August 17, 2024

Listing Department **Code: *532321***
BSE LIMITED
P J Towers, Dalal Street,
Mumbai-400001

Listing Department **Code: *ZYDUSLIFE***
NATIONAL STOCK EXCHANGE OF INDIA LIMITED
Exchange Plaza, C/1, Block G,
Bandra Kurla Complex,
Bandra (E),
Mumbai-400051

Sub: **Transcript of the post results earnings call held on August 9, 2024 pursuant to regulations 30 and 46(2)(oa) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ("the Listing Regulations")**

Dear Sir / Madam,

Pursuant to regulations 30 and 46(2)(oa) of the Listing Regulations, please find attached the transcript of the Company's Q1 FY25 post results earnings call held on August 9, 2024.

Please find the same in order.

Thanking you,

Yours faithfully,
For, **ZYDUS LIFESCIENCES LIMITED**

DHAVAL NARENDRA SONI
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COMPANY SECRETARY

Encl.: As above

“Zydus Lifesciences Limited Q1 FY25 Post Results Earnings Call”

August 9, 2024

MANAGEMENT: **DR. SHARVIL PATEL - MANAGING DIRECTOR, ZYDUS LIFESCIENCES LIMITED**
MR. GANESH NAYAK - EXECUTIVE DIRECTOR, ZYDUS LIFESCIENCES LIMITED
MR. NITIN PAREKH - CHIEF FINANCIAL OFFICER, ZYDUS LIFESCIENCES LIMITED
MR. ARVIND BOTHRA - SENIOR VICE PRESIDENT, INVESTOR RELATIONS, ZYDUS LIFESCIENCES LIMITED
MR. ALOK GARG - SENIOR VICE PRESIDENT, MD OFFICE, ZYDUS LIFESCIENCES LIMITED

Moderator: Good afternoon, everyone. Welcome to Zydus Life Sciences Limited Q1 FY25 Earnings Conference Call. Please note that all participant lines will be in 'listen only' mode and there will be an opportunity for you to ask questions after the opening remarks. Please note that this conference is being recorded. I now hand over the conference to Mr. Ganesh Nayak - Executive Director of Zydus Life Sciences. Thank you and over to you.

Ganesh Nayak: Good afternoon, ladies and gentlemen. Welcome to our post results teleconference for the quarter ended June 30th, 2024. For today's call, we have with us, Dr. Sharvil Patel - Managing Director, Mr. Nitin Parekh - Chief Financial Officer, Mr. Arvind Bothra - Senior Vice President, Investor Relations and Mr. Alok Garg - Senior Vice President from the Managing Director's Office.

Let me now give you a broad overview of the developments during the quarter.

It's my pleasure to share that we commenced fiscal 2025 on a strong note, sustaining the growth momentum across the businesses during the quarter. Overall, we delivered a strong double-digit growth during the quarter. This, coupled with sustained profitability improvement, has helped us achieve the highest ever operating profit and margins during the quarter. Our India branded formulations business outperformed the market growth with 13% year-on-year growth. The consumer wellness business delivered an industry leading double-digit growth during the quarter, aided by improved demand scenario and an extended summer season. Our US formulations business delivered a stellar performance both on a sequential and year-on-year basis, driven by new launches and volume expansion in the base portfolio. Our international business continued its growth trajectory during the quarter.

With that, let me take you through the financial numbers for the quarter gone by. We registered consolidated revenues of Rs. 62.1 billion, up 21% on a year-on-year basis and 12% on a quarter-on-quarter basis. EBITDA for the quarter was Rs. 20.8 billion, a growth of 38% on a year-on-year and 28% on a quarter-on-quarter basis. EBITDA margin for the quarter stood at 33.6%, which is an improvement of 430 basis points on a year-on-year and 410 basis points on a quarter-on-quarter basis. Net profit for the quarter stood at Rs. 14.2 billion, up 31% on a year-on-year and 20% on a quarter-on-quarter basis. We deleveraged our balance sheet during the quarter by repaying the entire debt.

Now, let me take you through the operating highlights for the first quarter of FY25 for our key business segments.

Our India geography, which comprises of the formulations and consumer wellness businesses, accounted for 37% of the total revenues during the quarter and grew 15% year-on-year.

As mentioned earlier, our branded formulations business in India grew faster than the market during the quarter with 13% year-on-year growth. The business outpaced the market growth both in the chronic and acute segments. Portfolio of key pillar brands and innovation products registered strong volume growth, driving the overall performance during the quarter. We launched 10 new products, including line extensions with three first-in-India launches. We retained our leadership position in the nephrology and remained the fastest growing Indian company in oncology in the IPM. The business grew faster than the market in key therapies of cardiology, gynaecology, derma, respiratory, anti-infectives and super specialty therapies of oncology and nephrology. Contribution of chronic portfolio has increased consistently over the last several years and stood at 41.3% as per IQVIA MAT June, 2024, which is an improvement of 430 basis points over the last three years.

Our consumer wellness business recorded revenues of Rs. 8.4 billion, up 21% on a year-on-year basis. The growth was broad based and largely driven by 17% volume growth. The personal care segment, which comprises of Nycil and the EverYuth brands, continued to deliver robust performance with yet another quarter of strong double-digit growth. Food and nutrition segment witnessed recovery during the quarter and posted double digit growth as well. Gross margins continued to improve both sequentially and on a year-on-year basis.

Now let me take you through the performance of our US formulations business. The business accounted for 51% of the consolidated revenues during the quarter with revenues of Rs. 30.9 billion, up 23% on a sequential basis. We launched seven new products during the quarter. New launches for the quarter include the launch of our second 505(b)(2) product, viz. Zituvimet in the area of metabolic disorder management and Mirabegron ER tablets. We filed five additional ANDAs and received approval for six ANDAs, including two tentative approvals, during the quarter.

On the international markets front, the demand scenario remains strong across key markets despite ongoing political and economic

challenges in some of the countries. Overall, the business posted revenues of Rs. 5.3 billion, up 9% year-on-year.

On the operations front, the USFDA has classified two of our injectable facilities located in the Ahmedabad SEZ and at Jarod near Baroda as 'Official Action Indicated', which is OAI. We are working closely with the USFDA to implement the necessary corrective actions as required.

Now this concludes the business review. I would now request Dr. Sharvil Patel to take you through the key drivers across businesses as well as initiatives in our innovation program. Thank you.

Dr. Sharvil Patel: Thank you, Mr. Nayak, and good afternoon, ladies and gentlemen. It is a pleasure to have you all here on the call today. We are pleased with our performance during the quarter. All our businesses continued their robust growth journey from the previous fiscal and performed on expected lines with a focus on fulfilling diverse healthcare needs of the customers across the markets. We remain committed to strengthen our core business and explore newer avenues to generate better outcomes for our patients.

On the India formulations front, our efforts are directed towards expanding the presence across focused therapies, and in turn, serve a larger set of customers. We have successfully leveraged our rich and diverse portfolio of innovation products to offer novel solutions to the patients to satisfy their unmet healthcare needs. We have been conducting various patient support programs and activities to create greater awareness amongst patients, particularly in the areas of the unmet healthcare needs.

In the US, multiple building blocks such as a comprehensive portfolio of generics across dosage forms, capability to deliver novel solutions to patients through the LiqMeds acquisition in the specialty space, and investments in rare disease space, are now in place. This will greatly enhance our ability to address diverse patient needs. This, coupled with strong customer relationships, a network of regulatory compliant manufacturing facilities and an agile supply chain will ensure sustained growth trajectory for the US business going forward.

On the international market front, our focus remains on expanding the presence in selected therapies across key emerging markets by leveraging our global R&D portfolio of generics and

specialty products. Our innovation pipeline across different areas continues to make progress and achieve the desired milestones.

With this, let me share some material developments on our innovation efforts during the quarter.

On the NCE research front, during the quarter, we completed patient recruitment for the Phase II(b)/ III clinical trials of Saroglitazar Magnesium for primary biliary cholangitis indication and Phase II(b) clinical trials of Saroglitazar Magnesium for metabolic dysfunction-associated steatohepatitis, which is known as MASH indication for the US. We also completed patient recruitment for Phase II clinical trials of Usnoflast, earlier known as ZYIL1, for Amyotrophic lateral sclerosis which is known as ALS indication during the quarter. In the biotech R&D space, we submitted a marketing authorization application for one of the monoclonal antibodies to the Indian regulator. On the novel biologics front, we initiated a Phase I clinical trial in India for an anti-properdin molecule during the quarter. Recently, in the month of July, we received marketing approvals from the Mexican regulatory authority for two products viz Bhava™, which is the biosimilar of Bevacizumab and Mamitra™ for the biosimilar of Trastuzumab. On the specialty and 505(b)(2) development front, recently, in the month of July, we received final approval for our third NDA viz. Zituvimet™ XR, which is the sitagliptin metformin extended-release tablets in the area of metabolic disorder management. With this approval, we now have all three NDAs of Sitagliptin and combination franchise approved through the 505(b)(2) route. All the three NDAs have received first cycle approvals.

Thank you. And now we can start with the Q&A session. Over to the coordinator for the Q&A. Thank you very much.

Moderator: We'll now begin the Question & Answer session. Anyone who wishes to ask questions may raise your hand from Participant tab on your screen. Participants are requested to use headphones or earphones while asking questions. Ladies and gentlemen, we will wait for a moment while the question queue assembles.

The first question is from Yash Gandhi.

Yash Gandhi: Thanks for the opportunity. Sir, congratulations again on a great set of numbers. I think, this quarter, we've got 33% EBITDA margin, one of the highest the company has ever seen in the history. So, I just want to understand the sustainability of this sort of margin going into the next two quarters or for the year.

Dr. Sharvil Patel: So, I think obviously, this quarter has been an exceptionally good quarter on the margins front. And as we have stated earlier that last year, we ended on a high with a 27.5% margin. And with looking at the phasing of the coming year, we expect to see an improvement in the margin by 100 to 150 basis points from FY24 margin.

Yash Gandhi: Okay. And sir, again on the US business. So, this year we've grown 26% YoY. This is an excellent growth. How do you see the trajectory of the US formulation business doing this year?

Dr. Sharvil Patel: So, we see healthy double-digit growth for the US business during the coming financial year, this financial year.

Yash Gandhi: Okay. Got it. That was it. Thank you.

Moderator: Thank you. The next question is from Kunal.

Kunal: Good afternoon. Sir, first question would be the revenue guidance that we had provided for FY25. We had said almost from high teens kind of top line growth that we expected. Since the first quarter has been meaningfully above that, are we revising it or we are staying with the same guidance?

Dr. Sharvil Patel: We continue to believe that we will deliver high teens growth for this year.

Kunal: And on one of the speciality portfolio across two geographies, one is US, wherein we have now few commercialized products like Zokinvy. So, would you be quantifying the current contribution of our speciality portfolio in US?

Dr. Sharvil Patel: I think it's still in the very early stages. As I said, the patient acquisition or the finding new patients is a slow process in the US. So, once it becomes sizable and meaningful, we will obviously talk about it differently. But right now, it doesn't form a major part of the overall revenue.

Kunal: And last one on the India business. We have a portfolio of speciality product with our in-house research like Saroglitazar and some of the first-in-market, biosimilar launches, etc. So, to that extent, we have also said that that portfolio has grown very strongly. Could you quantify the current contribution of that portfolio for us?

Dr. Sharvil Patel: I don't think. Our focus on India is not driven by dosage form. It's a therapy and disease focus and brand focus. So, I don't think we do it that way. But as I said, they do form an integral part of the

overall future innovative portfolio that we have, which is both, as you mentioned, the Saroglitazar and the breast cancer and other oncology therapies that we are working on. So, it's more a disease area where we look at it and how much share of that area we do have. And as we alluded, like in oncology, we are now the largest and the fastest growing organization. And similarly in nephrology and other segments. Obviously, aided by both the proprietary products that we have, but also the products that are required beyond just the couple of new drugs that we have.

Kunal: Is it fair to say that there'll be more launches coming, and hence this portfolio will keep getting bigger and bigger, which is high growth?

Dr. Sharvil Patel: Yes, that is a right statement. We do expect these products to become the largest brands for the organization, which will obviously mean that they'll form a larger part of the overall portfolio.

Kunal: Thank you.

Nitin Parekh: Can the coordinator ensure that all others are on mute? There's some noise coming for other people talking.

Moderator: Thank you, Kunal. The next question is from Neha.

Neha: Yeah, thanks for taking my question. Sir, given you're maintaining your margin guidance of the 150 basis points margin expansion. Is it fair to assume that the cost base that we've seen in this quarter, let's say the R&D cost or the other operating cost, R&D would materially increase from here, the SG&A cost would remain at these levels? Because this was a seasonally strong quarter for the India business as well as US, we did higher. So how should we think about the operating cost from a run rate perspective?

Nitin Parekh: Excluding R&D, Neha, there has been an increase in this particular quarter, but about 125 crores in this quarter are of one off nature. And therefore, I think 1,200 to 1,250 other costs excluding R&D would be the right basis for you to project.

Neha: What is this 125 crores related to Sir, the one off that you mentioned?

Nitin Parekh: There are some ERF related costs, there are some legal cost provisions, there are some project related consultancy assignments, some professional fees, many items within that. But they are of non-recurring nature.

Neha: Okay. And on the R&D, how should we look at the R&D, given we have the patient recruitment completed for two of our NCE products?

Dr. Sharvil Patel: So as I said, our expectation is that we will see around an 8% kind of spend on R&D. And that's what we hope to maintain.

Neha: 8% of sales for a full year basis.

Dr. Sharvil Patel: Yeah.

Neha: Understood. My second question is on the US business. Obviously, this quarter we had the benefit of the Revlimid as well as Mirabegron. As we think about the subsequent… first, in this quarter, was there any improvement in the base business besides Revlimid and Mira, and was Revlimid flattish quarter-on-quarter, higher quarter-on-quarter, any qualitative colour there?

Dr. Sharvil Patel: So, Revlimid was obviously higher quarter-on-quarter and there was a ramp up to the base business also.

Neha: Okay. Understood. And as I think about the next three or four quarters. Other than Mira, can you give us some colour on what sort of launches we should be expecting? Any other meaningful launch that we should be seeing? Anything that you can provide us on the US for the base business?

Dr. Sharvil Patel: As I said, we do expect a double-digit growth in the US, and that factors in obviously our current base business and new product launches.

Neha: Okay. And how many launches should we be expecting this year, Sir?

Dr. Sharvil Patel: For the full year, we expect around 25 plus launches.

Neha: Okay. Understood. And my last question, given we have ample amount of net cash that we're sitting on, sorry, given the ample amount of cash generation, how should we look at capital allocation strategy for future growth? What would be two or three key areas that you will be focusing on for inorganic growth opportunities? And any ticket size that you're thinking would be, something that you'd be comfortable with?

Dr. Sharvil Patel: Yeah, so, I think as I had also tried to speak about in the last quarter. I think, our key focus will be scaling up our speciality business in the US. And for that, obviously we will look to see how do we deploy efficiently our capital to not only scale up the business, but also have a diversified large business on the

speciality front. The second area is India. India, we've done well. We understand the business well. We will continue to see if there are opportunities in India, both from the brand side or some other adjacencies. And recently, with the last five years' good scale up of our international business and also good profitability that we're seeing, we do believe there can be specific opportunities in the international businesses that we will look to do.

Beyond that, I think, as I said, we have transformed from just being a pharmaceutical business to more of a life sciences organization. And that would mean that, how do we create the right solutions for the patients in different areas will become important. So, going beyond the pill becomes very critical for us. So, whether it is companion diagnostic, med devices or medical med devices or direct-to-patient services, we will be looking at many of these opportunities to scale up our business further.

Neha: Understood, okay. Thank you so much, sir.

Moderator: Thank you, Neha. The next question is from Bino.

Bino: Hi, good evening. I have a few questions. To start with on Mirabegron, how do you look at it?

Moderator: Bino, your voice is not audible. Can you speak loudly?

Bino: Hello, is it better now?

Dr. Sharvil Patel: Yes.

Bino: Okay, great. How do you look at the timelines on Mirabegron? I know it's difficult because litigation is going on. But do you think this can be a few quarters' opportunity or will it last till the next patent expiry? How do you look at it?

Dr. Sharvil Patel: I think you answered it saying it is difficult to answer that question. But at least, I think, short term, at least for the next couple of quarters, it is what it is today. But a little longer term is still very difficult to answer.

Bino: Second on this product, Opsumit or Macitentan. I believe you had an FTF in that. Is that still valid? Because I saw somebody got an approval whom I thought was not an FTF.

Dr. Sharvil Patel: So, I won't have a direct answer on this. It's better my team gets back to you on it specifically so that I don't give it. But I do remember that we did have some first-to-file status. But I'll request my team to give you more specific details on it.

Bino: Sure, sure. And regarding Cabometyx which we recently in-licensed. I believe there was a court verdict expected sometime around this time. Is it, has it come yet?

Dr. Sharvil Patel: I'm sorry. Could you repeat the molecule? Which one did you say?

Bino: Cabometyx. Which we in-licensed recently?

Dr. Sharvil Patel: The one from MSN, right?

Binu: Yeah.

Dr. Sharvil Patel: So, I think that's under still litigation. So as and when we have any outcome on that, we can discuss that. But obviously, it seems to be a good product for the future.

Bino: And finally, on Saroglitazar PBC indication. When do you expect the readout? Any timeline?

Dr. Sharvil Patel: It will be in the next financial year. Hopefully in the end of, I mean, second quarter of next financial year.

Bino: Okay, so FY26. So, filing would next year? So, it could be an FY27 opportunity if everything goes well?

Dr. Sharvil Patel: Yeah.

Bino: Thank you. I'll join back.

Moderator: Thank you. The next question is from Harsh.

Harsh: Hi, good afternoon, sir. My question is pretty broad based on the US industry. So, after COVID, we had a couple of years of, not for the company, but overall, at the industry level, we had some sort of headwinds in terms of price erosion and lower demand. So, just wanted to get a macro view over the next 2-3 years. What kind of environment are we seeing in terms of FDA approvals and the pricing of the base generic formulations?

Dr. Sharvil Patel: So, I think on the approval side, FDA continues to deliver good number of approvals. So, I think fundamentally, that remains constant. I think also, I don't think the nature of business has changed in the US. It is a highly competitive, price sensitive market. And so, whether it was COVID or earlier or now, we don't see any fundamentally different ways of behaving in the market. I think what succeeds in the market is portfolio, your service levels and how fast are you able to deliver your products and what kind of service levels you are able to maintain with your customers, and strong focus on profitability helps you make the right

decisions, I think. So fundamentally, all those things remain the same for that market, whether it was in the past or for the future.

Harsh: And in terms of demand scenario, do you feel anything is different for next 2-3 years compared to what it was after COVID between 2020 and 2023? And in comparison, do you feel the demand scenario changing materially over the next 2-3 years?

Dr. Sharvil Patel: No, I think at least when we look at our generics business, it all depends on large molecules going off patent. And as you can see, till the next five years, there are significant amount of products that will still go off patent. So, the pipeline of future generic portfolio remains attractive.

Harsh: Sure. And for the international business, the rest of the world business, we see a lot of pharma companies now focusing on that pie of the market. So how does it sit in your overall strategy? And what kind of growth do you foresee over next, if I have to take a 3 to 5 years kind of horizon?

Dr. Sharvil Patel: Yeah, so I think, for us, the international businesses have delivered a consistent double-digit CAGR over the last five years, and also have shown significant improvement in profitability. So, we believe going forward, the business will definitely scale up meaningfully with strong double-digit growth, and also will continue on the improvement on profitability. So, we are quite bullish on the international market. And that's why we said we will also continue to look at adding more products and geographies to expand it.

Harsh: Sure. Thank you. And that was from my end. Thank you.

Moderator: Thank you. The next question is from Saion.

Saion Mukherjee: Yeah, thanks for taking my question. Dr. Sharvil, your comments suggest that scaling up US specialties is one of the things that you will be pursuing. I'm wondering if you can provide some aspiration that you carry with respect to the US business. How you want to do this? We have mixed experience, it seems to be a tough one. I just want to understand what capabilities you would need to sort of develop, to address that opportunity in a way that, and what kind of risk and size of acquisition are you looking at? Because, I would understand that it probably would require an acquisition for you to meaningfully scale up US specialty. So, if you can give some colour. I mean, we are aware of some of the products that you're developing, the rare disease, the liver disease. It would be

great if you can give some clarity as to how you're thinking about this business and what are the steps we should expect.

Dr. Sharvil Patel: Sure. So, I think there are two areas that we are focusing on when it comes to the US specialty side. One is the rare disease business through our business unit of Sentynl Therapeutics. So, today we have two commercialized products, one which we just recently acquired, and one which we had done a few years ago, a year ago. And we have a third molecule, which is the CUTX-101, which is in the NDA stage of filing. So currently, it's a three-asset business. And the way we look at it is that, slowly build that business up over the next two years, mostly through small inorganic opportunities, to scale that up, and build a niche rare disease business.

Now in the rare disease business, the focus has to be, obviously for us to have a product-to-market, because again, the disease is very rare. But then it is to find new patients, which means a lot of work that needs to get done in education, in getting early diagnosis, and getting the right diagnosis and treatment, because these are life-saving drugs. So, our effort is on creating a larger access for some of these drugs and finding the patients at the right time so that we can make them available.

With respect to the orphan disease business that we hope to build, today, we have one asset, which is Saro. If everything goes well, it's a calendar year 27 kind of opportunity to commercialize. I do agree that our aspiration is to be in more than one product and not just a single product, though Saro on its own has a good business profile that we can build on. But we will look at an inorganic opportunity over the next two years to have a commercially ready footprint in the US when Saro comes up for launch. And that is what we hope to do in the next two years, to find a commercial asset that we can either partner or we could acquire, and build a front end commercial asset in the US, which can also take Saro with it. Even if it doesn't, we do already have an organic plan to build our own commercial team in the US. But we will keep both options open for us for the orphan side of it in the US. So, these are the two areas we hope to build. We definitely don't want to be a one product company. So, Saro is very important right now, but we will hope to build on to it either through licensing or inorganic opportunity. And if you look at the timeline, obviously, '27 is Saro, but our future molecules are 2030 and beyond. So, we do, in the next five years, require some more options beyond just Saro. So that's what we will focus on.

Saion Mukherjee: Great. The second question I had was on biosimilars. So, you have done quite well in India, plus some emerging market approvals have also come through. But unlike many of the peers who have global development targeting US and Europe, you have generally avoided that space. So, while you are pursuing a different strategy here, is there any change in thought process with the evolving regulation, or the competitive dynamics? Anything that you can share given the capabilities that you've already built for India and emerging markets?

Dr. Sharvil Patel: Yes, I think, we are quite aligned in terms of what we need to do for India and US, both in terms of the offerings that we can give in terms of a large pipeline of biosimilars, and also the annual capacities that we have built for, which is quite large and total monoclonal capacity of almost 350 KL. I think why we decided not to enter the developed markets, were two reasons. One is both from the investment point of view, the investments were pretty large and sizable for doing a generic version of a biologic. And the second was obviously access to the market looking at the high rebates that exist in different markets. So, I think we found it very difficult to justify the investment from our point of view.

I think two reasons will make us think again about it. One is obviously, if the investment thesis comes down, which is, if we can go towards more generic strategy, which is a PK-PD strategy, then we can look at taking up some of the developed markets. And second, which we seem to think it is happening, is the interchangeability of biosimilars that may come to effect. So, if both those triggers happen, we would look to take development for the developed markets also. But currently, we are limited on that aspect.

And again, it's also to do with our allocation in terms of resources. We do have enough opportunities on the novel side, which has still higher risk, but obviously greater opportunity. So, we are focusing our efforts more on that side. But as I said, if both of these changes do happen, we would potentially look to see if we want to take it up for the developed market.

Saion Mukherjee: Yeah, great. Thanks. I'll join back.

Moderator: Thank you. The next question is from Kunal.

Kunal: Hi, thank you for the opportunity again. So, one on the product i.e. that was approved today Ingrezza. Is that a near-term opportunity that we should build either in FY25 or FY26?

Dr. Sharvil Patel: No.

Kunal: So it's more of a longer term opportunity?

Dr. Sharvil Patel: Yeah.

Kunal: Okay. So we have settlement, I guess, right? So, it should be in line with that settlement, is it a good way to put it?

Dr. Sharvil Patel: Yeah, it's definitely not a near term opportunity. And as I said, we do have exclusivity and sole exclusivity as we have stated. So, whenever that market formation happens, that will be the opportunity.

Kunal: And another one on the R&D expense, I'm not sure if this question was asked earlier. But we had said it would be between 7 to 8%. So, do we maintain that guidance even in the, let's say this year and in the medium term?

Dr. Sharvil Patel: Yes, for FY25, we maintain that guidance.

Kunal: Sure. And beyond FY25, do you think that some of the trials maybe for NASH etc., it could be large clinical trials, and we might need to accelerate the R&D?

Nitin Parekh: So, earlier we had guided that our R&D year on year may range between 7 to 9%, with average for three years around 8%. So, we continue with that guidance even today.

Kunal: Sure, sir. Thank you and all the best.

Moderator: Thank you Kunal. We'll wait for attendees to raise their hand and ask questions. The next question is from Saion Mukherjee.

Saion Mukherjee: Yeah, hi, thanks. On Sitagliptin and other approvals that you have, Sitagliptin and combination approvals for the US, how are you thinking about it based on the experience so far? I think you talked about possibly mid-high single-digit market share there. What are your latest expectations around the product?

Dr. Sharvil Patel: Yeah, so I think it's been a good learning for us on trying to see how do we get a 505(b)(2) market and successful. So, I think what we can say comfortably is that, because of this opportunity, and what we've been able to do, it's definitely not a one-year opportunity, but at least a three to five year opportunity. So, we will see consistent revenue on this business from this franchise, which is very meaningful and good for the organization and learning. So, as I said, it's not a one-year opportunity, but will continue for a longer period of time.

The second is we continue to see how do we get more access to the overall Gliptin franchise and we hope to build more market share from what we have done today. And we're seeing some good opportunities. So, time will tell whether if we can take up further opportunities for the coming year. But overall, it will be a meaningfully good product for us over the next three to five years.

Saion Mukherjee: Right? So, will Sitagliptin go generic before that? I mean, I'm just wondering whether you would have a window of five years to scale this up.

Dr. Sharvil Patel: It will go generic before, but we have a long-term contract which will not get renewed till five years.

Saion Mukherjee: Okay, understood. And, and the second one, I wanted to check on vaccines. I mean, it seems, you know, you talked about it FY27-28 timeframe. Any update on that, especially on the export side that you can share?

Dr. Sharvil Patel: Yes, I think we are on track for that period of time. There are three aspects that are important for our success. One is, pre-qualification of the facilities for the three vaccines. The second is the clinical trial completion at different stages and for post pre-qualification, to make sure that we can achieve that in that timeframe. And once we're able to achieve those two, then obviously is to participate in the public tenders that come up in FY27. So, we are on track to do that. No immediate hiccups, and at least on the PQ and other things we're going on a positive direction now.

Saion Mukherjee: So this is fiscal '27 or calendar '27 when the tenders come up?

Dr. Sharvil Patel: Ideally, it will be more fiscal '28. Calendar '27, fiscal '28.

Saion Mukherjee: Understood. Okay sir, thank you.

Moderator: Thank you. Requesting attendees to raise their hand for further questions. The next question is from Kunal.

Kunal: Thank you, sir. So, one on the ALS, for which we are doing the clinical trial for ZYIL1. If you could provide some colour on the disease landscape in terms of number of patients, potentially current treatment lines, and where are we planning to differentiate?

Dr. Sharvil Patel: So, I think more detail, I would definitely request Arvind to give you specifically. But on broader side, today, there are no critically

approved treatments for ALS. ALS is one of the classified orphan, rare diseases that exist. So, there is a sizable population of patients, both in India, if you look at it from a home market point of view, or obviously in US and other countries. So, a highly unmet need exists for patients with ALS. As you know, the lifespan is meaningfully only two to three years or less or around that period. So, it is a very debilitating disease. And as I said, with currently no class of treatment that is very effective, we see a good opportunity for Usnoflast in this area. Our Phase II trial recruitment is over. And if everything goes well, if we see good data and good blood barrier penetration, this will move into a rapid Phase II(b) or Phase III directly from a global program point of view. So, we are quite excited. I think the timeline for this trial would be shorter because of the need and the endpoints. So, it looks good in terms of a speedy development timeline for this drug, if we are able to meet the critical endpoints and the safety margins that we are required to do so.

And as I said, this therapy class has a broader opportunity in any motor neuron disorder. So, ALS is our first target. We will continue to explore Parkinson's as the other indication. And then, there are some other opportunities beyond that. But currently we are focused on these two indications.

Kunal: And one on the Saroglitazar. I think we had got some FDA voucher of… I think, fast-track designation or orphan drug designation. If you could remind us what that is and how that helps us in terms of development timeline or the exclusivity?

Dr. Sharvil Patel: So, we do have both those status. I think we don't have a voucher. Voucher you achieve when you get full approval. And then, if you still maintain both of those things, then you get a voucher. But I think voucher is not something that we are built in for right now. But we do get expedited review depending on the competition at that point in time and how many drugs are approved. So, I think, coming next financial year, we can give you more update once we file the NDA to suggest whether we are still in. We are definitely in the orphan space, but whether we are also in the fast-track space or not.

Kunal: Sure, sir. And any update on our recent compliance issues at Jarod facility? How are we planning to tackle it? Have we submitted more detailed CAPAs or have we kind of onboarded some consultant to resolve those observations?

Dr. Sharvil Patel: Yeah, I think we're taking it very seriously to make sure that we address the concerns. So, as a first step, we have obviously done

the response to the FDA in terms of the remediation that we have done and continue to do. The second aspect is to request the FDA for a meeting to talk about our long-term plan with both these sites, which we hope to do over the next quarter. And post that, we can keep you more updated to see how do we tackle the observations at the site. But we are working very closely to do so and we'll keep you updated if we have any more updates on that.

Kunal: And are there any compliance-related expenses already baked into our Quarter 1 number?

Dr. Sharvil Patel: So, right now, we are not using any external faculty. So, currently we don't have any external expenses. But whatever has to be built in, has already been built in.

Kunal: Sure, sir. Thank you and all the best.

Moderator: Thank you. The next question is from Nitin.

Nitin: Hi sir. Thanks for taking my question. Sharvil bhai, on the US business, this year, obviously, because of the Revlimid, as well as Mirabegron playing out the way it is playing out, and next year, we still have meaningful Revlimid tailwinds for us. Now, I mean, when you look at the US business, say FY27 onwards. I mean, do we have enough drivers in the business to really grow on the top of the high base that we'll end up creating in '25 and '26?

Dr. Sharvil Patel: Yes, I think, we do still have a good amount of pipeline of products to come through. Second, as I said, we do have some settlements which allow us sole exclusive launches in the years to come, which are meaningful. And so I think between the portfolio and exclusive launches, we do see an opportunity to continue to do well. And as I said, on the base business, we will continue to grow. So, we hope to continue to do that with the new launches.

Nitin: Thanks. And secondly, in the past, you've talked a bit about your plans for a) injectables and b) transdermals. So, if you can just give us a little more update on where we are on a complex injectable plans and on the transdermal launches?

Dr. Sharvil Patel: So, I think in transdermals, I think we are still couple of years away from full scale up. So, I think that business will continue to get built. On the injectables front again, I think most of our drug device kind of products are a few years out. So, nothing in the short term that we see. Many of these are more than a couple of years down the line plans. Transdermals is more nearer, but injectables is still a couple of years out.

Nitin: Okay. And secondly, on the India business. We've had a pretty good growth in this quarter. I mean, we have seen a meaningful pickup coming through in this business and improvement in momentum over the last few quarters now, as you've been highlighting. I mean, over this period of time, has there been a proportionate or meaningful increase in that domestic business profitability also, qualitatively?

Dr. Sharvil Patel: Yes, I think with the double-digit growth that we have delivered, we have seen good improvement in profitability also. And as I said, our sort of critical growth booster brands and key launches are now more than 45% plus of our business and growing very fast. So once that business becomes 60-65% of our overall growth driver, we will continue to see this strong momentum on growth.

Nitin: So, when you look at the next two years for the domestic business, what kind of market outperformance should one look forward to?

Dr. Sharvil Patel: I think we do expect to do better than market and register double digit growth.

Nitin: Okay. Thank you, sir.

Moderator: Thank you. The next question is from Alok.

Alok: So just a question which is pending on Asacol HD. Any update on that? Anything on the competition side?

Dr. Sharvil Patel: Yes, I think we still build for competition in this financial year. We were assuming there was some competition coming, but we haven't seen it yet.

Alok: And as per your intelligence, what is keeping the competition away?

Dr. Sharvil Patel: I think it's a difficult product to develop. So, we took quite a while to do it. I guess people are also struggling.

Alok: Okay. And for the US for this year, how many new product launches are being planned?

Dr. Sharvil Patel: 25 plus.

Alok: Okay. All right. That's it from my side. Thank you.

Moderator: Thank you. The next question is from Tushar.

Tushar: Sir, just firstly on generic Vascepa. How has been the scale up in this product? Are we now to the run rate where we expect to be, or we are yet to reach that stable run rate?

Dr. Sharvil Patel: No, we are far away. We will require, I mean, right now it's not at the run rate that we expected because of the capacities that we're not able to get from our partner. But meaningfully, I don't think anything in this calendar year can happen.

Tushar: Understood. So, is the capacity constraint on account of the regulatory issue at the partner's side, or the capacity build up itself is going to take much longer?

Dr. Sharvil Patel: The capacity build up. And pricing is very poor. So, we don't want to do it at this pricing.

Tushar: Understood. Sir secondly, just a clarification on EBITDA margin guidance of 28-29%. we are already at 29%. But this quarter was heavy both in terms of, let's say, Revlimid and consumer wellness compared to say the four quarters of FY25. And subsequently, it is going to be again, the fourth quarter to be of such kind of phenomenon. So still 28-29% guidance? Is it possible to call out other niche products in FY25, which can help sustain such kind of profitability apart from…?

Dr. Sharvil Patel: Last year, we achieved 27.5%. And our current guidance update for this year is about 100-150 basis points, better than FY24.

Tushar: Understood. And as the earlier participant was asking, this is considering Asacol HD competition. So, if that doesn't come true, we have scope to further improve the margins.

Dr. Sharvil Patel: Yes.

Tushar: All right.

Moderator: Thank you, Tushar. As there are no further questions from the participants, on behalf of Zydus Life Sciences Limited, that concludes this conference. Thank you for joining us. And you may now disconnect your lines and exit the webinar.

END OF TRANSCRIPT