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Joining forces

*Prohibitively high costs of R&D has made the process of drug discovery a commercial affair. Indian pharma companies are exploring various collaborative strategies to reduce the R&D burden. By **Katya Naidu**.*

Traditionally, Indian pharma has been a dark horse in the area of drug discovery. The reasons for this may be many, but the most discernible factor of drug discovery is the high development costs. The entire process of drug discovery, starting from target identification to marketing, can cost anything between $100 million to a billion. Adding to the prohibitive costs is the fact that the drug discovery process extends anything from eight to ten years and sometimes more.

"From start to finish, global pharma industry estimates that out of thousands of molecules screened in the discovery process, only one will finally make it to the market as an approved drug"

- Hitesh Gajaria
Pharmaceutical Sector Leader

KPMG

To make things more complicated, drug discovery carries with it, a very high probability of failure. "From start to finish, global pharma industry estimates that out of thousands of molecules screened in the discovery process, only one will finally make it to the market as an approved drug," says Hitesh Gajaria, Pharmaceutical Sector Leader, KPMG. Agrees Dr Villoo Morawala Patell, CEO and Founder of Avesthagen, "R&D is one of the most expensive tasks because you don't know which way you are going, you are taking shots in the dark."

Yet, these factors are not discouraging companies to invest on research because the gains from a possible blockbuster are colossal. "In a changing market, R&D is going to give pharma companies an edge over others. It is going to be R&D and the IP that will distinguish good pharma companies from great ones," states Dr Sudershan Arora, President-NCE Research, Lupin.

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Since drug discovery is an essential, yet heavy-duty financial activity, many companies are experimenting with various R&D collaboration frameworks. Now, drug discovery has become a business in itself rather than just a passive part of it. "People do lots of research; many times they are not very fruitful or productive. Big pharma is looking at commercialising R&D earlier in the cycle. When people start research, they do have an eye on the market, even though it's a long way," says Sujay Shetty, Associate Director of PricewaterhouseCoopers.

" There is no VC for drug discovery in India. Partnering is the best way to cut short the time to the market.It is not the lack or presence of money but it is the shared capabilities"

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In addition to investments, R&D also puts forth requirements in terms of infrastructure. "We require one to two million in lab equipment for the early part of drug discovery for scale up. And for manufacturing, the cost is 100-200 crore, which is about 20 to 40 million," says Patell. These issues make it particularly difficult for pharma companies to drive the entire process of drug discovery all the way to the stage of marketing. "Most companies according to my analysis will go up to Phase II or Phase III clinical trials and then go in for out-licensing. Frankly, barring one or two exceptions, it is very difficult for Indian pharmaceutical companies to take an NCE to the market stage," says Gajaria.

In and out!

There are very few pharma companies, which can afford end-to-end drug discovery. Many pharma companies use various strategies to fill the gaps in the cycle like out-licensing and in-licensing. "R&D collaboration, currently, is done in one simple way. Once the basic research is done, you out-license to companies, who have deeper pockets, to carry through to subsequent levels, through the regulatory process to overcome financial limitations," says Gajaria. Out-licensing is a boon to innovator companies, which do not have the financial clout to take the molecule forward. This is the case, where the innovator gives away the molecule to a company with a global reach.

In spite of the transfer of a molecule, out-licensing could be a win-win

"In-licensing is definitely advantageous. However, in-licensing is not a substitute for in-house research. It is just complimentary to a research based company's R&D activity"

- Sujay Shetty
Associate Director

situation depending on the payoff pathways. These arrangements can have various revenue sharing options, wherein, either both the partners share the upside or the company which out-licenses, gets high payments for the work done so far. Yet another model is where one gets a minimum or a certain committed amount for milestones as and when they are achieved. Thereafter, there is a revenue sharing model, where revenues could be higher at later stages.

If a company, which is out-licensing, does not want to wait with uncertainty, it chooses to be rewarded immediately. This could be a low risk high reward strategy in the short term. However, over time, the same strategy could turn out to be a low risk, low reward deal as the same arrangement would give a very high upside to the other partner if the drug turns out to be a blockbuster. Though the out-licensing company gets the reward upfront, it would be far less than what the blockbuster drug is going to do for the pharma company which in-licenses the drug. But if the company chooses to forego immediate benefits of out-licensing with hope of better profits and plans to jointly approach the market; in such a situation, the strategy will turn out to be a high risk and high reward deal. This way, the company can look forward to higher potential rewards in the future.

Off for a spin

Spinning off the R&D units into individual companies is a visible trend in the Indian pharma industry of late. Quite a few companies are de-merging their R&D entities into a completely focused and a separate company. The main objective of this company is entirely in R&D, which will not be burdened by activities of the parent company like marketing, distribution and brand building. In addition, spin-offs also give an edge for companies to procure investments. "You have the benefit of a dedicated venture capitalist or a private financier, who may want to finance only R&D activity and may not be interested in the whole basket of pharma activities being carried out in the parent company," says Gajaria.

This phenomenon of separating R&D activity was triggered off by Dr Reddy's Laboratories (DRL), which formed an integrated drug development company called Perlecan Pharma. This specialised R&D venture has an equity capital commitment of $52.5 million from Citigroup Ventures, ICICI Ventures and DRL. It also has in its kitty, four of DRL's NCE assets. Perlecan will also have the first right of refusal on future pipeline of DRL at a fair market value.

The in-licence perspective

From the perspective of the company which in-licenses a drug, the advantages are numerous in terms of enriching its product pipeline and adding to the knowledge base. "In-licensing is definitely advantageous; you get good products from other companies. When you look at your pipeline profile over a number of years, one might not have all the right products. It's a part of the strategy, because obviously you can't make all the products here," says Shetty.

The type of strategy that a company chooses also depends on its competencies. For example, if R&D is the core for a company, out-licensing is the obvious choice. But if the competence of a

company is in marketing, in-licensing is a better option. Pfizer, a marketing major, is one such company, which has leveraged in-licening to multiply its product range. A press release from Pfizer states that the company invested more than $2 billion in 2005 alone in in-licensing agreements and strategic acquisitions to acquire new product candidates and innovative technologies which support drug discovery. "However, in-licensing is not a substitute for in-house research. It is just complimentary to a research based company's R&D activity," Shetty adds.

Glenmark R&D bytes

Glenmark has quite a few in-licensing and out-licensing deals to its credit. Some of them are:

- An out-licensing deal with Forest Laboratories, which will conduct clinical trials on Oglemilast (GRC 3886), a specific PDE-4 inhibitor, for asthma and chronic pulmonary obstructive disorder. This deal involves upfront and milestone payments cumulating up to $190 million by the time Phase II commences. Additionally after the commercial launch, Glenmark will earn a mid-teens royalty from Forest on net sales of the product and in addition, will supply all API for sale by Forest
- An out-licensing deal with Teijin Pharma, which will have the exclusive rights to develop, register and commercialise Oglemilast for all potential indications for which the product might receive approval in the Japanese market. For this, Glenmark will receive upfront and milestone payments for a cumulative value of $53 million. On the successful completion of each stage in addition to annual sums that are marginally higher than the first quartile of net sales of the product in Japan, towards the supply of API and royalties
- Glenmark has also in-licensed Crofelemer, Napo's proprietary anti-diarrhoeal compound in over 140 countries, including India. These include all markets outside North America, Japan, China and Europe to treat paediatric diarrhoea, acute infectious diarrhoea and chronic diarrhoea in people living with HIV AIDS. Glenmark will develop, register, commercialise and exclusively supply Napo's global API requirements for the development and commercial sales under cGMP manufacturing according to USFDA requirements. Napo will receive royalties ranging from high single digits to early teens on net sales of the product in different geographies

Holding hands

Instead of the in-licensing or out-licensing route, a few innovator pharma companies are embracing the middle route of R&D collaboration, where they co-develop a product and share its ownership. They join forces, divide work based on their area of expertise and share the fruits of research in an equitable manner. Collaborative R&D works for those companies, who are in need of funds to drive their R&D and yet do not want to part with the IP of their product. This trend is very much visible in small biotech companies, which are in need of funding. "There is no VC for drug discovery in India. Even if you had a VC, partnering is the best way to go about it because that's how biotech operates globally. It is not the lack of money or presence of money but it is the shared capabilities. This is the best way to cut short the time to the market," says Patell.

One such case of R&D collaboration is by Avesthagen, which is partnering with Cipla for the development of 11 products. Avesthagen does the R&D, which is funded by Cipla. After the

R&D is complete, the product will be transferred to a new company, Avestha Biotherapeuctics which is a 50:50 joint venture between Avesthagen and Cipla. This company will go ahead with manufacturing and scale up. Once the product is ready, it will be sold by Avestha Biotherapeuctics as an API to Cipla, which will go ahead with the formulation and marketing. "It is joint co-development model, wherein, we put in our expertise and equipment, while they fund the R&D. Avesthagen gets 12.5 percent royalty from the sale," says Patell.

Collaborations usually work in complementary markets. "Some companies are strong in regulated markets, while others may be strong in non-regulated markets. When they collaborate and use their R&D efforts jointly to ensure that the drug delivery comes through, there is commercial agreement on marketing rights in respective territories," says Gajaria. But will collaborations reduce the profit percentage due to the sharing model? Shetty denies this, "The question which goes is—would you like to have 50 percent of a lot bigger pie or 100 percent of a very little or zero pie. One has to look at it in that context."

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