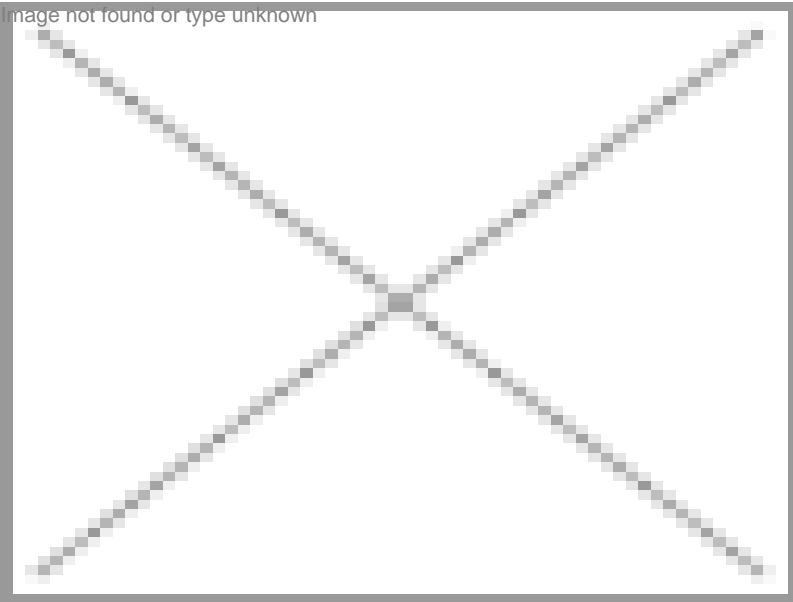


A deal undone: Biocon, Pfizer go back on alliance

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Ending of the ~~₹1,750 crore (\$350 million)~~ partnership with Pfizer means the Indian biotechnology major, Biocon, will have to find new partners to realize its growth plans. Pfizer too will have to find new avenues to mitigate its revenue drop due to patent expiration



path-breaking technology
 rolling out in the emerging
 began in 2005
 industry market of 250-350
 million pharmaceutical
 Pfizer's technology company
 Biocron of 2010 was
 catalyst for global
 Indian companies in R&D

According to the 2010
 report by commercial
 BioPharma
 Hunan Chargin Bio was
 received \$150 million from
 Pfizer for the development of
 regulatory milestones

A win-win situation for both parties bringing together Pfizer's strong marketing and commercialization capabilities, especially in the highly regulated developed markets of the world, and Biocon's expertise in biotech R&D. Insulin products were slated to roll out in the emerging markets by 2011, followed by Europe and the US in 2012 and 2015, respectively.

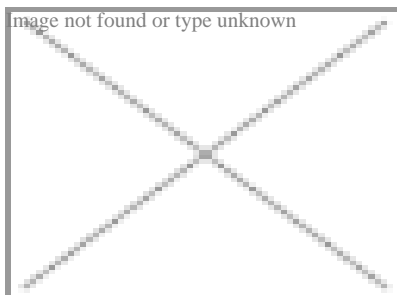
While the reasons for calling off the deal are yet to be revealed, both companies mentioned that their individual priorities for their respective biosimilar businesses propelled them to move forward independently. As of March 22, 2012, rights licensed to Pfizer will revert to Biocon and all insulin distributed under the brand names Univia and Glarvia will be commercially available from Biocon only and be exclusively manufactured, supplied, marketed and supported by Biocon. Also, Biocon would retain the upfront payment of \$100 million and the \$100 million that Pfizer paid as a escrow account for Biocon to develop insulin products will, however, have to go on \$150 million that it would have received from Pfizer for further developments and meeting regulatory milestones.

Biocon witnessed a sharp fall in licensing income in the third quarter ending December 2011 from the exceptional levels recorded last year, which resulted in a net loss. Commenting on the fall, Kiran Mazumdar-Shaw, CMD, Biocon, said licensing income is a timing issue and subject to periodic variability.

The impact

Financially, the termination will impact Biocon that has retained \$200 million in its kitty that market analysts predict could be used for R&D investments. "€ Biocon's products are yet to be collected and commercialized in the developed and emerging markets. Hence, financial impact would be minimal," says Sudarshan Padmanabhan, research analyst, Prabhudas Lilladher, an India-based financial services group. In fact, some experts also opined that the amount was significant enough for Biocon to set up its own facility, though the company would any day opt for a strategic alliance.

Lessons from partnerships



this partnership.â€?

deal can be a huge learning for
 partnerships at a time when an
 pressure on the revenues of big
 sia Pacific region is emerging as the
 y and manufacturing to counter high
 representative from Genentech, says,
 clash. In this case, it is assumed that
 d because the cost advantage went
 ey did not see much profitability in

Pharmaceutical companies have two ways of entering into partnerships. It can be a business model for cost advantage that can be done through outsourcing or it can be a partnership for innovation. For instance, if an

MNC is looking to leverage the benefits of the China market, outsourcing could be the most viable option. However, a long-term partnership is the right way for innovation.

“Specialty drugs and biosimilars are new avenues that have high potential, strategic fit towards the goal. Investing in these innovative areas can be a viable opportunity for both the parties. However, the opportunities are very big and the challenges are highly complex,” pointed out Ms Kiran Mazumdar Shaw, CMD, Biocon. She was speaking at the two-day BioPharma Asia convention held in Singapore on March 20, 2012.

The need to maintain marketing control can often restrict the choices available for strategic partnership, added Ms Shaw. “Also the need to explore products from a therapeutic perspective influences the choice of partner. The parties need to identify the requirements and then move forward.”

At a recently held biosciences conference organized by BioSpectrum in Singapore, Ms Cheryl McCaffery, deputy director, Industry Development Group, A*Star, Singapore, spoke about the various sides of collaborations. She mentioned that in the process of selecting a partner, a research company should understand the structure of the industry trends and niche areas where the technology could be applied. “One should analyze the strengths and weaknesses of the partner and then begin courting,” she said.

“It is a time-consuming process,” he says.

Amrita Tejasvi in Singapore

From a market perspective, it is definitely a blow for Biocon as the company will again need to scout for a partner with a strong presence in the insulin market, both in the developed and emerging markets of the world. Pfizer proved to

“Pfizer has a strong marketing presence in regulated markets such as the US and Europe. Pfizer would have given Biocon the opportunity to access such markets where the insulin market is huge,” says Mr Ranjit Kapadia, vice president, Centrum Capital, India. Scouting for an apt partner who could give access to these highly regulated markets would be a time-consuming

Dr Ajaykumar Sharma, practice head “Pharma, Healthcare Practice, South Asia & Middle East, Frost and Sullivan, agrees on this. “In the short term, Biocon will have to continue with regional partners and look forward to expanding its core business. This means some growth plans will have to take a back seat. In the long run, it will continue its growth by pushing into other biosimilars areas that the company is currently not

Mr Ranjit Kapadia of Centrum Capitals says the challenge for Biocon will be to look for a partner who is equal to or better than Pfizer. “Or it can invest in setting up its own facility with the money that it has in hand. But the fact remains that both are time-consuming processes,” he adds. Divesting its 70 per cent stake in its German arm, Axicorp GmbH, post the global alliance with Pfizer could be a missed opportunity for Biocon. “If Biocon had retained its stake in its German arm, Axicorp would perhaps have given Biocon access to the EU market today,” points out Mr Kapadia.

For Pfizer too, the deal termination could prove to be a setback. The company is already reeling under the pressure of a sharp drop in revenues post the patent expiration of a slew of its blockbuster products starting 2012. It is exploring profit-making avenues to make up for this loss. Biosimilars is one such growth area, and a deal with Biocon would have given the company access to the burgeoning global insulin market. Insulin is a \$14 billion global market and, by 2015, a number of insulin analogs will be out of patent protection, resulting in a significant opportunity for biosimilars.

“For Pfizer, it means looking at other areas of investment to make up for the loss of revenues due to some key drugs going off patent between 2010 and 2020,” adds Dr Ajaykumar Sharma of Frost & Sullivan. The company has already reported a drop in its fourth quarter (Q4 2011) revenues due to expiration of patent of Lipitor, one of its biggest drugs. The Q4 2011 revenues were \$16.7 billion, a decrease of four percent from \$17.4 billion for the same period a year ago. Expiry of patent for its next big product, Viagra, too will be a big revenue dampener in the coming year. Against such a backdrop, business in biosimilars and generics through partnerships could help mitigate its anticipated drop in revenues.

There are mixed opinions over whether this would impact Biocon's prospective partnerships with global drug giants and whether it has affected the global community's confidence in Indian companies. “There will be some dent in the trust factor. But Biocon as a brand is strong enough to tide over this scenario. They already have many regional partners and will continue to do their business,” says Mr Kapil Khandelwal, director, Makven Capital, while pointing out that every partnership deal goes through extensive scientific, commercial and market due diligence with milestones clearly articulated. “Hence, if any deal goes through or fails, it is dependent on its merits and achievement of milestones and not on the overall corporate performance. Biocon's future partnerships with MNCs will be based on the diligence of the research milestones and future potential of the product. Current termination will not have any impact on the future partnerships,” he remarks.

Regardless of the consequences of this deal annulment, MNCs are here to stay in India. “At the end of the day, India is a big market for MNCs and they will never think of restricting themselves from striking collaborations with Indian companies and investing in the country,” adds Mr Sudarshan Padmanabhan of Prabhudas Lilladher. The question remains as to who

could be Biocon's next prospective commercialization partner who could give the former the same bandwidth as Pfizer. "Novo-Nordisk, Eli-Lilly and Sanofi Aventis are the leading names in the insulin market. Biocon can look at these partners," says Mr Kapadia of Centrum Capitals.

How hot is biosimilars?

biocon is committed to delivering our biosimilars insulins portfolio to global markets in our endeavor to make a difference to diabetic patients across emerging and developed economies. We will continue to work with our existing partners in several markets and will pursue a commercial strategy on our own and through new alliances in other markets.

- Ms Kiran Mazumdar-Shaw, CMD, Biocon

We continue to be dedicated to developing a broad portfolio of biosimilars medicines, including monoclonal antibodies and recombinant protein products, both internally and through collaborations. In addition, we will continue to be active in our own research and business development efforts for diabetes, which represents a huge unmet medical need, and we remain committed to seeking new solutions to help physicians and patients.

- Diem Nguyen, general manager- Biosimilars, Pfizer

Biosimilars was slated as the hot segment for investment by Indian companies. Yet it has not taken off the way it was predicted two years ago. "Indian companies are yet to grapple with the fact that biosimilars is a different ball game than small molecules. There is no room for short cuts in biosimilars research. The research is complex and investments in time and money are huge. Also, marketing them in markets such as the EU and the US require strict adherence to quality standards," says an industry expert who did not want to

Dr Ajaykumar Sharma of Frost & Sullivan has a similar view. "Cost of development coupled with huge marketing costs has restricted biosimilars drugs to very few niche areas, such as diabetes, oncology and rheumatology. The highest selling segment in India is still the anti-infectives and cough and cold therapies that were launched almost 20 years ago. Biosimilars need to go beyond the current areas it is serving to make a real dent in the market,"

Mr Kapil Khandelwal of Makven Capital says that this has been a matter of debate and discussions at many industry forums. "This can be looked at from three angles: One is that many

Indian players have experimented on different business models. Some have succeeded, some have partially succeeded, and others have failed. We have not analyzed the reasons for the failures or partial successes and learnt from them. Secondly, pharma companies in emerging markets need leaders to address issues in the region. There is a leadership failure in getting the direction right. Lastly, in terms of regulations, we are just not attractive enough as compared to the emerging markets of China and Korea," he points out.

Mr Sudershan Padmanabhan of Prabhudas Lilladhar points out that even globally, biosimilars has not really taken off. "Apart from complexity in research, even in terms of regulations, in the US itself there is no pathway for biosimilars. The EU has one but that too is not clear. Once these markets open up, it could prove to be favorable for India."

Nayantara Som Banerjee
in Mumbai