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## Original Article

# Biotechnology business models: An Indian perspective

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**ABSTRACT** A typical business model consists of three components – value proposition, value-chain structure and revenue generation. These components are used to give a general description of a business. The biotechnology industry is not really characterised by specific business models and neither is there one single model for success. The sector is not only characterised by an enormous diversity, but is also driven by innovations, which makes the prediction of future development rather difficult. The enormous flexibility of biotechnology companies is a strength that has helped them survive in times of economic difficulties. In years of crisis, companies have managed to reorient themselves, change their business plans or even switch markets. Several Indian firms have focused their businesses on the development, manufacturing and marketing of biopharmaceuticals and providing services. The Indian companies appear well positioned to leverage their cost-effective manufacturing capabilities to corner some of the market share and compete on a global scale. This paper discusses the various business models and strategies adopted by the biotechnology companies that directed the growth of the biotechnology industry in the country based on the techno-economic dynamics and the key challenges faced by these firms.

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## INTRODUCTION

Business models for biotechnology companies have evolved over time. At each stage a different business model may be appropriate. The evolutions in the Indian biotechnology industry have been initiated quite recently and the industry can still be considered in a phase

of emergence of new models of organisation. These models of organisation do not only refer to the positioning of Indian companies on value chains destined to feed the domestic market. They also refer to the relations of these companies with downstream and upstream foreign public or private partners, as well as the targeting of foreign markets. Business models have to be continuously adapted to internal and external conditions. This means in practice, companies occasionally follow one particular business

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model in preference to others in order to adapt to prevailing financing mechanisms as well as to changing market demands. On the road to success, many biotechnology companies have adopted several different business models in order to be able to successfully operate under national and international conditions.<sup>1</sup>

Although business models in the biotechnology sector are not homogeneous, they are roughly divided into three to four groups such as the Platform, Product, Vertical and Hybrid models.<sup>2</sup> Typically, the Platform-based companies develop a set of tools or integrated technologies and provide these for use in different applications. One advantage of this business model is that revenue is generated relatively quickly. In addition, cost and time-savings are made in relation to product approval. The Platform business model was represented by enabling technology, tools and services, multiple alliances to validate platform, modest retained rights and royalty interests. This model was used by companies in genomics, combinatorial chemistry and high throughput screening. This model ran into difficulties because of the technology diffusion rates and adoptions were slower than anticipated. The Product or drug developing companies offer products manufactured with new, own or already-known technologies. This includes classical items like vaccines, therapeutic drugs and diagnostic products. The Product business model was represented by conducting basic and preclinical research, developing products in defined therapeutic areas, venture capital funding through preclinical development, public investors to support clinical trials, and licence away 'first-born' products. Very few companies succeeded with this business model, but many failed. The combination of product–platform business models leads to what is known as 'hybrid models' in which technology platforms are combined with services and the creation of products. The Hybrid business model represents the company characteristics like breadth of

integrated technologies, proprietary biology, focused therapeutic interests and capabilities, longitudinal product development, and renewable source of products along with contract research and services for the generation of revenue.<sup>3</sup> Contract research or service companies offer their services on the basis of known technologies, in the form of contract research or contract production. In the fully-or-vertically integrated biopharmaceutical company or Vertical business model, the drugs are developed up to end of clinical studies or up to approval, meaning that the creation of value is pursued as far as possible. On the other hand, virtually integrated pharmaceutical companies, only a small number of employees are focused on a specific area; other business areas are outsourced to external partners. It is simply an office-based company, dealing exclusively with project management and outsourcing all steps along the practical value creation work, from ADME tests, animal experiments to clinical studies.<sup>4</sup>

The Indian business models for biotechnology companies have had to evolve, adapting to changing market needs. Companies have entered the biotechnology sector in India mainly through large pharmaceutical companies, pure biotechnology startups, software giants and custom services firms. Eventually, Indian companies are becoming more attractive globally as collaborating partners for biotechnology activities across the value chain. There are basically three types of biotechnology companies in India. The top-tier or the fully integrated companies comprises the largest chunk, approximately half of which have gained international recognition. The middle-tier, platform–product-based hybrid companies have developed niche or greater expertise, and also have many relationships with the foreign partners. This middle-tier comprises the biotechnology sector in India, and of course, are aspiring to join the top-tier. In the lower-tier are a number of platform- or product-based or newly startup companies, some of

which are struggling to break into the middle-tier.<sup>5,6</sup> Therefore, this paper attempts to uncover the current developments in biotechnology in India and the main research questions included the following: (1) What types of biotechnology business models have evolved in India? (2) What relevant models and strategies are followed in India? and (3) What issues and challenges the Indian biotechnology firms face when moving down the product pipeline?

## MAJOR INDIAN BIOTECHNOLOGY COMPANIES

Indian biotechnology sector offers a wide variety of products and services. Indian companies are engaged in diverse activities to ensure sustenance by manufacturing biogenerics, developing technology platform while expanding to services in other areas. The sector is currently made up of four major segments: biopharmaceuticals (vaccines, human therapeutics, diagnostic products and animal healthcare); industrial biotechnology; agricultural biotechnology and custom services (contract research, contract manufacturing and clinical trials). Biopharmaceuticals remains the largest segment for Indian biotechnology industry. Strong clinical research expertise acquired through bio-services remains the mainstream for biopharmaceutical segment progress. Also, India is high on the radar of international pharmaceutical community for custom research, clinical research and bioinformatics opportunities.<sup>6</sup> The major Indian biotechnology companies and their means of primary and secondary revenue-generating resources are listed in Table 1, whereas Figure 1 illustrates the different business models evolved over time based on the industry's value-chain structure.

Large-scale international projects like the human genome project accelerated and continued to advance technological developments. Technology platforms became the method of financing young, innovative

biotechnology companies.<sup>7</sup> Under this model, the companies like Ocimum and Strand Life Sciences became self-financing through the sale of subscriptions or royalties for access to their own patent-protected technology. There were smooth transitions from this concept to becoming a contract research company for large-scale companies and academic institutions and it was also only a small step to the partnership model. Ocimum Biosolutions is a Bio-IT company with competencies in LIMS, bioinformatics, genomics tools, operating in the United States and India with support from partners in Europe and Canada that provides ready-to-use reliable, cost-effective software solutions for the biotechnology and pharmaceutical industry. The emergence of this model is driven by the need to reduce the risk in drug development by applying technology advances to drug discovery. It enabled companies to operate in a lower risk environment with lower profit margins. However, there is little scope for value generation and the technology that these companies rely on risks being commoditised. This model is used by companies that are developing bioinformatics solutions and bio-analytical systems.<sup>7,8</sup> For example, Strand Life Sciences leverage its core strengths in data mining, predictive modelling, computational chemistry and research biology to develop products for drug discovery. Likewise, Shasun Chemicals and Drugs with their expertise in fermentation and downstream processes manufacture APIs, their intermediates with a significant presence in some key generics. It has also emerged as a key player in contract research, custom synthesis, contract manufacturing and contract formulation services to clients.

Traditionally, India has been a very strong player in conventional generics owing to established track record of process engineering skills and capability to set up comparable manufacturing units at a fraction of the capital cost utilised overseas. This model includes product developers, who are often financed with VC on the one hand, and on the other

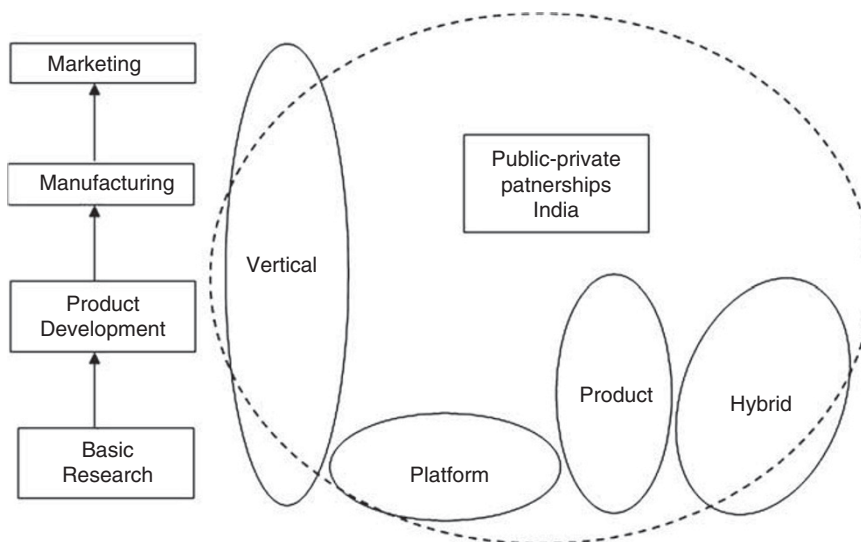
**Table 1: Biotechnology business models of the major Indian companies<sup>a</sup>**

Company	Products/technologies/services in the market		Business model
	Main sector	Subsector	
Advinus Therapeutics, Bangalore and Pune <a href="http://www.advinus.com">http://www.advinus.com</a>	Metabolic disorders, inflammatory diseases, neglected diseases	Contract Research Organization (CRO), screening	Hybrid
Avestha Gengraine Technologies, Bangalore <a href="http://www.avesthagen.com">http://www.avesthagen.com</a>	Agbiotech and transgenics, biosimilars	Biochips, bioinformatics, CRO, diagnostic instrumentation, screening	Vertical
Bharat Biotech International, Hyderabad <a href="http://www.bharatbiotech.com">http://www.bharatbiotech.com</a>	Recombinant drugs, cardiovascular diseases, vaccines	Other vaccines	Product
Bhat Bio-Tech India, Bangalore <a href="http://www.bhatbiotech.com">http://www.bhatbiotech.com</a>	Recombinant proteins, diagnostic markers	Contract Manufacturing Organization (CMO), CRO, diagnostic instrumentation	Hybrid
Bharat Serums and Vaccines, Mumbai <a href="http://www.bharatserums.com">http://www.bharatserums.com</a>	Plasma derivatives, monoclonals, hormones, serums, anesthetics, hormones, antifungals, anaesthetics, diagnostic products	Drug delivery systems	Product
Biocon, Bangalore <a href="http://www.biocon.com">http://www.biocon.com</a>	Industrial enzymes, recombinant protein therapeutic products and human growth hormone	Biosimilars, contract research and manufacturing	Vertical
Biological E., Hyderabad <a href="http://www.biologicae.com">http://www.biologicae.com</a>	Diagnostics, combination vaccines, antitetanus and antisnake venom sera	Other combination vaccines, CRO	Vertical
Dr Reddy's Laboratories, Hyderabad <a href="http://www.drreddys.com">http://www.drreddys.com</a>	Infectious and parasitic diseases, oncology, immune disorders, endocrine, nutritional and metabolic diseases, mental and behavioural disorders, diseases of the nervous, cardiovascular, respiratory and digestive systems	Generics, small molecule therapeutics	Vertical
Gennova Biopharmaceuticals, Pune <a href="http://www.emcure.co.in">http://www.emcure.co.in</a>	Hi-tech molecules in nephrology, oncology and cardiology segment	Other biosimilars	Product
Indian Immunologicals, Hyderabad <a href="http://www.indimmune.com">http://www.indimmune.com</a>	Pediatric and childhood vaccines, DNA-based vaccines, animal- and human-health products	Other veterinary vaccines	Product
Intas Biopharmaceuticals, Ahmedabad <a href="http://www.intasbiopharma.co.in">http://www.intasbiopharma.co.in</a>	Biopharmaceutical products in oncology	Contract manufacturing, analytical services, clinical trials	Vertical
Nicholas Piramal India, Mumbai <a href="http://www.nicholaspiramal.com">http://www.nicholaspiramal.com</a>	The export products cover a large number of indications in addition to diagnostics and vitamins	Other generics, custom chemical synthesis	Vertical
Ocimum Biosolutions, Hyderabad <a href="http://www.ocimumbio.com">http://www.ocimumbio.com</a>	Software for laboratory information management systems and bioinformatics solutions	Biochips, CRO, synthesis services	Platform
Panacea Biotec, New Delhi <a href="http://www.panacea-biotec.com">http://www.panacea-biotec.com</a>	Polyvalent vaccines, drugs/formulations for human indications including pain management, diabetes and renal disease	Anti-infectives, New chemical entities, ready-to-inject delivery systems	Hybrid

**Table I:** Continued

Company	Products/technologies/services in the market		Business model
	Main sector	Subsector	
Reliance Life Sciences, Mumbai <a href="http://www.rellife.com">http://www.rellife.com</a>	Blood plasma proteins, recombinant proteins, DNA-based diagnostics and plant products	Clinical research and cytogenetic testing services	Hybrid
Serum Institute of India, Pune <a href="http://www.seruminstitute.com">http://www.seruminstitute.com</a>	Vaccines and immunobiologicals for infectious and parasitic diseases	Other vaccines, CRO, CMO	Vertical
Shantha Biotechnics, Hyderabad <a href="http://www.shanthabiotech.com">http://www.shanthabiotech.com</a>	Combination vaccines for infectious and parasitic diseases	Other recombinant human healthcare products, diagnostic kits	Hybrid
Strand Life Sciences, Bangalore <a href="http://www.strandls.com">http://www.strandls.com</a>	Bioinformatics platform for modeling, data analysis, visualization, and target-focused synthetic compound libraries	Other <i>in silico</i> tools	Platform
Shasun Chemicals & Drugs, Chennai <a href="http://www.shasun.com">http://www.shasun.com</a>	Fermentors for new expression systems, conjugation and protein pharmacokinetics	CRO, CMO	Platform
Wockhardt, Aurangabad <a href="http://www.wockhardt.com">http://www.wockhardt.com</a>	Mostly bio-generics for various indications	Other generics, drug delivery systems	Hybrid

<sup>a</sup>Source: Indian biotechnology database (<http://www.indianbiotech.com/in/db/index.php>) search and companies' websites.


**Figure 1:** Biotechnology business models based on the value-chain structure.

usually have Big Pharma partners for the later development phases. The Product business model aims to generate value by progressing products along the drug development chain process and licencing them out to

commercialisation. This is a relatively high risk model and typically requires quite substantial investment.<sup>7,8</sup> Companies (for example Bharat Biotech, Bharat Serums, Gennova Biopharma and Indian

Immunologicals) have adopted this model which leads to partnerships and strategic alliances for risk sharing, or to outsourcing production. Bharat Biotech International specialises in product-oriented research, development and manufacturing of vaccines and biotherapeutics. Zydus Cadila and Bharat Serums and Vaccines have set up a joint venture (50:50) company to produce a new drug delivery system (NDDS) for an approved anti-cancer product for the global markets. Gennova Biopharmaceuticals (GBL), a spin-off of Emcure Pharmaceuticals, is involved in developing products in cardiology, oncology and nephrology areas, and is active in the field of biosimilars. GBL has collaborated with the PATH Malaria Vaccine Initiative and created a dedicated malaria vaccine manufacturing facility. Indian Immunologicals is a wholly owned subsidiary of National Dairy Development Board that provides livestock products and services and other veterinary vaccines such as anti-rabies vaccine, thileriosis vaccine, bacterial vaccines, canine vaccines and a host of other combined vaccines.

Globally, an increasing number of larger biopharmaceutical companies are finding it difficult to conduct the entire drug discovery process-in-house. India, on the other hand, provides a cheaper infrastructure. This has given rise to contract and/or clinical research organisations specialising in drug discovery services along with custom manufacturing services. These services are largely focused on molecular biology, chemistry, pathology and bioinformatics. Thus, a major structural shift in the biopharmaceutical industry has opened up a new option of platform-product Hybrid business model. The dual-hybrid model adopted by a range of companies (for example Advinus, Bhat Bio-tech, Panacea Biotec, Reliance Life Sciences, Shanta Biotechnics and Wockhardt) is an offspring of the product and platform business models that is capable of generating a pipeline of products together with contract research, clinical trials and manufacturing services. It gives investors the

benefits of reduced risk and near-term revenue generation, without compromising the potential for greater value creation.<sup>9</sup> Advinus Therapeutics is a R&D-driven company focused on the new drug discovery and development of pharmaceutical and agrochemical products. It is partnering with the global pharma (Merck, Samaritan Pharma) companies for its discovery programmes. In addition, Advinus is involved in sponsored research from global not-for-profit organisations (DNDi) for their 'Neglected Disease' programme. Bhat Bio-tech India is specialised in the design development, manufacture and marketing of diagnostic test devices. Panacea Biotec has significant presence in development, production and marketing of prophylactic vaccines that adheres to international standards of manufacturing and clinical development. The company has registered consistent growth in revenue contributed by vaccines supplied to UNICEF as well as to the domestic market through the joint venture (Chiron Panacea Vaccines Pvt. Ltd) company. Reliance Life Sciences participates in medical, plant and industrial biotechnology including cell-based therapies, plant tissue culture, plant metabolic engineering, biofuels and biopolymers. Shantha Biotechnics launched India's first r-DNA vaccine in 1997 and has focused its business on the development, manufacturing and marketing of innovative vaccines. At the forefront of developing new generation products, Wockhardt has launched India's first automatic insulin device. Wockhardt's market presence covers formulations, biopharmaceuticals, nutrition products and vaccines.

Some of the larger biopharmaceutical companies in India were created when an existing parent company opted for the biotechnology diversification as a viable investment strategy. The first generation companies like Biocon (traditionally an industrial enzymes company), Dr Reddy's Laboratories (previously in generics) have adopted the Vertical model primarily through

acquisitions, controlling the entire value chain with the hope of maximising and sustaining a superior financial return. In order to adapt to changing market needs and to deliver expected returns to investors, this new business model has emerged. This model represents a fully integrated organisational structure with access to internal development, manufacturing and marketing capabilities. The main attraction of this model is the potential for value generation throughout the entire value chain. It operates in a high risk environment, but it offers the potential for high returns on research investment and strong profit margins, similar to that of the pharmaceutical sector.<sup>7-9</sup> Although this model has proved successful for some companies, such as Avestha Gengraine, Biocon and Biological E (BE), some companies initially had difficulties in obtaining the levels of finance required to support it. Avesthagen, a leading integrated systems biology company, is focusing on the preventive personalised healthcare. The RPO platform offers solutions ranging from genome, transcriptome and metabolome analysis to lead optimisation and bioinformatics. Biocon's fully integrated business model spans the entire drug value chain, from preclinical discovery to clinical development to commercialisation. The company businesses in custom research (Syngene), clinical development (Clinigene) besides biopharmaceuticals that provides multiple revenue streams to balance risk, drive innovation, deliver products and accelerate growth. The company is also involved in the in-licencing of late stage or approved products for marketing and out-licencing of biosimilars and novel therapeutic products. Increasingly, Indian biotechnology firms are using strategic partnerships to expand their innovative capacity. Several Indian firms are currently developing vaccines based upon technology transferred from abroad and more are looking to foster such relationships. For example, Nicholas Piramal, Bharat Biotech and the Serum Institute have in-licenced various vaccine technologies from institutions in

Canada, the United States and the Netherlands. Also, BE has focused on building its pharmaceutical business in India with core competencies in development, manufacturing and marketing of pharmaceuticals. BE is sought as a resource for innovative APIs, formulations, vaccines, natural and veterinary products. BE has partnerships with Nederland's Vaccine Institute, Intercell AG, Austria and NIH, the United States for developing products preventing major life-threatening illnesses. Dr Reddy's Laboratories has predominantly been a generics player, with North America accounting for nearly half its revenue. Today the company is concentrating on the biologics, biosimilars, combination drugs and improved versions of existing drugs based on drug delivery technologies. Intas Biopharmaceuticals has received European Union-Good Manufacturing Practice certification for its manufacturing facility. It has entered anti-cancer market with oncology products catering solid tumours, haematological malignancies and supportive therapies. Nicholas Piramal India has a medium-term business model with strong de-risked international business activities. The company's capabilities include sales and marketing, a US FDA site-approved plant for on-and-off patent APIs and intermediates, basic research, process innovation, custom chemical synthesis, formulations R&D, NDDS, and a world-class Contract Research Organization (CRO). Serum Institute of India is moving towards a more value-driven model comprising a mixed portfolio of products, targeting both developed and developing countries supplemented with aggressive marketing and cost-effective R&D and manufacturing. Serum has established itself as the world's largest producer of measles and DTP group of vaccines. It is estimated that two out of every three children immunised in the world is vaccinated by a vaccine manufactured by serum. The company is successful in bringing down the prices of newer vaccines such as

hepatitis-B, rabies and other combination vaccines.

## RELEVANT MODELS AND STRATEGIES

In its history, the Indian biotechnology industry has experienced several abrupt changes in direction. Companies have had to make drastic changes to their business models in order to adapt to prevailing financing mechanisms as well as to changing market demands.<sup>10</sup> The question about what type of business models and strategies will be successful in India remains to be fully explored. When it comes to developing business models, as a general rule, it can be said that business models in the biotechnology industry originally developed from strongly technology-oriented approaches to product-focused models. On the business model front, inorganic international growth seems to be the new trend and the Indian biotechnology sector is pro-actively repackaging itself from low-end research and manufacturing base to a value-added partner in the global marketplace. Biotechnology companies in India are increasingly focusing on high-end technologies, drug discovery and scalable products. A major problem with second-generation biotechnology companies is that their products are often only new drug candidates. However, a business model based on simply adding to the drug discovery data glut is not profitable. Thus, many biotechnology companies are redefining themselves as custom research or manufacturing organisations.<sup>11</sup> Contract research is a good revenue model for the startups. As Indian contract research players adapt and enhance their innovation capabilities, several forms of partnerships arise from the existing ones as pure play research services provider to risk and reward sharing models. Such partnerships also give enormous learning opportunities for both the Indian scientists and the marketing community. It makes clear business sense for Indian

companies to take the co-optition path to synergise the benefits of their differing business models.

The tools model involves creating marginally different products, such as computer-based drug discovery aids, that can be easily scaled. However, because of the limited potential of the tools model to generate significant revenue, many of the tools companies in biotechnology have shifted to the service model. Many diagnostic laboratories that offer genomic testing follow a service model, which has the advantage of short development time, but is typically slow to scale. Although it has not been demonstrated which business model will ultimately be the most successful in biotechnology, it is clear that continued advances in the field of biotechnology hinge on a continuous stream of financing from a variety of sources.<sup>10,11</sup> Companies that were set up with an emphasis on platform technologies and product-driven companies also took on parts of this business model. Most biotechnology companies tended to use a mix of business models and different concepts as required. What is certain is that very few of these companies are likely to be successful over the long term as currently configured, because there is no long-term business opportunity based on a narrow technology platform.

Many research-oriented biotechnology firms still find the product model attractive today. However, the image of the product model is deceptive. First, the biotechnology companies had to find out that their lead compounds and active substance candidates may not fetch a good price because of the enormous risk of failure ('attrition rate') and a long development period. Many firms may not show interest in early phase developments because of their still unwavering faith in their own ability to innovate and the belief in their own financial strength. The market for recombinant therapeutics is not the only one developing in India but the market for diagnostics offers tremendous opportunities to the company that apply the technologies to



the industrial production of antigens and antibodies to be inserted in diagnostic kits. Nevertheless, the dynamics of industrial reorganisation in the field of therapeutics and diagnostics present different technological and regulatory determinants and have to be studied separately.<sup>12</sup>

India's biotechnology industry consists of a number of different business models and possible niches. These can be categorised into small-to-medium-sized companies, biotechnology startups, CROs and Contract Manufacturing Organizations. Smaller biopharmaceutical companies which initially emulated the services model are moving towards innovative research and drug discovery realising that it is imperative to move towards a product-driven model to attract VC funding and scale up growth. A similar transformation is happening with India's champion bioinformatics companies who are fast incorporating wet labs for a sustainable growth. Clinical research companies are the new kids on the biotechnology landscape and are seen to be mushrooming in clusters across the country. Scarcity of risk capital investment in biotechnology has forced some of the Indian firms to adopt a revenue-generating growth model from inception. In general, it involved either a product- or service-based model or both. Many health biotechnology companies in India rely on manufacturing of generics and/or contract services to generate revenues, which are then reinvested into R&D work in other areas.<sup>10,11</sup> Looking at the framework for scaling-up biotechnology investments in India, it appears that two types of business models are likely to be scaleable in India: the fully integrated biopharmaceuticals and the platform-product hybrid companies, whereas, the 'fee for services' model will continue to remain an integral part of business strategy.<sup>12</sup>

The salient features of the Indian companies' strategies that are studied are: (i) strategies for technology and competency development are the central factor determining the success of these ventures.

Indian policy of research support and human resource development through the funding of several public research and teaching institutions is of course a critical factor determining the technology availability. The interactions between those public institutions and the Indian companies were the object of a specific analysis.<sup>13</sup> It appears that institutions and companies are learning to work together and the effects of this collaboration can help the companies at various stage of their development. It also appears that companies often adopt alternative solutions to partner with Indian institutes such as collaborations with foreign companies or institutions. The personal networks built by the managers of these Indian firms – many of them have had an international academic or corporate career – are the main determinant of those international connections. (ii) Concerning the marketing strategies, the global character of the Indian firms' strategies is obvious. The companies entering the market for biogenerics are targeting foreign markets and have the most ambitious plans to enter the most regulated markets (the United States and Europe). As for the companies with business models based on research partnerships in drug development, their businesses are almost purely export oriented. On the one hand, this trend is linked to the level of maturity of a company in terms of its capacity to convert technologies into products, and on the other hand, it is linked to growing demand from investors to increase the company's value by marketing products.<sup>14</sup> (iii) Concerning partnership-driven biotechnology companies, domestic companies are increasingly looking for consolidation across the value chain by forming partnerships or mergers with companies of complementary strengths. As drug discovery becomes more expensive, and the costs of administration and regulatory compliance continuously rise, these partnerships are becoming more central to companies' business proposition. India is evolving as the growing partnership between the pharmaceutical and biotechnology

industries to create complimentary capabilities in terms of research, products, marketing and manufacturing.<sup>15</sup> Such optimal alliances allow the biotechnology companies to enhance their drying pipelines and secure financial muscle to sustain efforts towards developing innovative products. Further, it enables companies to reduce time to markets via the established foothold of pharmaceutical companies across the globe. In conclusion, there is not just one effective bio-business model. The rationale for choosing to engage in strategic alliances is rather simple: any company needs to get profitable quickly, and then grow its profits fast.<sup>16</sup>

## ISSUES AND CHALLENGES

Despite the biotechnology industry's rapid emergence in India, critical gaps remain as obstacles for development compared to its western counterparts. The issues and challenges observed are: (i) one of the key factors that would help the sector to live up to the promise it holds and achieve a long-term sustainable growth on a global scale would be innovative research. With several products likely to go off-patent soon, almost all the Big Pharma companies are likely to lose a big chunk of revenues. Not only pharma but also biotechnology companies should learn from the present state and re-look at the entire strategy for research and new molecule discovery.<sup>17</sup> However, Indian biopharma companies lack the experience to successfully launch new molecules globally and the funds to make huge investments required for innovative research strengths of multinationals. It is crucial for companies to march forward with high risk but promising profitable products rather than bow down under pressure from short-term investors. (ii) The issues of intellectual property have constituted the main deterrent for the growth of the Indian biotechnology industry. After the Patent Amendments Act in 2005, Indian patent laws largely became TRIPS-compliant; although a few obscure issues such as patentability of new use of a known substance

remain to be fully settled. One such issue is on data exclusivity, where TRIPS article mandates India to protect patent dossiers of a candidate drug (submitted to regulatory authorities for marketing approval) for a fixed period of time. The protection of clinical data from unfair competition is of paramount importance for promoting clinical trials in India, and India has no such guidelines in place, although efforts are being made to do so.<sup>18</sup> (iii) Why do not foreign venture capital funds want to look at Indian biotechnology? Foreign venture capitalists believe that there is insufficient patent protection and access to patent litigation in India. India is high risk and Indian biotechnology firms' needs are so small that western funds do not find it worth their while to process such proposals. This perception is slowly changing as recently, the foreign venture capitalists like Matrix Capital Management LLC and HBM Bioventures have started looking for biotechnology opportunities in India.<sup>19</sup> But Indian startup companies, which are accustomed to a dearth of venture capital in the country, are sceptical that overseas funds will benefit the industry and the potential local VC partners are few and far between. Indian biotechnology companies remain starved for early-stage funding from the local resources as well. Indian funds like ICICI Ventures, APIDC, the N S Raghavan Foundation and Kotak Private Equity are stepping in, but it is still a small share. The type of products and the relatively small size of biotechnology enterprises contribute to this reluctance of VC funding. Biotechnology companies are increasingly looking to banks for funding. Bank of America and Citibank are eyeing India's biotechnology sector, and some funds from abroad are beginning to trickle in, including investment from the International Finance Corp, the private-sector arm of the World Bank group.<sup>9,20</sup> (iv) The regulatory framework is still developing, and is now a multiplicity of bureaucratic organisations and processes. Many pharmaceutical firms avoid India because their drugs can be transformed

into domestic generic equivalents by Indian scientists without legal repercussions.<sup>21</sup> (v) Also, the skilled labour receives a poor rating because of the brain drain from the best universities. Many of the best-educated scientists in India leave for the United States and Europe to receive much higher salaries than are available in India.<sup>22,23</sup>

Despite more advanced biomedical research base in India, major developments in the biotechnology companies have occurred in the western developed countries because of strong and persistent government funding, favourable policies, availability of venture capital and an entrepreneurial workforce. In India, the expertise required for manufacturing biologicals is vastly different and not yet available within the Indian biopharma industry. The most interesting challenge ahead is to understand and implement the regulatory requirements for biosimilars in order to market them in the regulated markets. In the present Indian biotechnology business scenario in order to minimise the go-to-market time for products, the country has to attain a sustainable competitive advantage globally.<sup>24</sup>

## CONCLUSION

The Indian biotechnology industry is mainly dominated by the healthcare sector having its roots in the pharmaceutical industry. This paper attempts to highlight the important characteristics of Indian biotechnology businesses by examining their evolution, structure and growth based on the products, technologies and the services provided by them. The firms that are active in the healthcare biotechnology sector mainly comprised medium-sized and newly dedicated biotechnology firms. The activity profile of these firms though quite diverse is mainly concentrated in the domain of recombinant therapeutics, vaccines, diagnostics, bioinformatics and custom research or manufacturing services adopting a Product, Platform or Hybrid business models. Indian biotechnology firms have exhibited alliances

both with national and international organisations. Foreign collaboration dominated among the firms, thereby reflecting their tendency to catch up with the new or cutting-edge technology or align with the global research network for higher growth. Global companies have recognised the Indian expertise and engage the services of Indian companies as pre-qualified vaccine manufacturers at highly competitive prices. The results indicate that the majority of the biotechnology companies have ventured and adopted the fully integrated business model of research; manufacturing and marketing successfully followed by the platform-product hybrid model for providing clinical and/or contract services in research and manufacturing of healthcare products.

The Indian biotechnology industry is following the strategies like technology and competency development for entering into the competitive global markets of biogenerics. It appears that institutions and companies are collaborating at various stages of their development by following the risk and revenue sharing model of public-private partnerships. There are challenges of innovative product development, attracting domestic as well as foreign early stage funding, installing EU/US FDA approvable manufacturing facilities, improving skill sets to run large bioreactors and processing plants, protection of intellectual property rights under the WTO agreement to recognise drug patents from other companies, developing robust regulatory framework, and retaining the human intellectual capital of the country and this would strongly decide the future of Indian biotechnology. Nonetheless, the government's initiatives like tax incentives, biotechnology parks and seed funding for biotechnology startups are indeed genuine efforts to make India a major player in the global biotechnology business.

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