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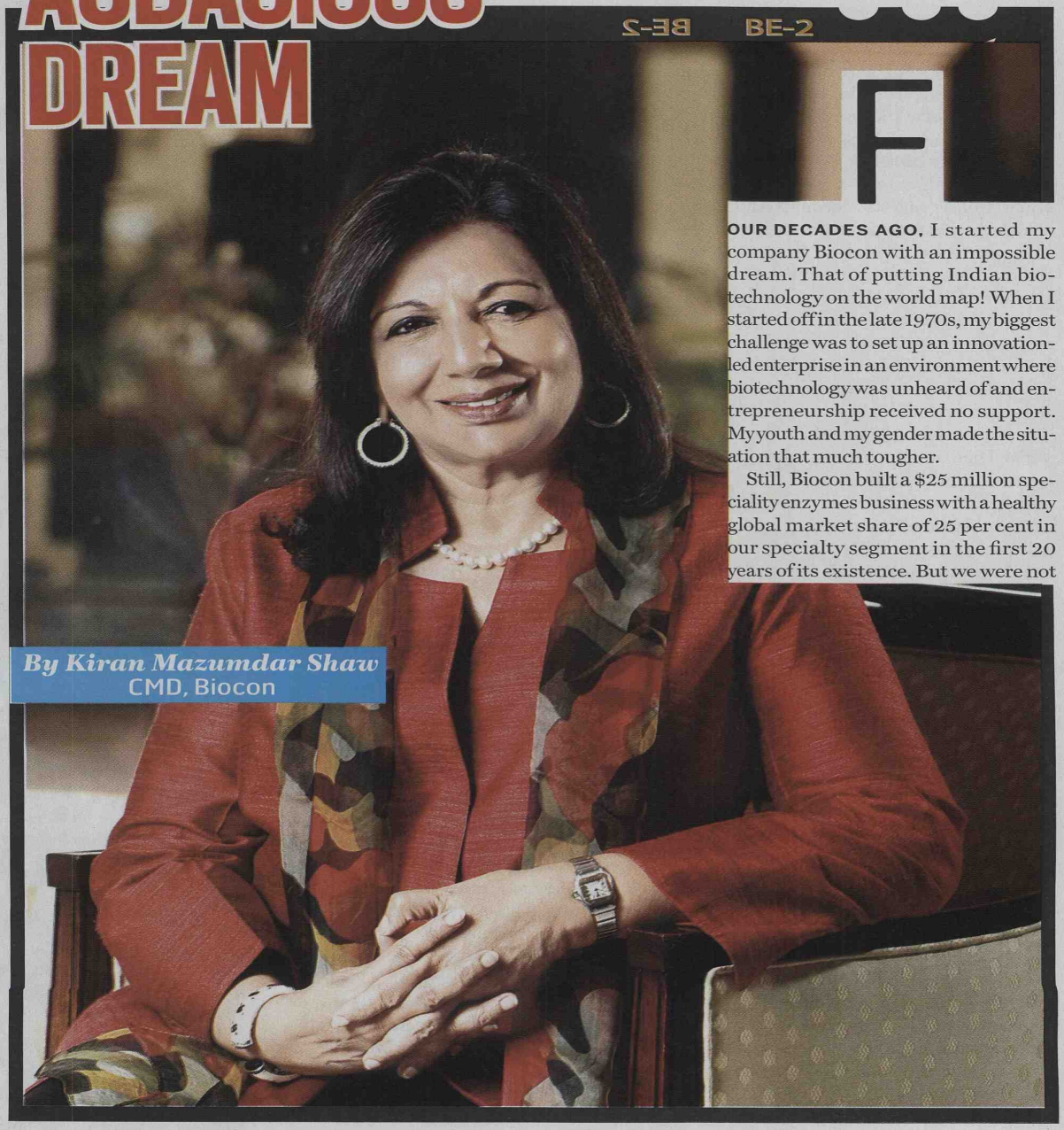
REALISING AN AUDACIOUS DREAM



By Kiran Mazumdar Shaw
CMD, Biocon

FOUR DECADES AGO, I started my company Biocon with an impossible dream. That of putting Indian biotechnology on the world map! When I started off in the late 1970s, my biggest challenge was to set up an innovation-led enterprise in an environment where biotechnology was unheard of and entrepreneurship received no support. My youth and my gender made the situation that much tougher.

Still, Biocon built a $25 million speciality enzymes business with a healthy global market share of 25 per cent in our specialty segment in the first 20 years of its existence. But we were not

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content with remaining a global enzymes player, we had set our sights higher. Our aim was to enhance global healthcare through innovative and affordable 'Made in India' biopharmaceuticals. At the turn of the millennium, we embarked on a biologics-led pharmaceutical journey at a time when targeted therapies were revolutionising the treatment of chronic diseases.

We knew the transition from enzymes to biopharmaceuticals would not be easy because developing biologics for global markets needed patience, deep pockets and an unwavering focus. As technology pioneer it would require us to climb a steep learning curve in terms of research, development, manufacturing and regulatory knowhow. Skeptics told us that a small biotech company out of India would never make it because the path was capital intensive, research-intensive and IP-intensive with inherently long gestational time lines for product commercialisation. We were also running counter to the prevailing business ethos favouring predictable and attractive ROCE (return on capital employed) ventures based on chemically synthesised generic drugs.

Our entry into novel biologics predates our entry into biosimilars, which are follow-on versions of novel biologics

Despite the obstacles, we plunged into the uncharted waters of innovation-led biotechnology research. We made significant investments in commercial scale, globally compliant manufacturing facilities across diverse technology platforms. We established robust regulatory and quality systems to develop and deliver complex therapeutics.

We forayed into biologics much ahead of other pharma and life sciences players in India. In fact, our entry into novel biologics predates our entry into biosimilars, which are follow-on versions of novel biologics. We successfully launched two novel antibody drugs, Nimotuzumab for cancer and Itolizumab for psoriasis for Indian patients. This approach enabled us to leverage the knowledge of immunology and antibody technology to embark on a global development program for a range of biosimilars. Today, our biosimilars pipeline includes recombinant human insulin, insulin analogs, other recombinant proteins and monoclonal antibodies.

Biocon is now the only company from India to have two biosimilars approved in the US. Ogivri, a biosimilar drug to treat an aggressive form of breast cancer, is the first biosimilar Trastuzumab to be approved in the US, and Fulphila, a biosimilar drug prescribed for chemotherapy patients, is the first biosimilar Pegfilgrastim to be launched in that country. Two years ago, we were also the first company from India to have commercialised biosimilar Insulin Glargine for the benefit of diabetes patients in Japan, which is also a developed market. Recently, we successfully obtained EU approval for Insulin Glargine and are close to obtaining approvals for two biosimilars, Trastuzumab and Pegfilgrastim. Some of our biosimilars are already being marketed in emerging markets. We have earned the distinction of being one of the top three global players of biosimilar insulins in volume terms.

We had debuted on the Indian bourses in 2004 with a market valuation of $1 billion on the first day of listing. Today, our market cap is over $5 billion. While I had dared to dream alone it was the collective belief of my over 6,000 colleagues that has led Biocon to emerge as a world-beating innovator in biopharmaceuticals and one of the most recognised Indian names in the global biotechnology sector. BW