

# Reliance Life plans to launch biosimilar drug in Europe

## Co Completes Required Tests, Awaits Final Regulatory Approval

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**T**HE Mukesh Ambani-owned Reliance Life Sciences plans to launch its biosimilar drug to stimulate red blood cell production in Europe within a year since it has completed all required testing and now awaits final regulatory approval.

Unlike the pharmaceutical market that is flooded with generic versions of drugs, the biosimilar market, or market for generic versions of biological medicines, is relatively untapped. The global market for biosimilars is estimated at over \$19 billion, and like all new things, the industry expects to make significant profits in the initial years.

Reliance Life Sciences will take the path of least resistance, KV Subramaniam, president and CEO, Reliance Life Science told ET. "The US doesn't worry us. There is a pathway in Europe, and Erythropoietin (the red blood cell stimulant) will give us the confidence to take others to market." The company is privately-owned by Mr Ambani and doesn't disclose numbers.

In the recently-passed US Health Bill the data exclusivity period for biological drugs was extended to 12 years from seven earlier, which is seen as detrimental to development of biosimilars. Countries are sceptical to allow biosimilars because they contain living active ingredients and are relatively new, so regulators have less experience in testing and dealing with them.

While Europe has a policy that approves of biosimilars, Indian companies have found it hard to crack the code. Dr Reddy's has been in talks with regulators to launch a biosimilar since 2006 and is still waiting. Biocon acquired a company in Germany in 2008 to reach the market. Some global players like Novartis, Hospira and Teva have a head-start because they are marketing some products in developed markets.

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Unlisted Reliance Life Sciences that



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swung to profits in the just-ended year, already has four biosimilar products in India, and plans to launch another three in this year, said Mr Subramaniam.

The company is also developing biosimilars for five monoclonal anti-bodies that are in pre-clinical stages. Monoclonal antibodies are used to treat a variety of diseases, including cancer, cardiovascular, and inflammatory problems. The company focuses in gastro intestinal, oncology, gynaecology, neurology and nephrology treatments.

"The objective is to find unmet need and discover new therapies," said Mr Subramaniam.

Reliance Life Sciences makes four generic pharmaceutical drugs that are used to treat cancer. The company plans to grow this, said Mr Subramaniam. "To take it to culmination, we would need to look for acquisition. Perhaps a year later."

"Valuations are a big issue," he said, adding "What promoters expect is too high." Valuations of pharmaceutical companies have shot up in the last year. "We are a conservative company. We won't offer so much premium."

Reliance Life Sciences would like to acquire companies that will give it access to developed markets like the US, Europe, said Mr Subramaniam. The company isn't particularly looking at significant operations in India, he added.

Reliance Life Sciences is most known for

the stem cell therapies that were once considered the solution to all illness. "People are selling false hope," said Mr Subramaniam. There are hardly any studies of stem cell research to prove consistent performance of solutions, he said. Much of it is owing to under-regulation in the area, he added.

The company has a stem cell treatment to repair the Limbus in the eye that's between the cornea and the white part of the eye. It is currently testing one to repair conjunctiva cells that form a thin film covering the eye.

"It is 60% efficient at the moment. We expect to bring product to market within one year," said Mr Subramaniam. Yet another one for retinal cells is under development, but it is more complex and will take several years before it is ready, he added.

The company also hopes to enter regenerative therapies for acute kidney injuries and wound management, he said. However, the biggest concern with stem cells is that so far it is not scalable.

Therefore mass, ready to use solutions are not available. At present, the original cell has to be taken from the patient, grown and then used. This is a lengthy and expensive process.

A large central repository of stem cells will be required to find matches for every patient and make stem cell treatments mass, said Mr Subramaniam. "That is still many years away."

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**STRONG DOSE**