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BIO/SECL/SP/2024-25/26

May 23, 2024

To, The Secretary **BSE Limited** Department of Corporate Services Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai – 400 001	To, The Secretary **National Stock Exchange of India Limited** Corporate Communication Department Exchange Plaza, Bandra Kurla Complex Mumbai – 400 050
Scrip Code- 532523	**Scrip Symbol- BIOCON**

Dear Sir/Madam,

Subject: Transcript of Earnings Call Q4 FY24

This is further to our earlier letter dated May 17, 2024, regarding presentation and video recording of Q4 FY24 Earnings Call held on May 16, 2024, please find enclosed herewith the transcript of the Earnings Call.

The same is also available on the website of the Company at https://www.biocon.com/investor-relations/financial-information/earning-call-transcripts/.

Kindly take the above said information on record.

Thanking You,

Yours faithfully,

For **Biocon Limited**

MAYANK VERMA
Digitally signed by MAYANK VERMA
Date: 2024.05.23 15:09:06 +05'30'

Mayank Verma
Company Secretary & Compliance Officer
Membership No.: ACS 18776

Encl. as above

Biocon Limited Q4 FY24 Earnings Conference Call Transcript

May 16, 2024

Speakers and Participants from Biocon Limited, Biocon Biologics Limited & Syngene International Limited

- **Mr. Peter Bains** – *Group CEO, Biocon Limited*
- **Mr. Siddharth Mittal** – *CEO & Managing Director, Biocon Limited*
- **Mr. Shreehas Tambe** – *CEO & Managing Director, Biocon Biologics Limited*
- **Mr. Kedar Upadhye** – *Chief Financial Officer, Biocon Biologics Limited*
- **Ms. Rhonda Duffy** – *Chief Operating Officer, Biocon Biologics Limited*
- **Mr. Abhijit Zutshi** – *Chief Commercial Officer, Biocon Limited*
- **Mr. Matthew Erick** – *Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited*
- **Mr. Susheel Umesh** – *Chief Commercial Officer – Emerging Markets, Biocon Biologics Limited*
- **Mr. Manoj Pananchukunnath** – *Chief Scientific Officer, Biocon Limited*
- **Mr. Sandeep Athalye** – *Chief Development Officer, Biocon Biologics Limited*
- **Mr. Sibaji Biswas** - *Chief Financial Officer & Executive Director, Syngene International Limited*
- **Mr. Saurabh Paliwal** – *Head - Investor Relations, Biocon Limited*

External Participants during Q&A session

- **Damayanti Kerai** – *HSBC Securities and Capital Markets (India) Private Limited*
- **Jainil Shah** – *JM Financial Institutional Securities Limited*
- **Surya Narayan Patra** – *Phillip Capital (India) Private Limited*
- **Neha Manpuria** – *BofA Securities India Limited*
- **Ankush Mahajan** – *Axis Securities Limited*
- **Nitin Agarwal** – *DAM Capital Advisors Limited*

Prepared Remarks Session

Saurabh Paliwal:

Good evening, everyone. I am Saurabh Paliwal from Biocon's Investor Relations team, and I would like to welcome you to today's earnings call for the fourth quarter and full year fiscal 2024.

I would like to indicate that all the participants will be in a listen-only mode, and there will be an opportunity to ask questions after the opening remarks conclude. Should you need to ask a question please select the raise hand option in the reaction tab of the Zoom application. We will call out your name and unmute your line to enable you to ask a question. While asking a question please begin with your name and organization. Please note that the chat box is disabled but you can raise any technical concerns by sending us an email to investor.relations@biocon.com

I would like to bring to your attention that this conference call is being recorded. The recording will be made available on the website within a day, and the transcript will be made available subsequently.

As part of today's presentation, we have Group CEO, Mr. Peter Bains; Mr. Siddharth Mittal, CEO and MD of Biocon Limited; Mr. Shreehas Tambe, CEO and MD of Biocon Biologics Limited, along with other senior management colleagues from across our business segments to discuss this quarter's business performance and outlook for the company.

Before we begin, I would like to remind everyone of the safe harbor linked to this conference call. Comments made during this call may be forward-looking in nature based on management's current beliefs and expectations. They must be viewed in relation to the risks that our business faces, that could cause our future results, performance, or achievements to differ significantly from what is expressed or implied by such forward-looking statements. After the end of this call, if you need any further information or clarifications, please do get in touch with us.

With this, I would like to turn the call over to Mr. Peter Bains, our Group CEO, for his opening remarks. Over to you, Peter.

Peter Bains:

Thank you, Saurabh, and good evening, everyone, and thank you for participating in this review of Biocon Group's Fiscal '24 quarterly and full year financial results. Before presenting the results in detail, I would like to start with some opening remarks.

Overall Performance

Overall, '24 has been a year of balanced progress in which each of Biocon's three core business verticals, Biocon Generics Biocon Biologics and Syngene have delivered significant operational successes and made clear advances in preparation for the future growth while at the same time, facing and addressing a range of operational challenges. Overall, the balanced momentum has been positive. Let me now expand a little on each of the verticals and start with our Generics business.

Generics business

On the Generics front, we have seen encouraging growth in our formulations business expansion, driven by new

product launches, strengthening of our U.S. business footprint, and further traction in our wider geographic expansion initiatives through both our direct-to-market and strategic partnerships model. Momentum in our formulations business balanced the challenges we faced in pricing pressures on our API business, which witnessed a contraction over the year, resulting in Generics delivering a modest 1% year-on-year growth.

We were very pleased with our recent landmark success in our peptide portfolio through securing approval for Liraglutide, a GLP-1 receptor agonist prescribed for diabetes as well as obesity in the U.K. This was the first generic approval of a GLP in a major regulated market, represented another first for Biocon and represents a clear signal of our capability in development and manufacturing of complex GLP drug device products.

Biosimilar business

Turning now to our Biosimilars business, where during this fiscal and in what has been a transformational year, we completed the full transition of the acquired Biosimilar business globally. We maintained strong revenue growth momentum, delivering robust volume growth, evidenced by improvement in market shares of our products in all regions, especially in the United States, and we expanded our geographical reach, accessing new markets and patients and cross the USD 1 billion revenue threshold. All in all, this was a hugely eventful start to the new post acquisition, Biocon Biologics era.

Along with our peers, we faced inertia in the formation of the biosimilar Adalimumab market in the United States, which we do not see materially opening until calendar year '25. During the year, we prepaid USD 250 million of acquisition-related balance sheet debt. And as stated in earlier calls, reducing debt will remain a management priority.

Syngene business

Moving on to Syngene. Syngene delivered a 9% year-on-year revenue growth while absorbing a research services sector-wide funding slowdown in the fourth quarter. Syngene's rapidly evolving contract research, development and manufacturing platform provided revenue diversification to offset what is already expected to be a transitory slowdown in research funding, with its development and manufacturing divisions, especially Biomanufacturing, delivering a strong performance.

All three of Biocon Group's major business segments are at exciting inflection points and are developing improved positions for growth opportunity in the near term and beyond.

Q4 FY24 Financial highlights

I will now move on to present the key financials. And turning now to the financial highlights. I will start with quarter 4 at group level.

Total Revenue for the quarter was INR 3,966 crores, up 1% year-on-year. **Revenue from operations** at INR 3,917 crores came in slightly more strongly, up 4%. At the verticals level, Biosimilars revenue from operations grew a robust 12% year-on-year while Research Services and Generics saw sequential growth of 2% and 7%, respectively. I will elaborate more on this later in my remarks.

Group core EBITDA for the quarter stood at INR 1,176 crores, representing a core operating margin of 30%. Quarterly R&D spend stood at INR 246 crores, corresponding to 8% of revenues, excluding Syngene. EBITDA for the quarter stood at INR 964 crores with a margin of 24%, with Profit before tax and exceptional items stood at INR 328 crores versus INR 500 crores last year.

Net Profit for the quarter, excluding exceptional items, stood at INR 144 crores versus INR 335 crores last fiscal last

quarter. Reported Net Profit for the quarter was INR 136 crores.

FY24 Financial highlights

Now if I move on to the full year and start with those numbers. **In fiscal '24, Total Revenues at the group level** came in at INR 15,621 crores, a growth of 35% year-on-year. Total revenues included INR 530 crores of stake dilution and fair valuation gain in Bicara pursuant to their December fund raise and an operating income of INR 350 crores from the divestment of the two non-core business units in India to Eris Lifesciences by Biocon Biologics in Q3. The Biologics segment contributed the bulk of the full-year growth with operating revenues growing 58% to INR 8,824 crores. The Research Services segment grew by 9% to INR 3,489 crores, while Generics came in with 1% growth at INR 2,799 crores.

Group core EBITDA was up 10% to INR 4,195 crores, representing a core operating margin of 29%. R&D investment for the full year was INR 1,154 crore, up 3% year-on-year and representing 10% of revenues, excluding Syngene. EBITDA for the year was up 44% at INR 4,164 crores versus INR 2,888 crores in the same period last year, with an EBITDA margin of 27%. Adjusting for the step-up gain in Bicara and the Eris transaction, EBITDA would stand at INR 3,284 crores with an EBITDA margin of 22%.

Profit before tax and exceptional items stood at INR 1,537 crores, up 29% year-on-year, with Net Profit for the year before exceptional items coming in at INR 1,030 crores versus INR 787 crores in fiscal '23, up 31% year-on-year. For the full year, exceptional items amounted to INR 8 crores net of tax and minority interest compared to INR 324 crores last fiscal. Consequently, reported Net Profit after exceptional items for fiscal '24 is INR 1,022 crores versus INR 463 crores last fiscal.

Let me now turn to the segmental business performance during the quarter and let me start with the performance for Generics.

Generics business

In Q4, the Generics segment reported an operating revenue of INR 719 crores, a 3% decline year-over-year, but a sequential quarterly growth of 2%. Core EBITDA for the quarter was INR 155 crores, representing a margin of 21%. Profit before tax stood at INR 50 crores and on a full year basis, Generics recorded an operating revenue of INR 2,799 crores, up 1% year-on-year. Core EBITDA was INR 627 crores flat versus last year with a margin of 22%.

Profit before tax stood at INR 230 crores with a Profit before tax margin of 8%. Overall, the full year Generics' performance came in below expectations due to pricing and demand challenges in the API business as well as the impact of some regulatory delays. Notwithstanding this, we are pleased with the traction that we've seen in the formulations business, which grew 36% year-on-year, reflecting the investments we've made in building our formulation capabilities, capacities, and product range over the past few years.

Statin and Immunosuppressant formulations led the growth momentum, which was also seen across all major geographies. During the fiscal, formulation share of product sales increased to approximately 35% from 25% last year, and it is expected to increase and overtake APIs as a share of our business mix in the coming years. It's also important to note that despite the challenges faced in our API business, we were able to maintain core EBITDA margins at the same levels as last year due to cost control and saving initiatives.

On the regulatory front, the approval for our generic Liraglutide in the U.K. was a notable highlight with Biocon becoming the first company globally to receive a generic GLP approval in a major regulated market. This approval is not only important as a step towards entry into the U.K. market itself, but also reinforces our technical and development

capabilities in bringing complex GLP drug device products to the market. This augurs well for Biocon's ability to access and capture future GLP opportunities that will be a major driver of growth momentum in the coming years as we develop and look to bring to market our extensive pipeline of GLP products across global markets.

Over the full year, we made filings for 38 drug products and 37 APIs and received approvals for 24 products and 20 APIs across global markets. I am also pleased to report that during the year, we had multiple facility inspections from international regulatory agencies across various sites, all with positive outcomes.

On the manufacturing front, in fiscal '24, we continued our focus on enhancing our capacities and capabilities to support ongoing and future growth, particularly in Formulations and Peptides. To strengthen our foothold in the North American market, Biocon acquired an Oral Solid Dosage U.S. manufacturing facility located in New Jersey. The acquisition of this FDA-approved facility, our first in the United States, will strategically enhance and complement Biocon's existing manufacturing capabilities and is expected to begin commercial operations in fiscal '25, subject to regulatory clearance.

In India, our Immunosuppressant facility in Vizag received a Certificate of Suitability or CEP, from the European regulator EDQM. We expect the facility to be inspected and subsequently qualified for commercial supplies by other major regulators during this fiscal. Our Peptide facility in Bengaluru also successfully completed process validation activities, an important step in preparation for future product launches. Enhancements to our synthetic capacities in Hyderabad, non-immuno fermentation capacities as well as a new sterile injectables facility in Bengaluru, remain on track. We are continuing to expand our product pipeline with a clear focus on formulations and peptides to cater for our mid- and longer-term business opportunities and requirements.

Coming to leadership updates in the generic business, I am very pleased to announce the appointment of Vishal Nayyar as Head of Supply Chain Management and Amit Kaptain as Head of Commercial for our global API business as well as for Generic Formulations in select emerging markets. Overall, and despite the revenues coming in slightly below expectations to the pricing pressures in the API business, fiscal '24 has been a year of important progress for the generic segment with strong momentum in the formulations business, strengthened footprint and capabilities in the United States, enhanced reach and partnerships across global markets and a key first registration in our GLP market ambitions.

As we look ahead, formulations are expected to be the key growth driver for fiscal '25, and we would expect performance to build throughout the year with a stronger second half pull-through. Our GLP portfolio, including Liraglutide, Semaglutide and Tirzepatide is expected to play a major role in the mid- to longer term. We see GLPs as the major growth driver of the business from fiscal '26 onwards. Market data here indicate the market opportunity of GLPs to reach nearly USD 100 billion by the end of this decade, and we have a comprehensive pipeline to address and compete in this major strategic market opportunity.

Biosimilars business

Turning now to the Biosimilars segment. Let me start by providing an update on Q4 business performance. With the full transition of the acquired Viatris business successfully completed in December '23, 1 year ahead of schedule, this was the first quarter where Biocon Biologics directly managed a fully integrated business across all geographies globally. We have been able to achieve this while ensuring a seamless experience for our patients, our customers, and our partners and at the same time, maintaining significant in-market growth momentum.

A clear highlight for the quarter has been the performance in the United States where only 2 quarters post transition, we can report strong demand and enhanced market share performance across all our commercial products, Fulphila,

our biosimilar Pegfilgrastim increased its market share to 21% from 14% in March'23 and was the only product in the category increasing market share. Ogivri, our Biosimilar Trastuzumab increased share to 18% from 10% last March and is seeing increased pull-through at the physician level.

We have also secured 4 new commercial formulary agreements, including United Healthcare's Commercial Medical Benefit Drug Policy effective 1st of May this year as a United Healthcare preferred oncology product. Semglee and insulin Glargine franchise has increased its share to 15% and is the fastest-growing brand in the segment. As you are aware, IQVIA reported share does not include close-door networks, which would add an estimated 3% additional market share.

Overall, the continued momentum of market share performance of our Biologics products in the United States since transition has been very encouraging and positions us well as the market dynamics continue to evolve in the U.S. private and government sectors.

I would now like to comment briefly on our biosimilar Adalimumab franchise. Adalimumab has been a significant success for our Biologics business product portfolio and our franchise in Europe has been very successful and continues to be a key value and growth driver for us. We have earned market shares of 20% in Belgium, 18% in Germany and 11% in France, which reflects the strong confidence patients and prescribers have in our product since we launched in 2018.

In the U.S., as you will all know, the biosimilar Adalimumab market formation has emerged significantly slower than anyone had anticipated. As previously advised, we think that while the market will begin to open in CY'24, it will not really develop fully until CY'25 as formularies start excluding the originator, and biosimilars secure exclusive or preferred coverage. Biocon Biologics intends to leverage its relationships with U.S. customers and PBMs to pursue opportunities across all channels but expects that this will take some time to fully fructify and translate into sales.

Turning now to Europe. We are pleased to report that our market shares remained robust and stable across all major markets in the first quarter after completing full transition in December. Fulphila held 8% share, Ogivri 10% share and Abvemy, biosimilar Bevacizumab remained at 6% at the end of December'23. We are also seeing significant success in capturing new market opportunities and expanding reach in the top 5 European countries.

On the Emerging Markets front, Biocon Biologics posted its highest ever quarter revenue led by strong growth across its major regions in Latin America, Africa, the Middle East and Turkey and the Asia Pacific regions. Revenues were driven by the consolidation of the self-led and the partner-led business models and supported by 7 product launches during the quarter. We have seen strong demand for our recently launched biosimilar Bevacizumab in Brazil and we have expanded patient reach in Mexico with additional insulin supplies to our partner there to address the unmet needs of insulin-dependent patients grappling with market shortages of insulins.

Turning now to the Eris transaction. As we have previously announced, Biocon Biologics entered a long-term commercial collaboration with Eris Lifesciences to expand access to our portfolio of Metabolics, Oncology and Critical Care products in India. This was for a total transaction value of INR 1,242 crores representing a value accretive multiple of 3.4x revenues and 18x EBITDA. This strategic collaboration with Eris aligns with Biocon Biologics commercial strategy to maximize patient reach and market potential while unlocking value from its Branded Formulations business in India, built up over the past 2 decades. We have also signed a 10-year supply agreement with Eris for these products as part of the collaboration.

Turning now to the full year financial update for Biosimilars. Revenue from operations was INR 2,358 crores, up 12%

year-on-year. Excluding the onetime INR 350 crores income from the divestment of the 2 non-core business units in India to Eris in Q3, this would have translated into sequential growth of 10%. Core EBITDA was INR 698 crores with a margin of 30%. EBITDA margin for the quarter was 24%, with R&D investments at 7% of revenues.

On a full year basis, Biocon Biologics crossed the USD 1 billion revenue mark with revenue from operations at INR 8,824 crores representing a 58% year-on-year growth driven by the step-up from the acquisition, along with robust underlying growth in the core businesses. The business delivered INR 2,190 crores in EBITDA, representing a healthy margin of 25%. We also continue to invest in our pipeline to support future growth with an R&D spend at 10% of revenues.

You would also have noticed a reduction in operating expenses versus Q3 in fiscal'24, reflecting the decrease in costs linked to the integration and one-time related costs. Reducing our acquisition debt remains a key priority. And as I mentioned, we were able to allocate USD 250 million to this end over the full year.

Turning now to regulatory updates on the Biosimilars front. We are pleased to share that the U.S. FDA has accepted our Biologics License Application for Biosimilar Ustekinumab for review under the 351(k) pathway and we have signed a settlement and license agreement with Janssen Biotech Inc., and Johnson & Johnson that clears the way to commercialize the product in the U.S., subject to regulatory approval, no later than February 22, 2025.

This now positions us to be amongst the first wave of entrants into the U.S. market. Biocon Biologics has also signed a settlement agreement with Bayer and Regeneron that paves the way for the introduction of YESAFILI, our biosimilar Aflibercept into the Canadian market no later than July'25. The product has already been approved by Health Canada.

Also on the regulatory front, the FDA was unable to undertake an inspection of our Bengaluru facility that manufactures our Biosimilar Bevacizumab within the initially proposed goal date timeline and therefore, issued a supplementary CRL. The CRL did not identify any outstanding scientific issues and we have submitted all required documentation to the agency.

Turning to our Malaysia site. Here, we have completed the implementation of all the corrective and preventative actions (CAPA), as per the committed timelines and have provided the U.S. FDA with a comprehensive update. As a next step, we are now anticipating the agency to visit and to inspect both the Bengaluru and Malaysia sites, which subject to outcome, would pave the way for approval of our biosimilar Aspart from the Malaysia site and our Biosimilar Bevacizumab from our Indian site. It is important to note that the same facilities are already cGMP certified by leading global regulators, including the EMA and Health Canada.

With regard to biosimilars leadership updates, delighted to announce the appointment of Dwight Hanshew as its new Chief Quality Officer this quarter. Dwight brings with him over 30 years of global leadership, experience and expertise across Operations, Quality and R&D. And most recently, he was the Head of Quality for Cipla in the United States.

In summary, fiscal ‘24 has been a truly transformative year for Biocon Biologics with the company emerging as a unique, fully integrated, and leading global biosimilars player. The business delivered strong in-market performance, crossing the USD 1 billion revenue threshold, grew share in all its products in the key U.S. market, had its highest ever quarterly sales in Emerging Markets while simultaneously maintaining business continuity and integrating a highly complex geographically diverse business across 120 countries, 1 year ahead of schedule.

Looking ahead, we will consolidate and strengthen our focus on leveraging the advantages of our fully integrated model to accelerate growth for existing products and continue to expand our geographical footprint. Preparing for new product

launches will also be a major focus. A flow of new product launches is now on the horizon, and these new launches will be key catalysts in the near to medium term to drive both sustainable growth and margins. Behind this, we will continue to invest in advancing and building a highly competitive global pipeline and expect R&D investments to be in the 8% to 9% of revenues range.

Novel Biologics

Let me now give a brief update on our Novel Molecules. These are novel assets targeting autoimmune disease and cancer. Let me start with Itolizumab, a first-in-class novel anti-CD6 monoclonal antibody licensed to Equillium for certain markets. Itolizumab is being developed by Equillium for acute graft versus host disease and for systemic lupus erythematosus and lupus nephritis.

During the fiscal, Equillium presented positive data from Phase 1b EQUALISE study of Itolizumab in patients with lupus nephritis at the annual meetings of the American Society of Nephrology and the American College of Rheumatology. In April, it also announced positive top line data from a Phase Ib EQUALISE study in patients with lupus nephritis, where the study demonstrated clinically meaningful response in highly proteinuric patients with more than 80% of subjects achieving over a 50% reduction in urine protein creatinine ratio. Itolizumab also demonstrated a favorable safety and tolerability profile. Equillium has entered an Option and Asset Purchase Agreement with Japan's Ono Pharmaceuticals, granting them an exclusive option to acquire Equillium's rights for Itolizumab. Their option decision is expected in the second half of CY'24.

Boston-based Bicara Therapeutics is developing BCA101, a first-in-class EGFR TGFβ-trap bifunctional antibody. During the fiscal, Bicara presented positive interim data from its ongoing open-label Phase I and Ib dose expansion study of BCA101 at the European Society for Medical Oncology evoking strong investor and investigator interest. In December 2023, Bicara closed a Series C funding of USD 165 million. Post this fundraise, Biocon's shareholding in Bicara has now diluted to 14% and the company is no longer considered an associate company of the Biocon group.

Syngene

Let me now turn to Syngene, our Research Services segment. Syngene's fourth quarter Revenue from Operations was INR 917 crores, a growth of 7% on a sequential basis, while degrowing 8% year-over-year. For the full year, Revenue was up 9% over fiscal '23 to INR 3,489 crores. Revenue performance during Q4 and the full year was impacted by lower demand for research services stemming from a reduced capital funding environment in the United States.

On a full year basis, Syngene delivered 9% year-on-year growth with reported EBITDA growing 10% to INR 1,105 crores, with stable EBITDA margins at 31%. Profit before tax was INR 632 crores and up 6% year-on-year.

This performance was underpinned by Syngene's diverse business platform with its development and manufacturing services, especially in biomanufacturing delivering strong growth throughout the year and more than compensating for the slowdown in research revenues.

During the year, Syngene successfully concluded the acquisition of the strategic biologics manufacturing facility from Stelis Biopharma, which will add 20,000 liters of manufacturing capacity, trebling Syngene's biomanufacturing capacity and providing the basis for future growth opportunity. The completion of the facility modifications and qualification remain on track and are expected in the second half of fiscal '25.

Syngene also acquired 17 acres of land in Genome Valley in Hyderabad to support long-term growth in the Research Services division. The recent step-up now seen in new funding in the U.S. biotech is encouraging and is expected to

drive a recovery in demand for Research Services and Development Services in the coming quarters.

Syngene's guidance for fiscal '25 includes revenue growth at single digit to low double digits on a constant currency basis. operating EBITDA margin to be similar to fiscal'24 levels and Net Profit growth in single digits.

So, in conclusion, as I said, for Biocon as a group, fiscal'24 has been a year characterized by both significant operational successes and clear progress in preparation for future growth opportunities across our businesses, while at the same time, facing and addressing a range of operational and market challenges, which I have described in my commentary.

On balance, we have made good progress. Two important elements of fiscal '24 have been the traction seen in our base businesses and the progress made on investments to underpin near-term growth. For Generics, these include the manufacturing capacity investments, primarily for formulations and peptides in Vizag, in Bengaluru, and in our Hyderabad sites as well as the acquisition of the Oral Solid Dose facility in the United States.

In Biosimilars, we have made investments towards capacity enhancements of our Malaysia Insulin facility to ensure we can meet the increasing demand we are seeing right across the global markets. We are also realizing the benefit of past investments to meet increased demand for our monoclonal antibody portfolio. And in Syngene, we have had the acquisition of Stelis Biologics facilities, which adds substantial biologics drug substance capacity and a commercial scale high-speed fill-finish unit. Syngene also acquired land in Genome Valley in Hyderabad, as I mentioned, to support the longer-term growth in our Discovery Research Services. These investments on top of the existing base businesses opportunities and our new product flow, put the businesses in a good position to capitalize and deliver on the market opportunities ahead.

So, looking to fiscal '25, we expect it to be a year of both consolidation and of transitional and accelerating growth. Consolidation will build off the recent business model expansions and capacity and capability evolutions we have invested in behind our businesses. Transitional accelerating growth will come from revenue growth building off these enhanced models, that will start modestly and pick up in the second half of the year, driven by growth from existing products in existing markets supported by accelerating growth from existing products in new markets and, of course, from new growth from new product introductions into new markets.

In Generics, while we expect continued pressure on the API business, given the current business environment, we also expect growth driven by formulations, especially new formulation launches in the second half of the fiscal. Transition and acceleration in the Generics business will come from the new flow of GLP opportunities with the impact becoming visible in fiscal'26.

In Biosimilars, our base business is expected to deliver robust volume growth through its strengthened vertical model and expanded global footprint. Favorable FDA inspections of our biologics facilities in Malaysia and Bengaluru would be key transition events; subject of course to agency review and decision, and any favorable outcome would likely have limited impact in fiscal'25 with more material impact in fiscal'26.

For Syngene, the long-term demand drivers for the sector are positive, and with the expected recovery in U.S. biotech funding, Syngene is very well positioned to capitalize on demand recovery across research, but also from the tailwinds in biomanufacturing and the fallout from the U.S. Biosecurity Act, which will gradually accelerate the China+1 opportunity.

Overall, Biocon group companies have strengthened business models with greater global reach and scale and are increasingly well-positioned to take advantage of significant and emerging market growth opportunities.

With this, I would now like to open the floor to questions.

Q&A Session

Saurabh Paliwal: Thank you, Peter. We will wait for the questions to be assembled. We will take the first question from Damayanti Kerai from HSBC.

Damayanti Kerai: **So, my first question is on your commercial biosimilars in the U.S. So good pickup seen in all the 3 products, Ogivri, Fulphila and Semglee. So, it appears that upcoming launches will most likely make a meaningful impact a year later from now, whether it is Bevacizumab or Aspart or other biosimilars. So just want to understand in the commercial biosimilars, what kind of further headroom do you see for growth? And how should we see this biosimilar growth trajectory from USD 1 billion mark?**

Peter Bains: Thank you, Damayanti, for the question. I'll start with my response, but perhaps Shreehas and Matt can add to this. I think, first of all, we're very pleased with the momentum we're seeing only 2 quarters out from taking the business over in the United States, we're seeing some very robust market share increases. These are, of course, driven by volume demand for our products, and they are coming along with some pressures on pricing, but we see sustained demand in volume for our products, I think, both in the private and the government sectors.

And we see that coming across our full range of products in market today. And I would also comment that I think you are right, Damayanti, that I think the new product launches while they could have some impact in this fiscal, the major impact would be seen in fiscal '26.

Shreehas, maybe you want to build upon that and Matt probably with some details on the end market demand profile in the United States, in particular.

Matthew Erick: Yes, sure. Absolutely. Thank you for the question. Look, what we are seeing is really the ability to understand in the U.S, the Part D side, and Part B in our portfolio. And we are building upon this through this relentless focus we have, not only with our sales team, but building those relationships with market access. So, we are building on the foundation and setting ourselves up for a nice portfolio in Oncology, Diabetes and even Immunology as we prepare to launch new products as we go into the latter half of FY'25 and then continue to set us for success in FY'26. Maybe we have Shreehas now, but those are my thoughts there, Peter.

Peter Bains: Thank you, Matt. Shreehas, did you want to add anything? I think Shreehas may be struggling with technology. So, Damayanti, does that answer your question?

Damayanti Kerai: **Yes, it does. My second question is on your progress in first to gain market access and payer coverage for Adalimumab. So, you basically commented the market will**

notably start opening up in calendar year 2025 or maybe bit later. So meanwhile, can just update us on your effort on the payer coverage side.

Peter Bains: Sure. And let me start again. I mean I'll repeat that Adalimumab for Biocon Biologics has been a real success story, as you can see from our positions in Europe. We are going to look to build on that experience in the United States. And as I said in my commentary, we don't really see the market opening up in calendar '24, but we'll see it begin to open up more materially in '25 as formularies take the originator off their lists. And we will be working to establish our foothold as that opens and then build from there towards a stronger position through calendar '25.

Matt, again, can comment a little bit more on the channel details and the model on that and our strengths that we are putting to work.

Matthew Erick: Yes. Thank you, Peter. We are still seeing the foothold of Humira on most of the formularies. As Peter stated in the opening remarks and just data, too, this will start opening up in 1/1/25. What we've been able to do is secure some positions within our market access team in regard to having not only Humira but having Biosimilars on there. So as the payers start to transition Humira off, we will start using our sales force to start pulling our products through to increase that market share.

The other thing I would say is that we have tremendous relationships. As you know, we have been working market access since we launched our products in 2018. So, the payers are very familiar with Biocon. We are aggressively pursuing these opportunities, and we do see some opportunities lifting and will be in position in 1/1/25 to be able to take those advantages in which the payers decide.

Saurabh Paliwal: We'll take the next question from Jainil Shah from JM Financial.

Jainil Shah: **My first question is on Denosumab. Sandoz has settled with the innovator. And do you believe that we will be in the first wave of launches because we will be filing by the end of this year. So, what are your thoughts on that?**

Peter Bains: Yes, as I said in my opening remarks, we think we will when we are delighted to have secured that opportunity and are working, as you'd imagine, toward that, very aggressively. And again, this is an opportunity where we can put some of our existing capabilities and strengths to work in that market. And again, perhaps, Matt, you'd like to pick up on that and maybe on the regulatory status as well.

Sandeep Athalye: Matt, this is Sandeep. If...

Peter Bains: Yes, Sandeep, that would be helpful.

Sandeep Athalye: Yes. Certainly, I mean, I can confirm that we are in a good position to make the filings in the next few months. And we will be the first cohorts that can launch in the U.S. and Europe as well.

Jainil Shah: **And any timelines for approval for both Denosumab, Stelara, and any risks that you see to those timelines?**

Sandeep Athalye: Our package looks good. The data is looking fine. I think I am very optimistic in terms of going through the approval. It takes a regular cycle of about 12 months for the FDA and about 15 months with the clock stop for EMA. So that will be standard as expected for all the molecules.

Jainil Shah: **Sure. And just one on the CapEx that we are planning for the next 2 to 3 years?**

Peter Bains: Let me take that. I think that what you will see is that Capex will taper down, calibrate down from recent levels, but we will be maintaining the necessary investments to support the capacities that we are building to underpin both the existing near-term growth opportunities and mid-term opportunities that we are moving towards. So, you will see some calibration down, but we are not going to stop investing behind the very substantial near-term mid and longer-term opportunities that we've been building towards over the last few years.

Jainil Shah: **Sure. And just one more, if I may. In the Generics business, what is our growth guidance? And how many launches do we expect next year? We have alluded towards being stronger, but if you can give us some guidance on how many launches are there? How do we expect Vizag to start contributing? So, your thoughts?**

Peter Bains: Sure. I will ask Sid to provide more detail. But again, I will comment that what we are looking at is transitional acceleration, and we see that picking up in the second half of this fiscal, built on the new product launches, especially in formulations that we have invested in over the last years. And as I said in my commentary, we have made a large number of regulatory submissions. We have had good success and approvals, and we expect to see that momentum continue and that will underpin the growth that we'll be looking for in the Generic business over fiscal '25.

Sid, do you want to add anything more to that?

Siddharth Mittal: I think the only optics, which I would like to give is, of course, this is a combination of products that we have filed in the U.S., which includes a few injectables and few OSDs, which are either approved by the FDA and waiting for launch or they are under final review with the FDA and we will launch during the course of the year. Plus, as we mentioned earlier that Liraglutide in U.K. will be launched by our partner, Zentiva and by us by end of this calendar year. And our file is also in the advanced stages of review with European authorities. And once we receive those approvals, that product could be launched as well in the second half of this fiscal year.

So, a combination of the launch of Liraglutide in U.K. and Europe, plus few products in the U.S. will drive that growth. I cannot give you the exact number of products. Our portfolio continues to be limited in terms of total number. But of course, these are differentiated high-value products that we are working on.

Saurabh Paliwal: We'll take the next question from Surya Patra from Phillip Capital.

Surya Patra: **My first question is on the Biosimilar business. So having seen strong volume growth in the recent quarters, for the already marketed products. The like-to-like**

growth in Biosimilars looks either muted or declining for FY'24, versus last year. So given that and the kind of price competition, although there is volume ramp up that is visible. And also likely the ramp-up in the key products in FY'26. So, what growth one should really think of for the Biosimilar portfolio in FY'25?

Peter Bains: Surya, I think that there's strong momentum in the in-market products in the biosimilars business. As I have said in my opening remarks, this includes market share gains that are not insubstantial market share gains across all our products in the United States. Robust market share performance in the quarter that we transitioned the business in the United States, leading market shares in many instances in Europe. And the highest ever quarter that we have seen in the Emerging Markets business. So, I think there's positive growth momentum in the Biosimilars business. And we would expect that growth momentum to continue during fiscal '25.

Matt's given some comments on some elements of that. But we have seen extremely robust demand for our products, and that's reflected in very high-volume pickup in the last 2 quarters of the prior fiscal and we expect that momentum to push through into this fiscal. So, I do not quite see the market starting point, as you've described. But I think we are building off a very encouraging momentum and we'd look to see that push on through.

Shreehas, you can put a little bit more color on that?

Shreehas Tambe: It's pretty comprehensive, Peter. I just say, Surya, that if you look at the products that we have brought in the market in the United States, which is a very large market, each of those products now command a fifth of the market share, a fourth to a fifth. And I think that is something which will clearly demonstrate that we have got a sizable piece of the opportunity there.

In Europe, you are seeing us move from the 2-country approach that we had in the past to the other countries, the other large countries in Europe and Emerging Markets, Peter just talked about the strong response we are seeing from our key emerging markets. The current immediate focus is on the products that are commercial. But if you want to look at how things are shaping up in the near-term future, that will be on the back of new product launches.

We talked about 2 in the opening remarks, and we also have the risk-free launches that we're looking at from new products into major geographies. So, I would think it is a very strong expectation in terms of how we are moving things forward. We have good momentum, and we expect to drive this in the years to come.

Surya Patra: **Sure, sir. The second question is on the, let's say, about Humira to be specific end of the pipeline products, including Ustekinumab. So, starting with Humira. We have seen Humira has seen some kind of revenue decline in the recent quarters, but that has not translated to any kind of improvement in Biosimilars. So, does that mean Humira is losing out business to some competing products and if that is the case, whether Biosimilar opportunity is likely to be shrinking for adalimumab?**

Peter Bains: Shreehas, do you want to pick up on that? I think we have covered some of it.

Shreehas Tambe: Yes. Thanks, Peter. And Surya, that is a very fair question. Just to index this properly, Adalimumab in the U.S. was the first product that in that sense, saw Biosimilars coming up in the -- in what the U.S. market calls as the pharmacy benefit space or the Part D space. And that operates very differently than the previously launched products that we have seen in the oncology space.

So, to understand that space a little bit different than how the oncology products, which are more buy-and-bill operate. So, this was, I think, in many ways for all the players, including the payers and the PBMs to understand how this opportunity unravels itself. And I think what we have seen is that everyone's trying to understand how a USD 20 billion asset eventually plays out. And like Peter mentioned in his opening comments, we had always said that '23 is when it may open up, but it will only begin in '24 and some meaningful progress on the Biosimilars will only happen in 2025.

And I think we have probably seen that starting to happen in '24, where you're seeing 1 or 2 Biosimilars players starting to get some market share through some innovative models that the PBMs have come up with. And '23 essentially was where the innovator continued to hold more than 98% of the market. Now this is something that was a first experience for everyone in the pharmacy benefit space for such a large asset. Stelara will, of course, play out following this. There will be some learnings of this including things like product attributes, including interchangeability, including our ability to negotiate, all of this will help the industry, the biosimilar players as well as the PBMs to help shape this as we go forward, Surya.

Surya Patra: **Okay. Sir, just last clarification from my side, sir, in fact about the marketing arrangement what we had with Viatris at the time of acquisition of the Biosimilar business in U.S. Whether -- when we are saying that we have now integrated ourselves. So, whether that marketing arrangement is effective for FY'25, that is there or not?**

And secondly, about R&D spend, the fourth quarter have seen some kind of moderation to around 8% of the revenues, excluding of Syngene. So, whether it is the kind of fair run rate that one should build for next year?

Peter Bains: Let me start with that. I will start with the second question first on R&D. As I said in my remarks, Surya, I think you'll see -- as you've identified in Q4, a calibration down from previous levels. But this is in part due to the cyclical nature of where assets sit in our R&D and particularly the development pipeline, it is not a constant spend. It does modulate as you move assets from early stage and into later stage development, which is more expensive.

So, there is a natural curve there. But the other comment I want to make is we are going to continue to invest behind building a very globally competitive pipeline of assets. And that has been something that Biocon Biologics committed to many years ago, and it is a theme that we're going to persist with.

We are confident about our ability to build a competitive global pipeline that will serve our

growth aspirations in the mid and the longer term. And as I said also, we now have an exciting and visible flow of new products on the near-term horizon. I'm sorry. Sorry, your first question was...

Surya Patra: **Marketing arrangement was...**

Peter Bains: Marketing arrangement, yes. I'm going to ask Shreehas to comment as well. The marketing arrangements with Viatris have now all successfully completed, and the handover is complete. We have no lasting marketing arrangements left in terms of marketing and commercial capability. Obviously, within that transaction with Viatris, we have got some great people that have come over and join Biocon Biologics. And their expertise, their capabilities are helping underpin the exciting growth momentum that we're seeing in these early quarters as we complete the full transaction. But just to be clear, Surya, on this one, there are no marketing arrangements left here.

There may be some small peripheral support activities related more to administration, but there is no marketing legacy contractual remains here. This is now fully the Biocon Biologics team driving this momentum.

Surya Patra: **Okay. Sure. So, will this lead to some absolute increase in either employee cost or any other cost element for us?**

Peter Bains: I mean the short answer to that is yes, because in the previous collaboration model with Viatris, they had those costs. But of course, they took a lot of the profit as well. So now we have those costs, and you will have seen that reflected in some of last year's numbers. So, we are now carrying the cost of that commercial marketing team and activity. But now we are capturing the full value of those efforts. And it is, as I said, very encouraging to see the market share gains and the momentum building, and we are capturing all the value now in this fully vertically integrated model.

Shreehas, do you want to add anything to that?

Shreehas Tambe: No, Peter, I think you covered it well. Perfect.

Saurabh Paliwal: The next question from Neha Manpuria from Bank of America.

Neha Manpuria: **Just a follow-up on the Humira -- the biosimilar Humira that we talked about. The 2 private label launches that we've seen by biosimilar companies seem to be gaining good traction, at least that's what the initial data seems to show. So, as we talk about the market opening up in 2025, does that put our ability to then get in and get meaningful share at risk with these existing players probably scaling up over the next few months?**

Peter Bains: Neha, I think it is a very interesting question. It is one that the team have been looking at for some time, and I think are advancing our own thinking on that, not simply for Humira but beyond. I am going to ask Matt here to comment a little bit more on that and perhaps develop a little bit our thinking there.

Matthew Erick: Sure. And I will let Shreehas, please chime in as well. So, you are correct. We are seeing the private labels starting to migrate. And the reason is, is that recently, CVS announced

that they were transitioning from Humira. And remember, as we look at this, we look at a commercial piece, we look at Medicare, Medicaid, there's multiple channels. And also, there's 2 other large commercial entities that are available to play in which we are bidding now for 1/1 start dates. So just as we are seeing these private labels migrate, that does not leave all the market out for Biocon.

The market is open in the commercial, in the Medicare and the Medicaid business. So, we are actively set up in pursuing those opportunities, and we are also keeping a close eye and understanding how the private label and how that's switching and the progress there. But we still believe we have an opportunity in which we are currently bidding on for more growth in FY'25 starting in 1/1/25.

But anything, Shreehas, you would like to add?

Shreehas Tambe: No, perfect Matt. I think this is good.

Neha Manpuria: **That's very helpful. And my second question is, Peter, you mentioned in your opening remarks that debt reduction remains a priority for the company. Given that a lot of the launches are going to be back ended with bulk of the benefit in FY'26, how should we think about net debt reduction for BBL and Biocon in the next year? I mean, what avenues are we looking at to reduce debt? Or if you could give any number, that would be great.**

Peter Bains: Right. So, Neha, let me start by saying that we are -- while debt reduction, as I said in my opening remarks, is a priority. We are comfortable with our ability to service all our obligations. We will be looking to reduce debt. And as you have seen in the last fiscal, we allocated USD 250 million to acquisition-related debt reduction. We have an extensive range of options, and we are going to explore all of them, and we'll look to make the right decision at the right time on that. We have bank opportunities, we have equity opportunities, we have hybrid opportunities. There are a pretty extensive range of levers that we can look at, and we are exploring, and we will make debt reductions during the course of this year. We will do them, I think, at the right time, and I cannot give any specific quantitative guidance on that. But for sure, you will be updated as and when we become active there.

Saurabh Paliwal: We will take the next question from Ankush Mahajan from Axis Securities.

Ankush Mahajan: **So, my question is what's the outlook for the debt on, sir?**

Peter Bains: Was that question on the outlook on debt?

Ankush Mahajan: **Yes, sir, outlook on debt.**

Peter Bains: Okay. Ankush. As I have said, I think the starting point is to understand that we are comfortable in servicing in the debt that we have. But we are also going to be looking to reduce the debt levels. And we have a wide range of options to explore. As I said, we can look at bank options on debt, we can look at equity options, we can look at hybrid options.

There are other levers. We are exploring that. We will be looking to reduce debt this year, but I can't give details of when and how much we will be looking to make those decisions

as appropriate during the year. And of course, we will be updating you as and when we do.

Saurabh Paliwal: We take the next question from Nitin Agarwal from DAM Capital.

Nitin Agarwal: **I have two questions on Generics. What are you thinking about the approvals for the U.S. market, which...**

Peter Bains: I am sorry, I didn't hear that question.

Siddharth Mittal: Where are we on the approvals for GLP-1 in the U.S. market was Nitin's question.

Peter Bains: Sid, why don't you take that?

Siddharth Mittal: Yes. So, the file is under review with the FDA, and we are quite positive that we should hear back from the FDA. Of course, this requires a facility inspection as well because this product was filed from Biocon Biologics Injectable Facility. And as Peter alluded to in his opening comment, we are expecting FDA to inspect the facility in the coming months. And hopefully, when they come to review the facility, inspect the facilities, they will look at it for Liraglutide as well.

So, I think Peter also alluded to the fact that we expect Liraglutide to meaningfully start contributing to the growth from FY'26. And even if the approval comes through later part of this year, we will see a meaningful difference coming in from both now Europe and U.S. in FY'26.

Nitin Agarwal: **And secondly, if you can provide some clarity -- some color on how would the immunosuppressant new facilities scaling up? What kind of capacity utilization do we have? And how do we see that part progressing?**

Siddharth Mittal: So, the existing capacities, of course, we have done a lot of process optimization to enhance the capacity while we qualify Vizag and again, as you know that we have got the CEP from the European authorities, so we can already start commercializing part of those quantity capacities in Europe. But of course, for us, the bigger market is the U.S. and Latin America, and we are expecting FDA to come in and inspect the facility, after which we will be able to address the demand. Of course, when you look at our current facility and Vizag, we will have a huge opportunity to capture a much larger market share for immunosuppressants at a global level.

Nitin Agarwal: **And so, with your capacity of the increase scale coming through, do you foresee a situation of increased sort of pricing competition in this space? I mean is the demand there to absorb such a large capacity that you are going to bring on board.**

Siddharth Mittal: Well, the demand is growing because the volume share is going up. Now of course, there is competitive pressure. Whether it is from rest of the world or India and in some cases, other companies who has their own immunosuppressant fermentation capacities. So, we are also working with a lot of 505(b)(2) s.

As you know that we have a large customer, which was based out of U.S., they have their own 505(b)(2). And overall, when we look at the Immunosuppressants market, it is expected to grow. So, we of course, have to participate in the market going up and compete with others on the market share and winning additional business. I think last

quarter, we also got a very important approval in China for Mycophenolic sodium. And we also have other immunosuppressants, which are under review with the Chinese authorities. And China, as you know, is also a large volume market.

So, we would look at geographical expansion. We would look at increasing our wallet share. In our core markets like U.S. and Latin America and overall, the market share is growing up as the number of transplants grow.

Saurabh Paliwal: Thank you very much for your questions. That was the last question of the day given the timelines we are at. For the question that will remain unanswered, I request the participants to please send us an e-mail, and we will be happy to take them offline.

With this, we will conclude today's presentation. I thank every one of you for joining us today and have a great rest of the evening. Good night.

-Ends-

Note: The contents of this transcript have been edited to improve accuracy and readability.