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In Biocon, investors see a blockbuster pipeline

US nod to application for breast cancer drug is latest positive for the stock

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The Street remains upbeat on Biocon, whose stock continues to trade at similar levels after hitting an all-time high of ₹1,052 in January. The latest trigger is a US nod to a biologics licence application (BLA) for breast cancer drug trastuzumab in January. Biocon and Mylan had made their first regulatory filing to the US for the drug in November 2016. With the acceptance of the BLA, the Street expects approval of the product by September 2017.

Arun Chandavarkar, chief executive and joint managing director, Biocon, said, "It is a major milestone for Mylan-Biocon collaboration since it is the first US regulatory submission through our joint global biosimilars programme. The development positions Biocon and Mylan among the first companies to be able to address the critical need of US patients for high-quality biosimilars to treat certain HER2-positive breast cancers in the near future." Biosimilar is a drug of biological origin (such as a globulin, vaccine, or hormone) that is similar to a previously-approved proprietary biologic (biological products that include vaccines, blood and blood components, allergens, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins).

Trastuzumab, sold under the brand name Herceptin, has global annual sales of \$6.5-7 billion, the US accounts for 35 per cent, European Union 30 per cent. Biocon had already submitted a marketing application to European Union for the drug in August 2016, a plea for its insulin product pegfilgratin in July 2016, and a filing for insulin glargine in November 2016. Thus, in all, the company has four filings in European Union and the US.

The commencement of filings had sparked the Street's optimism on the company's prospects. The stock, which saw lows of ₹430.8 in February 2016, has more than doubled since. The success of biosimilars could put the company in a higher growth orbit.



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REUTERS

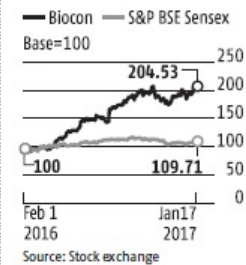
STRONG GROWTH PROSPECTS

Biocon	FY17E	FY18E	FY19E
Revenues (₹ crore)	4,332	5,165	6,400
% change y-o-y	24.3	19.2	23.9
EBITDA (₹ crore)	941	1,172	1,477
Ebitda margins (%)	21.7	22.7	23.1
Net profit (₹ crore)	540	699	843
% change y-o-y	23.5	29.4	20.5
EPS (₹)	27.0	35.0	42.1

E—Estimates

Source: Morgan Stanley Research

ON AN UPWARD TRAJECTORY



Source: Stock exchange

The compound patent for the breast cancer drug, which the company has filed for, expired in the European Union in July 2014, and will expire in June 2019 in the US. Biocon had already launched the drug in India in 2014 and is in the process of expanding its presence in other emerging markets. Currently, Biocon rivals are developing four other trastuzumab biosimilars. But analysts at Morgan Stanley believe Biocon can be the first in the US to submit a biosimilar marketing application.

Roche, which is marketing Herceptin, will try to defend its revenues. The company is said to be working on its developed product Perjeta and conducting trials to prove that Perjeta, along with Herceptin, can be a better treatment option than Herceptin alone. Success in trials will help Roche control market price and market share, say analysts

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at Nirmal Bang, who add that Roche can subsidise Herceptin by selling Perjeta at a premium. Besides, Roche can further incentivise patients and payers through co-pay discount and volume-driven bundled-pricing discount. In case Roche's trials fail, trastuzumab for Biocon will be a \$180-million annual opportunity in regulated markets (such as the US); if trials succeed, it will be a \$90-million annual opportunity, say Nirmal Bang analysts.

While clarity on revenues will come over time, launch of products in the US is some time away. Nevertheless, the biosimilar theme for Biocon is still playing out. The company's subsidiary Syngene is doing well in contract research and is set to record steady revenue growth. There are other generic opportunities unfolding for Biocon, such as launch of generics of Copaxone in the US. Analysts at Morgan Stanley, who remain positive on the company's prospects, say that value creation in the biosimilar pipeline is under way and the base business is scaling up nicely in emerging markets, especially with Malaysian facility turning commercial in the second half of the financial year. They continue to see Biocon as a leading Indian play on biosimilars. Morgan Stanley has a target price of ₹1,156 for the stock that now trades at ₹994.65 levels.