Creating a healthy nation, we need a faster and accurate detection and diagnostic technologies. Going forward, high quality and affordable diagnostics will play a key role in solving many of the healthcare challenges before the nation.

- Dr Satya Prakash Dash, consultant

BioPharma and diagnostic sector will grow faster than other sectors as the economy is picking up. Many new products will see as the industry is picking up steam.

We, at Bhat Bio-Tech, are planning to introduce several products. They include:TB diagnostics based on signature molecules present in the blood of infected people. We have identified several specific molecules and more than 3-4 molecules will indicate the infection. The ELISA-based kits are being tested in several centres, PCR-based molecular diagnostic kits are being developed for several infectious agents and they are also being tested and will be launched this year. We will be launching low-cost PCR machine which will enable to do the molecular diagnostics in mid level diagnostic centres. We will also be launching voltage-dependent PCR amplicon detection system that will not require gels or labels. Similarly, LAMP-based molecular diagnostic kits are also being developed and planned to be released this year. Agriculture-based diagnostic kits are also being developed and we hope to have them ready for launch this year.

- Dr Shama Bhat, chairman & managing director, Bhat Bio-Tech India

There have been interesting developments in the field of stem cell biology with approvals granted by the US and Canadian FDA for use of stem cells in osteoarthritis and graft versus host disease. Many more difficult to treat indications that have so far not been adequately treated by the existing drugs and biopharmaceuticals are being explored in various clinical trials across the world.

Indian stem cell research has seen completion of the Drug Controller General of India (DCGI) approved phase II work on the role of mesenchymal stem cells in certain indications and the inspiring results have paved way for phase II b studies. Once these trials are completed and the results analyzed, stem cells will play a role as alternate/ adjuvant in certain difficult to treat medical conditions.

One among the bedside procedures with increasing acceptance and clinical use is platelet rich plasma which is being attempted for various clinical situations requiring growth factors. Literature is abundant on its role both in

medical and dental applications and its use in India though not yet legally approved is on the increase. What is required now is for the drug control authorities to be aware of such developments and ensure approvals are not delayed for meaningful research in such areas.

Recombinant platelet derived growth factors have already been approved for phase III clinical research in certain conditions and if the results are good will pave the way for India to join the main stream of approving the addition of adult stem cells into the therapeutic armamentarium of physicians open to considering cellular therapies. Based on above, biologicals, biopharmaceuticals and biotechnology will continue to be main stream mechanisms in drug development for the year 2013 and beyond!

- Dr Ramananda S Nadig, director, Science and Research, Jnana Sanjeevini Medical Center

ReaMetrix looks forward to the year 2013 with a lot of excitement. We expect the formal launch of our hardware platform for research and diagnostics in the market this year. We are working on novel assays for HIV and TB diagnostics that would see the market shortly. With a number of innovation-driven medical diagnostics businesses getting established in India along with the support provided by the government of India through the Council of Scientific and Industrial Research (CSIR), and Department of Biotechnology, we feel that 2013 could be a break-out year for the industry.

- Mr Sridhar Ramanathan, executive director, ReaMetrix