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May 6, 2022

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 FY22

This is further to our earlier letter dated April 29, 2022 regarding presentation and video recording of Q4 and full year FY22 Earnings Call held on April 29, 2022, 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
Company Secretary & Compliance Officer

Encl. as above

Biocon Limited Q4 and Full Year FY22 Earnings Call Transcript

April 29, 2022

Speakers and Participants from Biocon Limited and Biocon Biologics Limited

- **Dr. Kiran Mazumdar-Shaw** – *Executive Chairperson, Biocon Limited*
- **Mr. Siddharth Mittal** – *CEO & Managing Director, Biocon Limited*
- **Dr. Arun Chandavarkar** – *Managing Director, Biocon Biologics Limited*
- **Mr. Shreehas Tambe** – *Deputy Chief Executive Officer, Biocon Biologics Limited*
- **Mr. Indranil Sen** – *Chief Financial Officer, Biocon Limited*
- **Mr. M.B. Chinappa** – *Chief Financial Officer, Biocon Biologics Limited*
- **Mr. Abhijit Zutshi** - *Commercial Head - Global Generics, Biocon Limited*
- **Mr. Nehal Vora** - *Commercial Head - Global API, Biocon Limited*
- **Mr. Matthew Erick** – *Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited*
- **Mr. Paul Thomas** – *Chief Commercial Officer - US, Biocon Biologics Limited*
- **Mr. Susheel Umesh** – *Chief Commercial Officer – Emerging Markets, Biocon Biologics Limited*
- **Ms. Aishwarya Sitharam** – *Head - Investor Relations, Biocon Limited*
- **Mr. Nikunj Mall** – *Head - Investor Relations, Biocon Biologics Limited*

External Participants during Q&A session

- **Damayanti Kerai** – *HSBC*
- **Surya Patra** – *Phillip Capital*
- **Harith Ahamed** – *Spark Capital*
- **Prakash Agarwal** – *Axis Capital*
- **Sameer Baisiwala** – *Morgan Stanley*
- **Ankush Mahajan** – *Axis Securities*
- **Nithya Balasubramanian** - *Sanford Bernstein*
- **Tarang Agarwal** – *Old Bridge Capital*
- **Vipulkumar Shah** – *Individual Investor*
- **Dr. Dinesh Mahajan** – *Individual Investor*

Prepared Remarks Session

Aishwarya Sitharam:

Good morning, everyone. I am Aishwarya Sitharam from the Biocon Investor Relations team and I would like to welcome you to Biocon's Earnings Call for Q4 and full year FY22. I would like to indicate that all participants will be in the listen-only mode, and there will be an opportunity for you to ask questions after the opening remarks conclude. Should you need to raise questions, please select the 'Raise Hand' option under the 'Reactions' tab of your Zoom application. We will call out your name and unmute your line to enable you to ask the question. While asking, please begin with your name and your organization. Please note that we will not be monitoring any questions on the chat box, but you can raise any technical concerns that you may be facing for our support team to help. I would also like to bring to your attention that this conference is being recorded and the recording will be available on our website within a day and the transcript for this call will be available within next 5 working days.

To discuss the company's business performance and outlook, we have today with us the Biocon leadership team comprising of **Dr. Kiran Mazumdar-Shaw**, our **Executive Chairperson** and other senior management colleagues.

I would also like to take this opportunity to remind everyone about 'Safe Harbor'. Today's discussion may be forward looking in nature, based on the management's current beliefs and expectations. It must be viewed in concurrence with 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 any clarifications, please get in touch with Nikunj or me.

I would now like to turn the call over to **Dr. Kiran Mazumdar-Shaw**. Over to you, Ma'am.

Dr. Kiran Mazumdar-Shaw:

Thank you, Aishwarya. Good morning, everyone. I welcome you to Biocon's earnings call for the fourth quarter and full year fiscal FY22. I would like to start this earnings call on a note of optimism, on the back of a strong performance in the year that has just concluded. Biocon reported revenues of ₹8,397 crores or US$1.1 billion this fiscal. This year, Biocon has entered into a transformative acquisition with its long-term partner, Viatris, to acquire its biosimilars business portfolio for US$3.335 billion. This is in order to create a vertically integrated structure that will ensure an efficient value chain, with embedded agility and competitiveness. We believe that this deal will enhance Biocon's position as a true biosimilar powerhouse.

At Biocon, our key priorities of 'Patient Centricity' and 'Access to All' drive our decisions and the way we operate. Environment, Social and Governance (ESG) has now further assumed a greater prominence in our business objectives. Recognizing our sustainability practices, EcoVadis, a global sustainability rating agency, placed Biocon in the 'Bronze' category, with an overall score of 52 as against 35 in the previous year.

Let me emphasize the fact that our pipeline - our research pipeline - is our lifeline. We continue to invest significantly in research and development to drive long term business growth. Towards this objective, we invested over ₹700 crores in R&D this fiscal, to advance our development programs in the Biosimilars and Generics. During this quarter, two of our Wave 2 biosimilar molecules, bDenosumab and bUstekinumab, moved into the clinic. We also continue to build a strong pipeline of niche formulations such as injectables as well as peptide and potent APIs in our Generics business. We believe these investments will help us further our pursuit in providing high quality and affordable healthcare access to all, whilst we drive further value creation.

Before I discuss the performance of the business, I would like to share a Board Update.

I am pleased to welcome Naina Lal Kidwai, a veteran banker and a business leader, as an Additional Director on the Board of Biocon limited. An MBA from Harvard Business School, she is the recipient of several awards and honors, including the Padma Shri for her contribution to trade and industry. She is the past president of Federation of Indian Chambers of Commerce & Industry (FICCI). She retired in 2015 as Chairman of HSBC India and Executive Director of HSBC Asia Pacific. We look forward to Naina's leadership, which we believe will provide a strong impetus to our growth journey.

I will now present the key financial highlights, starting with the Quarter and followed by the Full year.

At a consolidated group level, revenues for Q4FY22 grew 21% year-on-year basis and 11% sequentially to ₹2,476 crores. Revenues from our Biosimilars Business delivered a strong year-on-year growth of 48%, while that of our Generics Business grew at a healthy rate of 26% and Research Services revenue grew by 15%.

Our Gross R&D spend was at ₹232 crores, an increase of 70% over last fiscal, corresponding to 14% of revenue, ex-Syngene. Of this, ₹191 crores is expensed in the P&L, while the rest has been capitalized.

Core EBITDA margin, which is EBITDA margin net of licensing, dilution gain on account of our startup, Bicara, mark-to-market loss on investments, forex and R&D was higher at 33% compared to 32% in the same quarter last year, on account of an improved performance in both Biosimilars and Generics.

EBITDA for the quarter was ₹659 crores, reflecting a 3% year-on-year growth. EBITDA margins stood at 27% as against 31% reported in Q4 last fiscal, primarily due to, as explained earlier, the higher R&D spends in Biosimilars and Generics during the quarter.

Exceptional items for the quarter included professional fees towards the Viatris deal.

Profit Before Tax and Exceptional Items for the quarter stood at ₹384 crores, up 9% over ₹353 crores during the same quarter last fiscal.

Net Profit before Exceptional Items for the quarter stood at ₹262 crores versus ₹257 crores last fiscal.

Net Profit, adjusting for exceptional items, stood at ₹239 crores.

Adjusting for the mark-to-market loss on investments and gain on dilution in Bicara, on a like to like basis, growth and margins are higher compared to the same period in the previous fiscal, which translates to:

- 37% growth in core EBITDA versus reported growth of 11%,
- 32% growth in EBITDA versus reported growth of 3%,
- 75% growth in Profit Before Tax and Exceptional items, versus reported growth of 9% with a 5% higher margin
- 176% growth in Net Profit before Exceptional Items versus reported growth of -6 and a 5% higher margin.

Let me now turn to the full year financial highlights

At a consolidated group level, revenues for FY22 were ₹8,397 crores versus ₹7,398 crores, a year-on-year growth of 14%. Adjusted for the gains from dilution in our Bicara stake, the overall revenues, grew by 16%.

Revenues from our Biosimilars Business delivered a strong year-on-year growth of 24% and our Research Services grew at a healthy rate of 19%, while revenues for our Generics Business remained flat.

We recorded a Forex gain of ₹58 crores this fiscal.

A loss of ₹28 crores arising on account of mark-to-market adjustment on investments is also reported this year.

For this fiscal, we also recorded a gross R&D spend of ₹711 crores, which is 13% higher over last fiscal and corresponds to 13% of revenue, ex-Syngene. Of this, ₹595 crores is expensed in the P&L, whilst the balance has been capitalized.

Core EBITDA margin, as explained earlier, stood at 32% compared to 31% last year, on account of an improved performance by Biosimilars.

EBITDA for the fiscal was ₹2,183 crores, reflecting a 14% year-on-year growth, with a consistent EBITDA margin of 26%.

Exceptional items for the year included provisions for export incentives, impact on modification of terms of certain debt instruments, and professional fees towards the Viatris deal.

Profit Before Tax and Exceptional items for the year, stood at ₹1,094 crores, up 4% over ₹1,055 crores last fiscal.

Net Profit Before Exceptional items stood at ₹722 crores versus ₹744 crores, whilst Net Profit for the year after Exceptional Items stood at ₹648 crores versus ₹740 crores reported in FY21.

However, as we explained earlier, with a like-to-like adjustment:

- EBITDA growth was 25% versus the reported growth of 14%
- Growth in core EBITDA was 18% versus 10%.

Let me now turn to segmental business performance during the quarter and for the full year.

Generics Business

The Generics segment delivered revenues of ₹717 crores during the quarter a year-on-year growth of 26% and a sequential growth of 18%. Profit Before Tax for the quarter was ₹116 crores versus ₹73 crores last year and ₹67 crores in the previous quarter. Profit Before Tax margins were higher at 16% as against 13% last fiscal and 11% in the previous quarter.

The improved business performance in Q4 was driven by key factors, namely, a ramp up in API sales, new drug product launches in the US, particularly, Everolimus, and the normalization of operational challenges that we have faced earlier in the year.

On a full year basis, the Generics segment delivered revenues of ₹2,341 crores compared to ₹2,363 crores in the previous fiscal. Profit Before Tax stood at ₹261 crores versus ₹291 crores in the previous fiscal. The segment witnessed a muted performance, given the COVID led operational and supply challenges at the start of the fiscal, which started running to normalcy in the second half of this fiscal. However, profitability continued to be impacted by higher logistics and input costs, particularly raw materials, solvents and fuel. Pricing pressure headwinds in several markets further added to this impact.

During the quarter, approvals were received from the US FDA for Posaconazole, an antifungal drug, as well as Dorzolamide, an ophthalmic product, which were also recently launched in Q4.

We continue to expand in emerging markets and commenced our first commercial supplies of Tacrolimus capsules to Mexico. We also received our first approval in Singapore for Tacrolimus and in the UAE, for Rosuvastatin and Tacrolimus.

In January this year, we also had a successful regulatory site inspection at our API manufacturing unit, located in Biocon Park, Bengaluru, by Health Canada.

We are on track to qualify and validate our Greenfield, fermentation-based, immunosuppressant API manufacturing facility in Vishakhapatnam. We also plan to augment our existing API manufacturing infrastructure in Hyderabad and Bengaluru, as well as, set up a new injectable facility in Bengaluru.

As part of our sustainability focus, we have diversified our renewable power consumption to include both solar and wind energy.

We are confident to grow our Generics business in FY23, supported by new product launches and our expanded manufacturing capacities. Once we continue to be resilient, we are cognizant of potential headwinds, such as pricing pressure and rising input costs, and we will continue to focus on building cost and operational efficiencies to sustain growth.

Biosimilars

Biocon Biologics recorded revenues of ₹982 crores for Q4 a year-on-year growth of 48%. Core EBITDA, excluding R&D, forex, licensing income and mark-to-market loss on investments stood at ₹382 crores up 78% year-on-year. Core EBITDA margin increased from 33% in Q4 last fiscal to 39% this quarter, demonstrating continued healthy profitability. EBITDA for the quarter was up 56% year-on-year at ₹257 crores and Profit Before Tax and Exceptional items stood at ₹144 crores up 109% year-on-year. I'm also pleased to say that our Malaysia operations became profitable for the first time this quarter.

Moving on to full year performance, Biocon Biologics recorded revenues of ₹3,464 crores in FY22 a year-on-year growth of 24%. This rate of growth is much faster than the 21% witnessed in FY21 and this, I might add, is in-line with our guidance. We witnessed significant improvement in profitability at all levels this year. Core EBITDA for the year was at ₹1,320 crores, up 30%. Net R&D spends for the year was at 9% of revenue in-line with the FY21. EBITDA for the year stood date ₹1,013 crores a year-on-year growth of 35%. Profit Before Tax and Exceptional items has grown by 49% year-on-year. The growth in profits is attributable to higher revenues and improved margins.

Let me now share some highlights of the biosimilars business.

The most significant growth driver has been our 351(k) interchangeable biosimilar insulin Glargine in the US market which has attained a double-digit market share at the end of this quarter. Viatris expects to end CY2022 with mid to high teens in terms of market share. Ogivri's market share in the US reported consistent improvement during the year attaining-double digit. Fulphila US market share was resilient despite a highly competitive market. In Europe, both these products continue to witness gradual improvement in performance. Abevmy, our biosimilar Bevacizumab, was launched in select European markets during the year, further bolstering our oncology franchise.

Continued improvement in the performance of our existing products coupled with potential US launches of biosimilar Aspart, Bevacizumab and Adalimumab will enable the current Viatris-led business to deliver robust growth over the next two years. Our economic interest in Viatris collaboration products will significantly increase, once we

consummate the deal with Viatris.

We have seen impressive growth in our B2B and Branded Formulations India (BFI) businesses. We've recently been awarded a three-year contract for Insugen® in Malaysia, valued at approximately US$90 million. We expect our B2B business to be bolstered by the integration of the Viatris transaction, allowing us to target a larger segment of emerging markets.

The BFI business recorded a year-on-year growth of 35%. We expect that the continued focus on salesforce excellence, brand building and KOL engagement will generate sustainable growth for the business.

Moving on to pipeline updates, we have advanced two unpartnered, wave 2 biosimilar molecules into the clinic, namely Denosumab and Ustekinumab. We have exercised the option to acquire Viatris' rights in its biosimilar Aflibercept as a part of the transaction. Viatris filed the first biosimilar of Aflibercept in the US. Our portfolio of next wave of biosimilars will address a market opportunity of approximately US$20 billion to drive growth in the medium term.

The Viatris and Serum deals are progressing towards regulatory approvals. We expect deal closure in the second half of the CY2022.

In summary, Biocon Biologics has delivered strong revenue and profit growth this fiscal. Combining the Viatris biosimilar business with BBL accelerates the build out of our commercial capabilities in developed markets, in order to become a strong global brand. Vertical integration will drive operational efficiencies and business agility, thereby underpinning cost competitiveness. The vaccines alliances with Serum and our continued investment in R&D, adding products to our portfolio, opens up new growth avenues for Biocon Biologics in the coming years.

Novel Biologics

Equillium, our partner, initiated a pivotal Phase III clinical trial of Itolizumab in patients with acute graft-versus-host disease or aGVHD in March this year. The randomized, double blinded study will assess the efficacy and safety of Itolizumab versus Placebo, as a first line therapy for acute GVHD in combination with corticosteroids.

Our Boston based associate, Bicara, initiated dose expansion cohorts evaluating its lead molecule, BCA101, in patients with head & neck squamous cell carcinoma, squamous cell carcinoma of the anal canal and cutaneous squamous cell carcinoma. In February 2022, Bicara has secured the first round of seed funding from external investors to support the clinical development of BCA101 and other pipeline assets.

Research Services – Syngene

Revenue from operations stood at ₹758 crores for the quarter, indicating a year-on-year growth of 15%. Profit before tax for the quarter was at ₹179 crores against ₹158 crores in Q4 previous fiscal, which is a growth of 14% year-on-year.

For the full year, revenue from operations stood at ₹2,604 crores, indicating a year-on-year growth of 19%. Profit before tax for the quarter increased by 19% year-on-year to ₹515 crores.

The fourth quarter growth was also driven by performance across all divisions. Development Services had a particularly strong quarter, as it caught up on the projects delayed due to supply chain issues and other COVID related disruptions.

Phase three of the expansion plan at the Hyderabad research facility was completed during the quarter and the

facility now accommodates around 500 scientists. Further expansion is being planned in the year ahead.

Concluding Remarks

As we come out of the pandemic with a strong performance, I would like to announce that the Board of Directors have recommended for approval by the shareholders, a final dividend of 10% of face value of each share for the financial year 2022.

I would like to conclude by saying that the year ahead holds tremendous promise for all our business segments. The most significant growth is expected to come from the acquisition of the Viatris' biosimilars business as well as through the vaccine alliance with Serum. And with this, I would like to open it up to Q&A.

Q&A Session

Nikunj Mall: Thank you, Ma'am. Should you need to ask a question, please select the 'Raise Hand' option under the 'Reactions' tab of your Zoom application. We will call out your name and unmute your line to ask the question. The first question is from Damayanti Kerai from HSBC.

Damayanti Kerai: **Good morning. Ma'am, my first question is on biosimilars. We have seen a good pickup in prescription volume in most of the launched products but when we look at the reported sale for fourth quarter, sequentially it's looking flat despite having full quarter benefit of Semglee. So, can we have some clarity there, whether it's due to more squeeze on the pricing? How is the pricing environment for most of the launched products, especially insulin Glargine?**

Kiran Mazumdar-Shaw: So, let me start by saying that the insulin Glargine business is showing a strong pickup, like you mentioned, and as it has already been reported, from a 3% market share in the earlier part of the year, we have now registering a double-digit market share by the end of this fourth quarter. Yes, I think there has been almost like a flat performance of biosimilars in Q3 and Q4, but you must understand that this is more reflection of the kind of market improvement of the business. Q1 tends to be slightly sort of lower quarter in terms of being able to pull out growth as such. But regardless of that, I would like to mention that our biosimilars business is tracking in the right direction, we have not seen a greater growth because of certain tenders which open up later in the year, like for example, we just won that tender from Malaysia, which obviously will start only reflecting in our numbers in the year ahead. I would like, perhaps, my colleague, Shreehas to add to what I've said.

Shreehas Tambe: Thanks, Kiran. I think Damayanti you have two questions, one is to see as to why these numbers have been more or less flattish and a concern if this has anything to do with pricing pressure in the US. I think let me lay to rest the first part of it, the part related to pricing, we do not see the pricing pressure at all on this aspect. We've got a formulary

listing through Viatris and that's something that we see staying consistent to the course of the year. So that's really, the second piece there.

I think the aspect related to the flattish numbers that you talked about, let me draw your attention to the earlier part of the fiscal, where we had a run rate of about ₹750 to ₹800 crores in the early part of the year as our revenues for the quarter, which we broke through in Q3 in that ₹950 to ₹980 crores range, which is largely on the back of the launch supplies for our 351(k) interchangeable insulin. What you saw in Q4 effectively is the ramp up of that market share from what Kiran just said which we ended at less than 3% last year to actually the secondaries moving up from there into that 10% and the teens as we move it forward. What will happen going forward is you will see that market share strengthen further and the profit share starting to move in the coming quarters, towards the latter half of the year. That's really how that market is expected to shape. So, you will see us breaking through from that ₹750-800 crores per quarter range to the ₹950-980 crores and then the subsequent quarters, you'll see us getting past ₹1,000 crores mark in the first two quarters and then ramping up further. So, I would say that the way to read this is over a wider horizon rather than just a sequential number over one-on-one quarter.

Damayanti Kerai: **And my second question is again, on pricing environment for some of the products which we are anticipating to launch, say Bevacizumab, once we get finally FDA approval. So, what numbers we saw reported by some of the competitors in the similar space, I guess the volume were steady to growing but even they mentioned declined in ASP. So, can you comment on pricing for some other biosimilars where we are looking to enter?**

Shreehas Tambe: One of the important things to note is that the pricing overall has remained the same for a very long time. We do see pricing tending towards the decline, which is also a factor of the competition that we see increasing with the number of players there, which is expected when you have this kind of market condition. But, as you rightly pointed out, the CAGR in terms of the volume growth in the US alone has been at around that 4-5% range and in Europe, even higher around that 14-16% range. So, the underlying opportunity is still sizable, and still growing. Very few players who really had the opportunity to offer a complete product portfolio, like we would have, once we complete it with Bevacizumab as we come in, once we get the agency to inspect us. One of the key changes from what we have discussed with you last time is that now we have the agency past that dialogue that we've had visiting us in Q2 of this year and we should hopefully get passed into the approval stage shortly, which then allows us to partake in this sizable opportunity alongside other players. So it will certainly be an upside which we had expected to happen in FY22, but now that the agency is finally able to make it to Bangalore, we will see that happening as we go along.

Damayanti Kerai: **Last question and then, I will get back in the queue. Some of the programs which we discussed during Ma'am's opening remarks, they are entering into clinics. So, in line with that we have seen gross R&D jumping 30% sequentially. So, over next**

12-15 months, how should we look at R&D spend as more and more of these program progress in clinical trials?

Shreehas Tambe: Damayanti, let me give you a flavor of how we have progressed. If you looked at how the R&D spend have been for the course of FY22 for our programs, we have said that we will be moving into the clinic towards the end of the year and that's exactly what we have announced today. You have seen two of the major assets get into the clinic. We have announced Denosumab and as well as Ustekinumab getting into clinic and you will see the R&D spend moving up in the line with the progress of these molecules. I would let Chini talk through the specifics on what those numbers would contribute to the P&L.

M.B Chinappa: This year we ended at 9%, as Shreehas has just said, but as we see the two new products entering in the clinic, we expect R&D spends to increase in the coming quarters. Of course, the additional revenues from the vaccine at the Serum deal and Viatris deal will help us increase our investments in R&D as we progress our next wave of biosimilars. Overall, we expect R&D investments to be around 10% to 15% of revenues going forward. Of course, quarterly distribution will be lumpy.

Damayanti Kerai: **Thanks, I'll get back in the queue.**

Nikunj Mall: Thank you, Damayanti. I will request all the participants to limit to two questions only and we can follow up with additional questions. The next question is from Surya Patra from Phillip Capital.

Surya Patra: **Yeah, thanks for this opportunity and congratulations on the good set of numbers. My first question is again on the biosimilar sales. In fact the sequential flatness, what we are witnessing in the Biologics sales, despite the ramp up what you have mentioned in the prescriptions for interchangeable insulin, which obviously you have not witnessed any pricing pressure as such. And even in the previous quarter, we had witnessed a delta of almost like $30 million in the Biologics sales. So the profit share of which would have come this quarter despite that, and the branded pricing of interchangeable insulin, despite all these three factors, we have not seen any sequential improvement. It has remained flattish. So, although you have responded to that question, but I am still not able to sense. So can you just clarify a bit more on it?**

Kiran Mazumdar-Shaw: So, I think I just want to add to what Shreehas has said and then Shreehas can add to what I will say. I think he mentioned very clearly that you have to look at this in context of what the sales values were before the Glargine kicked in. So they were at roughly the ₹700-750 crores kind of range in the first two quarters and now they bumped up to almost ₹1,000 crores. So that is the addition of the Glargine sales for these last two quarters. And obviously we expect a further ramp up to take place because, as you know, two of our programs, which are Aspart and Bevacizumab have been delayed in terms of approvals for various reasons largely attributable to US FDA not being able to

come and inspect our facilities. So I think, you can expect the ramp up to really happen in the coming fiscal. So, I think to really contextualize it on a sequential growth may not be the right way of looking at what Glargine has done for the business.

Shreehas Tambe: Just to comment further on what I said earlier, and what Kiran is saying. The way to look at this would be to say that, Q3 would essentially have marked the launch supplies as we sent the product from Malaysia into the channel, making sure that drove Day 1 sort of launch supplies into January 2022, we got the product into the market. And to view Q4 essentially as that shift in market share, as it moved from that 3% into that 10% as we left March 2022. So effectively, you're seeing one as the quarter where we actually did the channel stock supplies and then the other one where we have seen increasing market shares as the secondaries have gone up and what you will see happening during the course of the year, as the market share ramps up further, is you'll see a cumulative effect of launch supplies transitioning into repeat supplies and then increased profit share as the market share goes up. So I would say that not to look at it as just a sequential one quarter, but take a broader view of 2 or 4 quarter horizon, which then gives you a full picture on an annualized basis than just a sequential part given the sizeable shift that we will see in the US market because of the 351(k) interchangeable Glargine.

Surya Patra: **Sure, sir. Thank you. This is useful. My next question is on the small molecule side. You have mentioned about your entry into this injectable, API manufacturing, as well as expansion of fermentation-based APIs. On the vertically integrated formulation business side also, we are witnessing a steady progress. So, I think this space looks really interesting in the global market from here. Given whatever the global situation that we are witnessing, that is also matching with your aggression towards building capabilities. So if you can just give some sense on this business, let's say in a 2-3 year timeframe, given the ongoing projects and anticipatory project on the injectables and the complex products. So what is the thought process there and what growth contribution that we should be seeing over next three year time from this space?**

Siddharth Mittal: So, let me take that, Surya. Let me probably give a broad context before I specifically answer your question. All of you are aware that we have a very strong capability and manufacturing capacities in the fermentation space since the last two decades. We are building on to those capabilities by adding peptides, high potent oncology APIs, as well as large scale synthetic APIs, now that's purely from API perspective. As we forward integrate, we have formulations, spreading across oral solids, injectables and various other forms of formulations. We are creating a very strong pipeline in terms of differentiation and the complexity of these molecules. We are not chasing a large number of filings, like many other generic companies do. We are looking at forward integrating, while we do source API from outside, if we find an attractive opportunity for a differentiated formulation. Now, as we add to the pipeline, we need manufacturing capacities and today, we do have a couple of injectable products which are manufactured in our Biologics manufacturing site and a couple of CMOs, but as we get

closer to the launch, we will have our dedicated facility for small molecule injectables and the construction of this facility is what's going to start this quarter. We also have, as you know, expanded our immunosuppressants API manufacturing capacity in Vizag, where the commissioning is almost complete and the validation would start this fiscal, but that is only for immunosuppressants. We also see a huge potential for non-immunosuppressant APIs and that's where the mention is that we are expanding our existing fermentation facilities in Biocon park, where we will significantly enhance our capacities. And the third is we are building a very large-scale, synthetic API manufacturing facility in Hyderabad. Now with all these investments and advancement of our pipeline, we will see a good growth coming in in the next couple of years. I would not specifically give a number for next three years, but compared to FY22, which we saw was flattish overall compared to FY21, in FY23, we definitely expect growth to be there. As some of the capacity enhancement projects are complete, we expect to start supplying from these facilities. We also expect launch of new products in the US in FY23 and I'm quite hopeful that we'll be able to deliver double-digit growth in the next fiscal.

Surya Patra: **So, on the capex front for these, can you give some sense? Are you becoming a bit more aggressive in terms of capacity expansion plans here?**

Siddharth Mittal: No, I have always indicated that we are going to be spending roughly US$100 million of capex in a year for three years. So overall guidance has been US$300 million of capex over a period of 2020 to 2024 and we stick with that guidance.

Surya Patra: **Thank sir.**

Nikunj Mall: Thanks Surya. The next one is from Harith Ahamed from Spark Capital.

Harith Ahamed: **Good Morning, thanks for the opportunity. My first question is on the vaccine alliance with Serum. I believe you had talked about revenues of almost US$350 million from this alliance for FY24. So with commercialization expected from second half of FY23, do we have visibility on which of the products and the markets? I'm asking because this is almost 20% of the US$1.8 billion pro forma revenues that you have guided for FY24, so it's a significant share of that. So any color that you can provide will be helpful.**

Kiran Mazumdar-Shaw: Let me respond to that by saying that obviously it is not a particular segment of vaccines, we have access to the complete portfolio of vaccines. As you also know, the Serum Institute has recently received regulatory approvals from the European agencies, the Australian agencies, Health Canada, and they're also hopeful of getting US FDA regulatory nod for the Novavax vaccine. It is not just the COVID vaccines that we are looking at, we're looking at many other vaccines. We remain committed to making sure that these numbers are a part of our future revenues and I think, we are very confident that Serum Institute will provide these revenue numbers going forward. So as you yourself have mentioned, the numbers will only get reflected from the latter half of FY23

and then the full year numbers will get reflected from FY24, but Serum Institute is very confident of providing us these revenues.

Harith Ahamed: **Thanks, Ma'am, that's helpful. My next one is on Bicara. So will you be able to share Biocon's stake in Bicara post the dilution which happened during the quarter? What I'm trying to understand is if there will be a lower PAT loss pickup next year, and this was around ₹200 crores in FY22. Just trying to understand if this number could be lower in FY23. And, if you can also give a sense of this valuation at which this round of fund raise happened at Bicara.**

Siddharth Mittal: Harith, the fundraise is not yet complete. I don't want to discuss about the valuation right now because discussions are still going on. While we have raised a certain amount in March, there is also an additional amount being raised in this month and there are also discussions going on, as I said, to raise further funds in this quarter, but after all the rounds are complete, Biocon would have just around 50% of equity in Bicara. So, by June end, you can expect that Biocon's stake will be around 50%.

Harith Ahamed: **Yeah, and last one with your permission. When I look at the R&D spends, it is roughly ₹300 crores of R&D spend outside Biocon Biologics, which I believe is primarily the Generics business, so if you could confirm that the ₹300 crores of R&D spend ex-Biocon Biologics is primarily for the Generic Business and some indication of the split between Generics and Novel Biologics. And secondly, the R&D spend for the Generics segment, how should we think about that for FY23 and beyond, because, currently, the profitability of the business is on the lower side and that is primarily because of the higher R&D spend that we are doing for that business as the ANDA fillings ramp up but is there a case for some kind of operating leverage kicking in the Generics Business as the R&D spends flatten out or will it continue to increase, is what I am trying to understand.**

Siddharth Mittal: R&D spend in FY22 was 12% of revenue, so to be precise is roughly ₹250 crores on Generics. Novel was a very small number because the expenses on Bicara molecules are not part of R&D and the only spend that we have is on Itolizumab and partially on Tregopil - it's a very small number. So, for next year, I would continue to hold R&D guidance between 12-14% of Generics revenue.

Harith Ahamed: **Okay, that's all from my side.**

Nikunj Mall: Thanks Harith. The next question is from Prakash Agarwal from Axis.

Prakash Agarwal: **Hi, good morning to all. Thanks for the opportunity and congratulations on good numbers. My first question is on clarification of the R&D, when you say 10-15% of sales, normally you said biopharma sales. So from second half onwards, we will have Serum sales coming in and we would have probably Viatris also kicking in. So when we say 10-15%, is it at what base, is it biopharma ex of these?**

M.B Chinappa: As I have clarified earlier, it is on the total biopharma / biologics BBL revenue that include current BBL revenues, the new revenue from Viatris and Serum.

Prakash Agarwal: **Okay. So, the new molecules that you have mentioned, the two new additions in the biosimilar pipeline. What is the approximate cost for doing these now? In the past it has ranged from $50-100 million. Currently, when we are looking at this, what is the R&D budget approximate we have for these kind of molecules? And correct me if I'm wrong, these are spread over 4-5 years?**

M.B Chinappa: Yes, 2-3 years but roughly along those lines, $50-100 million per product.

Prakash Agarwal: **Okay. Why I asked this is because when I see the competitive landscape, there are few players already in Phase 3. We have entered clinical now. So I'm trying to understand that we could be little late in the game? What is the management thought process here?**

Kiran Mazumdar-Shaw: So, we are trying to basically see how close we can be to the LOE date on both these programs. We may not quite meet LOE dates, but we are trying to see as close as we can get to the LOE date but suffice to say that yes, there are a few companies who have entered into the Phase 3 trials, but we also have a strategy to see how quickly we can catch up.

Prakash Agarwal: **Okay, fair enough. And with the background of this 10% to 15% R&D guidance, which is fairly broad, what kind of margins we are looking at? I mean, would it be similar to what we are already having or is there a chance of inching up given the pipeline and as Glargine and other products start kicking in a significant manner?**

M.B Chinappa: Prakash, I will encourage you to really focus on the core EBITDA.

Prakash Agarwal: **Yeah, core EBITDA or whatever you can mention. So, on the core side also, do you think margin would inch up ex-R&D as well?**

M.B Chinappa: Keep it in the same lines. Of course, as we consolidate the Serum and the Viatris business, we have given you a guidance for FY24. That will give you the real picture of the combined business, the guidance that we have laid out for FY24.

Prakash Agarwal: **Ok. Lovely. Thank you, that's all from my side. All the best.**

Nikunj Mall: Thank you, Prakash. The next question is from Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala: **Thank you very much and good morning, everyone. Just for the end market products for biosimilars in the US, what's the revenue outlook for Pegfil and Trastuzumab for FY23? I basically want to get to the volume and price dynamics.**

Shreehas Tambe: To my knowledge, we have not given out product by product specific sales guidance and numbers. Chini, do you have any additional colour to that?

M.B Chinappa: Sameer, again to the point of guidance that we have given post the Viatris acquisition, we have indicated that the FY23 growth will be biased towards Semglee and FY24 would have the full benefit of Semglee plus the launch of Beva and Aspart. So these are the key drivers of revenue growth before Adali kicks in. We have not currently modeled growth around the other products, of course. we will continue to pursue opportunities there too.

Sameer Baisiwala: **Sure. I am just trying to see what's the framework, do these products trend down gradually or do you think there is still some room to grow them. I am not looking at any specific numbers, just philosophically how you think about this?**

Kiran Mazumdar-Shaw: So, maybe we could ask Matt Erick to basically comment on that.

Matthew Erick: I think if you look at our oncology portfolio, there's opportunity in both of those areas as we add Bevacizumab to continue to grow that oncology portfolio. There's a great foundation there that really understands the buy and bill. Of course, there's some downward pressures, but it's also in regards how are you looking at this space and how can you continue to grow based on the market share piece. So we have a great foundation to do that and I think that will give us that opportunity to continue to grow in that market and be successful.

Sameer Baisiwala: **Okay, great. And the second question is about the contracting outlook for insulin Glargine for CY2023. I'm not trying to get any market share number, I am just trying to understand how does the system work? Do you retain your current contracts that you are enjoying in 2022 and then build over it or do you start all over again? Any flavor on that would be great.**

Matthew Erick: Thanks for the question. Look, all those relationships are important and again leveraging the franchise from the standpoint in diabetes, to continue to grow in that and to grow that portfolio is very important as you deal with payers in the diabetes space. So, we'll continue to work with them as we add additional products within diabetes.

Sameer Baisiwala: **I'm not asking about adding new products. I'm asking about the current in market products. How does the system work and how does the contracting for 2023 will work? Do you start all over again or do you build on the current contracts and grow that?**

Matthew Erick: Sure, thank you for that and sorry about that. Look, the contracts do come up each year but once you're in that contract position, you do have an advantage from that standpoint to renew because you're in that position regards to current payers and the formularies there. So, we'll continue to maintain those relationships in that market, and then continue to build upon that with additional payers as we go into the following years.

Sameer Baisiwala: **That's great, Matthew. That's very clear. And one final question from my side, how are we thinking about Aspart in terms of resolution of the pending CRL and the regulator's visit to our facility and do you think you can still be in time to contract for calendar 2023 for Aspart?**

Shreehas Tambe: Thanks, Sameer, for that question. As you know, when we received the CRL, we have pointed out to the two aspects that the agency had raised the question. One was regarding the diluent that is used particularly for a small segment of pediatric patients largely, who needed it alongside the vial. And the other one was related to further updates on the CAPA actions that we have provided for the observations that the agencies had made during the inspection. Now, we have been in constant dialogue with the agency, and we've responded to the CRL based on the conversations that we've had with the agency earlier this month. So, our response to the CRL has been sent and we expect the agency now to see that it gets towards approval. Now whether it will be exactly in time for the formulary contracting cycle, that's our hope. I know we've discussed that before as well but that's the discussion that will be ongoing with the agency. It will be unfair on our part to probably commit on behalf of the agency on when they will be able to approve the product.

Nikunj Mall: Thank you, Sameer. Next question is from Ankush Mahajan from Axis Securities.

Ankush Mahajan: **Thank you, Sir and congrats for the good set of numbers. My question is, there is a fall in gross margin. So, what is the impact on gross margins, if there is any fall in realization? I want to see, if you see, in the US market in Trastuzumab we have gained the market share and in Semglee also we have gained the market share. So, is this gain in market share due to fall in realization and its impact on gross margin?**

M.B Chinappa: I will speak specifically for the biosimilars business. We have seen improved margins this year. Our core EBITDA margin has gone up from 36% to 39% for the full year FY22 and our Q4 margin is also in line with that margin.

Ankush Mahajan: **Sir, would you throw some light on this Generics business? The Q4 growth is 17%, that's a good growth. How do you see the competition in Generics segment going forward, especially the price erosion and no doubt, there are new launches out there but what about the price erosion? How do we see the growth in this Generic business?**

Siddharth Mittal: Ankush, I had already addressed this in a previous question, that we do expect new launches to come up next year, both in our API as well as Formulations business, which should drive double-digit growth. From a pricing perspective, there are headwinds in the market, especially in the US. There are many reports already there that say that continued pricing pressure has impacted all Generics companies and we have also

been impacted. Now you have to choose whether you continue to be part of that pricing pressure, continue to lower prices or you opt out of some of these tenders and of course, we have to do both depending on the circumstances, but I also request Abhijit, who heads our Generic Formulations business to add his perspective.

Abhijit Zutshi: Thank you, Siddharth. Yes, you're right. I think you summed it correctly that the pricing pressure is there and the key is to add new products and we are planning for new launches through a dual strategy of in-licensing products as well as internal pipeline kicking in, so you would see more launches as we grow in this business.

Nikunj Mall: Thank you, Ankush. The next question is from Nithya Balasubramanian from Bernstein.

Nithya Balasubramanian: **Thank you. First one is actually on Humira. There are obviously multiple factors at play here - interchangeability, the citrate free formulation, the low dose versus high dose. So two questions, one is what is Viatris' product presentation? Are you likely to go after interchangeability at some point? And, two based on your recent conversations with payers, what are you picking up as important factors, is interchangeability important and how important?**

Shreehas Tambe: Thanks, Nithya. This is a topic of interest for everyone, I think we're watching this closely as well. Let's get the two key things out of the way for us. One aspect is to have the right product formulation, which is, as you rightly said, the citrate free formulation and that's something that we can confirm that Viatris has been able to secure and the other thing is to see that we get the approval for all indications, and that is something that we can confirm as well. So I think that out of the way, basically now, looking at the other variables that are under discussion which are whether it's the strength of the formulation, whether it's interchangeability to the device versus the syringe, etc., I think these are conversations which are currently ongoing, with also the citizen petition that's been filed at this point in time. Different players will probably launch with a different approach, some with the high strength, some with low, some with an interchangeability study and some without. I think the key nuance here is that while the agency will provide guidance on some of these in the coming days, is the interchangeability aspect here although important is probably really commercially relevant to the first player who would have exclusivity for a period of one year post launch and that is really going to happen with the first player getting into the market. There will be others who will conduct similar studies and we have seen other players have that as well. But the aspect of making a difference commercially will play out only a year hence, considering that interchangeability is a consideration for a product of this kind. But given that there are going to be close to a dozen players, a 10 or 11 players in this opportunity, with the pie being as sizable as it is, there is going to be room for almost everyone to play. If you were to look at the question that you asked on, what are we hearing from payers? I think there is still that 'wait and watch' in terms of how the market is going to shape up and what is the offering that each player is going to bring to the market, but clearly as I said before, there is going to be ample opportunity for everyone to play because of the size of the opportunity that we are working about.

Nithya Balasubramanian: **Shreehas, can I summarize that as maybe 2023 might not see as much biosimilar penetration as you would anticipate, given that payers are likely to want to wait to see what is the product presentation, who has interchangeability, who doesn't?**

Shreehas Tambe: I think that will probably be jumping the gun to say whether there will be sizable or not, I think there will a tiered entry, with Amgen entering first as we now know publicly and then a whole bunch of companies entering towards the second half of the year and while each one will have a different proposition, I would refrain from commenting on commercial strategies and how we expect to win in the market and I'll probably reserve it for a later date as we get closer to launch.

Nithya Balasubramanian: **My other question is also, are you likely to chase interchangeability?**

Shreehas Tambe: So, this is another aspect as I said, we have been watching this closely. Given that the timing of the interchangeability study really matters to only the first player, and then everything else is nearly a year later from them, we are committed to doing whatever it takes to be successful in that and interchangeability study is one of those things that we could be considering as well.

Nithya Balasubramanian: **One last one on vaccines, I think there report last week that Serum Institute is sitting on a large pile of vaccines with not enough takers. So now that you're closer to kicking off the deal with the SII, what is your latest visibility or your ability to push the 100 million doses in a year for the COVID vaccines?**

Kiran Mazumdar-Shaw: So, as I mentioned Nithya, it was not just about COVID vaccines. So yes, whilst they on sitting on stock of basically the Covishield vaccines, I don't think they're sitting on such a large stock of other vaccines.

Nithya Balasubramanian: **Sorry, correct me if I'm wrong, I thought FY23 and FY24 is COVID and what's in the pipeline is likely…**

Kiran Mazumdar-Shaw: I am saying that the stock he is talking about is the Covishield vaccines. They also make as you know, Covovax and all the other vaccines, which are non-COVID as well. And what we are we have access to is every vaccine that they manufacture, so I would not draw any conclusions from the statement he has made just on Covishield vaccine overstocking.

Nithya Balasubramanian: **I'm sorry, I'm just going to push out a bit of clarity here. When you say all other vaccines as well, are you talking about the MMR and the MR, the typhoid vaccines as well that SII is producing? Do you have access to those in the near term?**

Kiran Mazumdar-Shaw: Everything is what we have access to but I just want to caution you that don't draw conclusions from a statement that he has made, which really pertains to Covishield vaccines.

Nithya Balasubramanian: **Understood, thank you.**

Nikunj Mall: Thanks Nithya. Next question is from Surya Patra from Phillip Capital.

Surya Patra: **Thanks for the follow up. So, in fact, for the Malaysia plant, you mentioned about that achieving positive profitability this year. Could you clarify what is the number in terms of revenue, EBITDA from that setup because potentially that would see a kind of meaningful improvement in FY23. That is the first question.**

Shreehas Tambe: Chini, you may want to take it.

M.B Chinappa: Shreehas, if you could just give a perspective of how Malaysia is ramping up and I'll share the numbers. But Surya, did you have a second question, I didn't hear?

Surya Patra: **Yeah, so I have a second question as well. So I just wanted to have a sense on the new Biosimilar User Fee Act what today's being approved. So do you think greater competition that would be likely to come in the overall biosimilar space and more and more interchangeability opportunities will be competing with each other and hence, the way the competition that we have witnessed in the normal chemical based generic business, similar trend can possibly emerge in the biosimilar space? Is that the concern or are there some opportunity that you find from the Biosimilar User Fee Act?**

Kiran Mazumdar-Shaw: So, let me first take a shot at answering your question. First and foremost, we are watching the interchangeability space and I might also mention, that Biocon is a frontrunner when it comes to having a combined portfolio of insulins and mAbs, which I think is a unique portfolio offering that we have. And we do believe that we have this early mover advantage in the insulin interchangeability space. We will look at obviously at the mAbs interchangeability and have a strategy for that, but I think these are early days and we will have to see how we can basically take advantage of interchangeability or not.

Surya Patra: **Sure and about the Malaysia plants, if you can respond.**

M.B Chinappa: You're talking EBITDA in $20 million range and PBT in the $10 million range, that's on a quarter basis.

Surya Patra: **No, for FY22 as a whole. So I think that was the loss making set up?**

M.B Chinappa: On a full year basis, as we have indicated, we have been incurring losses in Malaysia but Q4 reflects that turnaround and that will be the basis to look ahead. There's no point of going back.

Surya Patra: **Okay. Just one more clarification I wanted about the loss from Associates and JVs. What we have reported this quarter is more than ₹50 crores of losses and this was expected to be the last quarter of such charges. So some clarity on that and also whether it is only related to Bicara or is it something relating to even the UAE subsidiary or UAE JV, which now we have activated. Can you just clarify on this and whether we should build similar charges even in FY23?**

Siddharth Mittal: Surya, it does have a component of our joint venture in UAE, small though. We have not reactivated the joint venture. Let me clarify that we are going direct in the market for our own drugs, but we still have certain products in that joint venture and unfortunately, because of legal issues going on with our joint venture partner, we cannot wind down this entity, so we are going to sunset that business in the next year. But that business is profitable, so there is a profit aspect of that joint venture in the number but the number primarily, as I said is, from Bicara. You are right, the expectation was that whatever we had at the end of Q3 would exhaust by Q4, but we also had given a debt to Bicara in the previous quarters and in-line with fundraise that Bicara is doing, we have taken a decision to convert that debt into equity. Of course, we have not pumped in additional cash into the business and hence, the loss pickup was higher this quarter. We have a carrying value of US$10 million as of March end, which will come as a loss pickup in the next fiscal. So, if Bicara continues to raise funds, there is a step-up gain on the existing investment that happens as per the accounting standards and that kind of adds to. It gets offset against additional expenses that come in the next quarter but there could be a mismatch between when the step up gain happens and when the expense against that gets offset.

Surya Patra: **That means this US$10 million will evenly distributed across the four quarters next year?**

Siddharth Mittal: No, it would be on first-come-first-serve basis. The run rate or the burn rate for Bicara is going to be lower, it is going to be approximately US$5-6 million and looking at our equity of 50-60%, we will have a loss pickup of roughly US$3-4 million and that will exhaust as soon as the $10 million get exhausted.

Surya Patra: **Ok. That is it, sir. Thank you.**

Nikunj Mall: Thanks Surya. The next question is from Tarang Agarwal from Old Bridge Capital.

Tarang Agarwal: **Good morning. Two questions from my side. One just to get a better sense on the Biosimilars business - while building a product and deploying in the R&D dollars there, what's the ballpark EBITDA margin that you bake in post the amortization of all the R&D spend? I asked this because, when I look at a core EBITDA margin today on ₹1,000 crores of revenue, 39%, it really doesn't accommodate for the R&D spends that might have been incurred on the products historically. So just to get some sense that if on the ₹1,000 crores that the business is earning today,**

what would really be the margin on the business? I'm not sure if I was very clear on what I am trying to understand.

Kiran Mazumdar-Shaw: I think, we have indicated that this is net of R&D, of course, when you talk about core EBITDA margins, it excludes R&D. And I think we have also indicated that the R&D spends you should factor are roughly about 10-12% of revenue. So, if you were to look at it that way, and of course it gets lumpy, so in some quarters it might even get to 15% but I think, you need to factor that R&D spend and then calculate the EBITDA margins based on that. So if you were to look at that, then you can be in that 26-27% EBITDA range. As you know, without investing in R&D, there's no future growth.

Tarang Agarwal: **Yes, ma'am. So basically, what I wanted to understand was that today with Peg, Trastu, Insulin, and host of other biosims that are currently in the portfolio and generating ₹1,000 crores of revenue on a quarterly basis, would it be fair to presume that these products would be generating maybe 25 to 26% EBITDA margin, assuming that the R&D spends that were incurred to bring these products online would be amortized over the revenue generating life of these products? I'm not talking from an accounting standpoint, I'm purely talking from a cash flow standpoint.**

Kiran Mazumdar-Shaw: I understand what you mean. Maybe Chini want to respond.

M.B Chinappa: I will clarify and then, Arun, if you can just give a color on overall R&D. But just specifically on the numbers, the core EBITDA margins before R&D really reflects what we are earning on the past investments that we have made and products that we have brought to the market. So today our sales of Trastu, Peg and now insulin Glargine are reflected in our revenues and core EBITDA margins indicate what we are earning from this business.

Kiran Mazumdar-Shaw: I hope that helps, Tarang, because what he's saying is that once you make those investments, obviously your margins are much higher.

Tarang Agarwal: **Ma'am, not really, but I'll probably take it offline. So can I just probably take two more minutes, so hypothetically, if say ₹1,000 crores or ₹2,000 crores were spent on R&D for these three products, over the life, I mean, historically over the last 6-8 years and assuming that that the entire amount was sort of capitalized. I am not saying it has, assuming that it was capitalized, and now once these products start generating revenues and I start writing off those ₹1,000-1,500 crores, whatever, I spend on R&D over the lifetime of the products, will probably fetch me what I am really earning out of those products today. So that is the figure that I am looking at. I am not saying I don't want you to give out the figure for the current ₹1,000 crore revenue, I am saying what is it that you all sort of forecast when you're building…**

Kiran Mazumdar-Shaw: Let me answer that question by saying that look, Chini just mentioned. Let's look at today's numbers in biosimilars. It's actually pertaining to the products that are in the market and that does not reflect the current R&D spends on those numbers, but it actually basically takes into account all the R&D that has gone into shaping these molecules. And basically, if you look at the way we capitalized all the R&D spends, and if you look at your core EBITDA numbers, it includes the amortization on these spends at the current levels. So, only thing that you are now having to factor is the additional R&D spends.

Tarang Agarwal: **For the future pipeline.**

M.B Chinappa: If I may, Tarang, I'll just clarify one more time. Basically, when you say core EBITDA, it excludes R&D spends on both new programs and old programs. Most of the old programs were either expensed out of Viatris and some portions capitalized and those capitalized are being amortized below core EBITDA. So when you are looking at core EBITDA that is really giving you the true picture of profit on past investments.

Tarang Agarwal: **Thank you. Second question for me, the ₹3,400 crores of CWIP on the Balance Sheet, what would be a major portion of that and what would trigger the capitalization of it and further annual cost impact of that on P&L?**

M.B Chinappa: The CWIP largely represents expansion of our drug substance capacities for mAbs. We expect one of these facilities to come online in this fiscal, that's FY23, and the other second facility to come online in FY24-25 timeframe. As they come online, they will, of course, give us additional opportunities, particularly as Bevacizumab gets approvals. We will have additional capacities to service that but on the flip side, you will have increased depreciation, interest and other costs associated with the facility.

Tarang Agarwal: **Thanks.**

Nikunj Mall: Thanks, Tarang. The next question is from Vipulkumar Shah, who is an individual investor.

Vipulkumar Shah: **Congratulations on the good set of numbers. I have 2 questions, what is the exit capacity utilization of the Malaysian plant and second what is your guidance for full year losses for Novel Biologics? Thank you.**

Shreehas Tambe: Let me take the first one, Vipul, if I heard you correctly, the question was what is the capacity utilization we see in Malaysia, that was your question. The important thing is to see that the capacity utilization over the second half of the year in Malaysia has significantly improved over the first half of the year and it's reflected in the supplies and the revenues that we've got during the course of the second half of the year. We've also guided that we are making investments in expanding capacity further as we see not just increased interest in the products that we brought to the market, but also for products to follow. So we will see capacity expansion further in Malaysia for drug product and drug

substance in the years to come. But clearly, capacity utilization of our current investments has grown significantly, leading to that Malaysia facility turning a profit towards the end of the year as we closed and exited FY22. I think your second question was more related to Novels, couldn't hear that well and could you repeat that and maybe, Siddharth, you can take that.

Vipulkumar Shah: **What is your guidance for losses annually for Novel Biologics for FY22-23? And regarding Malaysia, my question is what was the exit capacity utilization for the fourth quarter? Thank you.**

Siddharth Mittal: Let me take the question on guidance on Novels. I would talk more qualitatively rather than numbers. I think I've already indicated that we have a very small spend on Itolizumab and the Tregopil trial is also complete. So there we do not expect any additional costs coming in for Tregopil. For the BCA101 or the Bicara trial, which is ongoing, the cost is not coming in the R&D expense, it's coming through the cost of JV. More directionally as Kiran had mentioned in the opening remarks that Equillium has started the Phase III trial for acute GVHD and it's a global trial so we expect significant progress to be made over the next two years from a clinical perspective for Itolizumab. We are also going to start maybe another trial for the indication in India in this fiscal year. And now we have the BCA101 or Bicara clinical trial going on in the US, we expect data to come out in FY23 and FY24. So, those are the two lead molecules that we have where we do expect a progress over the next two years.

Nikunj Mall: Thank you, Vipul. The next question is from Prakash Agarwal from Axis Capital.

Prakash Agarwal: **Thanks for the follow up, quick one here, on the gross margin side, we have seen some drop, partly I think due to Syngene, research services and partly maybe, higher input costs. So how do we see FY23 given that most of the other product launches are now in calendar 2023. So how do we see FY23 for gross margins, please?**

Siddharth Mittal: Let me just break it up, generics is down 2% on a full year basis, biosimilars is down 2% and research is down 5%. Generics is down mainly because of increase in input costs in the solvent prices. I don't see, at least, in the Generics business, a recovery in gross margins next year. We do expect to continue at the similar levels as full fiscal of FY22.

Prakash Agarwal: **BBL?**

Siddharth Mittal: Chini can answer but again, as you know, there are many moving parts for BBL because of Serum and Viatris. Chini can hazard a guess.

Prakash Agarwal: **Just broad colors should help.**

M.B Chinappa: In the base business, as we see an increase in revenues and profit share coming from the US markets, our overall gross margin should be maintained but I take it that, when

you say gross margin we are saying revenue less material cost, not the core EBITDA margin, right?

Prakash Agarwal: **Yes.**

M.B Chinappa: Well, the gross margin we should be able to manage within a 1-2% range.

Prakash Agarwal: **Thank you, and second one is on the Biocon Biologics IPO timelines. In the past, we have said 12 to 18 months. Is it still looking that way or given that so much development, Viatris and Serum etc. has happened, so..**

Kiran Mazumdar-Shaw: Obviously, it is going to be pegged to the date of closure and the way we can basically integrate the business. So obviously we will look at that and then decide the timing.

Prakash Agarwal: **Right, perfect and all the best for that. Thank you.**

Nikunj Mall: Thanks, Prakash. Given we are running out of time, we will take one more question for the day. The next question is from Nithya from Bernstein.

Nithya Balasubramanian: **Thank you. So, two quick ones, so on Stelara and Ustekinumab there are two product presentations, the IV one and the injection one, are you chasing both? And the second one is, what color can you give us on the Sandoz programs?**

Shreehas Tambe: On the Ustekinumab, the response to that first question is yes, which is in both. The question that you had on the product pipeline, we are looking at products which would basically have market formation towards the end of the decade and that is something we have been working on. As these product progress towards that, we will be bringing more information in the public domain.

Nithya Balasubramanian: **As of now everything is pre-clinical, is that how we should read it?**

Shreehas Tambe: Yes, it is at pre-clinical stage.

Nikunj Mall: Thanks. We have one more question from Dinesh Mahajan.

Dr. Dinesh Mahajan: **Thanks and congratulations for the good set of numbers. I have been a practicing doctor. India being the diabetes capital of the world and right now, the Management seems to be more focused about US market, any special strategy we have to grow the Indian market share when it comes to Semglee or Insugen or your diabetes portfolio you have for the Indian market. Like I see MNCs dominating in India, does Biocon have any special strategy in place or are they focusing on growing market share in India?**

Susheel Umesh: Thank you, Dr. Dinesh, for that question. The India business for us is very important. It's a home country for us and it's important that we drive market share in India and we are

very conscious about that as well. In terms of Basalog®, the interchangeability study or the science that we are selling had a very strong impact on the doctors in India. So the focus is very high. In terms of field force, we have ramped up our field force as well. We know the need of education, the need of training of field force will only go up and that is where we are focusing. A lot of focus being done in India on sales force excellence and also high scientific activity with doctors in the country as well. So, we are driving very strongly and in FY22, we have seen results coming as well indicating towards increased market share. So, the focus will be very strong in India, not only for diabetes but also for oncology and the other portfolios that we have.

Dr. Dinesh Mahajan: **Thank you. And one more if I may, Biocon Biologics will be listed as a separate entity, so anything your old previous Biocon shareholders should look at? Any share listing for them or any other opportunity for them?**

Kiran Mazumdar-Shaw: At this point in time, I really won't be able to say much but we are quite a while away from the IPO, so let's wait.

Dr. Dinesh Mahajan: **Thank you.**

Nikunj Mall: Thank you, Dinesh. Thank you, everyone. That was the last question for the day. We thank you all again for joining us today. If you have any additional questions, please feel free to reach out to Aishwarya or me. We will be seeing you again next quarter. Have a good day.