Biocon

THE

Biocon Limited Q4 FY21 Earnings Conference Call Transcript

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Speakers and Participants from Biocon Limited and Biocon Biologics

Kiran Mazumdar-Shaw – *Executive Chairperson, Biocon Limited*

Siddharth Mittal – *CEO & Managing Director, Biocon Limited*

Arun Chandavarkar – *Managing Director, Biocon Biologics*

Shreehas P Tambe – *Dy CEO, Biocon Biologics*

Indranil Sen – *Chief Financial Officer, Biocon Limited*

M.B. Chinappa – *Chief Financial Officer, Biocon Biologics*

Susheel Umesh – *Chief Commercial Officer-EM, Biocon Biologics*

Paul Thomas – *Chief Commercial Officer-US, Biocon Biologics*

Nehal Vora – *Head – Commercial – API, Biocon Limited*

Abhijit Zutshi – *Head – Commercial – Generic Formulations, Biocon Limited*

Ankit Gupta – *Head-Investor Relations, Biocon Limited*

Nikunj Mall – *Head-Investor Relations, Biocon Biologics*

External Participants during Q&A session

Prakash Agarwal – *Axis Capital*

Damayanti Kerai – *HSBC*

Neha Manpuria – *JP Morgan*

Shyam Srinivasan – *Goldman Sachs*

Surya Patra – *Phillip Capital*

Sameer Baisiwala – *Morgan Stanley*

Milind Karmarkar – *Dalal & Broacha*

Vipul Shah – *Sumangal Investment*

Tushar Manudhane – *Motilal Oswal*

Sheersh – Individual Investor

Charulata Gaidhani – *Dalal & Broacha*

Dr. Harith Ahamed – *Spark Capital*

Nithya Balasubramanian – *Sanford Bernstein*

Prepared Remarks Session

Melvin George:

Very good morning to one and all. A warm welcome to all the ladies and gentlemen to Biocon Limited's Q4 FY21 Earnings Conference Call. All the participants will be in the listen-only mode, and there will be an opportunity for you to ask questions after the opening remark concludes. Should you need to raise questions, please select the "raise-hand" option under the reaction tab of your zoom application. We will call out your name and unmute your line to let you

ask the question; while asking, please begin with your name and your organization. Please note that we will not be monitoring questions on the chat box, but you can raise any technical concerns, you may face for our support team to help. This conference is being recorded, and I would now like to hand the conference over to **Mr. Ankit Gupta** from **Biocon Investor Relations**. Thank you, and over to you, Ankit.

Ankit Gupta:

Thank you, Melvin. Good morning, everyone. I hope you are fine and in good health. I'm Ankit from the Biocon Investor Relations team, and I welcome you all to the Earning call for the quarter. To discuss the Company's Business Performance and Outlook, today we have the Biocon leadership team comprising **Dr. Kiran Mazumdar-Shaw**, our **Executive Chairperson**, and other senior management colleagues.

I want to take this opportunity to remind you about the **Safe Harbor statement**. Today's discussion may be forward-looking in nature based on management's current beliefs and expectations. It must be viewed in concurrence with the risks that our business faces, which could cause our future results, performance, or achievements to differ significantly from what is expressed or implied by such forward-looking statements. At the end of the zoom call, if you need any further clarifications, you can get in touch with us.

Now, I would like to turn the call to **Dr. Kiran Mazumdar-Shaw**. Over to you, ma'am.

Kiran Mazumdar-Shaw:

Thank you, Ankit. Good morning everyone, and I welcome you to the Earnings call for Biocon for the fourth quarter and the full-year fiscal 2021.

I want to start on a note of hopeful optimism that we will overcome this devastating second wave of COVID-19 sooner than later through mass vaccination. I wish you and your family good health and safety. The central government's announcement that all Indians above the age of 18 will become eligible for vaccination starting May 1 will enable corporate India to vaccinate their employees and immediate family members, which will help us build the much-needed vaccine-induced immunity against hospitalization. Biocon is also at the forefront of this fight against COVID-19. Our subsidiary Syngene has an accredited vaccination center, and we are offering our vaccination services to all companies operating in the Electronic City area. The Biocon group is also catering to the country-wide demand for Remdesivir, Itolizumab, and CytoSorb.
Meanwhile, we have taken significant precautions and measures to ensure that our employees continue to work in a safe environment and, wherever possible, work remotely. We continue to assess the situation and operate as per government guidelines as they evolve in different regions. This second wave has once again introduced uncertainties in our business operations as well as supply chain logistics. However, we will do everything to serve our patients and customers in every possible way despite all these challenges.

Now let me discuss with you the key development of the quarter; let me start with some management updates:

- Shreehas Tambe, former Chief Operating Officer at Biocon Biologics, has been promoted to Deputy Chief Executive Officer of the company effective March 1, 2021. Shreehas has been with the company for over 20 years in operational and strategic leadership roles. He has led large, diverse teams at manufacturing, quality, R&D, and projects and engineering during his tenure within the Biocon Group.
- Biocon Biologics also appointed Sushil Umesh as Chief Commercial Officer - Emerging Markets. Sushil has over 30 years of experience in the Pharmaceutical industry, working in India, France, and Sub-Saharan Africa for leading global pharma companies. With Dr. Arun Chandavarkar taking over as the Managing Director of Biocon Biologics, Shreehas Tambe as the Deputy CEO, and Sushil as the CCO - Emerging Markets, I believe we now have a strong leadership team to drive the future growth of our biosimilars business and return the company to its high growth trajectory soon.
- I would also like to announce the appointment of Indranil Sen as the CFO with immediate effect, concurrent with Anupam Jindal, who has stepped down from the position of CFO at Biocon Limited for personal reasons. Indranil was earlier the Vice President of Finance at Biocon since 2014 and has performed various key leadership roles within the Finance Department.

Now coming to key highlights of the quarter:

- Biocon Biologics received Marketing Authorization approval from the European Commission for both biosimilar Insulin Aspart and biosimilar Bevacizumab. This is a very important development. These are products which we

have co-developed with our partner, Viatris, and we expect to launch these products in the near future.

- In our generics business, we received USFDA approval for Everolimus (gAfinitor®), an immunosuppressant indicated to prevent rejection of organ transplants and used to treat renal cell cancer and other tumors.
- We also entered into a partnership with Libbs Farmaceutica, a leading pharmaceuticals company in Brazil, to develop and commercialize our portfolio of generic drugs in Brazil, the world's sixth most populous country.
- Our Research Services Business- Syngene - crossed a significant milestone with the extension of the collaboration with BMS until 2030. The new agreement includes an expansion across the breadth of drug discovery research, a 40% increase in the number of scientists, and an additional 50,000 sq. ft. of dedicated laboratory space.

I will now present the key financial highlights starting with the quarter and followed by the full year.

The fourth quarter delivered a year-on-year growth wherein Revenues increased by 26% to ₹2,044 Crore compared to ₹1,621 Crore in the corresponding period last year.

Revenue from Operations stood at ₹1,839 Crore, up 18% driven by healthy growth of 53% from biosimilars. Our research services business grew 8%, while the generics business reported modest growth of 3%.

We recorded Gross R&D spend of ₹136 Crore for the quarter, which corresponds to 12% of revenue, ex-Syngene. Of this amount, ₹127 Crore is expensed in the P&L as R&D expenses while the balance amount has been capitalized. The increase in R&D expenses accounts for higher spending in novel biologics, biosimilars, and generics

We booked a Forex gain of ₹7 Crore this quarter, compared to a gain of ₹35 Crore last year. EBITDA for the quarter is ₹641 Crore compared to ₹382 Crore for the same period in the previous financial year. EBITDA margins for the quarter stood at 31% as against 24% in the Q4FY20. Net Profit for the quarter is ₹257 Crore.

During the current quarter, Biocon ceded control over the Board of Directors and Operations of Bicara Therapeutics Inc. It enabled it to operate independently under a US-based leadership team and raise funds to advance its development programs.

As a result of this change, Bicara was classified as an Associate from a Subsidiary under IND-AS. Consequently, the investment in Bicara was fair valued, resulting in a gain of Rs.160 Crore, which is reported under "Other income" for the quarter

Adjusting for Bicara's fair valuation gain:

- Our EBITDA during the quarter was ₹481 Crores reflecting an EBITDA margin of 26%
- Net Profit from Continuing Operations (excluding exceptional expense, net of taxes) for the quarter was ₹97 Crore, down from ₹132 Crore last year.
- Core Margins (i.e., EBIDTA margin, net of licensing, forex, and R&D) stood at 32%

Financial Highlights for the Fiscal year 2021

During Fiscal 2021, Total Consolidated Revenues grew to ₹7,360 Crore, up 14% compared to ₹6,462 Crore last year.

Revenue from Operations was at ₹7,106 Crore, up 13%. Biosimilars reported a 21% growth from ₹2,315 Crore to ₹2,800 Crore in FY21, followed by Research Services, which delivered 9% growth, to report ₹2,184 Crore in revenues. The Generics business grew 6% on a year-on-year basis, reporting revenues of ₹2,336 Crores.

We incurred a Gross R&D spend of ₹627 Crore during the year, corresponding to 13% of revenues excluding Syngene. Of this amount, ₹553 Crore is reported in the P&L as R&D expenses while the balance amount has been capitalized. The capitalized amounts relate to biosimilar development expenses.

For the full year, we booked a Forex loss of ₹9 Crore compared to a gain of ₹65 Crore last year. EBITDA grew at 8% for the year to ₹1,907 Crore. EBITDA margins stood at 26% in FY21, down from 27% last year. Net Profit stood at ₹754 Crore. Adjusting for Bicara's fair valuation gain:

- Our EBITDA for the full year was ₹1,747 Crore, reflecting a margin of 24%
- Core Margins stood at 32%, down from 33% last year.
- Net Profit from Continuing Operations (excluding exceptional expense, net of taxes) for FY21 was ₹594 Crore,

down from ₹789 Crore last year.

Coming to the review of our business segments' performance for the 4th quarter and full year

Generics

Our generic segment reported modest growth during the quarter on account of headwinds we encountered by way of pricing pressure on both APIs and formulations. Travel restrictions that delayed regulatory approvals also denied us from certain growth opportunities and relatively subdued API revenues and formulation launches. The segment reported quarterly revenues of ₹578 crores, a 3% growth over the last fiscal year.

The quarters' PBT stood at ₹73 crores versus ₹71 crores. PBT margins were at 13% versus 13% in Q4 FY20. On a full-year basis, our revenues grew by 6% to ₹2,336 crores with a profit before Tax of 13%, supported by double-digit growth in generic formulations and modest single-digit growth in APIs.

As we indicated in the previous quarter, revenues for our API business in the second half of the fiscal were relatively subdued compared to the first half, attributable to stockpiling by customers anticipating Covid related supply disruptions. This, of course, led to high demand for APIs in the first half. The absence of new product launches impacted our revenues for the formulation business due to delays in the inspection of our facilities, as I mentioned earlier.

We have also witnessed pricing pressure for some of our critical products. To mitigate the impact of pricing pressure, we continue to undertake several initiatives in cost improvement and optimize our systems and processes to drive operational excellence.

We received four drug master file approvals for our products in the US, EU, and most of the world markets during the quarter. While the travel restrictions have impacted new market entries of APIs, we've been working relentlessly to expedite geographical expansion. 10 DMFs were filed in most of the key world markets.

After some initial covid related delays, the construction of our Greenfield immunosuppressant plant at Vishakhapatnam has started returning to normalcy. However, we have to watch the progress based on the second wave. While we expect the facility to be commissioned in CY2022, we must be aware of potential disruptions from the second wave of this pandemic.

Our key Statin products continued to retain mid to high teens market share in our formulations business in the US. Our first immunosuppressant formulation, Tacrolimus, launched in Q3 FY21, has started to gain market share. We also received US FDA approval for Everolimus, a generic Afinitor, and this is an immunosuppressant indicated to prevent organ transplant rejection. It is also used to treat renal cell cancer and other tumors. Everolimus is a vertically integrated product that further fortifies our global positioning in immunosuppressants. We expect to launch this product in FY22.

We continue to build on our generic formulations portfolio by filing abbreviated new drug applications for vertically integrated products in the US in addition to market authorization applications and dossiers in Europe and most of the world markets. The expansion of our generic formulations business outside the US remains a key area of focus. Our partnership with Libbs Farmaceutica in Brazil was a key highlight this quarter in another crucial progress towards establishing a strong presence beyond the US. We received a GMP-compliant certificate from MHRA, UK, for our formulation manufacturing facility located at Biocon Park in Bengaluru.

Overall, the generics business continues to be in an investment mode. We remain focused on our strategic priorities and will continue to deploy capital for creating capacity and adding new products through our R&D efforts. As we work towards strengthening our generics business, we expect this segment to demonstrate modest growth in FY22 and a strong uptick from FY23.

Novel molecules

Our novel assets continue to be driven by our inherent capabilities and external collaborations. Equillium, our US partner, reported encouraging developments on the clinical advancement of Itolizumab, a first in class anti-CD-6 monoclonal antibody. Equillium remains excited about Itolizumab's therapeutic use in acute Graft versus Host Disease, Lupus and Lupus nephritis, and uncontrolled asthma. While Covid delayed clinical studies in 2020, we

are awaiting clinical data from all their studies in CY2021.

Itolizumab was also launched in India for the treatment of COVID-19 under emergency use. We will have the first cut data on the ongoing phase IV studies shortly, which will further validate the potential of Itolizumab in effective ARDS treatment. As you must have seen for Itolizumab, the demand is far exceeding our ability to supply during the second wave of the COVID-19 pandemic, and we expect to catch up with the demand sometime in mid-June.

Our Covid portfolio comprising Remdesivir under a voluntary license from Gilead, CytoSorb, and Itolizumab continues to serve COVID-19 patients in the wake of this second wave.

Biosimilars

Biocon Biologics has recorded revenues of ₹664 Crore in Q4 fiscal year 2021, a year-on-year growth of 53%. EBITDA margin was at 25%, with absolute EBITDA growth of 81% year-on-year. However, I must point you to the fact that last fiscal, the quarter was an exceptionally low quarter. We have seen a sequential decline of 14% in revenue and 22% in EBITDA. Profit Before Tax stands at ₹68 Crore.

Moving on to full year performance, Biocon Biologics recorded revenues of ₹2,800 Crore, representing year-on-year growth of 21%. EBITDA margin was at 27% versus 33% in the fiscal year 2020. Net R&D cost increased from ₹178 Crore in the fiscal year 2020 to ₹284 Crore in 2021. This reflects a good progress on several of our programs. Profit Before Tax for the year stands at ₹365 Crore against ₹428 Crore in FY20. I would again like to emphasize that R&D investments are critical to future growth. We believe that this investment needs to be looked at very differently compared to other expenditures.

Over the last year, we have seen a slight uptick for Fulphila in the US and steady growth for Ogivri. Despite competition, these products have shown resilient performance. We had launched Semglee in the US in fiscal year 2021 and have seen a slow but steady ramp-up in market share. In Europe, our sales continue to improve on the back of new market entry and improved market share in key markets. Based on IQVIA data, Ogivri continues to be the leading biosimilar Trastuzumab in Australia and Canada.

While we have seen decent growth of 21% in FY21, there were certain business challenges, amplified by COVID-19, restricting our ability to achieve our targets. Our partner, Viatris is deploying various strategies to ensure the good growth of our commercialized products in the US and other developed countries.

While COVID-19 presented some challenges in emerging markets, such as tender delays and reprioritization of budgets within the healthcare systems, we continue to see strong demand for our biosimilars in these markets resulting in good growth in our B2B emerging market business for the full year 2021. We have garnered a significant market share in many key markets such as Algeria, Brazil, and Malaysia.

Moving on to Biocon Biologics' R&D pipeline, we are pleased to receive European Commission's approval this month for our biosimilar Bevacizumab, developed in partnership with Viatris. This follows the approval of our biosimilar Insulin Aspart in Europe last quarter giving us a robust portfolio of five approved biosimilars in Europe along with an economic interest in two more approved in-licensed products. We are awaiting feedback from the US FDA on the timing of site inspections for biosimilar Bevacizumab. We have noted that the US FDA has recently issued guidelines for virtual inspections for overseas facilities and we are working with the agency to see how soon we can effect this inspection. We also look forward to receiving a positive outcome from the US FDA on our BLA submission for Insulin Aspart. Last quarter, we received WHO prequalification for our biosimilar Trastuzumab which covers 46 LMIC countries.

While we had recovered from the impact of the first wave of the pandemic, uncertainties with the second wave continue in the near term. So far, we have not seen any significant impact on our operations, but we closely track the evolving situation. While becoming increasingly competitive, the biosimilar market continues to offer attractive opportunities for vertically integrated players like us. We expect to continue the momentum and improve market share for our current commercial products and expect to launch biosimilar bevacizumab and insulin aspart in the developed markets in FY22. We also expect to make good progress on our robust R&D pipeline.

We believe that we are well-positioned to grow our biosimilars business globally on the back of our robust business fundamentals, scientific know-how, low-cost manufacturing setup, early-mover learnings, and a broad product portfolio. I would also say that at this point that we are confident that in FY22, we are in a position to show higher

growth than this fiscal.

Research Services (Syngene)

During the quarter, Syngene reported revenues of ₹659 Crore, up by 8% over Q4FY20. PBT for the quarter stood at 24% versus 25% for Q4FY20. For the full year, Syngene reported revenues of ₹2,184 Crore, demonstrating growth of 9% against the corresponding period last year. PBT for the year stood at 20% versus 22% for 2020. Syngene's Mangalore API manufacturing facility completed the qualification process during the quarter and is now a GMP -certified unit. Syngene continued to build on its integrated drug discovery and development portfolio during the year, including a five-year collaboration with 3DC, the drug discovery development subsidiary of Deerfield Management Company (Deerfield) and is proud of its partnership with Albireo Pharma to develop a drug that will help to treat specific genetic liver diseases, primarily in children.

Syngene also continued to support its clients on various research projects, including leukemia, Parkinson's disease, inflammatory disorders, fibrotic disorders, and orphan diseases. Based on Syngene's strong fundamentals, sound business model, robust liquidity position, client base, and healthy financial risk profile, CRISIL and ICRA upgraded Syngene's credit rating during the year.

In conclusion, I would say that these are challenging times testing our resilience, intelligence, agility, adaptability, and other attributes that a business must display to stand out in a crowd. At Biocon, we are conscious that the pandemic is far from over, and it may continue to riddle us with new challenges at regular intervals. That said, we have spent the past year adapting to the new normal. We identified areas that needed work and made amends. We worked hard over the past year to prepare ourselves to tide over past eventualities. Big or small these eventualities were something we were very much focused on overcoming. Consequently, despite the headwinds, which resulted in some setbacks, we had a string of encouraging developments that laid a solid foundation for our future growth. We are confident of the long-term opportunities in every segment where we operate and our ability to deliver value to patients, customers, and stakeholders worldwide.

In FY22, we expect to retain the growth momentum led by higher revenues in biosimilars, research services, and generics. We will continue to focus on the portfolio, strengthening the development pipeline and fast track capacity enhancement. These initiatives will bolster our pursuit of enabling access to affordable therapies to patients worldwide and will have us positioned well to deliver on the expectations of our partners and stakeholders.

With this, I would like to open it up to the floor for questions and answers.

Q&A Session

Prakash Agarwal: **Hi, thanks for the opportunity, and good morning to all. My first question is on the guidance. Is there a rethink on the guidance? In the last quarter, we said that we would review the guidance for our biosimilar business**

Kiran Mazumdar-Shaw: Prakash, last quarter itself we had indicated that our $1 billion targets were unrealistic at this point, which was already conveyed to you. In terms of guidance, I think we will need a few quarters before we indicate what we see as the growth opportunity, but all I can say is that we have seen a growth in the biosimilars business of 21% this fiscal. I can confidently say it will be higher than that.

Prakash Agarwal: **That helps, and secondly, on your Q4 performance, you had a detailed opening remark, but while you mentioned that you know there has been a Q-o-Q decline in the biosimilar business and also EBITDA margin has come off. So, when we see the market share data is largely stable or marginally increasing, do we conclude that there has been a higher pricing erosion in the US or developed market. Would that conclusion be correct?**

Kiran Mazumdar-Shaw: Certainly, there has been some price erosion, but I think more than that we have had certain increased costs, and as you can see, our R&D costs have also been very high

this fiscal. So, all that has contributed to this, and we do need to make sure that we focus on higher revenue growth and that we get greater contribution as a result of that to our EBITDA and EBITDA margins

Damayanti Kerai: **My first question is on some of the in-market products in the US, such as Trastuzumab and Pegfilgrastim. So especially for Pegfilgrastim, our market share has been steady if we look at the market data. Still, we have seen a really strong pickup from some of the competing biosimilars, which have entered relatively recently. So, my question is: Do we have scope to improve our market share from here, and what could be the factors helping us achieve better market share in market products?**

Kiran Mazumdar-Shaw: So, I think Viatris is certainly looking at the market share opportunities in the developed markets. I think they will focus on how they take on the competitive forces they see today. So, I'm very confident that Viatris will focus on garnering market share, but that will likely lead to some price erosion as well. So, I think it's a question of how you want to play the market. But I think that Viatris is very aggressive.

Damayanti Kerai: **My second question is on Bevacizumab, which we hope to launch in the US in the near term. So again, when we look at the competitive scenario, now 65% market share is taken up by two biosimilars that have entered before us. So, with this kind of, you know, the market share going to the incumbents, do you believe Biocon will make any, I'll say, significant market share or sales given the competition and pricing erosion in that particular segment?**

Kiran Mazumdar-Shaw: So, Damyanti, first and foremost, yes, it is most unfortunate that Covid denied us entry into the US market as we were expecting to get approval in December 2020. But that said, I would think that given the fact that we are extremely competitive in Bevacizumab, Viatris and Biocon believe that they can still enter the market and quickly garner good market share. It will take some time because it is always beneficial to the early entrants, and it takes time for the follow-on companies to take away market share. Still, we believe that this will be a very large opportunity over the next few years. Given the market competition that we're seeing, we believe that we are in a good place.

Neha: **On the biologic business, the 14% revenue decline that we have seen, is it fair to assume that all of that decline is essentially due to price erosion in the US, or are there any other moving parts?**

Kiran Mazumdar-Shaw: No. Generally, what happens is that as you know, Viatris' year ending in December and we always see a slight decline in our fourth quarter, because what we generally see is that they cover their requirements in the third quarter. Then we see a slight decline in the fourth quarter. So, we believe that although the third quarter had a higher realization than the fourth quarter. We believe that this is a natural trend that we see every year. So, we're not that concerned, but basically, what we believe is that we have lost significant opportunities because of our inability to launch Bevacizumab in the US market. That was a significant hit for us, and there has been Covid impact which has not allowed certain existing products to garner increased market share. So, we believe that you will see improvement in the coming quarters.

Neha: **In that case, ma'am, the EM business wasn't impacted quarter-on-quarter that continued to show momentum. That would be a fair assumption?**

Kiran Mazumdar-Shaw: Yes, the emerging market business did see growth, and we expect it to be even greater in the coming quarters.

Neha: **My second question is on the guidance you mentioned that you know FY22 growth is likely to be higher than the 21% we have reported. One does that assume a launch of Bevacizumab in the US, biosimilar Beva in the US. Second, what would be the moving parts for that growth? Would the developed markets drive it all, so you know**

you mentioned emerging markets or how much of it that growth is dependent on the US and Europe?

Kiran Mazumdar-Shaw: While I can't share the break-up, all I can say is that we expect a very significant contribution from emerging markets. We expect good contribution from the developed markets and new products as well. So, all of these are expected to contribute to good growth in the coming fiscal. And to answer your question, yes, it is also riding on some revenues coming from Bevacizumab.

Shyam Srinivasan: **My first question is on the biosimilar core EBITDA margin. There has been a lot of variabilities and around R&D Q-o-Q. So, I'm looking past that and looking at Core EBITDA margins. I think the press release talks about 36% for fiscal 21, but I'm just curious about Q4, the core EBITDA margins for Biocon Biologics, and just trying to link it to the pointer on price erosion. Has there been a material Q-o-Q impact in that core EBITDA margins?**

Kiran Mazumdar-Shaw: So perhaps I would like to turn this question over to my colleague's MB Chinappa and Arun Chandavarkar.

MB Chinappa: Hi and good morning. The core EBITDA margin for the quarter is 33%, but on a full-year basis, it's 36%. I encourage you to look at the full year instead of the quarter. The quarter has some moving parts, some one-off items that skewed our numbers. The full-year average is a better indication of the performance.

Shyam Srinivasan: **Is it the pricing pressure that has led to that 33% versus 36%, and when we look forward, how should we look at the number not the 21% of growth but what about margins core EBITDA margins?**

MB Chinappa: I think we believe that the sequential dip in Q4 is a one-off. I mean, look at it on a full-year performance; the one-off items have skewed and brought the Q4 down lower. It's not structural; the full year is a better view of the performance.

Shyam Srinivasan: **Sorry to persist on this - severance pay. Does it come in that number there?**

MB Chinappa: Yeah, these numbers are just revealed as excluding severance pay and excluding exceptional items.

Shyam Srinivasan: **My second question is on the rest of the business, the generic business. Again, pretty flat kind of growth for the year, but just you know, is there an outlook we begin started to see maybe at least some of the API numbers start picking up again for if I look at trade data if I look at competitors, so just curious around the outlook for this business for fiscal 22.**

Siddharth Mittal: Shyam, I think Kiran already alluded to in her opening commentary that we expect double-digit growth for formulations business in FY22, and we expect low single-digit to flattish growth in our API business for two reasons, one as we are getting ready to launch our formulations in the US, lot of the APIs that we were earlier commercializing would be used for our formulation sales and second is as we create new capacities we are currently running our plants full so till we get Vizag commissioned and ready to commercialize, and we get our Hyderabad facility where we are investing in a large synthetic facility, commissioned and ready to be commercialized, we do not expect API business to grow significantly, and I think that this is also in line with the guidance that we had given last year. If you recall, we had given similar guidance that we expect API business to grow mid-single digit and our formulations business to grow mid-teens to high teens, and that's what happened in FY21. We expect a similar trend in the next fiscal year, and again as Kiran mentioned, we expect the growth to start in the generics business starting in FY23. That's when we expect more launches in the US in our formulations business. Plus, we expect additional capacities to be commercially ready to increase the sales in our API business.

Shyam Srinivasan: **Yeah, thank you, and this data point 80-20 is that the same split of API to formulations.**

Siddharth Mittal: That's right.

Shyam Srinivasan: **Last accounting question, this one ₹160 crores of gain don't seem to be showing up on tax line similarly, is it not a cash gain? I'm just trying to understand that**

Siddharth Mittal: Yeah, there's no tax impact on that ₹160 crores. It is a one-time step up that we have taken because of the change in the way Bicara was accounted, and that has been shown up in the other income. Still, for all practical purposes, it's not the cash income that is there and but there is no tax associated with this gain.

Surya Patra: **So just wanted clarification on Bicara. So, we have reduced our exposure, and hence is it fair to believe that this R&D intensity will see some moderation because of that and whether this quarter also the sequential reduction in the R&D is because of that fact?**

Siddharth Mittal: That is correct, Surya, so this will no longer be consolidated with our financials, but it will be treated as an expense or loss coming from associates. So, there were roughly ₹70 crores of expenses in R&D for Bicara, which have not been included in the R&D line.

Surya Patra: **So anyway, it is not impacting as of now?**

Kiran Mazumdar-Shaw: So, this will be discontinued. As an associate, the R&D expenses of Bicara will no longer be directly impacting us. But maybe Siddharth, you might want to explain it.

Siddharth Mittal: Yeah, so since this is no longer a consolidated entity and Bicara is looking at fundraising, Biocon will be diluted further. We have lost control over the appointment of the Board of Directors because that's the way fundraise happens in the US. There are certain rights that the incoming shareholders look at, and they don't really want the parent company to control the board, and hence we have to give up the board, right. So on a go-forward basis, our financial obligations are no more there for Bicara; we have already funded $40 million so far in Bicara to get Bicara to this stage, and all the future funding will be raised directly by Bicara through a combination of various funding rounds and since our obligations are restricted the future loss that we will take on account of Bicara will also be restricted.

Surya Patra: **Thank you, and my second question was on the kind of margin trajectory for a sustained period. While the opportunity on the biosimilar side looks very strong, there is no change to the kind of ultimate expectations and all. But obviously, last year was an abnormal year because of the Covid, which impacted our biosimilar progression. So, going ahead, while that is still there and the impact of that is still visible, we have seen a static kind of situation in terms of penetration of our product or market share of our products. So possibly that could lead to a kind of a further price correction from our side in terms of offering and could impact the margins and subsequently even on the various revenue stream front whether it is on the Syngene front or in the small molecule business front, there are enhanced activities that are on which possibly will start benefiting FY23 onwards. So, what is the kind of margin expansion, or what is the kind of margin scenario that one should expect in the subsequent period, or, let's say, in FY22?**

Siddharth Mittal: So, Surya, I would answer it slightly at a higher level; I would say that the core margin is something that you should look at rather than the reported margin because of R&D being lumpy, as we have said in the past. Both generics and biosimilars businesses continue to invest in R&D and some of the activities; I mean, whatever delays we saw in FY21, we expect activities to resume in FY22, increasing the R&D expenses. But from a core margins perspective, we do not see a directional shift in FY22 at a group level.

Surya Patra: **So, if I can just add one more, this ISPE award for our new Monoclonal or mAbs**

facility, is this having any kind of meaningful implication for us to think about this opportunity.

Kiran Mazumdar-Shaw: Yes, I believe this is an important recognition. This is a huge expansion for Biocon, and there are many opportunities. It's also obviously expanded for our growing pipeline of products, but it allows us to scale where we can address large opportunities. So, I believe that this plant will serve us well in terms of various growth opportunities in the future.

Sameer Baisiwala: **A quick question: biosimilars look like a great opportunity when we look at a macro level. You know it's not only Developed Markets. In the emerging markets, we have a whole basket of products, their multibillion-dollar per product sort of addressable market, and just two to four players right now in the market. So, it looks good, but at the same time, when we look at micro-level and what is getting translated into your kitty into your P&L, then the numbers are very small, and it is not going up. So just wanted to understand what will change this, what's going to take our market share up? You got multiple products in multiple countries, but it's not showing up in our results.**

Kiran Mazumdar-Shaw: That's a good question, Sameer. I think the way I look at it is the following. Let's also accept that CY2020 was a very difficult year for everyone, especially us, because you can see that we were left out of the market for no-fault of ours. I mean, if you look at the inability for plant inspections, I can tell you that that was a really bad miss for us because we were looking forward to the Bevacizumab approval. Everything went seamlessly till this last minute. We actually are well-positioned to garner market share. As you know, in many situation our timing of entry into markets especially, the US were flawed; for instance, I do know that Viatris did miss out on a contracting cycle opportunity for Glargine in 2020. So many misses have happened as a result of either timing or delays of approval, etc. So, I am very confident that we will have a very large growth spurt when we get over these impediments and hurdles. As far as emerging markets are concerned, we are putting in all efforts to ensure that we are a significant player and are able to tap the opportunities.

As you know, we have had a management change, and we are looking at all these opportunities in a very different way. We expect that this will come back to the kind of growth trajectory levels that we were always pursuing. So, I would say that you will start seeing better growth and improved performance in FY22. I think from FY23 you will see a very strong uptick; that is my take on the opportunities, the performance, and capabilities to garner market share globally. I think this is a huge opportunity. There are few players and we have all that it takes to be very successful, and we want to deliver on that.

Sameer Baisiwala: **You had discussed in the previous call that there should be three more biosimilar drugs that would get into clinical trials as we go forward. Any update timelines on that and what it can do to your R&D spend in fiscal 22?**

Kiran Mazumdar-Shaw: Yeah, so the FY22 R&D spend is, of course, likely to increase over FY21, and these are important programs because, as you know, it's a bit of a catch-22. If you don't invest in R&D, you're not going to grow through new products in the future. And if you invest in R&D, it does challenge your financials in some way. But we believe R&D is a very necessary investment for our kind of business. So, we will continue to invest in R&D. You mentioned three molecules, and we are on track to get them into the clinic. There will be increased spending, but we are calibrating the spending based on our business.

Sameer Baisiwala: **Looking at the FDA's guidelines for virtual inspection, how executable or how onerous they look like? And relative to that is how did the UK issue the marketing authorization for both Aspart and Bevacizumab? I mean, did they come down to inspection, or how was that made possible?**

Kiran Mazumdar-Shaw: Maybe I'll ask Shreehas Tambe to answer these questions.

Shreehas Tambe: Thanks, Sameer. I think the guidance is pretty clear regarding how they want to conduct

inspections remotely. We've had experience with other agencies, including the EU, to have done these inspections and even in the other emerging markets where they've moved over to remote inspections. The approval that you specifically asked about, the European agencies have leveraged even our previous inspections while approving our Bevacizumab facility in India and the facility in Malaysia. So, we do have approvals for both Bevacizumab and Aspart for one in India and Malaysia from the European agencies.

Sameer Baisiwala: **OK, any timelines Shreehas that you can share for Bevacizumab of a virtual audit by US FDA and the approvals that can come about?**

Shreehas Tambe: Yes, so at this point, Sameer, we don't have specifics in terms of when they will come over exactly, or will they conduct remote inspection but needless to say, both Viatris and Biocon are working closely with them to get a sense of how quickly we can get that accomplished. As we've said previously, there are no outstanding scientific questions about Bevacizumab, and we're looking forward to getting the pre-approval inspection accomplished so that we can get the product to patients as quickly as possible.

Milind Karmarkar: **I had two questions. The first one was on Insulin Glargine; I just wanted to understand that you have said that it was unfortunate that the timing was not correct for Glargine during a couple of previous questions. Still, now we're getting into FY22, do you think that we will be able to sort of garner more share as we go ahead? That was my first question, and my second question was for the biosimilar target, which we had put off a billion dollars which we have said is as of now looks unrealistic. Still, I suppose that is in terms of timing, and so in the future, do we see very strong growth in biosimilars considering the pipeline we have and the existing products ramping up? These were my two questions. Thank you.**

Kiran Mazumdar-Shaw: So, let me answer your first question; I think we will get to the billion-dollar target as soon as we're able to get back to a high growth trajectory. But as I said, we have indicated that it would happen by FY22, which is unrealistic. It won't happen by FY22 and give us a little bit of time to get back to a certain growth trajectory. Today there are so many uncertainties; at least you know the US and other markets have opened up for business, so we hope that things will improve. That is our anticipation, but as you know now, India is not great, so we have to make sure that we continue to watch the situation. But we hope that our international markets will perform well. Now, in terms of growth, as I indicated earlier in my comments, we expect much stronger growth than this year, and we will keep you posted on how soon the billion-dollar target can once again become visible. As far as Glargine sales are concerned, I will maybe ask Paul to comment on the Glargine sales. Still, we expect that FY22 should see an improved performance in Glargine and you know Viatris will be able to respond to many of these questions with far more granularity. Still, we believe that our biosimilars business in the US should see a greater performance.

Paul Thomas: I'll just add a little bit. I think we've seen some pickup in share already over this year. As you stated in the formula cycle, there's an annual calendar year-oriented formula cycle. Hence, as we get into calendar 2022, there's an opportunity to get into the new cycle, and that's a process going on now and Viatris is very much engaged in, and we look forward to growing through that process. Viatris has noted the complexity in bringing this type of product to the market and the expectation that there will be a long revenue stream with a slower ramp-up that we see because of these factors. But we do expect growth as we go into the new formulary year.

Vipul Shah: **So, I just wanted to know the R&D spend for Bicara during FY21?**

Siddharth Mittal: So, the total amount of R&D for Bicara was around ₹180 crores.

Vipul Shah: **Sir, would you like to comment on the performance of the Malaysian plant or FY21 at the EBITDA level? Was it EBITDA positive or EBITDA negative, and would you like to give any qualitative color on the performance of the Malaysian plant?**

MB Chinappa: Malaysia continued to operate at a loss in FY21. We see a lot of improvement in FY22 but waiting for the Glargine to pick up in the US to turn profitable and give us the desired ROI. But presently, it is still operating at a loss.

Vipul Shah: **Would it be possible to quantify the loss?**

MB Chinappa: We have two parts to it, at the PBT level; it was $33 million of loss and for EBITDA we broke even at roughly $4 million gain.

Tushar Manudhane: **Just on the R&D front, while there would be incremental spend on the three molecules, but at the same time, Bicara R&D is not going to be consolidated if you could quantify the overall R&D**.

Siddharth Mittal: I think what you're asking is the R&D spend going up on three molecules and the Bicara R&D spend no longer being there. And if the question is regarding the guidance on R&D for next year, I think in the ex Syngene we mentioned that we would be somewhere between 12 to 15% of revenues. And broadly, that guidance, give or take few 1-2% here we maintain. In generic specifically, we incurred 8% of revenues in FY21. We're looking at spending 11% in FY22 and maybe Chinappa if you want to give a specific number for biosimilars in terms of the spend as a percentage of revenue in FY21 and FY22. I think you'll be able to calculate what the spending should be.

MB Chinappa: The net R&D spend for the biologics business was 10% of revenues in FY21. We see that trending upwards, but we're not giving guidance yet on the specific numbers because it's dependent on the progress of the molecules.

Sheersh: **Good morning to all. I want to understand the capex plan for the coming year and also what has been the total capex for the foregone year. And my second question was about the increased cash in the books. And we see the debt going significantly in the northward directory. There has been significant cash, yet there has been a spurt of increase in debt. So wanted to understand what has been on your mind.**

Siddharth Mittal: So maybe I'll answer the second question. Last year, we did a couple of rounds of private equity fundraising in Biocon Biologics. We raised almost ₹1900 crores, and a large part of that money was used to repay the debt that was there between Biocon and Biologics. So, the cash that is being held is primarily lying with Biocon to fund the future investment. So, the net cash balance in Biocon as of March '21 is roughly ₹1500 crores. And the debt that you see maybe Chinappa can explain because a large part of that debt is sitting in Biocon Biologics.

MB Chinappa: Some of the debt was raised in the early part of the year before the private equity funds came in. So, the debt in Biocon Biologics has increased. Towards the end of the year we receive money from ADQ; that money is sitting on the other side as cash.

Siddharth Mittal: The Goldman Sachs money is also treated as a debt, the fundraise from Goldman Sachs.

MB Chinappa: Yeah, for accounting purposes, the Goldman Sachs investment is also treated as debt and called out separately.

Siddharth Mittal: You might also want to give the capex guidance for biosimilars, then I will ask Indranil to give capex guidance for generics

MB Chinappa: For FY21 total net spend, part of the funding was $125 million. In FY22, we expect $100 million of capex.

Indranil Sen: For FY21, our capex in generics was about ₹250 crores. In the past, we've guided around ₹2000 crores with the capex over the next three years, and at this stage, we continue to maintain that guidance.

Charulata Gaidhani: **I have two questions. How many ANDAs do we have pending approval in small molecules?**

Siddharth Mittal: At this stage, we have 10+ ANDAs, which are at various stages. And there are two ANDAs where we had a target action date in FY21 where we have no more pending queries with the FDA, but we got CRL on those two filings because of want of the facility inspection by the FDA. But we are looking at multiple launches next year. We have three products that are already approved and will be launched next year and subject to the approval and two products that were to be approved in FY21. We're hoping that the FDA can do a virtual inspection and launch those two products next year. But apart from these four or five launches in next year, we also have many other products which have been filed and are under various stages of review. But the launch date for those products is beyond FY22.

Charulata Gaidhani: **Ok. So, we can expect three launches in FY22.**

Siddharth Mittal: Yeah, as I mentioned, there are three new launches in FY22 on already approved products. Two products are more vertically integrated products where we are expecting the FDA to inspect the facilities and give the approval. So, you will have new launches in FY22, and that's what will drive that double-digit growth that we guided for the formulations business of the generics vertical.

Charulata Gaidhani: **OK, and how much is the investment in the new mAbs facility?**

MB Chinappa: If we look at the numbers, we've got about $250 million. A substantial part of that is for the two large mAbs facilities coming on-stream in the future. One of the facilities that just got the award and another single-use bio-reactor plant is also under construction or under qualification really.

Charulata Gaidhani: **Ok. And my third question pertains to the WHO prequalification. How much business do you expect to generate from that?**

Shreehas Tambe: I think that WHO prequalification is an important step because several countries look forward to this to commercialize the product in those geographies. At this point, we wouldn't like to give specific guidance in terms of revenues from each of these markets, but needless to say, it is in line with our mission to see that we can get product accessible to as many geographies as possible, so it's a part of that mission.

Harith: **On Bicara, what is our stake now? Have we lowered it from the 100% we used to hold earlier? And the increase in the share of losses from associates in JVs to around ₹70 crores this quarter. Is it coming on account of Bicara, and will this be a recurring number?**

Indranil: Thank you for the question. So after losing control, our current stake in Bicara is at about 87%. The current quarter spends of ₹70 crores; in one of our earlier comments, we mentioned that we expect to pick up losses up to ₹200 crores in next year, which will be limited to the extent of the carrying value of our investment in the associate.

Harith: **So, ₹200 crores for FY22 will be the share of losses by Bicara.**

Indranil: That's right.

Harith: **Can you confirm the gross and net debt at the consolidated level?**

Indranil: So, the gross debt at a consolidated level is about ₹4500 crores, and net debt is around ₹700 crores.

Nithya: **Hi, a quick one, can you update the interchangeability status for Insulin Glargine at the US FDA?**

Shreehas Tambe: As we have said before, we are in conversation with the agency and this is a first of its kind for the agency. We have been receiving encouraging feedback. Conversations have progressed to a point, and we believe that under the 351K pathway, we will have an opportunity to move this forward. But at this stage, the agency isn't able to give us firm guidance on where they stand on this, although we remain optimistic about that progress.

Nithya: **So, just to follow up, do you have a TAD date and do you have any updates on whether this would require a pre-approval inspection?**

Shreehas Tambe: So, they haven't specifically guided us on a pre-approval inspection at this point, but you know we're watching how this progresses. As you know, we already have the approval, and we have the comparability for this. So we're not looking at physical facility inspection at this stage.

Nithya: **Is there a TAD date? Do you have a date on which you're expecting to hear back?**

Shreehas Tambe: There has been general guidance on where the agency would like this to be, but at this stage, given the pandemic situation, I think a lot of this has been fluid Nithya, in the recent past.

Ankit Gupta: Thank you, ladies and gentlemen; this was the last question. We thank you again for joining us today. If you have any additional questions, you can reach out to us anytime. We wish you good health and look forward to seeing you again next quarter. Have a good day. Thank you.