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It's Biocon's day in the sun

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It's been a long winter for Biocon Ltd's shareholders and they must be happy finally, provided they have held on, of course. The chart shows how Biocon's shares have done versus the broader markets since its listing in April 2004. They have underperformed the broader markets in the past decade but have seen a decisive move up since 2016. Biocon has also outperformed the BSE Healthcare Index after a long stretch.

The main reason for this shift is its steady progression towards launching a biosimilar in the developed markets of Europe and the US. The latest provocation for the rise in the stock was that its biosimilar trastuzumab, whose reference product is Herceptin—used to treat breast cancer—has got a recommendation for approval from the Oncologic Drugs Advisory Committee (ODAC) of the US Food and Drug Administration. The final

approval will come from the US FDA and one should hear further news in the first week of September.

Here's where it gets a bit complicated. Unfortunately for Biocon, this good news is diluted somewhat by the post-inspection observations it received from the US and European regulators. It has clarified that these are normal observations and is confident of getting a final approval. Investors cannot be blamed for being a bit cautious, given their experience with regulators at other companies.

Even then, Biocon's shares are understandably on the ascent, having risen by 26% in the year so far as its biosimilar programme began to progress towards a launch in US/Europe. Herceptin is a blockbuster product of Roche Holding AG, with \$7.1 billion in sales in 2016 (based on current exchange rate for 1 Swiss franc to dollar) or Rs45,760 crore. Two-thirds of this product's sales are from the US and Europe.

Mylan has entered into a settlement with Roche over

Taking the lead

Shares of Biocon have outperformed the broader markets since July 2016.



Herceptin, which clears the way for a launch globally. That means it can launch in the US, without a hitch, once it gets the US FDA's final approval. Biocon's ability to get plant-level clearances and Mylan/Biocon's ability to pass the remaining regulatory process are what one needs to keep an eye on.

Mylan will launch the prod-

uct in most developed markets, including the US and Europe, while Biocon will launch it elsewhere. How much Biocon gains really depends on when trastuzumab is actually launched, for how long it remains the sole biosimilar in the market, and the share of revenue/profit it is entitled to. The first full quarter post-launch should give an

idea of that. It should be good, given the current size of the market.

That is not all. The Mylan-Biocon partnership has six products, including trastuzumab. The progress made by this product raises the odds of the other ones also making it to the market.

Those odds will improve further when trastuzumab actually makes it to market. This, too, has contributed to the increase in Biocon's valuations. More importantly, it validates Biocon's competence in what everyone agrees is a complex field and requires significant investments. It has been much ahead of its peers in this area, who were more focused on generic pharmaceutical drugs.

What are the risks? An actual US/Europe market launch is the next milestone to be watched for and delays will cause anxiety. Getting accepted in the market is another. Other competitors getting approvals, at some point, can lead to price erosion, making an early launch imperative. Will other prod-

ucts in Biocon's pipeline get a similarly smooth pathway or was this a one-off event, is a question investors may ask.

Lastly, Biocon is in a position similar to its larger peers, when they got key generic drug approvals for the US market. Its sales, profits and cash flows should see a significant increase as these products launch. These will eventually taper off, as it did for them. Many of them seem to not have reinvested wisely in improving processes, partly explaining their regulatory problems.

It has been more than 13 years since Biocon listed to reach here. It has shown it can play the long game. In 2017, that has made it one of the sought-after stocks in the healthcare market. Some of the money it earns from biosimilars will be useful to fund its own ongoing biosimilar programmes or repay debt. These are short- to medium-term objectives. If its pipeline delivers, they can also help play the building blocks for Biocon's next decade in this industry.