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Differentiated Growth.**



Biocon Limited Q1 FY24 Earnings Conference Call Transcript

August 11, 2023

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

- ✦ **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. Abhijit Zutshi** – Commercial Head - Global Generics, Biocon Limited
- ✦ **Mr. Nehal Vora** – Commercial Head - Global API, Biocon Limited
- ✦ **Ms. Rhonda Duffy** – Chief Operating Officer, Biocon Biologics Limited
- ✦ **Mr. Matthew Erick** – Chief Commercial Officer – Advanced Markets, Biocon Biologics Limited
- ✦ **Mr. Susheel Umesh** – Chief Commercial Officer – Emerging Markets, Biocon Biologics Limited
- ✦ **Mr. Sandeep Athalye** – Chief Development Officer, Biocon Biologics Limited
- ✦ **Mr. Michael Cutter** – Global Head of Quality, Biocon Biologics Limited
- ✦ **Mr. Sibaji Biswas** – Chief Financial Officer, Syngene International
- ✦ **Mr. Saurabh Paliwal** – Head - Investor Relations, Biocon Limited

External Participants during Q&A session

- ✦ **Damayanti Kerai** – HSBC Securities and Capital Markets (India) Private Limited
- ✦ **Surya Patra** – Phillip Capital (India) Pvt. Ltd.
- ✦ **Harith Ahamed** – Spark Capital Advisors (India) Private Limited
- ✦ **Neha Manpuria** – BofA Securities India Limited
- ✦ **Nithya Balasubramanian** – Sanford C. Bernstein & Co.
- ✦ **Shyam Srinivasan** – Goldman Sachs Group, Inc.
- ✦ **Tarang Agrawal** – Old Bridge Capital Management Private Limited
- ✦ **Yash Tanna** – Ithought Advisory
- ✦ **Masira Vasanwala** – FSSA Investment Advisors
- ✦ **Cyndrella Carvalho** – JM Financial Institutional Securities Limited
- ✦ **Vishal Manchanda** – Systematix Shares & Stocks (India) Ltd.
- ✦ **Nitin Agarwal** – DAM Capital Advisors Limited
- ✦ **Ishita Jain** – Ashika Stock Broking
- ✦ **Sai Priyanka** – Medsphere

Prepared Remarks Session

Saurabh Paliwal:

Good morning, everyone. I am Saurabh Paliwal from Biocon's Investor Relations team and I would like to welcome you to Biocon's earnings call for the first quarter ended June 30, 2023.

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

Today, to discuss this quarter's business performance as well as the future outlook for the Company, we have Dr. Kiran Mazumdar-Shaw, our Executive Chairperson and other Senior leaders from different businesses including Biocon Generics, Biocon Biologics and Syngene.

I would like to also take this opportunity to remind everyone of the Safe Harbor for this call. Comments made during this call may be forward-looking in nature based on management's current beliefs and expectations. They must be viewed in relation to the risks that our business faces that could cause our future results, performance, or achievements to differ significantly from what is expressed or implied by such forward-looking statements. After the end of this call, if you need any further information or clarifications, please do get in touch with us. With this, I would like to turn the call over to our chairperson for her opening remarks. Over to you, Kiran.

Dr. Kiran Mazumdar-Shaw:

Thank you, Saurabh. Good morning, everyone.

I welcome you to the earnings call for Q1 of FY 2024. And let me start by saying that the Biocon Group has started fiscal year 2024 with a strong revenue driven first quarter across all our businesses.

Before I dive into financials and business performance, I want to reiterate our commitment to delivering on Biocon's mission of enabling global health equity through affordable access to essential and lifesaving therapeutics. We engage on this mission primarily through the three principal business growth pillars of our enterprise model – Biocon Generics, Biocon Biologics, and Syngene.

While each of these pillars are at different stages of business maturity, we are very carefully and deliberately planning, building, and executing on strategies to ensure that each pillar is well positioned for differentiated and competitive growth to build true global leadership in the years ahead.

As we do this, we keep at the forefront of our commitment to our four principal stakeholder groups.

- The patients we seek to serve
- Our people, whose talent and capability aim to deliver our products and services
- Our investors, for whom we strive to repay their risk and patience with superior returns; and
- Our business partners who support and collaborate with us to achieve our mission.

Let me now begin the business review and turn to our three pillars, the first being Biocon Generics. In line with our business priorities, our Generics business continues to focus on growing its product pipeline, creating and capturing value through vertical integration with a clear focus on innovation and digital transformation. Building on its widely recognized strength in fermentation-based products, we are adding capacities and capabilities in newgrowth areas, such as peptides, high potent drugs and injectables. We will also continue to direct our efforts towards forging strategic partnerships to accelerate our expansion into key global markets.

I would now like to turn to Biocon Biologics, which is the next and biggest growth pillar for Biocon. We are building a unique fully integrated global biosimilars platform, driven by the depth and breadth of our portfolio, R&D excellence, cost-effective manufacturing, global quality standards, flexible supply chains, and growing global commercial muscle.

We have embarked on a transformational journey with the acquisition of the Viatris' biosimilars business. To remind you, this strategic acquisition creates a unique fully integrated lab-to-market and globally scaled biosimilars enterprise. It is well-positioned to compete in the exponentially growing biosimilars market. In a recent market review by McKinsey, the global biosimilars market is predicted to quadruple by 2030, benefiting from more than USD 200 billion of originator biologics losing exclusivity. In its new fully integrated form, with 8 in the market and 12 pipeline products, totaling to a portfolio of 20 assets, Biocon Biologics has become a truly global player and is well positioned to fully capitalize on the enormous future opportunity.

Having closed the acquisition in November last year, fiscal 2024 will see us complete the operational and organizational integration of Viatris' biosimilars business into Biocon Biologics, establishing the foundation of our fully integrated global biosimilars model.

I am pleased to report that we're making good progress against our plan, and I would like to provide you with some key updates.

To ensure business continuity, we had entered into a transition services agreement with Viatris to provide ongoing operational services for a period of two years to complete the integration in a phased manner. I am happy to report that we are tracking well ahead of this plan. On July 1, 2023, we successfully integrated over 70 countries in emerging markets into Biocon Biologics. This successful integration coupled with a strong leadership team, gives us the confidence to accelerate the transition of North America and Europe, and I can report that we'll integrate all markets into Biocon Biologics before the end of this fiscal.

Coming to Syngene, the third growth pillar for Biocon, with almost 30 years of experience, Syngene provides end-to-end therapeutic discovery capabilities, including differentiated research technologies and platforms across many disciplines, disease areas, and therapeutic modalities. Its extensive experience and deep expertise have made it a trusted partner to many leading multi-national startups and medium-sized enterprises as well as non-profit institutions and academic institutions.

With an established track record in discovery, research and development for small and large molecules, Syngene is now building its capabilities in commercial manufacturing, offering clients a one stop shop capability from drug discovery to commercial manufacturing for clients and more balanced model for investors. In fact, Syngene is now the premier and leading company offering biologics manufacturing capabilities.

Now coming to our FY 2023 integrated report. Having reviewed our operational pillars, I would now like to highlight Biocon's ongoing commitment to ESG. Biocon's ESG agenda continues to advance. We engage with our 16,500 strong work force to make progress towards our ESG-focused goals, including building a diverse, equitable,

and inclusive workplace. In FY 2023, we evolved a core growth strategy to integrate environmental, social, and governance factors. Embedding sustainability into our corporate culture and day-to-day operations enabled us to continue developing life-saving medicines in an environmentally and socially responsible manner.

Having closed an eventful FY 2023 on the business as well as the sustainability front, we are proud to have released Biocon's maiden GRI-aligned Integrated Report. I'm also happy to share that Biocon Biologics has also separately released its first Integrated Report. I would encourage you to read the reports and provide us with your feedback.

Before I discuss the business performance, I would like to start with a Board update. I am pleased to welcome Rekha Mehrotra Menon and Nicholas Robert Hagggar as Independent Directors on the Board of Biocon. Rekha is a leading industry voice on technology-fueled innovation and socioeconomic progress. She was a key player in Accenture's growth for nearly 20 years, including over seven years as Chair of Accenture in India. She was the first woman to serve as a Chair of NASSCOM.

Nicholas has over 30 years of experience in leading and building pharmaceutical and healthcare enterprises. He has held the position of Chairman of Zentiva, CEO of Insud Pharma, President of Medicines for Europe, and Regional Director, Sandoz. He is currently the CEO and Founder of HealthQube Ltd and a Non-Executive Director of Zentiva.

I will now present the key financial highlights for Q1 FY 2024.

At the group level, total revenue for the quarter was up 59% year-on-year to ₹3,516 crores.

The Biosimilar segment revenue more than doubled as compared to the previous year on the back of the acquisition of Viatrix' biosimilars business. Research services grew 25%, while Generics had a healthy growth of 15%.

Core EBITDA, which is the EBITDA before R&D, licensing income, forex, and mark-to-market movement on investments, grew by 42% to ₹936 crores, representing a healthy core operating margin of 28%.

R&D spends for Q1 stood at ₹315 crores, which is an increase of ₹117 crores as compared to last year and corresponds to 12% of revenues ex-Syngene.

EBITDA for the quarter was up 69% at ₹808 crores versus ₹478 crores last year. EBITDA margin stood at 23% as compared to 22% last year.

Depreciation, amortization, and interest increased by ₹353 crores over last year. This is primarily related to the biosimilars business acquisition cost.

Consequently, Profit before tax stood at ₹184 crores, and Net profit for the quarter stood at ₹101 crores.

I will now discuss the business performance in a segmental manner, and I will start with Generics.

The Generics segment reported an operating revenue of ₹700 crores for the quarter, a growth of 15% over the same period last fiscal. Profit before tax for the quarter stood at ₹64 crores with a PBT margin at 9%.

Revenue growth for the quarter was primarily driven by our US generic formulations business, where we have benefited from additional contracts that were secured last quarter. There were also new product launches in key ex-US markets. And on the API side, we continue to see traction with our immunosuppressant API's portfolio.

We received one key product approval from the US FDA – a tentative approval for Lenalidomide capsules, indicated for the treatment of multiple myeloma.

On the regulatory front, we had a successful outcome of a GMP and pre-approval inspection of the oral solid dosage

facility in Bengaluru, which concluded in June with zero observations. This is an addition to the successful outcome of the Hyderabad API facility's pre-approval inspection in May, reported last quarter. Both inspections are now officially closed by the FDA, and we have received EIRs for them with a 'no action indicated' status.

Coming to investments being made for capacity expansion. During the quarter, we broke ground on a new injectable facility at Biocon Park in Bengaluru. This facility will cater to the long-term sterile fill and finish requirements for our Generics business. Work has also commenced on the expansion of our peptide and fermentation capacities in Bengaluru. These expansions are expected to be completed over the next two years.

Now, coming to Biosimilars.

First of all, I am pleased to report that the market share performance of our key commercial products has significantly improved across key markets. This positions us well as we complete the transition and build on the positive momentum.

Looking first at the US market, we continue to see increasing demand for one of our key commercial products, Semglee, our branded Biosimilar's Insulin Glargine and unbranded biosimilar Insulin Glargine, translating to a market share of 12% in June versus 8% last year.

The higher NRx or new prescription shares of over 15% demonstrate strong ongoing adoption of our product. We continue to add significant new customers in the US with exclusive status for our Insulin Glargine, which includes a large managed care network from July 2023 and, more recently, another large payer, effective January 2024.

Ogivri, our biosimilar Trastuzumab in the US, has also steadily increased market share to 11% in June versus 9% last year with growth coming from new customer contracts. Fulphila, our biosimilar Pegfilgrastim, continues to gain market share in the US, capturing 16% share against 8% last year. The weekly market share in July has crossed 19%. It is now the biosimilar market leader, demonstrating physician and payor confidence.

We launched Hulio, our biosimilar Adalimumab, in the US on 1st July, representing a key milestone for the business. The US Adalimumab market comprises several channels, including Commercial, Medicare, Medicaid, Veterans' Affairs, Department of Defense, and many more with each requiring different strategies for success. Biosimilar uptake for Adalimumab has been more gradual than expected across the industry. Our dual pricing strategy is expected to enable Biocon Biologics to participate in all these segments and we are in active discussion with relevant stakeholders.

On the European front, we continue to see strong demand for our products in major markets. Our Adalimumab garnered market share of over 18% and 10% in Germany and France, respectively. We have also seen a strong uptake of Abevmy, or our biosimilar Bevacizumab, in Europe with a market share at 5% in May versus 1% last year.

Biocon Biologics' Emerging Markets business continues to see strong uptake of our flagship products, recombinant human insulin, Insulin Glargine, and Trastuzumab. The integration of 70 countries from Viatrix's biosimilar business allows us to expand our reach and portfolio within emerging markets.

Now, coming to financials. These increases in market share and the consolidation of the Viatrix's biosimilar revenues have led to Q1 revenues doubling over last year. On a sequential basis, we have seen revenues remain largely flat at ₹2,015 crores due to the phasing of the tender business in emerging markets and a one-off impact of rebates in the US for our Pegfilgrastim. This has translated to a Core EBITDA of ₹513 crores with margins at 28%.

It is important to note that in the case of Pegfilgrastim in the US, the revenue and margin for the quarter were impacted due to higher rebates based on legacy contracts with select customers, which will normalize in the coming quarters. Post-transition by the end of this fiscal, Core EBITDA margins are expected to return to the mid-30s. EBITDA margin

consequently for the quarter was at 23% with R&D investments at 13% of revenues. PBT stands at ₹24 crores.

Moving on to regulatory updates.

Yesafili, our biosimilar Aflibercept was the first biosimilar to receive a positive opinion from EMA's CHMP recommending approval. We are also the first company to receive conditional approval for Aflibercept biosimilar from Health Canada with the final approval linked to ongoing litigation.

The clinical trials for biosimilar Ustekinumab and Denosumab are progressing well, and we are on track for filing by the end of 2023 and 2024, respectively.

In July, US FDA conducted two cGMP inspections of our Malaysia facility, issuing six observations for drug substance and drug product units and two observations for the delivery device units. The inspectors did not identify any systemic non-compliance. We have submitted a comprehensive CAPA plan to the agency and expect to resolve this expeditiously.

We continue to strengthen our global leadership team as we transition the operations of the acquired business. We have appointed industry veterans Rhonda Duffy as the Chief Operating Officer, and David Gibson as Global Head of Business Development. These appointments are in line with our commitment towards operational excellence and focus on new growth opportunities.

In summary, we are pleased to see strong uptick in market shares of our products across geographies with a line of sight on multiple growth catalysts. Our business continues to grow with:

- A. better performance of our products in existing markets, such as Glargine in the US;
- B. geographic expansion of our commercial products, such as Adalimumab, Aspart and Bevacizumab;
- C. regulatory advancement of our pipeline assets, such as Aflibercept, Ustekinumab and Denosumab.

Finally, coming to Syngene.

Revenue from operations grew 25% to ₹808 crores over last year. Reported EBITDA was up 25% to ₹235 crores with margins at 28%. Profit before tax was at ₹123 crores, up 33% over last year.

The performance during the first quarter was strong, led by Development and Manufacturing Services, and well supported by Discovery Services and Dedicated Centers.

During the quarter, Syngene took important steps as part of its strategic priorities.

Earlier this month, it announced a deal to acquire a multimodal Biologics plant from Stelis that added an additional 20,000 liters of installed manufacturing capacity along with a high-speed fill and finish facility. The proposed acquisition strengthens Syngene's position as a leading biologics contract manufacturer and development service provider.

Syngene completed the acquisition of additional land in Hyderabad to support the long-term growth ambitions of its research services business divisions.

Together, these actions reflect meaningful progress on Syngene's strategy to straddle both research and manufacturing services and give it the capacity it needs for the next stage of growth.

In conclusion, I believe the Biocon Group of companies has delivered a strong business performance this quarter, essentially a very robust revenue led performance and established clear pathways for exciting new growth inflections.

Building on their shared heritage in Biocon's manufacturing and scientific excellence, Biocon Biologics, Biocon Generics and Syngene are now emerging as uniquely differentiated world-class players in the global biotechnology products and services markets.

I firmly believe that these are very exciting times for the Biocon Group, and I look forward to reporting our progress in the coming quarters.

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

Q&A Session

Saurabh Paliwal: We will start with the first question from Damayanti Kerai from HSBC. Please go ahead.

Damayanti Kerai: **Hello. Hi. Good morning. My first question is understanding the pricing environment for biosimilars a bit better. So, ma'am mentioned about Fulphila seeing an impact of higher rebates during the quarter, but can you talk a bit about how you're seeing pricing for other biosimilars? Say, Semglee or Ogivri. Because in terms of prescription, we have seen pickup in all the products, but when I compare the reported sales, excluding licensing income, we have seen sequential moderation. So, want to understand the pricing part better.**

Kiran Mazumdar-Shaw: Matt, Shreehas, over to you.

Shreehas Tambe: Matt, you can start, then I can jump in after you're done. Go ahead, Matt.

Matthew Erick: Yeah. So, the pricing that we're seeing in discount trends, they've not been uniform. So, when you think about your medical side or your pharmacy benefit side, they vary by product and therapeutic area and by channel, and there is a difference in between each one of those. So, taking a similarity that you would see in one product and comparing it to another does not necessarily translate. And so, I think what Kiran had said in the beginning, particularly around Pegfilgrastim, there is a change in how we're looking at the rebates that were legacy. And what we're seeing on the other products, we are seeing very active growth and good growth in those other channels like Semglee, Trastuzumab, etc.

Damayanti Kerai: **So, specifically, on insulin, what we have been hearing, I guess, there has been a lot of focus on lowering the prices from all the stakeholders in the industry, so from Semglee's perspective, did you see any such pricing pressure coming in?**

Matthew Erick: So, I believe, you are talking about the WAC's that are changing on 1/1/24. So, as we're seeing it right now, no, there is not that pressure. And, remember, on Semglee, particularly there are two channels, you have your branded and your unbranded products, and we're playing in both of those. So, there is a mixed variation on those rebates between low WAC and high WAC. But the mix continues to be in a positive manner that we're seeing with our Insulin Glargine and Semglee.

Damayanti Kerai: **Okay. Thanks. Thanks for your response. My second and last question is, post Hulio launch, can you update us on what you're hearing from payors or what has been their response, and any discussion which is currently ongoing for prices, etc.? And how do you see your share moving up in this particular market?**

Matthew Erick: Thank you very much for the question. These are very, very early days, and the payors' landscape is still developing. I think, what's important that you've seen is early announcements - let me remind you, the overall size of the pie is extremely large with the multiple opportunities we have and then co-existing with multiple players. So just these early announcements that you've seen come out on the commercial side and, as Kiran said in her opening remarks, there are multiple channels. Not only do you have commercial, but you have Medicaid, you have Medicare, you have government, you have GPOs, you have IDNs. So, these multiple channels allow us to continue to participate in many aspects as this market is continuing to develop, which is slower, the overall market has seen the payors taking their time.

But I think what's important to remember, the attributes of our products and our relationships and sales force are very strong with our two-click Hulio product, which payors as well as physicians like. We do have a strong sales force. We are supporting hub services and patient services. And so, we're in active discussions with all the payers as this market continues to develop, which you'll see through 2023 and into 2024 as this market continues to develop and we're well positioned to participate.

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

Matthew Erick: Thank You!

Saurabh Paliwal: Thanks, Damayanti. We'll take the next question from Harith Ahamed from Aventus Spark. Please go ahead.

Harith Ahamed: **Thanks for the opportunity. My first question is on the Core EBITDA margins that you disclosed for Biocon Biologics. It's at 28% this quarter and I see that it was around 39% last quarter. So, there is a sharp decline and you called out the timing of some tender business supplies in EMS and higher rebates for Pegfilgrastim. But if you can quantify the impact of these, that'll be helpful, because it's a fairly sharp decline?**

Kiran Mazumdar Shaw: Yes. I think, Shreehas, you should explain this.

Shreehas Tambe: Thanks, Kiran. Thanks, Harith, for that question. As Kiran said in her opening remarks, we've seen strong growth in our products, overall, in North America, in all our products we've shown the year-on-year growths that we've had. So, clearly, the business is trending in the right direction and our market shares are growing. We've had a situation with one product, where we've had these managed care customers, where the legacy Viatris contracts had a higher rebate, which is offered to select customers. Now, that was in the region of around USD 15 million. That has been since reset and most of those resets happened beginning of this current quarter, which is starting July. So, what we are seeing from here on is that we expect these to basically recover over the coming

quarters and we see business recovering to normal margins over the course, as we take these contracts again.

Important to note, Harith, is that, July onwards, we've seen Pegfilgrastim market share grow to 19% and we are now the largest biosimilar Pegfilgrastim in the US market. So, clearly, that is a good recovery from where we are, and we expect this to get better over the coming quarters.

Harith, does that answer your question?

Harith Ahamed: **Yes. I was on mute. That's helpful. My second question, if you can share the breakup between regulated markets and emerging markets for Biocon Biologics revenues for the quarter.**

Shreehas Tambe: So, that breakdown we can offer. Chini, do you have that breakdown overall between advanced markets and emerging? In the past, Harith, we've given a guidance that it's been roughly around that 70:30 mark. Chini, what's the breakdown for this, we can share with Harith.

MB Chinappa: Harith, good morning, it's 75% advanced markets, 25% emerging markets.

Harith Ahamed: **Okay. And a follow-up, the licensing income that you booked for the quarter, that is related to the regulated market geography or the emerging market segment? And one more question around the licensing income, this figure of ₹167 crores, this licensing income pertains to deals that were signed during the quarter or these are deals that we've partnered in the past and the revenue booking is happening now?**

Shreehas Tambe: Harith, as we said, even in previous quarters, we've had this discussion. In-licensing and out-licensing is a part of our business, and we will see this as we decide on our portfolio and we will in-license products and you will see that happen in a particular quarter and you will see out-licensing of certain assets that we may not see particularly wanting to develop or in a particular geography and we will see that happen across a certain quarter. We saw some of that happening this quarter and that was the recognition of that ₹167 crores that you talked about. So, you will see this happen in a particular quarter, may not necessarily happen in every quarter. As these opportunities mature or we make a strategic decision on what and how we want to pursue our portfolio, you will see these occurring over and around every quarter.

Harith Ahamed: **And it's a mix of emerging markets and regulated markets, that's the way to look at the numbers?**

Shreehas Tambe: Yeah. I mean, it could be emerging markets, it could be in advanced market, depending on how we are looking to license the portfolio and commercialize it going forward.

Harith Ahamed: **All right. Thanks, Shreehas. That's all from my side.**

Saurabh Paliwal: Thanks, Harith. We'll take the next question of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: **Yeah. Thanks for this opportunity. The first clarification about this US\$15 million**

charge relating to the Pegfilgrastim. So, is it fair to believe that this is a charge because of the new contract and relating to the next 12-month period? And depending upon the pricing situation and rebate situation and competition, a similar charge on the product would come in the subsequent period or subsequent contract? That is one. And, also, whether this kind of enhanced rebate and charge can come relating to other products like Herceptin and all that?

Shreehas Tambe: Let me respond to you Surya on this. I think, what we had clarified even in the opening remarks and now, this is about the past. So, there are legacy contracts that were signed in the past as Viartis is running the business today, and what we realized is that certain select customers in the Managed Care segment had been offered higher rebates. So, this is for a business that is in the past and those rebates are then passed on, our discounts are passed on as they book the revenues and those had to be reset. What we've done now is we've reset these contracts. So, going forward, that's why you will not see those things come in and hence we are saying that, in the coming quarters, these things will get better. Big part of this has changed starting July 1 and hence we are seeing these improve right away.

Did I clarify that part Surya?

Surya Patra: **Yes. Certainly, sir. But it will not be related, means, we will not see any kind of charge like this relating to other products?**

Shreehas Tambe: We are not aware of any charge at this point on any other product. This is related to Pegfilgrastim, and we've corrected that charge and reset those contracts and, going forward, we will be seeing those margins coming back to normal.

Surya Patra: **Okay. Now, sir, just one another clarification I wanted to have. When we talk about this market share for any product, in the US, let's say, so is it the total prescription that is really written or it is the prescription that is billed?**

Shreehas Tambe: Matt, do you want to respond to Surya's question?

Matthew Erick: Yes. Sorry, Shreehas, I couldn't really understand the question, I apologize.

Shreehas Tambe: Let me respond to that, Surya, a little bit and then see if, Matt, you want to add on. Surya, these are market shares that are reported today for say Glargine, since you asked about it, our market share between the branded and the unbranded products, we have two of them and that is a little under 12% today, and that's what we're saying has grown. The new prescriptions are trending at around 15%, so that's a leading indicator of where things are going. And Kiran did mention in her opening remarks that we also have on-boarded a large closed or managed care customer. Those numbers don't get necessarily accounted for in the market shares that are reported, and we believe that's also a very strong indicator in terms of how our Glargine will drive growth starting from the current quarter, moving forward.

But, Matt, if you want to add anything further to that.

Matthew Erick: Well, I think you covered it, Shreehas, and I apologize I couldn't hear that question. Thank

you.

Surya Patra: **My question was, sir, so recent studies indicate that the prescription generated or retained for any product in the biosimilars are meaningfully different than the prescription filled by the patient actually. So that is why, in terms of the market share when we are mentioning, so is it based on prescription written or based on prescription filled?**

Matthew Erick: I think, you're asking about what we can see as current prescriptions and then what's being written new. And if I'm hearing you right, so new prescriptions give you an indication for refills or continued prescriptions in the future. And I think what you're looking at it, particularly in Semglee or Insulin Glargine, if you're looking at the IQVIA data, you're going to see the trends of the prescriptions that are being filled and then you can look at the new Rxs. Normally, the indication of new Rxs will give you a good read on how the trends of the prescriptions are going to continue to grow.

Now, as Shreehas said, when we won this large closed network in July, those do not report in IQVIA and that can vary your market share and understanding, but what we're seeing is growth not only in new Rxs but growth in our partners, which will be closed door networks as well as payors.

So, hopefully, that answered your question. If not, I will try again.

Kiran Mazumdar Shaw: I think Surya to just simplify it, the 12% is the prescription filled and NRxs are the prescriptions written. 15% is trending towards how much extra is being written and 12% is really indicating how much is filled.

Surya Patra: **Oh, that is really helpful. My third question is relating to the integration thing what you mentioned in the opening remark, ma'am, about the Viatris strategy and the integration in the US and that is likely to be completed by second quarter, so what practical changes that we mean by this? Because we know that the marketing arrangement or the marketing support, we are currently taking from Viatris for next kind of one and a half year or so more, so this integration will bring what kind of a benefit, let's say, in the US?**

Kiran Mazumdar Shaw: So maybe, Shreehas, you would like to take that question?

Shreehas Tambe: Yes. Thanks, Kiran. I think, Surya, as you know, that we had signed up with Viatris for a two-year transition services agreement. And as you rightly said, the commercial team that Viatris had is a part of that deal that we had, which will be coming over from Viatris to us. However, the reason we had signed up this two-year transition services agreement is because there were functions that we needed to get ready outside of commercial, so that we can actually run a successful business in the US, and we had given ourselves a two-year window to be ready with that infrastructure.

Today, we feel confident having moved over 70 markets in the emerging market space. We're feeling quite confident with the leadership that we've put in place under Matt's leadership and the other leaders that we have brought on board in the US and in North

America and Canada, so we believe that we are in a good place to move the business over to be led by Biocon Biologics by the end of this quarter and we also have a very good alignment with the team that's coming over from Viatriis to us and that's why we believe that we can accelerate this transition, bringing greater focus to the business that will now be only focused on the biosimilars, which should then benefit what we're trying to achieve as a company.

Surya Patra: **Okay. Sure. Yeah. Thank you, sir. Thanks. Thanks a lot.**

Saurabh Paliwal: Thank you, Surya. We'll take the next question of Neha Manpuria from Bank of America. Please go ahead.

Neha Manpuria: **Yeah. Thanks for taking my question. My first question is on, I think in the presentation you made a comment about core margins going back to the mid-30s by the end of FY 2024. Based on your comment that the one-off that we saw in rebates should normalize, any reason for why we should see a more gradual improvement in core margins versus our full-year guidance of mid-30 to high-30 margins?**

Kiran Mazumdar Shaw: Neha, I said before the end of the quarters - I mean end of the fiscal, so I think we expect to see it sooner. But, basically, I'm guiding for the fact that to we have reset the rebates and hope that over the coming quarters, we get back to normalcy, as Shreehas mentioned.

Neha Manpuria: **Apologies, I was on mute. So, ma'am, just to understand this clearly, we're still holding a mid-30s guidance for FY 2024, the core margin guidance that we've given for biosimilars?**

Kiran Mazumdar Shaw: Yes.

Neha Manpuria: **Understood. And my second question is on Hulio. Shreehas, based on the contracts that have been announced so far and given that there has been a more gradual uptake in the entire Adali biosimilar market, what's your sense on when we can get clarity on how payors think about allocating volumes? And when would we get a better sense on what the opportunity could be for Biocon?**

Shreehas Tambe: Thanks, Neha, for that question. And, as Matt answered earlier, the opportunity is very sizable. So, the Humira opportunity in the US is a very sizable opportunity. We believe that this decision making will happen over the course of this calendar year, so we should have that clarity on how things will evolve. There are commercial plans, commercial health plans, which we'd make a decision, which is about, I would say, a part of that business, a large part of the US market. But outside of that, as Matt and Kiran in her opening remarks addressed, that there are several other pieces of the market, which would be the managed care market, the Medicare market, and I think basically while these decisions will be made during the course of the year, you will see, and we've said this in the past as well, that the business will track forward from 2023, yielding up to 2024 and you will see most of these things really consolidate towards 2025. I think this is what we've heard from all other industry players as well and that opportunity remains intact. And even from our perspective, we're very well positioned to realize that opportunity given the kind of product

that we've developed, the success that we ride on the back of what we've achieved in Europe, and the kind of team that we've got, which is very well aligned to commercialize Hulo in the US with the product and the patient service programs that we've got. So, we feel quite confident Neha, as the decisions get made over the course of the few months ahead of us.

Neha Manpuria: **And in your assessment, Shreehas, what portion of the market, the commercial contracts that have been announced that we've seen. I assume this would be for the next 12 months, and what portion of the market do you think has already locked in and probably not available for us?**

Shreehas Tambe: So, the two things that I want to draw your attention to, and I'll respond two things separately. One is, if you look at the overall US market, the commercial space is roughly 50% between the large payors and then a bunch of other smaller players as well. What we have seen made public so far are two commercial payors, two large commercial made announcements. And if you noticed that announcement, they've said that they continue to look at these as an evolving thing, it's not like this is it, and no one else will be looked at. So, we don't see this as a definitive position. What we see is what is announced at this point is a set of players who have been enrolled on two health plans and we see most of the other things still evolving as we go around. So that's why the commentary that Kiran had.

Neha Manpuria: **Understood.**

Saurabh Paliwal: Thank you, Neha. We'll take the next question from Shyam Srinivasan from Goldman Sachs. Please go ahead.

Shyam Srinivasan: **Good morning and thank you for taking my questions. Just the first one on the sequential run rate for the Biocon Biosimilar segment. How should we look at this as we go forward? We were expecting a faster ramp-up, I know you talked about the reset in Pegfilgrastim as well as the tender business change, but how should we look at it as we move through the quarters? And a related question is just on some of the market shares that we had aspirations for, especially Semglee, both branded and unbranded. You talked about the fact that in MCOs don't get added in IQVIA, I get that, but the high-teens market share that we were talking about earlier, is that something that we can certainly do? So, that's the first set of questions.**

Kiran Mazumdar Shaw: So, Shyam, let me answer that by saying that, yes, the USD 15 million impact that we see in the rebate on Pegfilgrastim has also impacted our topline as it has impacted our Core EBITDA and EBITDA as well. So, it has basically run through our financials. So, yes, that is the reason why you have not seen an uptick (in revenue) in terms of increased market share.

The second thing is, of course, we are very encouraged and confident that our performance in the US and many, many other markets is showing good growth, and we expect that to translate into both revenue and bottom-line growth. So, that's what I would

say at this point in time, but maybe Shreehas you'd like to add something.

Shreehas Tambe: Sure. Thanks, Kiran. I think, Shyam, to your question, two things, I would say. One is, we also partly responded on this to what Neha had said, if you were to look at that USD 15 million and if you add that back even in the current numbers, I think, like Kiran said to the revenues and to the Core EBITDA, the quality of earnings is already at that mid-30s. So, the business that is trending today is already quite strong, both in terms of the revenues that we're looking at and in terms of the margins that it's trending towards. I think, where the aspect of the uptick is also expected is in the emerging market side, which, as you know, a large part of that business is dependent on tenders and, as Kiran also alluded to in her opening remarks, some of this is going to be different from quarter-to-quarter. As you see those tenders realize in effect, you will see those move between quarters. But, otherwise, the emerging markets business has done well, but the advanced market business has really been driving that growth. And we see that in place.

And your second question, which was related to Semglee. I think, the closed-door managed care market, that customer will certainly add a huge muscle to that number, because that's a single supplier situation, which means there is no other competitor, and we are seeing a very high degree of conversion from the incumbent to us. We expect to see that driving growth for us. We also see that driving market share. And outside of this, Kiran also referred to the large commercial payer, so this is the managed care player, but there is also a large commercial player who's signed this on. Some of this will play out towards the beginning of calendar year 2024, which will then drive growth for us in the last quarter of this fiscal, Shyam.

Shyam Srinivasan: **Shreehas, so is there a change to the market share guidance on Semglee, I think that is where I was trying to arrive at?**

Shreehas Tambe: I think, we're still tracking to that mid-teens that we had said, Shyam. I don't think we are moving from that just yet. So, no reason for us to think differently.

Shyam Srinivasan: **Got it. And just going back to the opening on Hulio and the gradual progress and expectations have been or rather the actual has been slower than expectations and the ramp up over 2023, 2024, 2025. Just wanted to understand your experience in Europe, some of the numbers that you're sharing for Germany or France are pretty good numbers. So, do you think that is something that over time gets replicated in the US? Or you thinking dynamics are very different? So that was my second question.**

Shreehas Tambe: Matt, would you like to respond to that?

Matthew Erick: Look, thank you for recognizing Europe as being very strong and I agree with you. What we're seeing there is good, strong, steady growth. And as we go through this integration, as Kiran talked about, and fully transitioning away from Viatrix by the end of the year, I see that continue to grow, because we are going to have that 100% focus and we'll be able to drive additional Adali built off of a great base of what we're already doing in Germany and France and Belgium, and then taking that into expanding that

focus into other European countries. So, we are very optimistic around maintaining that strong, steady growth in Europe and maintaining our lead positions within Europe, France and then gaining traction in other countries within the European Union.

Shyam Srinivasan: **Helpful. Last question is for Siddharth, just on the Generics business, I think 15% growth, if you can just help us disaggregate that into what is happening in API versus formulation? There's been lots of commentary around the generic pricing. I think you, in your press release, talked about new contract wins, so help us walk through that, please? Thank you.**

Siddharth Mittal: Sure, Shyam. So, we've seen many new contracts, I mean, in the formulations business in the US. We have seen disruption in the US coming from other generic players and as a fully vertically integrated player, especially in the statins and immunosuppressant space, has led us to garner additional market share. I think, when you track the IMS for some of the products that we have in the market, it's doing very well. We are getting closer to between 30% and 40% market share in the statins and, soon, we expect that we will be able to get the additional market share for immunosuppressants.

And the bulk of the growth is from formulations. But as I mentioned that we've also seen a good traction of immunosuppressant APIs, which continues to be a focus area and a growth driver for us.

As far as the pricing is concerned, I think there are mixed trends. We've seen the pricing pressure taper down. We have seen our prices stabilize over the last few months and we just hope that this trend continues and at least in that way we are able to grow sustainably.

Shyam Srinivasan: **To that data point, just a split of, API and formulations? Thank you.**

Siddharth Mittal: See, our formulations business actually touched ₹200 crore this quarter. So out of ₹700 crores, ₹200 crores is formulations and little over ₹400 crores is API and the remaining is other income.

Shyam Srinivasan: Got it. Thank you, and all the best.

Siddharth Mittal: Thank You.

Saurabh Paliwal: Thank you, Shyam. We'll take the next question from Parth Shah from Bernstein. Please go ahead.

Nithya Balasubramanian: **Hi. This is Nithya from Bernstein. Quick one on Glargine. If you can indicate what is the incremental lives covered that you can now address with the new payor coverage wins that you've had?**

Matthew Erick: Are you talking about the lives?

Nithya Balasubramanian: **Yes. Incremental lives that is now being covered with the new payor wins you have had in Glargine?**

Matthew Erick: Yeah. As far as these are confidential right now from a standpoint of these closed-door in a large payor, I think what we continue to say is that it's really about the market

share.

Number of lives, because we've seen at one of the closed-door, if you're familiar with them, they will do pretty close to 90%, 95% conversion. And as we get into the latter half of this year or the last half of our quarter, in FY 2024, this is where the second payor will come on. And we're anticipating there, we will also be exclusive. So, we'll start seeing additional pull-through. But the number of lives do vary. That's why I didn't answer directly. It's really about the revenue and pull through. And we are exclusive on both of those contracts. So, you'll see that pull through over a period of time and the closed-door will pull through already and continue to grow as we go forward. Not trying to dodge your question, just lives aren't particularly the indicator. It's really the pull through with market share and are you exclusive on these contracts.

Nithya Balasubramanian: Got it. I think, I'll wait for whenever you're comfortable talking about the payer.

Matthew Erick: Thank you. Thank you very much.

Nithya Balasubramanian: On Hulio, if you can let us know what is the status of your interchangeability study? When are you filing it? When should we expect an approval? BI should lose their exclusivity in July, so will you be ready by then?

Shreehas Tambe: So, I think, Nithya, thanks for that question. Let me respond to that. I think, interchangeability - we are working on that study. We should be in a position to give you more details about when we'll have it.

We won't have it in July, since you have a direct question there, but we will have that study in play and as long as you have that information together, we believe it will work to our advantage.

Nithya Balasubramanian: Got it. One last one, if I may. On Aflibercept, I understand there is a litigation that's ongoing between Biocon, Viatrix and Regeneron. Early August was when the closing on arguments are supposed to be read, can you give us an understanding or understanding of when you are expecting the judgment to come through?

Shreehas Tambe: So, as you know, we are in an ongoing litigation on that. We feel as that is undergoing right now, there's not a specific date which has been set out and wouldn't be fair to comment anything further on it. But to say that we remain quite confident, and we feel good about how things have progressed.

Nithya Balasubramanian: Got it. Thank You.

Saurabh Paliwal: Thank you, Nithya. And we'll take the next question from Tarang Agrawal from Old Bridge Capital.

Tarang Agarwal: Hi. Good morning. Two questions from me. One, Chini, in terms of accounting, would there be any intersegment sale between the Hold Co and Biocon Biologics? If so, what would be the nature of these sales?

And, second, if you could give us the business-wise CapEx outlook for FY 2024 between Generics, Biologics, and Syngene? Thanks.

- M.B. Chinappa:** Tarang, most of the sales of Biocon Biologics is to third parties, the ₹2,015 crores, largely third parties, very little support services we provide to Biocon Limited or any of the other group companies.
- Tarang Agarwal:** **Okay.**
- M.B. Chinappa:** On CapEx, I'll let Indranil take the group, but BBL's CapEx projections for the year is USD 150 million, largely for the Malaysia expansion as we are ramping up our insulin capacities.
- Indranil Sen:** I'll take it for the Generics and maybe, Sibaji, you can talk for Syngene. So, Generics, we will be seeing close to USD 100 million CapEx for next year, between USD 80 million to USD 100 million.
- Sibaji Biswas:** Thanks, Indranil. And for Syngene, we will be spending close to USD 85 million and close to USD 50 million of that will be in research business, rest of it will be in development and manufacturing.
- Tarang Agarwal:** **Thank you.**
- Saurabh Paliwal:** Thank you, Tarang. We'll take the next question from Yash Tanna from iThought Advisory. Go ahead.
- Yash Tanna:** **Good morning. My first question is on Biocon Biologics. So, if I see the capital employed, it has grown at a much faster rate versus the profitability, which has led to ROCEs coming down for the BBL business. So, my question is, in the next two to three years, do we expect this trend to sort of reverse? Because, I believe, we are largely done with our expansions and acquisitions and profitability going ahead should support our return ratios?**
- Kiran Mazumdar Shaw:** Yes. That is the intent and that is what we're working towards.
- Yash Tanna:** **Right. And do we have a target number in mind, ma'am, for the next, let's say, three years down the line now, we have our internal benchmarks set for the business?**
- Kiran Mazumdar Shaw:** So, you do know that we are in the midst of the capacity expansion in Malaysia and as you know the sort of payback on that will happen once it's commissioned and, as you know, all these CapEx projects in the Biologics business is a multi-year kind of commissioning process and so, obviously, we will start seeing the ROCE reflected at a much healthier level, probably at the end of the fiscal year 2025 and beyond.
- Yash Tanna:** **Yeah. Got it. That's helpful. On the insulin side, I believe since we are in a position now to offer higher rebates to the pharmacy benefit. Have you seen any impact benefit of that because the other innovator companies have reduced the prices, right?**
- Kiran Mazumdar Shaw:** I've not understood your question, but maybe Shreehas, if you understood it, you could answer it.
- Shreehas Tambe:** Yeah. I think, what Yash is referring to is the high WAC and a low WAC dual pricing strategy and the opportunity to do that. I'll let Matt respond to it, and then if there is anything

more, I'll come back. Matt, would you want to respond to Yash's question?

Matthew Erick:

Yeah. Yeah. Sure. So, look, like I said before, it's a mixed play with the rebates and, look, I just want to say this before we start on just the economics. I mean, we do provide additional value with our products like Semglee or Insulin Glargine, but we will remain competitive. But the rebates between the high and low based on payor contracts can vary. So, as we look at the mix, it's very important how we consider when we did this process, what's of the branded Semglee and what's of the low WAC Insulin Glargine. We do see variations and these variations are by payor or PBM or by customer. So, what I would say from a standpoint, we're in good COGS position to maintain and compete with competitors.

And, also, to point out and, lastly, to remember, the WAC piece is just the list price. It's not the net. And so, when you see these WACs lowering, there is all kinds of things that can go into this. But, in closing, Biocon Biologics maintains a good cost position, and this is why you're seeing that maintain growth in the growth of that profitability.

Yash Tanna:

Right. That's helpful. Finally, on the debt side, is there any target number we want to reach by the end of the financial year 2024?

Kiran Mazumdar Shaw:

So, we are basically looking at our debt covenants and seeing how we can basically align with that, and we will raise funds accordingly.

Yash Tanna:

Sure. All right. Thank you, and best of luck.

Saurabh Paliwal:

Thank you, Yash. We'll take the next question of Masira Vasanwala from FSSA Investment Advisors. Please go ahead.

Masira Vasanwala:

I wanted to ask about the facility inspection in the biosimilar business, just maybe could you help us understand why we are having another round of observations in Malaysia, do we need to make more investments in people, processes, etc.? And then, yeah, just how are you thinking about this?

Kiran Mazumdar Shaw:

Yeah. So, maybe, I'll get our Quality Head, Michael Cutter, to answer this question.

Michael Cutter:

Yeah. Thank you very much, Kiran. So, yeah, thank you very much for this question. I think it's a very important question and I'm sure many people have this. So, the inspection that we had in Malaysia, was a routine inspection. We had our previous inspection some three years ago and we had some observations, six observations for the drug substance to the drug product and the laboratories, so it covered that as the scope, and we had two observations for our devices. So, there were two parts to the inspection.

The nature of these observations were not systemic. There was no data integrity. And I think the way that I would characterize these observations, they were really demonstrating that we are making good progress in this facility. So, there were no upgrades to the facility. In any case, we have the expansion project going on there, which is in-line with best practices in the industry. So, there are no infrastructure changes that we needed to make out of this. This is mostly procedural. They were training of some of our support people. This was the nature of the inspection observations. So, to that extent, there was nothing

that we intended to do in terms of structural modifications to the facility.

Does that answer the question okay?

Masira Vasanwala: **Yeah. I mean, the fact that our launches are getting delayed, because we're still waiting for the approvals on these facilities, is there more that needs to be done to sort of accelerate that?**

Kiran Mazumdar Shaw: So, let me answer that question, Masira, we have actually provided a CAPA plan, which has been accepted for those launches and approvals, of course, there are two approvals, as you know, one is for Insulin Aspart and the other one is for Bevacizumab. The Insulin Aspart CAPA plan has already been accepted by US FDA, and we're hoping that that is adequate. But we remain engaged to make sure that this is our understanding.

The second thing is, of course, as far as the Bevacizumab approval is concerned, that is in India, and that CAPA has also been given, the CRL response is also about to be given. So, that should also get resolved hopefully very, very soon. But beyond that, we can't really predict when it will happen, it's up to US FDA to really look at what we have provided them. We are hoping that the inspection in Malaysia will also further strengthen and address any concerns they have about approving Aspart, so that's as best as we can hope for.

Michael Cutter: Thank you for that, Kiran, and I think it summed it up very well. Masira, is that okay for you?

Masira Vasanwala: **Yeah. That answers my question. And just one more question, what is the net debt today or as of the latest quarter?**

Kiran Mazumdar Shaw: For the full company, Siddharth?

Indranil Sen: Can I answer that, Sid?

Kiran Mazumdar Shaw: Yeah, please go ahead.

Siddharth Mittal: Yeah, please go ahead.

Indranil Sen: Yeah. So, excluding the structured investments, we're at USD 1.2 billion net debt.

Masira Vasanwala: **Thank You.**

Saurabh Paliwal: Thank you, Masira. We'll take the next question from Cyndrella Carvalho from JM Financial. Please go ahead.

Cyndrella Carvalho: **Thanks for the opportunity. Just a little more clarification on Aspart and Bevacizumab approval. Beva you mentioned that we got a CRL. Was it related with the plant only that we are responding? Can you just clarify?**

Kiran Mazumdar Shaw: Yes.

Shreehas Tambe: Yes.

Kiran Mazumdar Shaw: It was actually because of the facility in Bangalore. There were some observations. We

have basically provided a CAPA plan and a CRL response, so that is what I was referring to.

Cyndrella Carvalho: **Okay. And in terms of our Beva approval, do you see anything pending from our end, apart from the facility?**

Kiran Mazumdar Shaw: So, there's never been ever any scientific concerns about any of our programs. So, as far as the CMC and others are concerned, this has never been a question. In recent times, the only observations we've had in a pre-approval inspection is pertaining to the facilities and that's what we've been addressing.

Cyndrella Carvalho: **Yeah. And, on the Aspart approval, do you think we wouldn't require a PAI sort of inspection again followed or, in your mind, it's not necessary? Because in my mind, it's not necessary, but I just need to clarify the same from you?**

Kiran Mazumdar Shaw: Well, that's what we also hope.

Cyndrella Carvalho: **That's really helpful. And just to Siddharth, how do we see the Generic growth given that you alluded to pricing being more stable in US, how should we expect our overall growth trajectory from the Generic side of our business?**

Siddharth Mittal: We guided for a mid-teen growth this fiscal. We would, of course, see a better second half, because some of our facilities which were commissioned last year and we've kind of doing the validation at this time and we expect the additional supplies to starting from these facilities, and these were brownfield capacity expansions, so does not necessarily need FDA to come and inspect as compared to the new greenfield facilities, which requires inspection and that adds more time for commercialization. And we also are looking at locking in additional business in the US on our formulation side and launching few new products as we go along. We've already got few approvals and I think this quarter itself we have two new launches that are there.

Cyndrella Carvalho: **So, should we look for a closer to a double-digit growth rather than a mid-teens, like a higher double-digit growth, is that right?**

Siddharth Mittal: That's what we hope for, quite honestly. It's high teen. I mean, the high double-digit, but the visibility that we have as we stand in the fifth month of the fiscal, I think, I'm confident on the mid-teens. But, of course, we would see what we can do to get to the higher double-digit.

Cyndrella Carvalho: **Thank you so much, and all the best, team.**

Siddharth Mittal: Thank You.

Saurabh Paliwal: Thank you, Cyndrella. We'll take the next question of Vishal Manchanda from Systematix. Please go ahead.

Vishal Manchanda: **So, my question is on the Generic business. On the peptide facility that's going to come up in the first half, can you guide how many filings we have on the peptide front? And, if possible, the total market that we're addressing through these filings?**

Siddharth Mittal: So, we have around 15 peptides at various stages of development, of which we've already filed Liraglutide in the US, Europe, and many other markets, both the strengths, Victoza and Saxenda, and they are being reviewed by FDA as well as the European Agency. And if you look at the overall peptides' opportunity, even though these 15 molecules are addressing diabetes, weight loss and other indications, but just the weight loss and diabetes management market size is expected to be over USD 100 billion in the next 10 years or so. So, we definitely see this being a huge, huge growth driver for the Generics business over the next decade or so.

Vishal Manchanda: **So, the other filings will follow up, so Liraglutide is done and the others will follow up from here?**

Siddharth Mittal: That's right.

Vishal Manchanda: **And second on the immunosuppressant facility, could you guide on the peak sales potential and the investments made there, the facility at Vizag?**

Siddharth Mittal: See, we've invested close to see ₹600 crores on that facility and we already have a significant capacity in Bangalore. So, this was an add-on facility and now we would be looking at locking in more customers, mainly in the emerging markets, where we also see a huge opportunity. But since our capacities were locked in primarily for US and few large markets, we were not able to address these opportunities and we definitely think that we will have a much bigger market share in markets like -- even China, where we are looking at addressing that market in the years to come.

But in terms of revenue guidance, I think it will be difficult to give right now, because we've of course been selling both the API as well as the formulations, which we will be commercializing in these emerging markets.

Vishal Manchanda: **So, the Vizag facility also houses our formulation facility?**

Siddharth Mittal: No, the formulations would be done in Bangalore. We've only one formulation facility for potent molecules.

Vishal Manchanda: **Right. So, if you could just guide us on the peak sales for the Vizag facility, the API business?**

Siddharth Mittal: That's what I've said. It will be a little premature to give that. I think we expect the revenues to commence sometime in second half of calendar 2024 and we are, of course, in discussions with customers to lock in and even with regulators where we're going to file from this facility. And I think we'll have a better sense, I would say, sometime next year in terms of the sales. We, of course, have internal numbers, which I don't want to communicate at this stage.

Vishal Manchanda: **Okay. And final one on Aflibercept, whether we are seeking interchangeability on the product?**

Shreehas Tambe: So, Vishal, the Aflibercept product we will be looking forward to that interchangeability.

Vishal Manchanda: **Right. And if interchangeability is granted, you might also be eligible for an**

exclusivity there?

Shreehas Tambe: Sorry, I didn't understand the question, Vishal.

Vishal Manchanda: **So, will you also be eligible for an exclusivity on Aflibercept considering that you are first to file?**

Shreehas Tambe: So, under the regulatory interchangeability guidance itself, the first interchangeable product has an exclusivity offer of one year since that launch. So, as an interchangeable product, you will have an exclusivity to claim interchangeability.

Vishal Manchanda: **Got it. Understood. Thank you. That's all from my side.**

Saurabh Paliwal: Thanks, Vishal. The next question is from Nitin Agarwal from DAM Capital. Please go ahead.

Nitin Agrawal: **Hi. Thanks. Siddharth, on the Generics business, there are future investments that you're making in the plants as well as in the R&D. Now, we are talking about 15% growth for this year from a growth revenue perspective. But if you can just do some sort of crystal gazing on where, I mean, how do you see this business over the next three to five years with the kind of investments we're making and what is the big picture story on the Generic business? Given the fact that we started out this business very late versus maybe a lot of the other peers?**

Siddharth Mittal: So, let me answer your latter question first, before I come to your first question. So, I think, in terms of the overall big picture for the years to come, we continue to invest in our fermentation, which has been our core in what we've been doing as a differentiated offering for more than two decades and we are building on to our portfolio in fermentation. So, that would continue to be one of our focus areas.

The second is peptides, I think the opportunity that peptides offer -- I had mentioned sometime back that over the next 10 years we look at almost USD 100 billion addressable market and, again, this has been, while many companies are attempting peptides, I think this is really about science, cutting edge science, and we think that the capabilities and the experience that we have had in developing molecules like peptides, we do have a good head start and we'll be able to play in this area very competitively in the years to come.

And, of course, we are looking at injectables as one of the focus areas where we would continue to forward integrate some of these peptides as well as the fermentation-based APIs into injectables and offer thereby continuity of supply and vertical integration to our customers.

And we will, of course, continue to invest in our synthetic pipeline, both onco as well as non-onco, because whether it's in the statin's basket, we will see us. I mean, you know that we have a leadership position in the statins globally both in the API and now in formulations in the US and we would continue to invest selectively also in the synthetic area.

Now, combining all the core strategies, which I mentioned, over a period of next four to

five years, on a CAGR basis, I definitely expect a high double-digit growth, so somewhere between, let's say, 17%, 18% to 20% kind of growth over a period of five years.

Nitin Agarwal: **And, Siddharth, on fermentation apart from the business you highlighted, peptides I understand, but on the fermentation barring immunosuppressants are there any large sub-segments you're focusing on, that can become bigger going forward?**

Siddharth Mittal: See, there are two ways to look at it. In the existing capabilities that we have here, we have not really worked on any new molecules over the last few years, and then we are working on handful of molecules. I mean, let me remind you that fermentation universe is not very large, there is still a limited number of molecules. So, some of the important molecules which we did not previously develop, we are working on it now.

The second aspect is, we are also looking at other areas of fermentation like potent fermentation, which we have never done in the past. There is precision fermentation, so there are other areas of fermentation where we can expand and we are evaluating what else can we do, including things like microbial fermentation.

Nitin Agarwal: **Nice. And last one from an inflection perspective, at what stage do you see the profitability inflection in the business?**

Siddharth Mittal: I think, I mean, of course, when I dissect our existing business, our fermentation business is quite profitable, but, of course, it's being cannibalized by the synthetic products, which have been under pressure for last few years. Now, from an inflection point, I think, the margin expansion should happen again from peptides, both API as well as formulation and majority of the profits are going to be driven by few molecules. And I think Copaxone, or glatiramer acetate is one drug which are hoping that we'll be able to get the approval soon. And, of course, the Liraglutides and all. these blockbusters launches are going to drive the profitability to higher levels.

Nitin Agarwal: **Thanks. And just last one on, what is debt that is there in the generics business ex. of what is sitting in Biologics?**

Siddharth Mittal: The Generics business is cash positive. I think, it's almost ₹1,100-1,200 crores of cash, actually it's almost ₹1,000 crores and there'll be some dividend paid out immediately after the AGM, but we'll still have ₹700-800 crores of cash in the system.

Nitin Agarwal: **And so, just, Chini, on Biologics, what would be the net debt situation right now?**

M.B Chinappa: It's just above USD 1.4 billion, Nitin.

Nitin Agarwal: **And this is taking the structured debt as equity.**

M.B Chinappa: Excluding structure debt. This is the bank debt that we talk about.

Nitin Agarwal: **And earlier you mentioned something about the covenants, so do the covenant will require any specific fund infusion during the year or next year?**

- Kiran Mazumdar Shaw:** We'll calibrate it.
- Nitin Agarwal:** **Okay, ma'am. Okay. Thank you.**
- Saurabh Paliwal:** Thanks, Nitin. We'll take the next question from Ishita Jain from Ashika Stock Broking.
- Ishita Jain:** **Hi. Good morning. Thank you for taking my question. My question is on Semaglutide, specifically. Novo Nordisk in their earnings commentary have mentioned shortage in the molecule and the demand is pretty strong, so is there a CMO opportunity for us in Semaglutide?**
- Siddharth Mittal:** Well, that's for, of course, Novo to decide if they want a CMO. There have been already couple of filers in the US, so we were not amongst the first to file for Semaglutide. We have it under development and we, of course, expect that will be on the 181-day of Semaglutide, but at this stage, honestly, we have not explored being the CMO, because typically you know that when these innovators look at CMOs, they don't look at competitors. So, since we do have a generic product under development, it's unlikely that they will pick any generic players as a CMO. If at all, then they will bar the generic company to launch their own drugs. So, I mean, Novo is already working with pure play CDMOs or CMOs to manufacture Semaglutide and I think that's what would be more apt for them rather than looking at a generic company.
- Ishita Jain:** **Got it. And can you talk about the strengths we have for Semaglutide that we will be filing for?**
- Siddharth Mittal:** Well, I think it's the science. As I mentioned that these are complex peptides to develop, characterize these molecules does require a lot of understanding of these molecules in the amino acids and how you kind of link them and synthesize these molecules and that's the..
- Kiran Mazumdar Shaw:** She was asking about the strengths, so I think we will develop both strands for weight loss and the diabetes.
- Siddharth Mittal:** Okay. There are three formulations for Semaglutide - Wegovy, Ozempic and Rybelsus – the oral, so we will be developing all three.
- Ishita Jian:** **Got it. Thank you so much.**
- Saurabh Paliwal:** Thank you, Ishita. The next question is again from Nithya from Bernstein. A follow-up.
- Nithya Balasubramanian:** **Thank you. This is again on Semaglutide. So, Semaglutide, the registered process is a recombinant process, but if you look at during discovery, it was actually done using a synthetic process. And I can fully imagine players trying to figure out a synthetic process because your COGS and operating efficiency is much better. So, do you see that as a threat to your cost position? And a broader related question which is that, if I look at Tirzepatide, I think it's a synthetic process? I know there are lot many more peptides in the pipeline, but do you eventually see synthetic route of synthesis being figured out for most of these and therefore your fermentation capacity is not really having long-term growth potential, how do**

you think about it?

Kiran Mazumdar Shaw: Contrary to your perception, actually recombinant processes are more effective and cheaper to produce.

Siddharth Mittal: Yeah.

Kiran Mazumdar Shaw: I think, the big question is the clinical trials that might be needed to establish the immunogenic similarity. I think, that's why people prefer to go down this synthetic route. But we have capabilities in both, and we will basically, closer to the timeline, decide how do we approach this particular opportunity.

Siddharth Mittal: So, we will have both the products, synthetic as well as recombinant. And I think that's what will be the differentiator compared to other competitors, who mostly have only synthetic product. And the regulatory path today, especially in the US, is more driving towards the synthetic than towards recombinant. And, as Kiran mentioned, if it's a recombinant product you need extensive Phase 1, Phase 3 kind of trials.

Kiran Mazumdar Shaw: Or at least Phase 1.

Siddharth Mittal: At least Phase 1. And COGS, I think, Kiran already mentioned, in fermentation, is lower than synthetic. But when you look at the overall cost of the drug product, it's not a big differentiator in cost, because the majority of the cost comes from devices and drug product filling than from the API alone.

Nithya Balasubramanian: Thank You!

Saurabh Paliwal: Thank you, Nithya. We will take the next question of Sai Priyanka from MedSphere. Please go ahead.

Sai Priyanka: **Hello. Good morning, everyone. Thank you for the opportunity. I would like to ask about Yesafili. And what were the key points presented in the closing arguments of the BPCIA patent dance case between Mylan product and Regeneron? And how might these arguments impact the approval and launch of the Yesafili? Thank you.**

Shreehas Tambe: So, let me respond to that question. See, there are things on the argument that I won't comment on, which is in the litigation, but I will tell you that this has been a very different litigation in terms of an expedited request that was made, where we are litigating on a number of patents which are limited. And we will look to see how the interim judgment comes through. As I've responded earlier, there is a guidance date, but we don't know exactly how that will play through.

Now, as regards to whether it has an implication on the approval, the answer to that is only for the final approval. The approvability through a conditional approval, like we talked, and Kiran referred to in her opening remarks, where Health Canada has already approved conditional to the outcome of the litigation or the loss of exclusivity basically. So that is where it does not affect. You've also seen the European Authorities recommend the CHMP for approval and we're looking forward to the FDA to do the same. So, we look at that conditional approval, subject to LOE.

Sai Priyanka: **Okay. Thank you.**

Saurabh Paliwal: Thank you, Sai. Ladies and gentlemen, that's was the last question for today's call. I thank you for joining us today. If you have any further questions or need clarifications, please do get in touch with us. With this, we will conclude. Have a wonderful rest of the day. Thank you.

- Ends -

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