"We are working on strategies for improving the reach of Insulins to LMICs"

With a master's degree in business administration and executive MBA from the prestigious Harvard business school, Amol Shah brought strategic focus and business opportunities for the growth of the company. His commitment for addressing the pressing need of Diabetes in the country has resulted in M.J.Biopharm becoming one of the leading insulin manufacturing company in India. With the support from Krishna Prasad as Vice President & Director and Dhaval Vashi as CFO & Director, Shah has been leading the company with total staff strength of 500+ (Technical and skilled staff: 200) to take it to the next level as it has set a target to hit Rs 200 crore for 2021-22 from the last year's sales of Rs 135 crore. In an email interview with BioSpetrum, Shah shared challenges before the company and its growth plans for coming years. ***Edited excerpts;***

« **Amol Shah,** Managing Director, M.J. Biopharm Pvt. Ltd., Mumbai

What prompted you to look at offering rDNA based human insulin raw material & formulations as an area of opportunity in 2000?

In 1990, M.J.Biopharm (MJ) entered into the insulin business both in India and in Commonwealth of Independent States (CIS) countries in a joint venture with Eli Lilly. MJ started with manufacturing and supply of animal insulin in India and we quickly realised that not only does India have a very large number of diabetic patients who are forced to rely upon imported insulin but there is also a shortage of insulin in the country keeping prices very high. Insulin was essentially monopolised by three large multinationals, thus economically disadvantaged people of India could not have access to highly purified human insulin.

To meet this gap and to provide high quality Insulin in India and globally at economical prices, then became a goal and a passion for MJ. This was the starting point where MJ made alliance with a European API supplier "Diosynth" to import Insulin Drug substance, which was then formulated into Insulin injections for sale in India.

Within few years of launch of Human Insulin in India by MJ, it became abundantly clear that to fulfil MJ's long term vision of making India self-reliant for Insulin, it was important to develop own Insulin Drug Substance. This was an aspirational and lofty goal considering that Insulin fermentation technology is not only extremely difficult, but also biotech facilities are extremely expensive to set up. Further, biotech facility also have long gestation period due to stringent regulatory compliance requirements. MJ acquired a semi constructed biotech facility in Pune in the year 2012. With hard work, determination, and self-belief, we finally succeeded in completing the facility to manufacture rDNA Human Insulin and after lengthy clinical trials got the final approval in 2018 to commercialise Human Insulin for Indian market.

What are your views now on the institutional sales model which you had opted earlier?

Congruent with the vision of founder of the company, MJ started with the challenge of registering the company with various institutions in India with a purpose of providing high quality domestic insulin at economical price. Over a period of three years, MJ has emerged as one of the main suppliers to several institutions around the country and a preferred supplier of Insulin to the prestigious scheme "Pradhan Mantri Bharatiya Janaushadhi Pariyojna" (PMBJP) to ensure availability of medicines at prices lower than MRP to the common Indian citizens. MJ continues to provide Insulin at preferred prices to the various institution to fulfil company's vision of making India self-reliant to meet the requirement of Insulin for diabetic population of India.

What were the challenges before M.J. Biopharm then and now?

MJ is a family owned company and thus access to capital and right manpower has been some of the significant challenges. However, putting that aside the biggest challenge for any biotech product manufacturer always comes from Regulatory requirements. Biotech regulatory landscape is constantly changing and the registration process is getting more complicated with each passing year

MJ is now working on in-licencing agreements and strategic partnership to launch modern insulins such as Glargine, Aspart and Lispro as well as peptides for diabetics in India. Two of the products are already in clinical trials, and expected to be registered in India before mid-2022, whilst two more modern insulin are under development in the Product development Lab within MJ Drug substance facility located in Hinjewadi in Pune.

making it extremely onerous and expensive to register a Biosimilar product. After registration of Insulin in about 30 countries, we have now embarked on the challenge of registering our product in US and EU.

M.J. Biopharm is working on four Recombinant Insulin range of products - Glargine, Liraglutide, Lispro and Aspart. When the customers can expect these range of products from the company?

Biotechnology development is a long and tedious process requiring abundant patience, plenty of resources and technical competencey in order to succeed. MJ has over the last 8 years developed the technical competence in biotechnology and has exhibited perseverance to achieve its goal as seen with the successful launch of rDNA Human insulin and the ongoing clinical development of Glargine.

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Do you have any plans of entering the branded business with your own range of Recombinant Insulin products in the coming years?

Over the next five years MJ intends to evaluate possibility of launching a full range of diabetic products in the domestic market. The ultimate aim for MJ is to reach every part of India with our diabetic range of products and to provide Affordable Quality Care in the fight against diabetes.

Although diabetes is one of the global concerns, how do you see the opportunity?

With ~470 million Diabetic population worldwide and ~77 million in India which is ~16 per cent, MJ has a crucial role to play to improve the Affordability and Accessibility of Biosimilars in Diabetes segment mainly Insulin, which is still a very effective line of treatment along with oral antidiabetic products.

Inspite of the competition and the challenges in domestic and international markets, MJ has fortified its position in Diabetes with its strong manufacturing capabilities. We are also working on strategies for improving the reach of Insulins to LMICs (Low and middle income countries). With our ardent efforts in setting up new facilities /expanding our current facilities, product registration in European Union (EU)/US and prospective strategic alliances we will emerge as one of the largest Biosimilar company in Diabetes segment.

What are your growth plans for the company?

MJ now has end to end capabilities ranging from biopharmaceutical Process development to Drug Substance and Drug product manufacturing on a large scale. MJ has been involved in pharma & biopharma manufacturing and services for almost two decades with its "Virtuous Business Model", which is self-driven and collaborative (manufacturing for their own captive requirements and providing manufacturing services to several companies in India).

By the end of 2021 MJ will be setting up a GMP compliant 100L Product development lab and a modern vial filling facility fully compliant with EU GMP /USFDA standards. This will enable MJ to provide Contract Development and Manufacturing (CDMO) services and support for drug substance of E. coli based products at 100L scale, commercial manufacturing of DS along with final formulations of the drug product in vials and cartridges. A new cartridge filling facility along with Disposable pen assembly and Drug substance facility at 10,000L fermentation scale is also planned to be ready for operation in the year 2023-24.

In addition to expanding our business in CIS, LATAM, MENA we intend to register our Biosimilars in US and Europe. BS

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