BioSpectrum the business of Bio & Health Sciences

Indus Biotech focuses on cost-effective drugs

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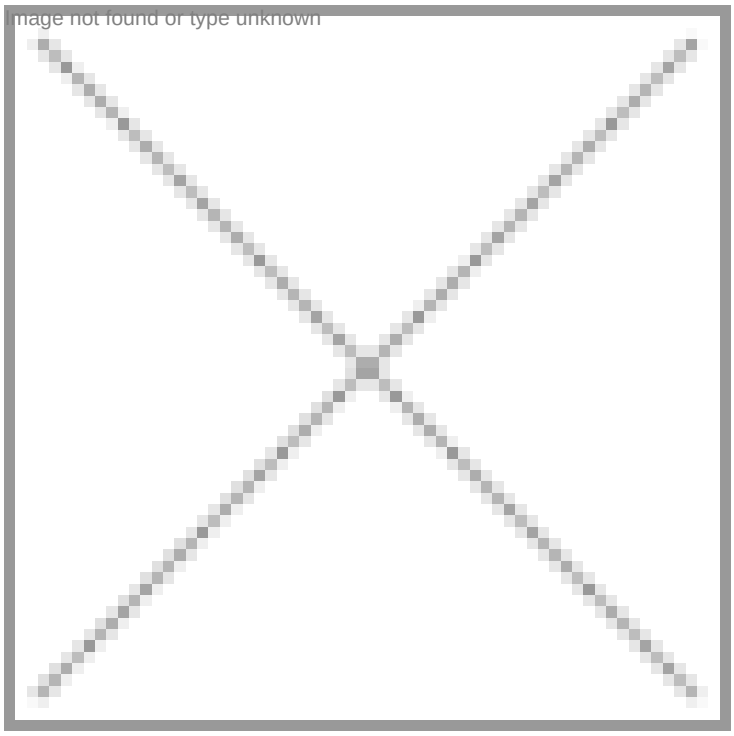
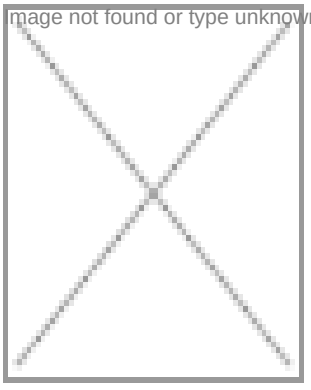
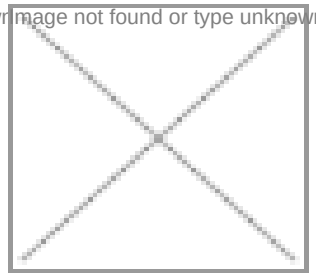


The company has redefined drug discovery by coming up with a model that is cost-effective, without compromising the quality of drug discovery

Founders of Indus Biotech



Sunil Bhaskaran



Rajan Srinivasan

The life sciences industry today faces a paradoxical situation. While on the one hand, there is a growing need for noveldrugs across different geographies, specially for diseases like malaria, dengue and Parkinson's disease; on the other hand, companies are going through the most tumultuous period in history, with drug pipelines drying up, due to poor R&D

productivity.

Adding to the situation is the sky rocketing increase of drug discovery costs, presently at over 7,500 crore a cost that is nearly impossible for small- and mid-sized biotechnology companies. Most importantly, the number of candidates failing phase III clinical trials have been growing by the day.

This is, when an innovative drug discovery model that is cost-effective, mitigates risks, yields high return on investments (RoIs) becomes a pre-requisite and Pune-based, Indus Biotech devised one such business model. The company, rather than looking at deriving molecules from synthetic-based compounds, extracts compounds from the plant kingdom, whose safety has already been proven, and which can have physiological effects on living organisms like the human body.

The genesis

In 1997, Sunil Bhaskaran teamed up with IIT-batch mate, Rajan R Srinivasan (presently Executive Director of Indus Biotech) and (Late) Dr Kris Venkat (who was then on the Supervisory Board of Strand Life Sciences). The trio put on their thinking caps to come up with a model that focused on the discovery of novel molecules for chronic diseases, and at the same time, one that would be cost- effective. Thus germinated the idea to set up a company, Indus Biotech. Recalls Sunil Bhaskaran, managing director, Indus Biotech, â€œDr Venkat believed that many interesting molecules can come in from the plant kingdom. Drug discovery costs at that time were becoming huge. When we started this business, the drug discovery costs were close to 4,000 crore. We then started thinking of finding a model that is cost-effective and requires less capital-to discover drugs for chronic diseases. That was the business thought behind setting up Indus Biotech.â€?

> â€œOur business model is basically to develop an NCE, and then license it to a Big Pharma but half way through, we will be able to sell some of these productsâ€?
> **-Sunil Bhaskaran**, managing director, Indus Biotech

The compounds in this case, are extracted from raw materials in the food chain. From here, the company has a three-way approach to keep the revenue streams flowing. The first approach is taking the molecule up to the level of a novel chemical entity (NCE), where it will be further licensed out to a big pharmaceutical company. Half way through the product development, it can be sold as a consumer healthcare product. The third option is to obtain approval from FDA as a Botanical Prescription Drug. â€œThere are always chances that during the course of the discovery and development process, the candidate might exhibit some additional useful physiological effects. So, we have developed an option where we can use it for other applications also. Our business model is basically to develop an NCE, and then license it to a Big Pharma but half way through, we will be able to sell some of these products as consumer health products,â€? adds Bhaskaran.

Like all business ventures, the promoters were faced with myriad challenges in the beginning, with funding topping the list. The promoters of Indus Biotech and angel investors together brought 1.13 crore to the company. Kotak India Private Equity Advisory headed by Nitin Deshmukh invested 31 crore about two and-a-half years ago.

â€œVery few venture capitalists at that time were ready to back a start-up with a fundamentally new business concept like ours,â€? adds Bhaskaran. This apart, the class of drugs Indus Biotech dealt with was often confused with that of Ayurvedic medicines. Says Madhu Kode, Technical Analyst, Indus Biotech, â€œThe biggest task was to make people understand the kind of model we follow. An ayurvedic medicine may constitute many compounds, but we will not be able to pinpoint the active compound within the medicine which will act against the disease. This is not the case for the class of drugs which we deal in.â€?

The third challenge was that a regulatory pathway for botanical drugs were not present anywhere in the world except in the US (which came out in 2004). While the European medicines agency (EMEA) is presently still in the process of coming up with guidelines for botanical drugs, India is yet to come out with a regulatory pathway.

Unique drug discovery model

The distinctiveness of the model is that it starts with in vivo studies at an early stage, that evaluates target activities of the drug, and assesses the failure and side effects of the drug. This drastically reduces the costs of development. Another advantage of the model is that it also looks at early stage proof-of-concept studies that evaluate human safety and efficacy of the drug. Thus, the risk of failure during the later stages of development is mitigated because, before reaching an Investigational New Drug (IND) approval, the safety and efficacy of the drug has already been established. The traditional drug discovery model cost costs about 3500 crore, and takes around six-and-a-half years for the molecule to reach regulatory IND approval. The drug discovery cost within the canvas of the Indus Biotech model is a fraction of 3500 crore - spanning a time period of four years - before it reaches the stage for IND approval.

The regulatory pathway for botanical drugs opening up in the US opens up a world of opportunities for Indus Biotech whocan

further work on drugs with proven therapeutic efficacy. The FDA guidelines permits poly-molecular assays with benign impurity profile, thus further reducing development costs. Indus Biotech is majorly targeting the US market for its consumer healthcare products due to the growing size of segments like the nutraceuticals. This will bring in quick revenues to the company, that can further be used to sustain their research work.

The star products

The company presently has seven NCEs in its pipeline, focusing on 13 therapeutic areas with the lead molecule being a HIV/AIDS drug candidate, IND02.

Last year, this lead candidate got the IND approval from the FDA. IND02 converts a HIV patient into what is called in scientific circles, a â€œHIV Controllerâ€?, and people can well live out their normal life span with the disease - without the concerns of the high cost of treatment, or the dramatic shortening of their life span. IND02 is a drug candidate that is an â€œenablerâ€?, that converts the HIV patient to a HIV Controller.

Interestingly, the molecule has also shown new indications for H1N1 strain as well as H3N2 strain (avian flu). Also, it has shown to be effective on Tamiflu-resistant strains. â€œWe have independently verified the studies in Japan and biosafety tests were conducted in the National Taiwan University Hospital in a P3P4 lab,â€? said Bhaskaran.

The company has not yet moved forward with clinical trials in the US for this candidate. â€œWe did some additional bioavailability (BA) studies of the candidate in India. We are now ready to start clinical trials in the USâ€?, adds Kode.

Other candidates include diabetes (completed proof of concept studies and ready for phase III), rheumatoid arthritis (RA) (completed proof of concept), Parkinson's disease (completed proof of concept, and will move onto human trials), Huntington's disease (preclinical), kidney disease and depression. The company is also looking at other segments like dengue and malaria.

The major hitch for the company has been the absence of a regulatory pathway in India for these class of drugs. This, Bhaskaran believes, can cost dear to the company. â€œSince India does not have a regulatory pathway for botanical drugs, the drugs have to be approved in the US, and hence the costs will rise because of the process of the application protocols, and then go through the clinical trials protocol in the US.â€?

Post the IND approval by the FDA for IND02, the company also put forward a dossier before the DCGI for IND approval in India. But the dossier was withdrawn due to a lack of guidelines. â€œWe have an active molecule presently, which we believe, will be a solution for dengue. But in India, there is no regulatory pathway for our kind of molecules. We will have to take it to the NCE level and then license it out to the big pharma, which is a prolonged process. On the other hand, dengue as a disease profile has a minor market share, resulting in less interest among the big pharmaceuticals,â€? opines Bhaskaran.

Presently, Indus Biotech has 35 patents already granted in different countries; and 25 patents awaiting approval. â€œWe have a total of 60 patents. A patent takes around four years to get approval, and the cost for one patent is about `6 lakh. So, we have invested a lot of money in Intellectual Property (IP) generation,â€? says Bhaskaran.

Looking to the future

To sustain their business model, Indus Biotech is now actively looking for partners that include both big- and mid-size pharmaceutical companies. Presently, the company is in talks with big pharmaceutical companies for licensing its NCEs, while for consumer healthcare products, Indus Biotech will first tap the US markets, and gradually move to Europe. The company's molecules for RA and Parkinson's disease, are in late stage development, with the Parkinson's one completing human data and proof-of-concept studies.

â€œWe also have a study on the side effects of oncology, for which we are creating human data. All our IND approvals, will be filed strategically when some funding is available,â€? says Bhaskaran.

The company is also looking at setting up a marketing subsidiary in the US, but not in the near future, as it presently has advisors in the US and in Europe.

Nayantara Som in Mumbai