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Biocon 5.0

Biocon Limited Q3 FY23 Earnings Conference Call Transcript

February 15, 2023

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
- ✦ **Mr. Indranil Sen** – Chief Financial Officer, Biocon Limited
- ✦ **Mr. Shreehas Tambe** – CEO & Managing Director, Biocon Biologics Limited
- ✦ **Mr. M.B. Chinappa** – Chief Financial Officer, Biocon Biologics Limited
- ✦ **Mr. Susheel Umesh** – Chief Commercial Officer – Emerging Markets, Biocon Biologics Limited
- ✦ **Mr. Matthew Erick** – Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited
- ✦ **Mr. Abhijit Zutshi** - Commercial Head - Global Generics, Biocon Limited
- ✦ **Mr. Nehal Vora** - Commercial Head - Global API, Biocon Limited
- ✦ **Mr. Sibaji Biswas** – Chief Financial Officer, Syngene International
- ✦ **Mr. Saurabh Paliwal** – Head - Investor Relations, Biocon Limited
- ✦ **Mr. Nikunj Mall** – Head - Investor Relations, Biocon Biologics Limited

External Participants during Q&A session

- ✦ **Tushar Manudhane** – Motilal Oswal Securities
- ✦ **Cyndrella Carvalho** – JM Financial
- ✦ **Damayanti Kerai** – HSBC
- ✦ **Dhawal Bhalodia** - Individual Investor
- ✦ **Harith Ahamed** – Spark Avendus
- ✦ **Surya Patra** – PhillipCapital
- ✦ **Shyam Srinivasan**, Goldman Sachs
- ✦ **Nithya Balasubramanian** - Bernstein
- ✦ **Sameer Baisiwala** – Morgan Stanley
- ✦ **Neha Manpuria** - Bank of America
- ✦ **Nihal** – Individual Investor
- ✦ **Utsav Jaipuria** – DAM Capital Advisors

Prepared Remarks Session

Saurabh Paliwal:

Good morning, everyone. I am Saurabh Paliwal from the Biocon Investor Relations team, and I would like to welcome you to Biocon's Q3 FY23 Earnings conference call.

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 once the management's commentary concludes.

Should you need to ask questions, please select the "Raise Hand" icon under the 'Reactions' tab of the 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 the chat box is disabled, but you can raise any technical concerns by sending us an email to investor.relations@biocon.com.

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

Today, to discuss the Company's Business Performance and Outlook, we have Dr. Kiran Mazumdar Shaw, our Executive Chairperson, Mr. Siddharth Mittal, CEO and Managing Director of Biocon Limited, along with other senior management personnel from business segments including Generics, Biosimilars and Research Services.

As I move on, I would like to highlight the 'Safe Harbour' related to today's conference call. Comments made during the call may be forward-looking in nature, based on management's current beliefs and expectations. It must be viewed in relation to the risks that our business faces that could cause our future results, performance, or achievements to differ significantly from what is expressed or implied by such forward-looking statements.

After the end of this call, if you need any further information or clarifications, please do reach out to me. Now, I would like to turn the call over to our Chairperson for her opening remarks. Over to you, Kiran.

Dr. Kiran Mazumdar-Shaw:

Thank you, Saurabh. Good morning everyone.

I would like to start with the national budget which was presented by the Honourable Finance Minister on the 1st of February this year. The budget has a favourable impact on our business especially with respect to Research. While details are yet to be published, the increased focus for R&D in pharma and healthcare through Centres of Excellence is certainly a step in the right direction.

Now coming to the Viatris transaction

Biocon Biologics successfully completed the acquisition of Viatris' global biosimilars business on November 29, 2022. Consequently, incremental revenues and profits post deal closure are reflected in its earnings this quarter.

Viатris continues to provide commercial and other transaction services to Biocon Biologics as part of a pre-agreed Transition Services Agreement. In parallel, Biocon Biologics is designing a bespoke country specific strategy and business model that optimizes for revenues and profitability. This we believe will create value for all our stakeholders. We have also drawn up a comprehensive integration plan and intend to start migrating business operations in a phased manner.

There are several upcoming launches, including biosimilar Adalimumab, in the US, making 'business continuity' one of the key imperatives of our integration plan.

I would like to take you through our debt reduction efforts.

To fund the acquisition of Viatrix' global biosimilar business, Biocon Biologics had made an upfront payment of US\$ 2 billion and issued US\$ 1 billion of Convertible Securities to Viatrix. The upfront payment was funded through US\$ 1.2 billion of debt raised by Biocon Biologics, US\$ 650 million of equity infusion by Biocon and US\$ 150 million of equity infusion by Serum.

Biocon had raised US\$ 420 million of mezzanine financing to part fund the US\$ 650 million equity infusion into Biocon Biologics. I am pleased to report that Biocon Limited has entered into definitive agreements with Kotak Strategic Situations Fund, for a structured funding of up to ₹1,200 Crores. This funding together with the recently concluded stake sale in Syngene will help to reduce our net debt.

It is important to point out that Biocon continues to maintain majority control in Syngene at 54.9%, post this divestment. Furthermore, we believe the divestment achieves two key objectives – reduction of the group debt and an increased public float for Syngene.

Biocon Biologics is also in discussion with Private Equity investors for an additional fund raise to pare down its acquisition debt.

I would also now like to touch upon recent concerns around regulatory inspections.

The post pandemic recommencement of facility inspections by the US FDA in India has reportedly seen a surge in the number of Form 483s issued to companies which has caused delayed approvals across the industry.

Biocon's new product approvals post pre-approval inspections have also been impacted with the issuance of complete response letters or CRLs by the agency. However, I would like to mention that Biocon has received facility and product approvals from other regulatory agencies, including EMA.

With the US FDA set to resume face to face meetings from March, we hope that this will allow us for greater engagement to address these issues. In the meantime, we are of course looking at this event as an opportunity for us to upscale and advance our quality management systems, so that we future proof our quality systems.

In terms of a leadership update, I am pleased to share that Shreehas Tambe was appointed CEO and Managing Director of Biocon Biologics in December 2022 following the retirement of Dr. Arun Chandavarkar, who will continue to serve as a non-Executive, non-Independent Director on the Board of Biocon Biologics.

I would like to thank Arun for his longstanding contribution to the Biocon Group and my best wishes to Shreehas for the transformational journey ahead.

I will now present the key financial highlights of the quarter.

At a consolidated group level, revenues for Q3 FY23 were up 36% on a year-on-year basis at ₹3,020 Crores. Revenues from our Biosimilars Business and Research Services Business delivered strong year-on-year growth of 54% and 23% respectively, and our Generics Business grew at a healthy 18%.

Core EBITDA, i.e. EBITDA excluding R&D expense, licensing income, forex movement, dilution gain in Bicara and mark-to-market movement on investments, grew 49% to ₹1,069 Crores, which indicates a very healthy core operating margins of 36% versus 33% in the same quarter last year.

Growth in core EBITDA was offset by higher R&D investments at ₹337 Crores, an increase of ₹199 Crores compared to the same period last fiscal and representing 16% of revenues ex-Syngene. This is a clear reflection of our advancing pipeline that will drive our future growth.

We also recorded a Forex loss of ₹44 Crores as compared to a gain of ₹19 Crores during Q3 FY22.

Reported EBITDA for the quarter was up 35% at ₹723 Crores versus ₹537 Crores in the same period last year, with EBITDA margin sustained at 24%.

Profit Before Tax and exceptional items stood at ₹246 Crores, compared to ₹269 Crores during the same quarter last fiscal. The drop in PBT is attributable to certain amortisation and interest costs related to the acquisition of the Viatris' business.

The Net Profit for the quarter, excluding exceptional items, stood at ₹140 Crores versus ₹187 Crores in Q3 FY22. It must be mentioned that there is a part impact of stake dilution of Biocon's shareholding in both Biocon Biologics and Syngene in the consolidated results.

I would now also like to turn to exceptional items during the quarter amounting to ₹182 Crores net of tax and minority interest, which primarily pertain to deal related expenses of the Viatris transaction. And this then leads to a net loss of ₹42 Crores this quarter. This, I would again emphasize is a one-off event and we expect it to return to normal from next quarter.

Now coming to segmental performance.

Generics

The Generics business delivered revenues of ₹718 Crores during the quarter, a year-on-year growth of 18%. Profit Before Tax for the quarter was at ₹72 Crores versus ₹67 Crores last year. Sequentially, revenues grew by 15%.

The performance during the quarter was driven by an increase in demand for immunosuppressant APIs as well as Generic Formulations, especially statins, as well as recent product launches. Margins compared to previous year were muted on account of continued pricing pressure in the U.S. market.

During the quarter, we entered into agreements with Zentiva, a leading European pharmaceutical company, under which Biocon will manufacture and supply Liraglutide to Zentiva for its commercialization in 30 countries across Europe. And as you know, in Liraglutide we are vertically integrated, this is a complex formulation, and it includes a drug-device combination used in the treatment and management of Type 2 diabetes and obesity.

We have also secured approvals for some of our key formulation products in Europe and we have also entered into a long-term strategic partnership with Farmanguinhos in Brazil for the supply and tech-transfer of an immunosuppressant finished dosage formulation. And collectively these agreements and approvals that we have received, it's important for me to say will actually allow us to drive that mid-teens growth over the next 5 years and beyond.

On the quality compliance front –

We were issued a Good Manufacturing Practice (GMP) Certificate of Compliance by the European Directorate for the Quality of Medicines & HealthCare (EDQM), for our Active Pharmaceutical Ingredient (API) manufacturing facility in Bengaluru, following a GMP inspection of the site conducted in September 2022.

With respect to our Visakhapatnam project, we continue to make progress in terms of our greenfield

immunosuppressant API facility and in terms of the new peptide facility in Bengaluru, this also is on track. We expect to complete the validation batches in both sites by H1 of FY24.

Biosimilars

Biocon Biologics recorded revenues of ₹1,507 Crores with a year-on-year growth of 54% pursuant to the closure of the Viatris acquisition and steady growth in the Biocon Biologics-led business.

Revenue for Q3 FY23 includes contribution from the acquired Viatris' biosimilars business effective from the date of closing of the deal on 29th of November 2022. Previously, Biocon Biologics recognized only transfer price and profit share of biosimilars marketed by Viatris. Post completion of the deal, it now recognizes the full value of sales and associated expenses.

The reported numbers therefore include one-month profit from the acquired business and a provision for interest expense and non-cash amortization charges related to the acquisition.

Core EBITDA for this business stood at ₹663 Crores, which is up 83% year-on-year. Core EBITDA margin jumped from 38% last year to 44% this fiscal.

This of course was then impacted by R&D investments for the quarter which increased to ₹280 Crores or 19% of Biocon Biologics revenues. We will see R&D investments normalize to around 12% levels of sales, as we accrue full revenues from Viatris' biosimilar businesses.

We continue to make good progress on our R&D pipeline. Denosumab and Ustekinumab biosimilar programs have completed recruitment for their global Phase I and Phase III clinical trials. Biosimilar Pertuzumab has entered Phase I trials for global markets. Viatris has initiated an interchangeability study for our biosimilar Adalimumab, allowing us to maximize the commercial value of Huloio in the US. We have filed our biosimilar Aflibercept in several global markets, including the US and EU.

EBITDA post the R&D and other expenses stood at ₹361 Crores, which is up 53% year-on-year. EBITDA margin was stable at 24%.

Depreciation, amortization, and Interest expense for the quarter increased by ₹146 Crores year-on-year, of which ₹97 Crores is attributable to the Viatris acquisition.

Profit Before Tax and exceptional items for this business stood at ₹102 Crores.

Advanced Markets continued to see a strong penetration of our commercialized products, holding now double-digit shares in the US. Glargine's total prescription market share is trending around 12% while new prescriptions are at 14%. We continue to see strong momentum in our biosimilar Pegfilgrastim's market share which has crossed 11%. In Europe, our biosimilar Adalimumab continues to see a strong uptake in key markets such as Germany and France where it has 18% and 10% market share respectively. We also saw an uptick in Trastuzumab market performance in Europe achieving 17% and 20% market shares in France and Italy, respectively. We continue to launch our products in new markets with biosimilar Bevacizumab in Australia and biosimilar Glargine and Aspart in Canada last quarter.

The Emerging Markets business continues to deliver strong performance underpinned by the insulin portfolio and biosimilar Trastuzumab. We have expanded our reach through 8 new launches across emerging markets and the franchise will be augmented by the integration of Viatris' Emerging Market territories.

On the regulatory front, the US FDA has accepted our CAPA plan pertaining to the pre-approval inspections of

Insulin Aspart in Malaysia which was cited in the CRL. The Bevacizumab CRL requires us to address the observations made during the site inspection for which we have submitted a CAPA plan and are awaiting a response. We are committed for closure of the actions within the stipulated timeline and we are confident of being able to resolve the asks of the US FDA.

In summary, the business continues to see healthy and profitable performance with several catalysts for growth such as the launch of biosimilar Adalimumab in the US. We believe the acquisition of Viatris' biosimilar business is a very key inflection point for Biocon Biologics as we transform into a unique, leading global biosimilars enterprise which we strongly believe will drive huge value for all our stakeholders.

Novel Molecules

As a part of the on-going pivotal Phase 3 clinical study of Itolizumab in patients with acute graft-versus-host disease (aGVHD), enrolment continues to ramp up. There are now 45 clinical study sites up and running.

Enrolment also continues in the Phase 1b clinical study of Itolizumab for Lupus Nephritis and Equillium expects to announce top-line data later this year.

I think it would be prudent for me to mention that many acute GVHD studies that were being conducted by various companies have actually not succeeded and this particular molecule showing robust data. So, I hope this will actually be able to hold its promise and get approval in the foreseeable future.

Patient dosing for the Phase-2 trial in India for the clinical study of Itolizumab in patients with Ulcerative Colitis, began in December, 2022.

Based on the very encouraging and promising data in acute GVHD, Equillium recently entered into an Option and Purchase Agreement with Ono Pharmaceutical Co., Ltd, Japan, where Equillium has granted Ono the exclusive right to acquire its rights to Itolizumab. We believe this is a very important event as Ono is a highly respected company that has brought several important molecules in the market through partners.

Research Services

Revenue from operations grew 23% to ₹786 crores over the corresponding quarter last year. Reported EBITDA was up 15% to ₹248 crores. Profit before tax was at ₹140 crores, up 9% over the corresponding quarter last year.

The third quarter results saw positive performances across all divisions with solid growth in Research divisions – Discovery Services and Dedicated Centres.

Development Services benefitted from repeat orders from existing clients, as well as an increase in the number of collaborations with emerging biopharma companies.

In Manufacturing Services, the highlight of the quarter was the successful inspection of its biologics facilities by the US FDA, EMA and MHRA. With Good Manufacturing Practice (cGMP) certifications from the regulatory agencies in place, the Company is now well positioned to fulfil its long-term contract with Zoetis and progress its biologics growth strategy.

Concluding Remarks

I would like to conclude by saying that we expect to end FY23 on a strong note, with healthy growth across all our businesses.

Biocon Biologics will be the key growth driver, as it begins to reflect the full quarter's revenues of the newly acquired Viatris business, from Q4 FY23.

Directionally, Biocon Biologics will be exiting FY23 at a US\$ 1 billion trajectory, excluding vaccines.

Growth in FY24 will come from the launch of Adalimumab in the US and continued growth in Glargine, Trastuzumab and Pegfilgrastim. Launches of Aspart and Bevacizumab in the US, post approval, will provide additional upside.

Biocon also is confident of delivering mid-teens growth in the coming fiscal.

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

Q&A Session

Saurabh Paliwal: Thank you, Kiran. We will take a moment for people to raise their hands to ask a question. I will request the participants to please limit their questions to two, to allow other people in line to get an opportunity. We will start with Tushar Manudhane from Motilal Oswal. Tushar, please go ahead.

Tushar Manudhane: **Yeah, thanks for the opportunity. Just on the Adalimumab clarification. So, we have approval for all the strengths, or a specific strength and secondly, with respect to interchangeability, what is the kind of timeline can we expect to get the approval?**

Kiran Mazumdar-Shaw: Shreehas, you might want to take this.

Shreehas Tambe: Sure. Thanks, Kiran. Thanks for the question. We've seen that there are several players in the market; there are low strength and high strength formulation players. We have a low strength formulation. We also have a product which really checks the key boxes of being citrate free, latex free and a device, which will really be what the patient experience is all about. So, we believe that we've got what it takes to be competitive in this market, Tushar.

Another important aspect that you're talking about is interchangeability, that is something that remains to be seen. We believe that may not necessarily be a criteria to win. We do not see other biosimilars which are currently taken up in the national formularies having interchangeability at this point.

Nevertheless, it's something that we will pursue, and we will have the right to win when we get our product into the market.

Tushar Manudhane: **Interesting. So, for our strength, what would be the market size?**

Shreehas Tambe: So, at this stage if you really look at it, the market from innovator perspective, has been moved to the high concentration, but we do not see high concentration or a low concentration really being the differentiator. We've seen a similar commentary from other incumbents who have come there and other players who have also looked at bringing products. We've also seen payor acceptance of other biosimilars, which have been launched. So that may not necessarily be a criteria for success.

Kiran Mazumdar-Shaw: And maybe should add that we have had a huge success in Europe where we had a very positive patient experience, we believe that would translate to the US market.

Shreehas Tambe: So, true, and I think to add to what Kiran just said, Tushar we are one of the few players who have been very successful, we have got a product launched in Europe, we've got over 18% market share in Germany alone and we crossed 10% in France, some of the big markets in Europe.

So, we come on the back of previous success and we're quite confident in how our product will be received when we launch it in the US.

Kiran Mazumdar-Shaw: Matt, if you want to make any further comments.

Matthew Erick: Just to add that we're already prepping with the Viatrix salesforce. So, we're getting ready and already getting out there and speaking to key physicians, so that process is starting.

We're now waiting to be able to talk about the key elements that both Kiran and Shreehas spoke about.

Tushar Manudhane: **Interesting, and secondly also if you could shed some clarity or visibility in the business from the vaccine segment?**

Shreehas Tambe: Your voice is very weak. But I think if I understood you correctly, you are talking about any visibility on the vaccines business, was that correct?

Tushar Manudhane: **Correct.**

Shreehas Tambe: Okay. Well, we have said that we've got the definitive agreement done. We are in the regulatory phase right now. We have secured the approval from the Competition Commission of India. The next phase is to get the National Company Law Tribunal approvals, that requires us to get approval in Karnataka where we are based and for Serum to do it in Maharashtra, where they are based. We are in the last stages in Karnataka and Serum has to move their application at the Maharashtra end as well, that is still pending.

Tushar Manudhane: **Effectively 2Q FY24 to be the timeline to look for.**

Kiran Mazumdar-Shaw: Yeah. So, we have not been able to reflect the vaccine numbers this quarter is what I can say.

Tushar Manudhane: **And lastly, if I may on this agreement with Zentiva any commercial outlook or guidance on this business?**

Kiran Mazumdar-Shaw: Maybe Sid you might want to take that.

Siddharth Mittal: So, there is no revenue outlook that I can give. All I can say is Liraglutide for us is a very important product. It is a differentiated product, and we feel we're very well placed to launch this drug along with Zentiva. At the time of market formation, Zentiva has semi exclusive rights, so, we will also commercialize directly, and we feel that the total value of this opportunity will aid to the growth in the coming years.

- Tushar Manudhane:** Alright sir. Thanks. That it from my side. Thank you and all the best.
- Saurabh Paliwal:** Thank you. Tushar. The next question is from Cyndrella Carvalho from JM Financial.
- Cyndrella Carvalho:** **Thanks for the opportunity. Just wanted to understand the \$1 billion exiting guidance that you are sharing for Biocon Biologics, can you please help us understand this in more detail.**
- Kiran Mazumdar-Shaw:** Perhaps, Chini you want to explain it. But, let me start by saying that you have already seen that we are at a ₹1500 crores level this quarter for Biocon Biologics and we expect this number when we capture the full financials of the Viatris business in Q4, to cross ₹2000 crores.
- M.B. Chinappa:** Cyndrella, morning. Just the way Kiran put it, ₹2000 crores is our expected revenues for Q4, excluding vaccines, that translates to a run rate of US\$ 1 billion per annum. And then as you look into FY24 you need to add growth from the existing molecules, the big opportunity in Adalimumab in the US and then the addition of, obviously once you get the regulatory approval for both Beva and Aspart, we seek to see incremental revenues coming through.
- Kiran Mazumdar-Shaw:** And of course, growth from existing products.
- Cyndrella Carvalho:** **Thanks for that. But how should we understand the facility planning, I mean we are still receiving CRLs.**
- Kiran Mazumdar-Shaw:** Yes, Cyndrella. But we are already selling products, please understand that we are still marketing Trastuzumab, we are marketing Glargine and we are marketing Pegfilgrastim in the US. Europe has all products being marketed. So please understand that we are looking at two products that need approvals and these numbers exclude those products.
- We have actually factored the fact that there may be a delay in that approval, we are hoping that we will get approvals in this calendar year, which will then be incremental to that billion dollars is what we are seeing. So, excluding all those products, we are still at US\$ 1 billion run rate, is what we want you to understand.
- Cyndrella Carvalho:** **Yeah, so that's helpful. Just wanted to understand in terms of where we are, what are the US FDAs requirement, which is taking or creating these delays, any color that you can help us understand.**
- Kiran Mazumdar-Shaw:** I think I had mentioned it in my comments, saying that our CAPA plan has been accepted by the US FDA for Malaysia, and we have also provided a CAPA plan for the Bangalore facility, which I'm sure will also be accepted by USFDA. We are in the process of basically implementing the CAPA plan that USFDA has accepted in Malaysia.
- And maybe I will ask my colleague, I don't know whether Michael is there on this call, but I will ask Michael to also add to what I am saying.
- Saurabh Paliwal:** Shreehas you want to pitch in? Michael is not there.

Shreehas Tambe: Yeah, so let me just add to what Kiran just said, Cyndrella. I think what is important to note is that all the facilities that we are talking about are supplying product to the United States already, so it's not something that is fundamentally wrong with it, that's the first thing that I want to state.

These are also products that have been approved by EMA and continue to be commercial in several parts of the world. The way to look at it is that certainly there is a greater expectation from the agency, which we're more than happy to upgrade our standards to meet.

And that's the exchange Kiran referred to when she talked about the engagement. We have provided a comprehensive response to the agency to see how we can meet with their expectations. We've got a response back from them saying they accept our proposal. So that's why we are quite confident in Malaysia with the Aspart submissions that we have made to be able to resolve it to their satisfaction.

We've recently received the CRL for Bevacizumab in Bangalore earlier this month. We are quite confident we will be able to get that also to the satisfaction of the agency. These are always standards that we have to work to improve upon. We look at this as an opportunity to improve and strengthen our systems. We do not see this as necessarily a lacuna overall, but an opportunity to strengthen it further.

Cyndrella Carvalho: **Yeah, that's very helpful. Just on the timeline for interchangeability and how do we expect the market formation any comments on that.**

Shreehas Tambe: Specifically any product you're talking about?

Cyndrella Carvalho: **Adalimumab.**

Shreehas Tambe: Yeah. So again, interchangeability is an important topic to understand how it really plays out commercially. Now we've seen already contracting happened in the US where the first biosimilar is not an interchangeable product and it's received formulary listing. So clearly, it's not a condition precedent to moving forward, you've seen similar things happen on the insulin end as well, so that's the first piece that it's not mandatory to success on the commercial side.

The second piece, which is related to how interchangeability plays out in real life is you can have one player who can get interchangeability approval and get some exclusivity post launch for a period of 12 months, which effectively means even if you were to have interchangeability approved, you would probably have to wait until that exclusivity runs out.

So again, from a commercial standpoint, it would really be another contracting cycle before you can get there. I would think that interchangeability is something which is nice to have, it is something that we are confident of anyway, but it's a very US specific phenomenon. We do not see that in rest of the world, as I said before and Kiran rightly pointed out, we've seen great success with our product Hulio (bAdalimumab), in Europe and we are quite confident that we will be able to get that success.

The real piece here is the patient experience and hub services which Matt can talk to you about in more detail. But it's about our device and we are very confident about the kind of device we're bringing to the market. It's a two click device and which should really be very helpful for the patients. So that really gives us that right to win, Cyndrella.

Cyndrella Carvalho: **Thank you so much. Just one last, if I may. And that is on, when do we expect the consolidation from the Serum side timeline, I'm asking, would it be Q1 or as the earlier participant highlighted it is first half of FY24. What should we try and building in terms of our models?**

Kiran Mazumdar-Shaw: Yes, I think right now we don't have clear visibility of the regulatory completion. But yes, maybe we can look at next fiscal for those numbers to be consolidated.

Cyndrella Carvalho: **Thank you so much. I'll join back the queue.**

Saurabh Paliwal: Thanks, Cyndrella. Next question is from Damayanti Kerai from HSBC.

Damayanti Kerai: **Hi morning. Thank you for the opportunity. My question is again on Adalimumab. So, you have mentioned, it's not mandatory for you to succeed in this market, but the interchangeability studies which you have initiated. What is the completion timeline, which you're aiming for?**

Shreehas Tambe: Damayanti, we can get you the exact dates on the interchangeability study. But as I said, the BBL dates of this would matter only after the first commercial launch of the interchangeable product, which we believe will be in July of 2023. So, until July 2024, even if you had an interchangeable product, it's really not going to make difference.

Kiran Mazumdar-Shaw: And by which time, I think we will have the interchangeability label.

Damayanti Kerai: **And this bAdalimumab launch which we are prepping for. So, in the current contracting cycle, how do you see your positioning so far in view of your discussion with payors, etc. So, once you ready to launch. So far, like how do you see your reach within this contracting cycle?**

Shreehas Tambe: Maybe Matt, do you think you want to comment on that?

Matthew Erick: Yes. Thank you for the question. Yeah, we are right where we need to be in our preparation. We are currently speaking to key payors and there are really four channels. In the first channel, we are speaking to the payors and we're having great discussions as we look for the paying cycle starting in July.

The next piece of this is we're having additional discussions as I mentioned getting out with physicians and understanding our product and two click as well as being citrate free, latex free all those key attributes, so they understand our product Hulio.

The other facet here is that we're speaking to and we don't mention a lot but is key to this is the specialty pharmacies. So, we're starting those discussions with specialty pharmacies those are ones that send the product to patients and act, it's not really retail component, they act as that pharmacy to be able to get the products to the patient that

the doctor has prescribed and then Shreehas had mentioned the other key channel is really the patient services.

So how do we help the patient and help the physician through the process that they're used to from the innovator. All four of those will be standing up and as I said, we're having detailed discussions with key payors right now and our anticipation of our launch that will occur in July.

Damayanti Kerai: **Thank you. My second question is on some of the launched biosimilars where you have gained notable market share as commented by Kiran ma'am in her opening remarks. So, I just want to understand how you see pricing scenario for these products? Although like we have gained market share, but what's your view on the pricing situation right now.**

Matthew Erick: So, would you like me to start and then jump in. Okay, great again, thanks for the question. We do see some of that deflation. But as far as to our models and our plan, they are aligned and as you look at the different channels the Medical side as well as the Pharmacy Benefit side. On the Medical side, with Trastuzumab and Pegfilgrastim you're speaking about, we're seeing nice steady states in our average selling price and this has allowed us to continue to grow share as well as to be able to maintain that deflation that is occurring, that you have seen in the marketplace.

Also, we have an extensive sales force, we're seeing great success in our commercial plans as well as our clinical side and I think that's attributed definitely to our sales force and the relationships we have in the understanding of our product in the pull-through.

I feel we're in a very good spot based on our modeling and our plan and also being vertically integrated, we have the staying power, as well as the broadness of the portfolio. When we think about oncology and the products we have there, wherein we are in a good position to be able to compete.

Damayanti Kerai: **Okay. So, you expect market share to go up further as you push more on the commercial efforts?**

Matthew Erick: We're seeing a nice trend and a continued upside in the market share and it's showing in the NRx's and the TRx's that you can see in the IQVIA data, we're making good progress.

Damayanti Kerai: **Sure, my last question is, what's your debt reduction goal? So obviously effort again is ongoing there, but anything say in next six months to one year, how much debt you want to reduce on your books?**

Kiran Mazumdar-Shaw: So, Damayanti if you will give us a little bit of time, we are in the process of raising this equity and we would like to share it with you once the process is complete. But needless to say, that we want debt at a very manageable and low level as much as we can get it to. So, let us share this data with you as soon as we complete the equity raise.

Damayanti Kerai: **Sure. Ma'am. Thank you. I'll get back in queue.**

Saurabh Paliwal: Thanks, Damayanti. The next question is from Dhawal Bhalodia. Request to please identify your firm.

Dhawal Bhalodia: **Hello. Yes. Hello, good morning. I have two questions. The first question is, for most of our current biosimilar, market share has stuck around higher single digit to lower double digit, except for the Lantus biosimilar, so since we have now full control of sales and contracting. Is there anything we will be doing differently than what Viatris used to do, so we can increase our market share and penetration?**

Kiran Mazumdar-Shaw: Matthew you want to answer this.

Matthew Erick: I had a little hard time understanding.

Kiran Mazumdar-Shaw: I think the question being asked is, are we going to do something different to what Viatris was doing in the market and get better market penetration. And the answer is yes, because, let me start by saying that we are looking at dedicated sales efforts for biosimilars. But I'll leave it to Matt to add to this.

Matthew Erick: Yes. Kiran absolutely we are doing more and we're seeing the opportunities, particularly in additional customers in the conversation that we're having. As we mentioned in previous calls, a lot of this is that we have 100% focus and we have some great opportunities as we look at not only the payor side, but the retail pull-through, our ability to talk to physicians and the integration is going well and we will continue to see that progressing as well as being able to talk to new customers, especially as we look at the vertical integration that we have at Biocon Biologics.

Dhawal Bhalodia: **Okay, thank you. My second question is, since most of our new biosimilar like Avastin and Humira, we maybe the fourth or fifth player in the market versus first or second, in case of Neulasta and Herceptin. So, do we have any particular strategy since we are fourth or fifth player to address to come with a particular strategy?**

And the second thing Humira has a wide use like it's a dermatological product, it's a gastro product, it is an autoimmune disease product and most of our biosimilar product is only oncology, so we have the separate sales staff for Humira or any other thing that we are doing for them?

Matthew Erick: Shreehas would you like me to start and then chime in?

Shreehas Tambe: Yes, sure.

Matthew Erick: Great so let's start with our product Hulio. We are going to be in that what I would call the first wave, Amgen did launch here over the last month or so, but in the first wave as you know, there is no one going to be exclusive. So, we have a tremendous opportunity to be part of each one of those formularies. Each of the payors have said that they will have at least a biosimilar plus 1 or plus 2 and we'll be in that first wave and have our plans to be able to participate and win with those payors. So being exactly a little bit

later than Amgen is not in my opinion a hurdle because the way the payors have opened this up and we're well positioned to win these formulary positions.

And then also as I mentioned, we're in a good position after winning the formulary with this sales force that we have, coming from Viartis and adding to it. We have that ability to pull through and then we also have a great understanding of the specialty pharmacy. The specialty pharmacy as I mentioned, is how the products are dispensed and then we're in the process of continuing to stand up and add additional patient services to what we're developing with Viartis to be able to have the patients, have those discounts co-pays or the ability for them to get additional services.

So, we're in a good position with our Hulio product as Shreehas and Kiran also mentioned, we have history, a lot of our competition doesn't have history. We have global history and market leadership in Germany and France, and to be able to talk about it as well as our product that has a two click mechanism and is citrate free which won't cause any pain in the injection side.

As it relates to, I believe you're asking about the oncology products. We are well established in our sales force, as well as our relationships with key physicians. So, as we launch products, even though we're not first which ideally, we'd love to be first we have the mechanism and the understanding of how that Medical Benefit works and to be able to pull that through on the oncology side with our sales force, as well as our payor as well as our ASP understanding of how the industry works.

Kiran Mazumdar-Shaw: And I might remind Mr. Bhalodia that Biocon was the company that received the first US FDA approval for bTrastuzumab or biosimilar Herceptin.

Dhawal Bhalodia: **Yes, yes. Thank you so much. And all the best for the whole year.**

Saurabh Paliwal: Thank you. We move on to Harith Ahamed from Spark Avendus. Please go ahead.

Harith Ahamed: **Good morning and thanks for the opportunity. You previously guided for US\$ 1.8 bn revenue for Biocon Biologics in FY24 and the US\$ 500 million EBITDA. So, are we maintaining that guidance given there is some delay in the closure of the transaction with Serum?**

Kiran Mazumdar-Shaw: Yes, maybe Chini you would like to respond to this. But basically, I think we will be focused on these numbers that we have shared with the market and we will basically look at, as you know there have been delayed approvals of bAspart and bBevacizumab. We are also trying to catch up with that particular gap. But we are looking at how to basically stick to these numbers, of course this does include, as you know, US\$ 300 million of vaccine revenues, so I think we will be looking at all these numbers and making sure that we share with you, any changes to these numbers.

There's also been an impact I think of the currency, parity between the dollar and euro and dollar and Yen. So, I think that also has impacted some of these numbers, but we are trying to see how close we can get to those numbers.

Harith Ahamed: Got it. My second question is on the R&D spend at Biocon Biologics specifically we've seen almost ₹100 Crores delta on a quarter-on-quarter basis and that's just a month of consolidation of the acquired business. So how should we think about the spend for next year. Do we still maintain that 12% to 15% of revenues guidance that we've given in the past on the much higher revenue base?

Kiran Mazumdar-Shaw: Yes, I think that's what I meant by saying that we will see normalization because this quarter you've only seen the impact of a month's contribution from the Viatrix business. But going forward, we expect to basically normalize R&D spends to that sort 12% to 15% levels.

Harith Ahamed: Thank you. And last one with your permission, there is an increase in the share of loss from JVs and associates and we were under the impression that given we had lowered the stake in Bicara, this number would be trending down. We've seen an increase on a quarter-on-quarter basis. So how should we think about this number going forward, is this a one-off quarter for that particular line item?

Siddharth Mittal: I wouldn't call it as a one-off, our shareholding is down to 53.5% and the expenses of Bicara has gone up as they are in middle of clinical trial and of course the advancement of the lead program and we do expect over the next few months further fund raise by Bicara which would further dilute our stake, but on an absolute number, which we are treating as a loss from associate shouldn't materially change because as they progress in clinic, the expenses would go up. They're also spending money on their follow-on pipeline. Of course, that said, at very early stages the expenses will not be significant but just from your model perspective, I do expect something in the similar range over the next few quarters.

Harith Ahamed: Got it. That's all from my side. Thanks for taking my questions.

Saurabh Paliwal: Thank you, Harith. Next question is from Surya Patra from PhillipCapital.

Surya Patra: Yeah, thanks for this opportunity. First question or rather couple of questions to understand better the integration of Viatrix operation. So, in fact see what we believe that okay with this acquisition of Viatrix biosimilar operation, we have seen vertical integration and theoretically, that should have supported gross margin sequentially. But we are not seeing any change this quarter, although this is not a reflection of a full quarter performance of the acquired operations. But is it fair to believe that the gross margin should see a kind of sequential up move post integration? That is one.

Secondly wanted to understand a bit more on the distribution charges, what we are paying to Mylan, in which line item that is getting captured whether it is.

Kiran Mazumdar-Shaw: You are muted.

Surya Patra: Yeah, so, okay. Sorry for that. Then I'll repeat my question, so about the integration some clarity I wanted. So theoretically, with the acquisition of the Viatrix operation that provides more integrated activity now and hence the gross

margins should have seen sequential improvement, but this quarter we are not seeing anything like that, it is slightly lower sequentially.

So, can you give some clarity about that, should we see and expect a sequential improvement in the gross margins after the integration?

M.B. Chinappa: Kiran, can I take that?

Kiran Mazumdar-Shaw: Yeah, please.

M.B. Chinappa: Surya, just to clarify gross margin, you mean net of material costs or the core EBITDA, which is net of all operating costs?

Surya Patra: **No, net of material cost.**

M.B. Chinappa: Yeah. Net of material cost at the BBL level, we have seen that improvement this quarter, improved by 2 percentage points over the same quarter last year.

Surya Patra: **Okay, so then possibly at the Biocon consolidated level, it would be pricing challenges or whatever that we would be seeing that could be one reason is that understanding, correct?**

Kiran Mazumdar-Shaw: Siddharth, you want to take this?

Siddharth Mittal: Maybe Indranil, you can just explain.

Indranil Sen: It is not so much of pricing, but it's also about product mix. So, we will see a quarter on quarter flux because of product mix. This should normalize going forward.

M.B. Chinappa: And just some comments, we really look at the core EBITDA performance, not so much around gross margins, so Biocon Biologics is at 44%, improvement over last quarter.

Surya Patra: **Okay. So now practically including the R&D spend. Why, because that is an integral part of our business and in the next couple of your time, we are likely to see an upward move only, absolute upward number in terms of R&D spend. So, the overall margin profile of Biocon Biologics, how should we see considering also the integration of the acquired operations?**

M.B. Chinappa: The SG&A cost that could come through post-acquisition. So, the full effect of the SG&A cost is absorbed when we report a core EBITDA and as I indicated, we are now trending above 40% this quarter and the previous quarter.

So, we see the overall SG&A cost to be comfortably positioned. As Kiran did mention that we're looking at bringing R&D costs down to about 12%. So, you would see EBITDA now then trending towards the high 20s nearing 30s, from a margin profile, if that was your question.

Surya Patra: **Okay. Yeah.**

M.B. Chinappa: So that's an improvement as you can see.

Surya Patra: Okay, just last question, let's say for the biosimilar business, so obviously the key product opportunities what we are having for let's say for FY'24 is Beva, Aspart, Adalimumab, rh Insulin. So how should we think given the kind of timeline that is there and the regulatory clearance that we are waiting for. So, in the contractual cycle also that is considering all that, whether these are considered to be the real FY'25 triggers for us to grow?

Kiran Mazumdar-Shaw: So, let me answer you Surya by saying that FY '24 certainly is going to be focused on the successful Adalimumab launch and I think we are also looking to see how much we can grow our existing products like Glargine, Trastuzumab and Pegfilgrastim in the US, but also we are focused on making sure that we focus on Europe for all the products that are approved there. As you know, in Europe we have all products approved, in fact we have seven products approved in Europe, of which the real focus up until now has been not all seven. So, we are looking at seeing how we can basically leverage and add to the business in terms of all products in Europe.

So I think that's the way we look at the FY '24 and of course we are hoping that Aspart and Bevacizumab will also be approved this calendar year, in which case, obviously there is some contribution to the FY '24 growth but FY '25 growth will see all these products contributing to strong growth.

Surya Patra: Sure. So, just one on the pipeline front, what is our now progress on the Aflibercept area and what is the timeline that we are expecting given the kind of regulatory progress and our preparedness and our positioning compared to competition, that front? And also, briefly on the generic business front, although this year we will possibly, likely to see a couple of greenfield projects contributing but in terms of the growth visibility for that segment, how should one really build into the model?

Kiran Mazumdar-Shaw: Shreehas, you want to take this?

Shreehas Tambe: Yeah, sure. Thanks Kiran. On the Aflibercept asset, Surya as you know we've exercised the option when we acquired the asset from Viartis. So, it's a first to file asset, it's undergone review with the FDA and at this stage, we are currently in litigation with the originator of that product. So clearly that's in the public domain. It's going through that entire patent dance cycle, so we will not comment on the proceedings beyond what's in the public domain. So clearly that's an area where we are leading that effort directly. We believe Aflibercept is a sizable opportunity, gets us into the ophthalmology space and we can talk to you more about how we're going about doing it, but we believe that it would be a nice area for us to build on. Being the first to file does give us the opportunity to look at such a sizable asset of almost US\$ 10 billion in revenues. So, this could be something, which can really be another game changer for us going forward. So, we are really focused on developing that.

On the second question that you asked. I'll turn it over to Sid to respond.

Siddharth Mittal: Thanks, Shreehas. Surya, so I think Kiran mentioned in her opening remarks that our immunosuppressants facility is undergoing qualification, also the peptide facility is undergoing qualification and we expect the qualification to complete in first half of next fiscal, following which we will of course file with the FDA to include those sites in our DMF and it would take some time, because we expect FDA to come and inspect these facilities. So, the revenues from these facilities are not expected to commence until FY25.

However, the growth will come from the other products what we have already commercialized, some of the new launches which we're expecting in the US. I'm talking about the generic formulation launches and also additional capacities in our existing facilities that we had increased in the last 12 to 24 months which will drive volume increase for our API business. So, combination of new launches, increased contracts that we've seen recently for statins and immunosuppressants in the US and increased API should drive the mid teen growth for the next couple of years.

Surya Patra: Yes, thank you wish you all the best.

Saurabh Paliwal: Thanks, Surya. Our next question is from Shyam Srinivasan from Goldman Sachs.

Shyam Srinivasan: Hi, thank you for taking my question and good morning, everyone. Just the first one on the billion-dollar run rate again, Chini if you could kind of break it down into developed markets and emerging markets. I remember historically I think emerging market did about ₹240 million for us so just where it is tracking now in that ₹1 billion number?

M.B. Chinappa: Of course, so even from the Viatris biosimilars' acquisition, we will have emerging markets in there so directionally as you look forward 70% of our revenues will come from developed and 30% from emerging markets. That was part of your question. Now if you're going back to the building blocks for the \$1 billion and from thereon, so in, in the \$1 billion roughly have about 25% in the emerging markets. But as we look ahead, you will start to see advanced markets pickup to 70% and emerging markets at 30%.

Shyam Srinivasan: Got it. You seem to suggest that the emerging markets will grow faster right, , did I get those numbers wrong?

M.B. Chinappa: Yeah. Okay, so take Viatris business that up to last quarter, we were roughly 50:50, next quarter as we get to ₹2000 Crores, we will actually go to 75:25 with advanced markets. But as we build on the emerging markets will finally come back at 70:30.

Shyam Srinivasan: Got it. And Chini, when we look at the margins for these two segments is that different or you don't calculate it that way given the infrastructure could be common, so just help us understand does making, splitting this based on these two geographical spreads, does it make sense or it's one large monolithic that we need to actually look at it.

M.B. Chinappa: From an operating cost structure it is one large monolith because our manufacturing plants supply both the emerging markets and the advanced markets. From SG&A point

of view, the Viatris acquisition will increase our SG&A cost, which is pertaining to the advanced markets, whereas we would expect advanced markets has a higher revenue profile and with margin and pricing, effectively a higher margin.

Shyam Srinivasan: **Helpful Chini. My second question is to Shreehas. I think you briefly touched upon Hulo interchangeability but what about Rezvoglar right, in which Lilly I think has got an approval recently. I think your exclusivity ends in December, if I recollect right but correct me. So, do you expect 13%, 14% NRx share, are we still on track to do the high- teens market share by the end of this calendar year. Is there any competitive activity even beyond Lilly that you think we need to be monitoring?**

Shreehas Tambe: Thanks, Shyam. I think let's first look at where this is coming from. I think this whole question on interchangeability was about breaking that myth about being able to not just have a biosimilar product but given that insulin is a chronic therapy, can the patient who is receiving the dose, using our innovative product, get the same numbers or would there be a difference and could it be used exactly interchangeably.

So I think that entire effort was to go past that hurdle and break the myth that there is any concern at all about this and I think FDA themselves called it a historic moment in how it approved Biocon Biologics' Semglee as the first interchangeable product, so it needs to be viewed in that lens first. Shyam to say that, why was it needed at that point in time to put to rest all arguments that not only is it a biosimilar but it can be used interchangeably whatever it is, that has been described, you can switch it or stop it at the pharmacy level and you will get the same therapeutic effect. I think that is what we achieved over the course of calendar 2022.

Before we got the interchangeable insulin, of course, there was Basaglar in the market and there was this increased market share that they had got vis-a-vis Lantus and that was there in the public domain. The question was about whether Biocon Biologics and Viatris when we brought our product to do that. We were able to successfully demonstrate that even going past the regulatory hurdle of being an interchangeable biosimilar and the first one at that.

Going forward, what we really see, and you're seeing that in the indices that you mentioned, which is the NRxs, we are already trending towards 14% and thereabouts clearly indicates the acceptance of the product and now you will of course expect competitor action, you would also expect some innovator action, but from here on its laid to rest the argument about efficacy, about the overall effectiveness immunogenicity, all of that is behind you and now it's a level playing field to go and win the market share.

So clearly 2023 is about building on all of this and seeing how we can not only grow market shares, get the pull throughs that Matt talked about in existing formularies but also win more accounts to see that we grow that confidence beyond what we have got.

So, I hope that gives you a perspective of how we are approaching Glargine overall.

Shyam Srinivasan: **Got it. Thank you. And my just last question.**

M.B. Chinappa: Sorry.

Shyam Srinivasan: **Yes, Chini. Go ahead.**

M.B. Chinappa: Wrongly classified certain markets particularly Germany, Japan, Australia, New Zealand and Canada so if I really look at it, today we are roughly between 60% to 65% advanced markets and that would go towards the 70%-75% particularly with Adali launched and the launch of the new molecules.

Shyam Srinivasan: **That's helpful. Actually, last question to Siddharth quickly, if I may, the confidence for mid-teens growth, I think, and maybe I clarify here, we are only talking mid-teens growth for generics right, because every other segment I think Syngene has their own guidance, I'm assuming Biocon Biologics has its own guidance looks like. So, the mid-teens are you referring to only Generics? That is question number one**

And two, what has given us the confidence for this mid-teen's growth. I know this quarter we have done 18%. We have grown QoQ also. But has there, but you mentioned in your opening remarks about even generic pricing pressure. So, what's changed that has given us a little bit better visibility. Is it just a launch momentum from our products?

Siddharth Mittal: Yes, so it's correct that the mid-teen growth is only for the Generics business and the confidence is basis two things as I mentioned, one is we have already got certain additional volumes in the US for the formulations we have launched, and we are going to launch additional products in the coming fiscal.

We do have a couple of important launches coming up later part of this fiscal itself. We know that Generic teriflunomide, which is the first to launch opportunity even though it's a competitive market with many players, but we are going to be one amongst others. And we do have a few other filings which were done where we are awaiting FDA approval in the next fiscal. So that would drive growth in the US, but yes, I did mention the pricing pressure does continue. We have seen normalization of pricing pressure more recently with some disruption in the US and supply chain caused by some of these facility issues from other Indian companies. So, what was a steeper price erosion last year, we're seeing normalizing trend and I also mentioned that we are expecting additional volumes to come in from our API business where we had expanded capacities in our existing facilities, and there were couple of again important molecules which were launched by our partners in Europe, specifically the latter half of this calendar year 22 and that will drive additional volumes in fiscal 24.

Shyam Srinivasan: **And thank you Siddharth and all the best.**

Saurabh Paliwal: Thanks, Shyam. Next question is from Nithya from Bernstein.

Nithya Balasubramanian: **Thank you. So, on Aflibercept, can you tell us what your TAD date is? Because Viatris had communicated that, it's more than three quarters since you said they filed the product. Second would you have already worked with the regulatory**

agency to ask for a switching study label for this product. Obviously on the back of what happened with the Lucentis biosimilar.

Shreehas Tambe: Just a quick thing I didn't follow the second question very well, but the first one. Given that Viartis is the first to file, market formation will not be just linked to patent expiry on the molecule, but also the data exclusivity, so that runs beyond the patent expiry into 2024. So, we will be watching that date and that would be the date that the FDA can grant approval, so technically they can't grant an approval until the end of data exclusivity.

Nithya Balasubramanian: **Understood. So, my second question was Coherus was actually able to get interchangeability for their Lucentis biosimilar on the back of immune privilege argument, have you also made a similar request to the FDA or is this something you will do later just touching on that.**

Shreehas Tambe: I think they will grant us that. For competitive reasons, we would not want to share that discussion right now but clearly Lucentis is a precedent for most companies to follow at this stage.

Nithya Balasubramanian: **All right. So, one on Adalimumab, Shreehas. I think interchangeability has actually made a difference. It's made a difference for you and bGlargine, it's making a difference for Coherus in Ranibizumab even though it's a medical benefit product. So, I'm just surprised with your commentary that you don't see that as an important factor. But come let's say July 2024 you will have, there are at least four of your competitors who are going after interchangeability for the 80mg version. So, in that scenario, how do you see a 40 mg product is being competitive?**

Shreehas Tambe: Fair question and we could argue it in several different ways. First thing I will point you to the success that we've enjoyed, and I'll be limited right now for Adalimumab in Europe where we've seen success, regardless of whether you had or didn't have interchangeability. So that's one point just to look at.

The next thing to see and classify the US market, also for Adalimumab, you're seeing the first product being put on the formulary does not have interchangeability clearly not a condition precedent to being listed on the formulary. So that is the second piece that I would point you to.

Point number 3, you would have almost five of us launching on, I would say, effectively the second wave of launch or the first wave of real launch after the first innovator, so not everyone and actually other than one company will have, interchangeability and almost every payor in the US has publicly stated that they would have at least an n of two or if not an n of three which means the signal is that it's important to have, it's nice to have an interchangeable product, certainly, it gives you the advantage nobody is saying you shouldn't have it. But it's not going to be the sole determinant of commercial success and that was the context to my comment if it led you to believe anything different then I would like to correct myself.

Nithya Balasubramanian: Just a follow-up on the fact that formularies are actually not restricted and they're fairly open in terms of the number of biosimilars they're adding so if, let's say, there are two or three biosimilars at parity with Humira, which is a sense you are getting from some of the peers commentary. Then does your commercial muscle therefore become more important? If there are two biosimilars and Humira at the same out of pocket expense level, what will help you differentiate?

Shreehas Tambe: I'll let Matt respond to this in a little more detail, because I think there's a lot of questions around this, but I think the first piece is what gets you to the table is price, interchangeability, as we discussed just now is something which is nice to have. But what will really determine success and pulls through is going to be the device that you have and whether it is the citrate free, latex free product that will reduce injectable side reactions and how are you going to be able to provide patient services so that you do not have a push back from the patient or prescribers that they're not comfortable given that they've got so many options now. I'll let Matt talk about the specialty pharmacy piece because given that you've got so many options in the US now there is an opportunity that you can get subbed even if you were to get prescribed. Maybe Matt, you can comment and give Nithya a little more color, on this.

Matthew Erick: Yeah Shreehas, you explained it very well. I'll just add a few other key attributes to that. One thing to remember, interchangeability is only to the innovator and we're watching very closely how that shapes up and you are correct in your comments that it is an important piece of the commercial side to be able to have those relationships, have the doctor understand the product itself and what we have in our Hulio product when they write their name of Hulio on there, it's in a great position for us. I don't want to underestimate, there is a lot that we have to understand which we are. And there is a key component of this and that's a little different than what we've seen prior, and that is the specialty pharmacy. And so, there are relationships that we are growing, establishing, and understanding the economics there as well, so we're not subbed at the specialty pharmacy level.

So, I'll reiterate the four key components of winning in Hulio is definitely getting the economics right on the payor side, understanding the ability for the sales force to create those relationships, have the physicians and patients get comfortable with our Hulio product in the two clicks. And the other attribute thirdly, is to making sure we understand, develop and continue to work with specialty pharmacy and at the end of this, if you aren't standing up, which we are, the right patient services to support the physician as well as the patient. Then we'll see if people fall down and as we go through these, we have a great understanding, especially with what Viatrix has already built. And we're adding to that for that growth to be able to be very competitive, whether it's interchangeable or not interchangeable as we think of the different channels that we have to be successful.

Nithya Balasubramanian: One last quick one, if I may, on the SII deal, I think your guidance was US\$ 300 million revenues. And that was in the context of COVID vaccines at US\$ 3 to US\$ 4 pricing. Now we know that the COVID vaccine demand has come off so I'm

assuming you will be selling a different set of products, that being the case, does the margin guidance of 35% EBITDA still stand on the ₹300 million revenue?

Kiran Mazumdar-Shaw: Well, that is the agreement that we have, Nithya. So, I don't think there will be any change to this.

Nithya Balasubramanian: **Got it. Thank you so much.**

Saurabh Paliwal: Thank you, Nithya. Next in line is Sameer Baisiwala from Morgan Stanley.

Sameer Baisiwala: **Thank you and good morning, everyone. Siddharth, can you talk about your positioning on Liraglutide in the US market and second is where do you see the market formation in both the US and Europe?**

Siddharth Mittal: Thanks, Sameer, I think, a very good question and I would like to first emphasize our focus on peptides as a company. We see a huge opportunity in peptide I mean today the peptide market is growing to US\$ 15 bn in sales globally and we expect by 2035 this to be a US\$ 60 bn opportunity in sales and just I'm talking about three or four key peptides whether its Semaglutide, Liraglutide or Tirzapatide and we are very uniquely positioned. We have already done the filing in the US, we have received our comments from the FDA, and we are working on addressing the questions that FDA has and we expect to hear back from FDA soon.

But the market formation as it's publicly known, there are couple of settlements for launch in the US for Victoza, which is the diabetes indication. There has been no settlement yet, for Saxenda, which is for weight loss and growing steadily. But from whatever at least is available in public domain, we have heard that the launch is expected in the end of 2024/early 2025. We are still under litigation with Novo Nordisk, so Biocon has not yet settled but we expect to be in the market as mentioned, end of Calendar 2024/early 2025.

Now from a competitive positioning perspective, we have seen couple of other generic companies file this drug starting with 2016 and there have been couple of filings in late 2018-2019 and 2021 and none of the competitors have received approval and we believe that we are very well positioned with the scientific data that we have provided to the FDA.

Sameer Baisiwala: **Okay, great. And you have filed for both Victoza and Saxenda?**

Siddharth Mittal: That's correct. We have filed for both Victoza and Saxenda.

Sameer Baisiwala: **And what is the market formation date in Europe?**

Siddharth Mittal: Europe is around the same time period, end 2024/early 2025.

Sameer Baisiwala: **And broadly for other peptides, have you done the filings or what would be the flow as we go forward.**

Siddharth Mittal: So Semaglutide which is the follow-on molecule for Liraglutide is under development. We're of course late to be in NCE minus one filer but we do expect to file in time to be in

the market in 181 day or Semaglutide. Of course, there are three different formulations for Semaglutide with the market opening up, starting in '29-30 and the market for some of the formulations is going as late as '32. The other drug that we are working on and again at different stages of development is Tirzepatide, as we know this is expected to be contributing almost 25 to 30 billion in sales and we are targeting to file this product as a day 1 on NCE minus one day. So, there's a lot of effort going on. We have a very robust pipeline of peptides, I just discussed three. but we have a pipeline of peptide, which is more than 10 numbers and that's again at different stages of development.

And we are adding incremental capacities to our peptide API manufacturing facilities. So what we mentioned at the beginning of the call, the large volume peptides facilities commissioned and validation is going to start and we are already looking at doubling the capacity of that facility in the next 12 months because we see a huge opportunity in the volume growing globally for peptides.

Sameer Baisiwala: **Great. And have you filed any other peptide other than Lira?**

Siddharth Mittal: Not yet.

Sameer Baisiwala: **And you would be doing third party API sales as well and I think that could be a big opportunity.**

Siddharth Mittal: Yes, that would be a huge opportunity. In fact, we have seen some of the early filers in the US, they had got API from that peptide specialist companies and the main concern that FDA had was on the characterization of the API and the quality of the data that supported the API. And we've been in discussions with some of these filers to qualify our API source in their file and we have seen very encouraging results, when they have, we have supplied them quantity to help them with the analysis and they, of course, have a comparison of our API with the other API and we feel we're very well positioned in terms of the quality of our API.

Sameer Baisiwala: **Sorry. Have you crossed that bar with FDA with your API?**

Siddharth Mittal: We have received comments from FDA asking certain questions on our API. We are in the process of addressing those questions. And we think every, most of the questions are addressable. We do not see any showstopper in our API quality in terms of the questions that FDA has asked.

Sameer Baisiwala: **Okay, great, thank you so much. One final from my side it's on BBL, Kiran, what's the plan for private equity raise. I think you did mention a bit about it, but anything concrete over there and the subsequent IPO that you were thinking of.**

Kiran Mazumdar-Shaw: So obviously, we are in advanced discussions with private equity investors and as I mentioned, we will be sharing that information with you, with more clarity and granularity when we are close to signing up because I think it's not right of me to really talk about that at this stage, but suffice to say that we are in advanced discussions for equity raise to lower the acquisition debt.

The other point is that as far as the IPO is concerned, we are obviously focused on the right timing of the IPO, and it will be based on a number of triggers. So, we will be looking at some of these triggers in terms of either product approvals, market performance and those will really determine the timing of the IPO, because the moment we start seeing a robust growth, I think that is the time for us to go to the market.

And in any case, Sameer, as you know, we do need to go through the integration process before we can initiate any IPO activity. So, I think from that point of view, I would like to focus on integration and then start the IPO preparations immediately thereafter.

Sameer Baisiwala: **So, it looks like 18 months or thereabouts.**

Kiran Mazumdar-Shaw: It could be sooner but definitely not earlier than 12 months.

Sameer Baisiwala: **Okay and Kiran if I may, the valuation benchmark which have been set for BBL based on the previous rounds of private equity and the conversion for Viatris, those stand, that is a benchmark for the new rounds of infusions.**

Kiran Mazumdar-Shaw: Well, what I would like to comment is to say that definitely the IPO valuation stands as has been discussed for the Viatris transaction that absolutely stands and we will be raising funding based on how things play out in the market.

Sameer Baisiwala: **Okay, great, thank you so much.**

Saurabh Paliwal: Thanks, Sameer. Next is Neha Manpuria from Bank of America.

Neha Manpuria: **Yeah, thanks for taking my question. Shreehas, could you give us some color on the filing timeline for Ustekinumab, Denosumab and Pertuzumab since we have just started trials for that one too?**

Shreehas Tambe: Sure, Neha. So, we are right now in Phase I / Phase III trial for Ustekinumab, we have guided earlier that end 2023, we should be able to get to filing. For Denosumab, we have got Prolia and XGEVA we are again doing combined Phase I and III trials, we're looking at end 2024 filing for Denosumab and since you asked about Pertuzumab, we just announced that we've gotten into the clinic for a Phase I study that we've started with that asset. And as we progress more into that we will be able to give you more clarity on the filing dates.

Neha Manpuria: **And on the emerging market piece. Based on the 35-40% that that's contributing currently. What's the expectation of growth given the amount of launches for Trastu and the insulin portfolio that we're making there, would the emerging market piece including the Viatris portfolio grow mid-teens, high teens. What is the expectation there? Not emerging market ROW ex-US-Europe rather.**

Shreehas Tambe: Susheel, do you want to comment on that?

Susheel Umesh: Yes sure. Along with Viatris, with both of us put together the growth would be in the range, which you have mentioned. Overall, the good thing should happen right now is between both of us. In the past, Viatris and us we had strengths in different areas, we

were stronger in the partner-driven insulin market area and Viatris is very strong with its Trastu and Beva portfolio and they also had feet on the ground in different markets. So, both together, I believe that the growth will be quite significant in the emerging countries and we will continue to do well as we are doing. The key focus of the emerging countries will remain what it always has been, we want to create access in more number of countries and we want to go deeper in the countries where we're already present. So, I think with the Viatris portfolio and the existing portfolio that we have the growth will be around the numbers which you mentioned.

Shreehas Tambe: So just to add to what Susheel said Neha, we continue to see significant growth in the, in what we have called as the BBL markets in the past where we were structured prior to the closure of the acquisition, and that trend continues. It of course gets better with the Viatris additions to the markets that we've been leading so far. But the question if you were to now look at what has become, Biocon Biologics now has a sizeable pie which has a larger contribution from advanced markets than we had before. So, as a percentage you may see that change, but in terms of on a standalone basis, these markets will continue to show growth.

Neha Manpuria: **And last question on Pegfilgrastim, with one of our competitive biosimilars likely to see the on-body injector launch sometime in the course of the year, does that impact our ability to take incremental market share. Do you see some of the biosimilars probably shifting to the on-body injector along with the innovator shift?**

Shreehas Tambe: See Pegfilgrastim US has been a very different market. Innovator action has been unique where we've seen the very aggressive pricing behavior on behalf of the originator. So that's one aspect. So, it's a very different dynamic that we're seeing there.

We also had said in the past that given the pandemic, which was an unexpected and unprecedented event, the on-body injector held on to a market share which was disproportional for a period of time, it even went up beyond 56-57%. We are now seeing that come off to about 45% or lower than that. So, you're clearly seeing that it's certainly a nice to have, the originator continues to hold that market share that you referred to just now, competition is likely to eat into that market share, but we will also release more into the syringe opportunity, which we believe will be for us to look at.

Some of the indicators that you would see from the recent market information that have come in, is many of these market shares that have been lost by players who had discounted aggressively, who had gone for market share. We are seeing that pickup in Biocon Biologics now. So, we will see a steady increase because we've always looked at holding onto a value maximized opportunity, rather than just chasing market shares, which always quote ASPs versus market shares at loggerheads and we've always played that balancing act. We'll continue to do that.

Neha Manpuria: **Understood. Thank you so much.**

Saurabh Paliwal: Thank you Neha. We'll take Nihal next.

Nihal: Hello. Good morning, everyone. Actually, I want to speak in Hindi, so everyone can understand. I have been invested in this company for past one year. The share price has dropped from ₹400 to close to ₹230 and has been continuously dropping. Even today, the stock price has been moving around 52-week low. So, what is the plan? Should we invest? Should we not invest? Because we shareholders are incurring too much losses.

Kiran Mazumdar-Shaw: You are seeing the way Biocon is becoming stronger. But there is little we can do when it comes to the share price. We will continue to focus on business delivery and business growth. The large acquisition should help the shareholders understand our growth trajectory to becoming a global player. We are working really hard to grow our business and drive success. But investors should also have faith in our capability, that what we are doing will be beneficial for India and the world as a whole. I would like to know which other companies are doing what we are doing. How many companies are manufacturing insulin? How many companies are manufacturing world class biosimilars? So, we have been able to achieve all of this with a lot of hard work. Our vision is to provide medicines that are accessible and affordable to the masses. But investors also need to have faith.

Nihal: What you are saying is absolutely right. But there has to be a way out, because the share price is on a continuous downward trend.

Kiran Mazumdar-Shaw: But there is nothing I can do about it. All I can do is work hard. As you can see, we have reported a revenue growth of 36%, we also mentioned the exit trajectory of US\$ 1 bn for Biologics and all our other businesses are performing really well both generics and research services. I'm not able to figure out the reason behind the drop as we are doing everything possible for the growth of the company.

Nihal: I salute you for the kind of work you are doing. I hope, post your commentary today, Biocon's price shows a good upward move.

Kiran Mazumdar-Shaw: We are putting efforts in building the leadership team and making sure people see our efforts. Our medicines are benefitting so many people across the world. And in India, our company is one of its kind and unique. I hope the investors understand our business and start supporting us in our journey.

Nihal: I hope this positive commentary helps in increasing the share price. Thank you.

Saurabh Paliwal: Thank you, Nihal. We have a follow up from Cyndrella from JMFL.

Cyndrella Carvalho: Thanks for the follow-up, Siddarth this is for you. You helped us understand the pipeline, especially on the peptide side. I want to understand the commentary on the profitability, EBITDA margin side, how should we look at it and what is the, if any guidance that you can provide on the EBITDA side. We have seen some sequential improvement in this business. However, the formulation business in US still has a lot of pricing challenges. So, what is your view on that?

And just one more addition to that is the newer facilities which are commissioning, how much of OpEx and depreciation it will add to our P&L over there and is it something significant that we need to consider?

Siddharth Mittal:

So, I think, let me answer your second question first. The new facilities will be capitalized once we received approvals from the FDA, which is expected in FY '25. So, I do not expect any significant impact in FY '24 from these large facilities or OpEx coming in. I think I'll be in a better position to quantify and give timelines, I think as we move along, in a few quarters.

In terms of the first question of course, of course the pipeline, we are making good progress, we do see the pricing impact. Our core EBITDA margins were in the range of 21% to 22% for the Generics business and we are investing, roughly 8% to 9% of revenues in R&D. So that reduces the EBITDA to anywhere around 14%, 15% and the PBT which we reported is around 10%-11%. I do expect the margins to continue at these levels. Of course, the margins are also dependent on the product mix we supply to our customers so, we've had few higher very profitable products which were supplied to our customers in Q3. So, for example, Fidaxomicin which we supplied to Merck or Tacrolimus which we supplied to some of our customers in the US, so we had seen a good product mix in quarter three. But going forward, of course, these could be lumpy in some quarters there might be no delivery of higher profitable products. So, we would see a fluctuation, but on a long-term basis, I would still say that we will till we get one of these blockbuster peptides, we will expect the margins to continue in the same range.

Cyndrella Carvalho:

That's very helpful and coming to just a confirmation on Serum, whenever the transaction is clear from the regulatory aspect, we will be able to see the booking from 1st October 2022, is that understanding, correct.

Siddharth Mittal:

That's correct. The effective date would be October 1.

Cyndrella Carvalho:

Yeah. And as ma'am highlighted the tracking of US\$ 300 million is as per the agreement that is also clearly understood right?

Siddharth Mittal:

Yes

Cyndrella Carvalho:

Any additional CapEx on both the sites that we are seeing, because I see from our Generic business side, you have highlighted we may need to double peptide but any CapEx that you would like to give a number on that? And on the additional site in terms of Malaysia, do we see the second phase beginning or what is the status there from a CapEx perspective? That's it from me.

Siddharth Mittal:

So, Generics I expect CapEx to be around ₹700 to ₹800 Crores per year, which includes the incremental capacities on our non-immunosuppressants fermentation plants, peptides, as well as the injectable facilities that we're building, and that should continue for the next one to two years. Over to Chini for Malaysia.

M.B. Chinappa: We have given guidance of ₹100 to ₹150 million CapEx per annum. This year we have spent ₹70 million. Most of the spend this year and next year is towards the Malaysia Phase II expansion.

Cyndrella Carvalho: **Thank you so much. And thank you everyone all the best.**

Saurabh Paliwal: Thanks, Cyndrella. We will take the last question from Utsav Jaipuria. Please go ahead.

Utsav Jaipuria: **Yeah, hi, thanks for the opportunity. So, my question was on the Syngene stake. Are there any plans for further dilution in the future?**

Siddharth Mittal: Not in the future. We are down to 54.9% but we do not have any plans.

Utsav Jaipuria: **Okay, thanks.**

Saurabh Paliwal: That was the last question for this earnings call. I thank, everyone for joining us today. If you need any further assistance or clarifications, please do reach out to us. Have a good rest of the day. Thank you.

- Ends -

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