Biocon

Biocon Biologics

Investor Presentation

Q1 FY22

Safe Harbor Statement

Certain statements in this release concerning our future growth prospects are forward-looking statements, which are subject to a number of risks, uncertainties and assumptions that could cause actual results to differ materially from those contemplated in such forward-looking statements. Important factors that could cause actual results to differ materially from our expectations include, amongst others general economic and business conditions in India, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currencies, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither the company, nor its directors and any of the affiliates have any obligation to update or otherwise revise any statements reflecting circumstances arising after this date or to reflect the occurrence of underlying events, even if the underlying assumptions do not come to fruition.

Biocon is a global biopharmaceutical company that is leveraging its affordable innovation model to reduce disparities in access to safe, high-quality medicines, as well as, address the gaps in scientific research to find innovative solutions to impact a billion lives.

The Biocon Manifesto

As a committed stakeholder of the global health agenda under the UN Sustainable Development Goals (SDGs), Biocon has drawn up a manifesto to deliver on its commitment to universal healthcare.

accessibility

- Use our science, scale and expertise to enhance access to essential drugs for patients on the lowest rung of the economic ladder
- Uncover new medical insights aimed at expanding the scope of therapy to address unmet needs

affordability

- Focus on the kind of innovation that adds the condition of affordability to accessibility
- Bring competition for expensive innovator medicines through our generics and biosimilars

availability

- Build strategic global and regional partnerships to make high-quality biopharmaceuticals available to the maximum number of people
- Create a robust portfolio of ‘blockbuster’ drugs with the potential to benefit a billion patients

assurance

- Demonstrate the highest levels of ethics, compliance and governance
- Assure continuous supply of high-quality products conforming to international regulatory standards

The Biocon Journey: A Continuous Evolution

1978-1999	2000-2004	2005-2009	2010-2015	2016-2018	2019 & Beyond
An Enzymes Company	**Transforming into a Biopharma Company**	**Building the Base Business and Expertise in Biologics**	**Strategic Global Alliance with Mylan for Biosimilars Expanded (2013)**	**Commercialized Biosimilars for Diabetes & Cancer in Japan, U.S., EU**	**Poised for Global Impact with Biosimilars**
	Successful IPO, Biocon listed in India (2004)	Enzymes Business Divested (2007)	Generic Formulations Business Unit set up (2013)	Global Partnership with Sandoz for Next-Gen Biosimilars (2018)	Investments in complex Generic Formulations
		Global Development of Biosimilars in Partnership with Mylan (2009)	IPO of Syngene (2015)		

Unwavering focus through the years on innovation & difficult to make, niche products to create tangible differentiators for sustainable growth

Biocon Today: Strategically poised for a strong global play

Rs 7,360 Cr
Revenue*

12,000+
Total Employees*

1,200+
Patents

25+
cGMP approvals from International regulatory agencies

120+
Countries where our products are available

Ranked 5
Among Top 10 Global Biotech Employers by Science magazine

*Fiscal year 2020-21

Battling the pandemic!

- Mounting ‘on-site’ infections coupled with lockdown posed significant operational challenges
- 20,000+ COVID-19 vaccines administered to employees, their families and our neighbouring communities
- Ramped up production of Itolizumab to serve patients in the second wave: 27,000+ lives impacted
- With vaccinations picking up pace, we are hopeful of the situation improving

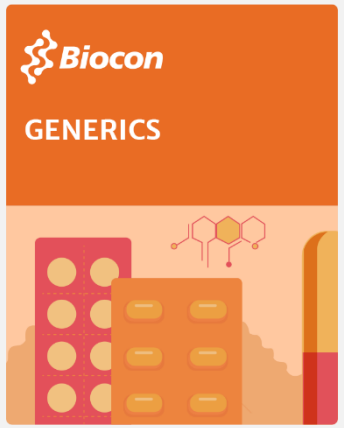
> When I came off the ventilator, I was told to be prepared for convalescent plasma therapy. But its need was mitigated by the administration of ALZUMAb-L (Itolizumab), which foiled the life-threatening impact of cytokine storm due to COVID-19. My turnaround was miraculous.
>
> **- Dr. Belani, Mumbai**

> I was admitted in the ICU when the doctors administered Itolizumab, following which my condition improved. I was moved out of the ICU the next day. Within a few days, I was helping other patients, even those in wheelchairs.
>
> **– Sanjai Rai, Mumbai**

Business Segments

Growth Verticals: Aligned With Shifting Paradigms

From pipeline to production, from drug discovery to drug delivery, we bring differentiated, high-quality and affordable healthcare products & services globally.



Ensuring access through quality, affordability, reliability

Expanding access through innovative, inclusive healthcare solutions

Partnering to deliver innovative scientific solutions

Pushing scientific boundaries to deliver impactful innovations

Generics: Investing into capacities and capabilities for the future growth

Differentiated API business

- **5 state-of-the-art facilities** across Bangalore, Hyderabad and Visakhapatnam in India to manufacture **high quality products with reliability and efficiency.**
- Expertise in **fermentation technology, large scale chromatography and synthetic chemistry** gives us a key competitive edge in APIs.
- Among the **world's largest manufacturers of immunosuppressant and statin APIs**
- **1,000+ customers** in **100+ countries** including the U.S, Europe and large emerging markets, with a **track-record of excellence for over 20 years.**

Growing Formulations Footprint

- **Solid oral & parenteral products** in both potent & non-potent categories
- **Focus therapeutic segments** – Metabolics, Oncology, Immunology & Auto-immune indications
- Generic Tacrolimus, Rosuvastatin, Simvastatin & Atorvastatin launched in the **United States**
- Entered partnerships to **expand Generic Formulations** footprint in **China, Singapore, Thailand**
- Regulatory licenses received from **MHRA** for import and distribution of our formulations in **UK**

Investments for future growth

- **Expanding our R&D capabilities** for newer fermentation-derived and chemical synthesis-based molecules.
- Focus on **developing niche, difficult-to-make, complex molecules** with relatively higher entry barriers.
- **Investing Rs. 6 billion in greenfield, fermentation-based manufacturing facility** in Visakhapatnam, Andhra Pradesh
- Focus on **adopting best-in-class quality practices and implement digital processes** in our quality and related functions
- Retaining leadership in key APIs with **structured cost improvement programs**

1000+

Customers

280+

Patents Obtained

50%

Global MS in orlistat API & world's leaders in immunosuppressants

800+

Metric ton cumulative weight of APIs supplied annually

Generics: Q1 FY22

KEY HIGHLIGHTS

- COVID-19 led operational and supply chain challenges in API manufacturing, expected to normalize in the coming quarter
- Gradual ramp-up of Tacrolimus in US while statins' market share was resilient
- Entered Labetalol and Esomeprazole in the US with estimated market size* of $63m and $230m, respectively
- Delay in site inspections, consequently launches, due to travel restrictions
- On track to commission greenfield Immunosuppressant API facility in Visakhapatnam in FY 2022

	Q1 FY22	Q1 FY21
Revenue	₹486Cr	₹621Cr
	22% YoY decrease	
Profit Before Tax	₹29Cr	₹96Cr
	6% of revenue	*15% of revenue*

*US Market value based on IQVIA

Biosimilars: Developing biologics for global markets at all scale

- Biosimilars are an attractive opportunity
- Robust biosimilar portfolio coupled with adjacent biologics (e.g., ADG20)
- Fully integrated – lab to market
- Global Footprint (120+ countries)
- Strong partners e.g., Viatris, Sandoz and Adagio
- Branded Formulations India (BFI) forms a robust commercial platform in India

Therapeutic Areas	Molecule	Product Status: US	Product Status: Dev. Markets: ex-US	Product Status: MoW[5]
Oncology	Pegfilgrastim[1]		EU, CANZ	
	Trastuzumab[1]		EU, CANZ	
	Bevacizumab[1]		EU	
	Pertuzumab[1]			
Immunology	Adalimumab[1,2]		EU, CA, Japan	
	Etanercept[1,2]		EU	
Diabetes	Glargine 100U[1,3]		EU, ANZ, Japan	
	Glargine 300U[1]		EU	
	Aspart[1]		EU	
	RHI[4]			
Undisclosed	7 Assets			

Early Dev./ Preclinical | Clinical | Filed | Approved

8 Approved Products[6]

2 Research & Development sites

3 Manufacturing sites (2 Bengaluru, 1 Malaysia)

25+ cGMP approvals (incl. FDA & EMA)

1 In partnership with Viatris; 2 Partner Viatris has in-licensed product (Biocon benefits from economic interest); 3 Japan is outside of Viatris partnership; 4 RHI non-partnered asset completed Ph 1 and considering potential Ph 3 waiver to be confirmed with US FDA advice, shown as Planned submission; 5 MoW represents Most of the World markets. Chart represents the status of the country where the product is in most advanced stage. Every country has a different status; 6 Includes Adalimumab and Etanercept which have been in-licensed by Viatris and Biocon Biologics has economic interest.

Biosimilars: Key updates in Q1 FY22

Biocon Biologics

KEY HIGHLIGHTS

- Strong growth in BFI business with significant contribution from COVID-19 portfolio, serving 50,000+ patients
- Steady performance of non-COVID products
- Continued improvement in market share for commercial products in the US
- Additional growth in US expected by launch of bBevacizumab and bAspart, and bGlargine interchangeability
- Near-term growth in EU to be driven by entry in new markets and product launches (bBevacizumab)

	Q1 FY22	Q1 FY21
Revenue	₹758Cr	₹692Cr
	10% YoY increase	
Core EBITDA[1]	₹271Cr	₹249Cr
	36% of revenue	
Profit Before Tax	₹101Cr	₹105Cr
	13% of revenue	*15% of revenue*

1 Core EBITDA defined as EBITDA before R&D, forex and licensing income

Novel Molecules: Pushing scientific boundaries to deliver impactful innovations

Disease Area	Asset	Current Progress
Diabetes	**Insulin Tregopil**- a first-in-class oral, prandial Insulin	• Phase I multiple ascending dose studies in Type 1 DM patients making progress in Germany. This trial is in partnership with the US-based Juvenile Diabetes Research Foundation (JDRF), a leading non-profit organization . • Phase 1 component of this trial expected to be completed in FY22
Inflammation	**Itolizumab**- A novel humanized CD6 antibody	• US, Canada, Australia and New Zealand rights out-licensed to the US-based Equillium Inc. Currently, Equillium is conducting clinical trials on the use of Itolizumab in the treatment of acute graft-versus-host disease (aGVHD), uncontrolled asthma and lupus nephritis. • The European Commission granted an 'Orphan Medical Product' designation to Itolizumab in the treatment of Graft versus Host disease in July 2021 • In 2020, Itolizumab was repurposed for the prevention and treatment of COVID-19 complications and we were granted Restricted Emergency Use approval in September 2020 for the treatment of Cytokine Release Syndrome (CRS) in moderate to Severe Acute Respiratory Distress Syndrome (ARDS) patients in India. Phase 4 studies are making good progress.
Immuno-oncology	**BCA101**- (formerly FmAb2, a first-in-class EGFR / TGFβ-trap bifunctional antibody).This asset is part of **Bicara Therapeutics**, a clinical-stage biotechnology company based in US*	• Entered a Phase 1/2 study at leading US and Canadian cancer centers in July 2020. • Under evaluation, both as a single agent and in combination with the checkpoint inhibitor Pembrolizumab, in patients with advanced EGFR-driven solid tumors, who no longer respond to the standard of care. • Bicara anticipates transitioning to dose expansion studies in the second half of 2021.

*In Q4FY21, Biocon ceded control over the Board of Directors and Operations of Bicara Therapeutics Inc. to enable it to operate independently under a US based leadership team and raise funds to advance its development programs. As a result of this change, Bicara was classified as an Associate from a Subsidiary under IND-AS.

Novels: Q1 FY22

KEY HIGHLIGHTS

- Equillium had Positive End-of-Phase 1 meeting with the US FDA on Itolizumab for acute GvHD*
- To initiate a Phase 3 pivotal study on Itolizumab in first-line acute GvHD* in Q4 CY 2021
- COMP** approved an Orphan Designation for Itolizumab for the treatment of acute and chronic GvHD* in EU
- Completed dosing for Phase 4 study of Itolizumab for treating CRS^ in moderate to severe ARDS# patients due to Covid-19

*Graft-versus-host disease ** Committee for Orphan Medicinal Products ^Cytokine Release Syndrome #Acute Respiratory Distress Syndrome

Research Services (Syngene): A global CRO delivering innovative solutions

- Offering integrated research, development and manufacturing services for both small and large molecules, antibody-drug conjugates and oligonucleotides backed by best-in-class bioinformatic services
- Combining world class research expertise, technology and infrastructure to reduce costs and time to market
- Talented scientific and techno-commercial teams, led by experienced management, moving beyond cost arbitrage to innovation
- World class infrastructure audited successfully by US FDA, EMA, AAALAC and major life sciences partners
- 400+ active marquee clients across multiple sectors
- World-class R&D and manufacturing infrastructure spread over 1.9 million square feet
- 4700+ talented team of scientists, including ~490 PhDs
- Strong track record of top-line growth with best-in-class EBITDA margins and Net Profit margin
- Listed in India on BSE and NSE in 2015

Research Services: Q1 FY22

KEY HIGHLIGHTS

- Growth across all divisions – Discovery, Development and Manufacturing services
- Significant contribution of Remdesivir in topline growth
- Mangalore API facility successfully completed ISO 9001:2015 certification audit
- Signed a five-year agreement with IAVI for manufacturing three anti-HIV mAbs for use in Phase 1 and 2 clinical trials

	Q1 FY22	Q1 FY21
Revenue	₹595Cr	₹422Cr
	41% YoY increase	
Profit Before Tax	₹95Cr	₹66Cr
	16% of revenue	

Financial Highlights

Annual Financial Highlights

		FY21	FY20	
Revenue	*+13%*	**₹7,360Cr**	**₹6,462Cr**	**Biosimilars +21% | Research Services +9% | Generics +6%**
Core EBITDA[1]	*+15%*	**₹2,430Cr**	**₹2,108Cr**	**Forex loss** of **₹9Cr** in FY21 vs **₹65Cr** of **Forex gain** in FY20
% margin		*33%*	*33%*	
EBITDA	*+8%*	**₹1,907Cr**	**₹1,765Cr**	**Gross R&D spends** at **₹627Cr** in FY21 (**13%** of ex-Syngene revenues) **R&D spends in P&L ₹533Cr** for FY21
% margin		*26%*	*27%*	
Profit Before Tax[2]	*(11)%*	**₹1,077Cr**	**₹1,215Cr**	Excluding Bicara Fair Valuation gain of 160 Cr: Core EBITDA **32%, dn 1%** EBITDA **₹1,747Cr** at **24%** **Net profit** at **₹594Cr**
% margin		*15%*	*19%*	
Net Profit #	*(4)%*	**₹754Cr**	**₹789Cr**	
% margin		*5%*	*9%*	

1 Core EBITDA defined as EBITDA before R&D, forex and licensing income; 2 from continued operations

Quarterly Financial Highlights

		Q1 FY22	Q1 FY21	
Revenue	*+6%*	**₹1,808Cr**	**₹1,712Cr**	**Biosimilars +10% | Research Services +41% | Generics (22)%**
Core EBITDA*	*(1)%*	**₹531Cr**	**₹532Cr**	**Forex Gain** of **₹17Cr** in Q1 FY22 vs **₹4Cr** of **Forex loss** in Q1 FY21
% margin		*30%*	*31%*	
EBITDA	*+1%*	**₹437Cr**	**₹432Cr**	**Gross R&D spends** at **₹136Cr** in Q1 FY22 vs **₹142Cr** in Q1FY21 **R&D spends in P&L ₹120Cr** for Q1 FY22
% margin		*24%*	*25%*	
Profit Before Tax	*(33)%*	**₹166Cr**	**₹249Cr**	**PBT ex Bicara** of **₹224Cr** in Q1 FY22
% margin		*9%*	*15%*	
Net Profit	*(44)%*	**₹84Cr**	**₹149Cr**	**Net Profit ex Bicara** of **₹142Cr** in Q1 FY22
% margin		*5%*	*9%*	

*Core EBITDA defined as EBITDA before R&D, forex and licensing income

Thank You

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