FORTIFYING
Our Position

Q&A
WITH THE CEO

Dr. Arun Chandavarkar,
CEO & Joint Managing Director

2018

Fulphila®, the first biosimilar Pegfilgrastim to be approved and commercialized by our partner Mylan in the U.S. in mid 2018, has garnered over 20% market share in the pre-filled syringes market.

Q. Biocon is among the front-runners in commercializing the first wave of biosimilars. How will it sustain this momentum?

A. **FY19 has been a landmark year for the biosimilars business. Commercialization of biosimilar Pegfilgrastim in the U.S. by our partner Mylan and the continued strong growth in biosimilars in emerging markets contributed significantly to a near doubling of our Biologics revenue in FY19, which crossed the USD 200 million revenue milestone.**

Our biosimilars strategy has begun to deliver with our key products gaining acceptance with prescribers and patients. Fulphila®, the first biosimilar Pegfilgrastim to be approved and commercialized in the U.S. in July 2018 by our partner Mylan, has garnered over 20% market share# in the pre-filled syringes market. Biocon- supplied products also hold dominant market shares for biosimilar Trastuzumab, rh-Insulin and Insulin Glargine in many key emerging markets.

This growth momentum can be sustained in the near term through a combination of key launches and new approvals for these first-wave products from our Mylan collaboration. A key milestone will be the launch of biosimilar Trastuzumab in the U.S. in 2019, which is already commercialized in EU and emerging markets. We also have approvals for biosimilar Pegfilgrastim in EU, Canada and Australia and have launched it in the U.S. We have commercialized Insulin Glargine in Japan, EU and some emerging markets. We have approvals in Austrialia and the next major near term milestone for this molecule will be its approval and launch in the U.S.

The growth will be augmented in the mid-term by our advanced pipeline of biosimilars comprising Bevacizumab, Insulin Aspart and rh-Insulin which are currently progressing as planned through their clinical development phase. In fact, rh-Insulin provides us the opportunity to establish a direct commercial presence in the U.S. and select markets elsewhere.

In the long term, our global partnership with Sandoz for a set of oncology and immunology biosimilars is progressing well and is preparing us for the next wave of biosimilar opportunities that open up towards the middle of the next decade. This will be bolstered by new opportunities to expand our biosimilar portfolio which is already amongst the largest and broadest, straddling monoclonal antibodies and insulin analogs. And these opportunities could leverage our direct commercial presence in many markets.

We will continue to support this broad portfolio through prudent investments in R&D and high quality manufacturing infrastructure to deliver on our commitment of providing affordable access to safe and effective biosimilars to patients around the world.

Q. Biocon has unlocked value several times in the course of its evolution. What do you see as the next value unlocking opportunity?

A. Biocon has successfully incubated new businesses within its fold and unlocked value in many of them. This is demonstrated by Biocon's own IPO in 2004 on the back of our successful statins business, followed by the divestment of our enzymes business in 2007 and then the listing of our Research Services business (Syngene) in 2015.

Our Biosimilars business has demonstrated success and established global credibility with three of our molecules being approved and launched in developed markets. This business is at an important inflection point as we gain commercial success with our first wave of products and invest in long term sustainability through broadening of our pipeline and commercial presence and further expanding our manufacturing scale. We have therefore begun acting on our intent to unlock value in the Biosimilars business by housing it under a separate subsidiary, Biocon Biologics. This, we believe, will enable this business to focus, invest, compete and win in the large and growing opportunity for biosimilars.

2019

Bicara Therapeutics has been set up in Boston to anchor the development of novel immuno-oncology assets.

Q. What will be the focus of Bicara Therapeutics in the U.S.?

A. There is considerable excitement around immuno-oncology therapies that activate an individual's immune system, enabling it to recognize cancer cells and destroy them. Rapid technological advancements are helping the growth of the global immuno-oncology market which is expected to exceed USD 100 billion by 2022, according to a report published by Research and Markets. Biocon has been pursuing the development of novel bi-functional fusion antibodies which work on the concept of preferentially targeting the tumor micro-environment.

We have recently set up a subsidiary, Bicara Therapeutics, based in Boston, to anchor the development of these novel immuno-oncology assets. This allows us to access the thriving innovation ecosystem in the U.S. and accelerate development of cutting edge therapies to improve outcomes for cancer patients. We will leverage synergies between our Boston and Bengaluru based talent pool and infrastructure to progress breakthrough innovation rapidly and in a cost effective way.

2019

Insugen® and Basalog®, our flagship insulin brands, reported combined sales of over ₹2 billion in FY19, in India.

Q. How does Biocon plan to accelerate the momentum gained by the Small Molecules segment in FY19?

A. The Small Molecules segment reported an increase of 18% in revenue in FY19, driven by a strong growth in APIs as well as Generic Formulations. The successful launch of formulations in the U.S., better product mix in APIs and an improved pricing environment contributed to the robust performance of this segment.

Biocon has always focused on leveraging its historical strengths in fermentation by creating a distinctive portfolio of fermentation based APIs. We will continue to expand our API portfolio where we can enjoy a competitive advantage in terms of manufacturing complexity. We intend to forward integrate into formulations for all our key APIs whereby our direct commercial presence will enable us to capture a bigger share of the value. We will also focus selectively on formulation technologies that ensure durability of commercial success through limited competition. We intend to replicate our early success in the complex area of biosimilars by investing appropriately in R&D and infrastructure for complex small molecules. This strategy of vertical integration encompassing APIs and Formulations will be backed by continued investments in Quality systems to sustain our exemplary track record in global regulatory audits.

Q. How is your strategy of returning the Branded Formulations business to a higher growth trajectory playing out?

A. Our focus on increasing market share for our specialty brands in critical therapy areas is working well. Our Top 10 brands in India grew 15% over last year, accounting for ~78% of sales, up from 76% in FY18. 70% of our overall India business is now accounted for by biologics / biosimilar products.

Basalog® is ranked as the No. 2* Insulin Glargine brand, while Insugen® is positioned among the Top 3* brands of rh-Insulin in India. During FY19, Basalog® sales grew 34% while Insugen® sales grew 21%, outpacing the covered market growth of 17% and 13% respectively*. Insugen® and Basalog® reported combined sales of over ₹2 billion in FY19.

We are also making a significant difference to cancer care in India. CANMAb™, the No. 1 brand of Trastuzumab in the country, garnered a value market share of 27%*. Our novel BIOMAb EGFR® has helped treat over 11,000 patients since launch in 2006.

Whilst we have witnessed an improvement in margins through a combination of portfolio rationalization and cost control, we do recognize that India is a price sensitive and fiercely competitive market. We intend to leverage our globally endorsed product portfolio to bring high quality biosimilars and other critical products to patients in India.

In the UAE, we continue to enjoy a dominant position in all our key brands. We are bolstering our current portfolio of branded generics and in-licensed products with biosimilars. During FY19, we launched the first biosimilar Trastuzumab in UAE under the brand name CANHERA, our second biosimilar introduction in the market after Glaricon® (Insulin Glargine) in FY18. However, in the near term our UAE business is impacted by certain adverse pricing decisions taken by the local health authorities and inventory adjustments.

Q. The high price of insulins has generated a lot of heat in the U.S. with lawmakers there calling for higher biosimilars competition to help rationalize the cost of therapy. How is Biocon positioned to benefit from this potential opportunity?

2018

We launched CANHERA, the first biosimilar Trastuzumab in UAE and our second biosimilar introduction in the market after Glaricon® (Insulin Glargine) in FY18.

A. Biocon is amongst the few global biosimilar players to have a strong presence in monoclonal antibodies as well as insulins. Our rh-Insulin and Glargine products are already benefiting people with diabetes in many emerging and developed markets through improved access and affordability. Our rapid acting insulin analog, Aspart, is progressing well in clinical development. We have invested, and continue to invest, in creating large scale high quality insulin manufacturing facilities. This gives us the full spectrum of insulins (regular, basal and rapid) and the global scale necessary to make a difference to diabetes patients in the U.S. We expect our partner Mylan to launch our first insulin analog in U.S. in 2020. We are greatly encouraged by the positive actions taken by the U.S. FDA in clarifying the path to approval for biosimilar insulins through transition from the 505(b)(2) to the 351(k) legislations and in terms of specifying requirements for an interchangeable designation.

Q. How do you see your Research Services subsidiary, Syngene, contributing to Biocon's growth in future?

A. Syngene has been a strategic growth driver for Biocon and in FY19 has delivered a revenue growth of 28% at ₹18,256 million driven by a robust performance across its divisions. Over the years its contribution to Biocon revenue has increased as reflected in FY19 performance where Research Services contribution to Biocon's revenue stands at 32%.

Strengthening its long term relationships with its prime clients, Syngene has further expanded its multi-year agreements with key clients like

Baxter till 2024 and Bristol-Myers Squibb till 2026. Syngene continues to acquire more clients and is currently servicing over 330 clients across the globe. Deeper engagement with various strategic clients along with a healthy demand in both discovery services and biologics augurs well for the future. Furthermore, the company's focus on investing in future-ready capability build up will provide a strong growth momentum for this business.

Syngene has expanded its expertise to include yeast display platforms for antibody discovery, sophisticated immuno-oncology assays, CAR-T design and micro sampling PK studies. These investments will support the company in addressing emerging client needs in both large and small molecule discovery programs, from target identification and validation all the way through IND.

We expect our Research Services business vertical to sustain a robust growth going forward.

Q. How is Biocon preparing to meet capacity requirements as product commercialization in global markets picks up pace?

A. We always dovetail capacity to our market plans and ensure that capacities come online to cater to increased market share or to anticipated regulatory approvals in various jurisdictions. Whilst we have adequate capacity to cater to our near term needs, we have triggered expansions of existing facilities and new greenfield constructions to support our future needs in Biosimilars and Small Molecule APIs and Formulations. These facilities are in various stages of construction or qualification with some expected to come online in FY20. We have also selectively partnered for local fill-finish manufacturing to benefit from any preference for locally manufactured drug product.

2020

Some of the facility expansions and new greenfield constructions we had triggered to support our future needs in Biosimilars and Small Molecule APIs and Formulations are expected to come online in FY20.

** IMS/IQVIA # Bloomberg Symphony data, Goldman Sachs report May 2019*