May 24, 2023

Listing Department **Code: *532321***
BSE LIMITED
P J Towers, Dalal Street,
Mumbai–400 001

Listing Department **Code: *ZYDUSLIFE***
NATIONAL STOCK EXCHANGE OF INDIA LIMITED
Exchange Plaza, C/1, Block G,
Bandra Kurla Complex,
Bandra (E),
Mumbai–400 051

Sub: **Transcript of the Post Results Earnings Call held on May 18, 2023**

Dear Sir / Madam,

Pursuant to Regulations 30 and 46(2)(oa) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, please find attached the Transcript of the Company's Q4 FY23 post results earnings call held on May 18, 2023.

Please find the same in order.

Thanking you,

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

DHAVAL NARENDRA SONI
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Date: 2023.05.24 17:39:35 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

“Zydus Lifesciences Limited Q4 FY 23 Post Results Earnings Call”

May 18, 2023

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

Ganesh Nayak: Good evening, ladies and gentlemen. Welcome to our post results teleconference for the fourth quarter and the financial year ended March 31,2023. On today's call, we have with us Dr. Sharvil Patel, Managing Director; Mr. Nitin Parikh, Chief Financial Officer; Mr. Arvind Bothra, Senior Vice President, Investor Relations and Mr. Alok Garg, Senior Vice President from the Managing Director's Office.

I'm sure you would have gone through the financials and other material which we have filed with the stock exchanges.

To begin with, let me give you an overview of the performance for the year gone by. As we progressed through the year, all businesses demonstrated strong momentum and delivered double digit growth consistently. Consequently, we close the year on an encouraging note, with overall revenue growth of 14%. Our EBITDA growth of 16% was faster than the revenue growth, thanks to margin improvement achieved during the year.

Our formulations business in India built further on the growth momentum from the previous financial year and registered double-digit growth through the year on a COVID adjusted base. Our consumer wellness business grew in double digits despite softer consumer demand due to increased inflationary pressure affecting discretionary spends. Performance of our US formulations business improved significantly during the year as the business grew sequentially every quarter on the back of volume expansion and meaningful new product launches throughout the year. As a part of our ongoing initiative, we continuously analyse our spend base and identify and implement various ideas across functions to unlock the efficiencies in our operations. Our innovation journey continues to make progress and achieve important milestones.

With that, let me take you through the financial numbers for the year gone by. During the year, we recorded consolidated revenues of Rs. 172.4 billion, a growth of 14% year-on-year. EBITDA margins expanded during the year despite high base and stood at 22.4% of the revenues, which is an improvement of 30 basis points over the previous year. EBITDA margin, adjusted for one-time COVID related inventory provision, stood at 23.1%. Consequently, the consolidated EBITDA for the year grew by 16% to Rs. 38.6 billion. Net profit for the year, adjusted for certain exceptional and non-recurring items and the impact of discontinued operations, stood at Rs. 26.6 billion, up 16%. The balance sheet strengthened further

as we had a net cash position of Rs. 5.5 billion as on 31st March 2023 against the net cash of Rs. 0.6 billion as on 31st March, 2022.

With this, let me go to our performance for the quarter gone by. I'm happy to inform you that our quarterly revenues crossed the Rs. 50 billion mark driven by robust performance across segments. Coming to the quarterly financial numbers, we registered revenues of Rs. 50.1 billion, up 32% year-on-year. Reported EBITDA for the quarter was Rs. 12.6 billion, up 75% year-on-year and 31% quarter-on-quarter. EBITDA margin for the quarter stood at 25.1%, which is an improvement of 620 basis points on a year-on-year and 260 basis points on a quarter-on-quarter basis. Net profit, adjusted for certain exceptional and non-recurring items and the impact of discontinued operations, stood at Rs. 9 billion, up 71% year-on-year.

We expect all our businesses to sustain healthy growth on the back of our rich portfolio of products and focused execution efforts.

Now let me take you through the operating highlights for the fourth quarter of FY23 for our key business segments. Our India geography, which comprises of formulations and the consumer wellness business, accounted for 41% of the total revenues during the quarter and grew 11% year-on-year. The India geography consistently delivered double digit growth in the current fiscal, adjusted for COVID related revenues in formulations business last year. Our formulations business in the India geography posted revenues of Rs. 12.9 billion, up 11% year-on-year. Excluding revenues from COVID related products, growth during the quarter was 12% year-on-year. On a full year basis too, the business delivered 12% growth, excluding revenues from COVID related products from the base. We continued to work towards strengthening our presence in our focused therapy areas. Our first new chemical entity, the brand Lipaglyn continued to enhance the reach as it expanded the patient base by 37% during the year. On the super speciality front, we retained our leadership position in the nephrology segment while in the oncology space, we were the fastest growing company. Our consumer wellness business recorded revenues of Rs. 7.1 billion, up 12% year-on-year. The business experienced gradual recovery in consumer sentiments during the quarter though the urban demand still remained stronger than the rural demand. However, the rural demand slowdown seems to have bottomed out and we expect recovery going forward. With appropriate price increases across the portfolio undertaken over the last few quarters coupled with

stabilizing inflation in key inputs except milk, the business registered improvement in gross margins, and was in line with the gross margin of Q4 FY22.

Now let me take you to the performance of our US formulations business. The business accounted for 46% of the consolidated revenues during the quarter with revenues of Rs. 22.5 billion and registered robust 17% growth sequentially. The business delivered sequential growth during each quarter of the current financial year. Growth during the quarter was driven by new launches and volume expansion in existing products. We launched eight new products during the quarter. New launches for the quarter include Topiramate extended-release capsules, which was the first generic launch of the product in the US market. During the quarter, we filed two additional ANDAs and received 28 new product approvals, including five tentative approvals. Our Emerging Markets and Europe formulations business continued to deliver healthy growth with all major markets contributing to the growth during the quarter. The business posted revenues of Rs. 4.4 billion, up 34% year-on-year, excluding revenues from COVID related products.

During the quarter, our Moraiya formulations facility successfully completed the pre-approval inspection for transdermal patches by the USFDA. Recently, we received the EIR report from the USFDA for this inspection. Our formulations facility located in Ahmedabad SEZ (known as SEZ 1 facility) was also inspected by the USFDA, which was a pre-approval as well as GMP inspection. The inspection concluded with three observations. We submitted our response to the USFDA within the stipulated timeline and are awaiting their response to the same.

This concludes the business review. I will now request Dr. Sharvil Patel to take you through the key drivers across businesses and initiatives in our innovation program. Thank you.

Sharvil Patel: Thank you, Dr. Nayak. Good evening, ladies and gentlemen. It is a pleasure to have you all with us today on the call. We are pleased with our performance during the quarter and the year gone by as both our large geographies India and US continue to deliver consistent results driven by focus execution. Our initiatives in R&D have continued to progress favourably in order to meet patients' demands across geographies. These investments provide us the assurance of sustainable revenue and cash flow stream in the future. On the regulatory front, our Moraiya formulations facility successfully completed product pre-approval inspection by the

USFDA. It was the second successful inspection in Moraiya during the year. We will continue to offer high quality, safe and effective healthcare solutions to patients around the world, thanks to a commitment to upholding high quality standards and continual improvement in the same.

Our strategic initiatives and interventions over the last six quarters have enabled our India formulations business to deliver consistent double-digit growth. We expect the trend to continue as we remain committed to deliver better than industry growth in the medium term.

The US formulations business had a very successful year with revenue momentum continued to improve every quarter driven by new product launches and volume expansion. We received 63 ANDA approvals during the year, which is one of the highest number of ANDA approvals received in a single financial year for the company. The complex products pipeline developed in-house over the years, coupled with strategic BD&L efforts should help to deliver sustainable revenue growth in the future. Our agile supply chain will help us capitalize on the one time buy opportunities that emerge in the US generics market.

On the innovation front, we are committed to improving patients' lives, as evidenced by the success of our first NCE Saroglitazar Magnesium since its launch. We have also created one of the most extensive pipelines of biologicals, serving multiple markets including low and middle-income countries. This has made the treatments affordable and accessible for patients and in turn, has delivered strong volume growth consistently.

With this, let me talk about some of the material developments on the innovation effort. On the NCE front, our lead molecule Saroglitazar Magnesium is currently undergoing a Phase II (b) clinical trial in NASH indication and a Phase II(b)/ III clinical trial for PBC indication for the US market. During the quarter, we received approval from the regulatory authority of Turkey to conduct trials for NASH. The molecule is also undergoing clinical trials in the US for PCOS with NAFLD indications. During the quarter, the USFDA also granted an orphan drug designation status to our molecule ZYIL1 and NLRP3 inhibitor. Earlier this year, the molecule achieved positive proof-of-concept in a Phase II clinical trial in patients with Cryopyrin Associated Periodic Syndrome known as CAPS.

Coming to our vaccines' effort, on the global development front, we submitted one of the dossiers of the vaccine to the WHO for the purpose of pre-qualification. This is a second submission to

the WHO. Our rabies vaccine has already been received WHO pre-qualification. On the speciality front, our wholly owned subsidiary Sentynl Therapeutics continue to work with a licensing partner Cyprium Therapeutics to complete the NDA filing of CUTX-101 targeted at Menkes disease. The company also continued to work towards adding both Menkes disease and MoCD A deficiency to key genetic lab panels in the US. We are also working towards ensuring early access to Nulibry to patients of MOCD Type A deficiency.

Thank you and now we start the Q&A session. Over to the coordinator for the Q&A.

Moderator: Thank you very much. We will now begin question-answer session. Anyone who wishes to ask questions may raise your hand from the participant tab on your screen. Participants are requested to use headphone or earphone while asking a question. Ladies and gentlemen, we will wait for a moment while the question queue assembles. First question is from Saion Mukherjee.

Saion Mukherjee: Yes, hi, am I audible? Hi, Dr. Sharvil, first question is around the US momentum. You've seen a good momentum here now. Can you throw some light on some of the key assets on Revlimid, Topiramate capsule, Asacol HD and the likes and how should we think about 270 odd million dollars that you've achieved in this quarter? How should we think about the quarterly run rate going forward?

Sharvil Patel: So yes, I think on the US front, as I said, obviously last year, we did continue to improve quarter-on-quarter. Going forward also, we still are seeing a strong quarter one as we move into the new year. And I think over the full financial year, we still expect growth on the current base.

Saion Mukherjee: Okay, on Topiramate particularly, how's the competition like in the market? And is the number going to come down significantly in Q1 versus what you've recorded in Q4?

Sharvil Patel: Yes, so on Trokendi, we believe competition will enter, will be there in Q1 versus Q4. Having said so, in spite of that, I think we will see a good growth in quarter one.

Saion Mukherjee: Okay, and two questions one on, the second question on your, I see a significant increase in employee cost this quarter, if you can give some colour on that, and your expectation on R&D spend for next year.

Sharvil Patel: First, may be Nitin bhai, you like to take it up.

Nitin Parekh: So, year-on-year increase in cost is because of impact of increments. And also, if you consider actuarial valuation that we have done. So, this time we had actuarial loss that we had to provide for and in the last year same quarter, we had actuarial gain. That's the other factor, which is impacting the personnel cost.

Sharvil Patel: On the R&D, as we continue to say, we are likely to be around the 8% range. And if we see better positive outcomes on more projects, maybe 8-8.5% but we are probably range bound around that 8% to sales going forward.

Saion Mukherjee: Okay, and I mean, you mean to say incremental investments will be largely on your innovation programs or on the generic side?

Sharvil Patel: I think more so the incremental growth will come from the innovation.

Moderator: Thank you. Next question is from Kunal Dhamesha.

Kunal Dhamesha: Hi. Thank you for the opportunity and congratulations on a good set of numbers. Just digging a little bit more on the US revenue, would you be able to kind of give the primary driver on a quarter-on-quarter jump out of $40 million in terms of whether it was majorly new product launches, or whether it was kind of existing product and above and also the price erosion scenario in this quarter?

Sharvil Patel: So, obviously the larger jump is always because of new products. But as I said, the base business also did well. But the majority of the growth is driven by new products and we have received rich number of approvals, and we are still expecting some good approvals in during the year with limited competition. So, we are seeing a good value creation on the new products in this coming financial year.

Kunal Dhamesha: So, would you say that Revlimid was one of the major drivers of sequential jump?

Sharvil Patel: No no, it was an important driver for sure. And Revlimid will continue in quarter one also.

Kunal Dhamesha: And secondly, on the impairment charge, like you have taken on Sentynl, I found that we had already done with that. So, was there anything incremental which led us to take this impairment and

right now, let's say in the goodwill number on our balance sheet, is there anything left on that front?

Nitin Parekh: So, goodwill impairment of Sentynl refers to the legacy business that we had acquired of Sentynl in 2017. So, now, we don't have any products in the market. Gradually we started discontinuing certain products. Now, there are no more products of legacy business and that is why we have provided. While the assets which are, two assets that we acquired, they have nothing to do with this and in fact, the valuation of the total businesses was much higher than the goodwill impairment, but once we at a concept level thought that legacy business we are not continuing, we provided full amount of the goodwill of acquired business.

Kunal Dhamesha: Right now, there is nothing left about Sentynl.

Nitin Parekh: No, nothing left.

Kunal Dhamesha: So right now, whatever I see on consol balance sheet is more or less Heinz acquisition?

Nitin Parekh: Yes, there would be some goodwill due to internal merger also and Biochem acquisition earlier which is about Rs. 500 Crores. But large part of the goodwill is related to Heinz acquisition.

Moderator: The next question is from Bino.

Bino: Hi, good afternoon to all. So hi, congrats for a great set of numbers. A couple of questions around the US pipeline. Sharvil bhai, in the last call, you had mentioned about one REMS product in the US this year. Are we on track? And will you be able to throw a bit more colour on it?

Sharvil Patel: Yes, so we did have a large REMS payment in the last quarter three. And I think we are still planning for a quarter one. We have two products. Between quarter one and quarter two, launch is still expected for both the products.

Bino: Oh, and still it's not time to reveal the products, is it?

Sharvil Patel: It defy the principles of competition if we say things beforehand.

Bino: Okay. Understood. Asacol HD, competition always the kind of push out by at least six months. So, it's the same this time as well? Do you have any visibility or do we don't see anybody for next six months?

Sharvil Patel: Yes, so our best estimate is similar to what you just said. But I think the good thing that we can see from the business is with the

current new products and the new products we are expecting to launch we are more than offsetting Asacol any future losses.

Bino: And on Saroglitazar, the PBC study Phase III study is that on going as per schedule? all timelines are intact?

Sharvil Patel: Mostly on track. We may be one month delayed, but not anything major.

Moderator: The next question is from Surya Patra.

Surya Patra: Yes. Thanks for the opportunity and congrats for the great set of numbers. So, the first question is on the US business. So, is it possible to share let's say ex Revlimid what could be the US growth this year?

Sharvil Patel: No, I don't think we can do ex product because this is something, the US business is a composite business of all our products. So, I don't think we are separating out new products. The way the US business grows, is you try and protect your base and grow on new products. So, I sometimes find it very difficult to answer this question that every time people want to remove products, and then the whole point of the US business is to launch new products. So, I think this way of continuing to ask these questions is not good in the light of what a US business is. And the other point I said on concern on Revlimid. Revlimid continues to drive value in the last quarter, in the coming quarter and will continue to drive value in the next two years. So, it's not a one-off product, which people seem to think.

Surya Patra: Yes, of course. So, but now having seen ramp-up and progression at Revlimid front, is there any sense about what volume share that we might be getting, some sense if not the specific number.

Sharvil Patel: Sorry, can you repeat that question?

Surya Patra: So, having seen the ramp-up on the Revlimid prescription front for you and also in the business so far, so could you give some sense so what is the kind of volume share that you are expecting, let's say for, let's say progressively till '26 because up till now we have not been commenting anything on it.

Nitin Parekh: So directionally volumes are going to go up but we can't obviously give specific numbers that being a settlement.

Surya Patra: Okay. So, my second question is on let's say, the kind of approval that what we have seen this year, that is a record number of course for US, but wanted to have a sense that see there are many

small values, small targeted value products that we have witnessed in the list. So, these are like old filing which will pending because of the Moraiya facility issue and now getting released or it is the filing of recent past which are getting.

Sharvil Patel: It's a mix of both. I think there's a lot of background noise where you're talking from so we are finding it difficult.

Surya Patra: Yes. So, I was asking about the number of approvals what we have witnessed this quarter or so, or this year also full year. So, whether these, I mean we planned and filed for this products having very low target value in US or?

Sharvil Patel: US, I think let me explain the strategy on US. US, we are servicing key clients, key customers. A representation of having a large product portfolio is very important for US generic business and that is always what we have believed in and we strongly believe that a completion or completeness of portfolio is critical. So, from our point of view, it's important for us from servicing the small value products also depending on the market situation, because there is a need to service the patients and customers. And of course, we are also, we also look and file the difficult to do products which have far larger opportunity, but from a strategy point of view, in US, we will be launching all types of products because one important aspect of what we do is to create access for these products. So, we cannot, we have a plan to do that.

Surya Patra: Okay. So, my next question is on the domestic business front. So, now, it is quite clear that the at least during last one year period, we have witnessed our core business delivering much faster than the industry growth or the complex portfolio. So, sure, progressively going ahead, how should we think and overall portfolio how should that be growing or performing versus the industry and whether we have seen improvement in the profitability in the domestic business and also if you can share the speciality portfolio's contribution in terms of percentages or in terms of mix in the domestic competition business for FY23.

Sharvil Patel: Yes, we are putting efforts behind India formulations business to continue to drive market growth or at least better than market growth. I think, so far in the last year, we have achieved most of the time better than market growth. And in the medium term, we also want to aspire for building better than market growth, which will mean gain in market share. It will be driven across the mass and chronic therapies. So, I don't think the plan is to only try one specific type of therapy but we are present both in mass segment as well as in the chronic speciality segment. So, all-in-all, I think on

the composite side that will deliver better, at least market growth and our aspirations to drive better than market growth.

Surya Patra: And improvement in profitability from the domestic base business, any sense on that?

Sharvil Patel: It's a good profitable business. On a medium term to long term, it will drive better profitability, but we will continue to look at opportunities to continue to invest in this business also. But yes, our effort is to drive profitability also.

Surya Patra: Okay. Just last one small clarification, Sir. WHO warning against artificial sweeteners. So how should that have impact on our let's say key brand under the consumer business.

Sharvil Patel: Very early to give an answer to that. This study is not a new study, but I think it doesn't say not to use the sugar substitute. It has come up with some finding that we are studying, but I don't see an immediate impact but we will keep, will have a plan to counter that effort also.

Moderator: The next question is from Prakash Agarwal.

Prakash Agarwal: Hi, good evening. Am I audible? Yes, congratulations on good set of numbers. A couple of questions. One is on trying to understand your comment on new launches and volumes for US growth, you mentioned is led by new launches and volumes. So, when you say new volume or one-time buying opportunity, these are like short term, three months kind of opportunity, these are six-month kind of commitments or a year kind of commitments and what is the typical size when we talk about it?

Sharvil Patel: So, one time buy, by the very nature are not long term. So, they are obviously for that month, not even for that quarter generally, but we continue to see those opportunities in that market. It varies product to product. So, it's not the same product all the time. So, I don't think these are like contracted or assured businesses, but those opportunities do exist in the market. As I say, on the overall guidance that I said, what we're trying to do is maintain and protect our base. So that's been the effort and that's what's important and will also deliver better results in the coming quarter.

Prakash Agarwal: Yes, but these are sizable in terms of like $10 million- $20 million kind of opportunities or these are small one?

Sharvil Patel: They are sizable.

Prakash Agarwal: Fair enough. And when you say new launches, you mentioned you had 63 approvals which is record, but how much was converted into new launches and how much of those 63 are yet to be launched?

Sharvil Patel: We launched 32 and we are planning to launch 35 this year.

Prakash Agarwal: And in terms of you mentioned that fiscal '24 is also looking good despite good base, which we have achieved in fiscal '23. So, you mentioned Revlimid and apart from these new launches and Trokendi still be a good product and there are two REMS, you mentioned right. So, one is expected this quarter and the other one is next quarter. Is that right understanding in terms of stacking the growth drivers?

Sharvil Patel: Trokendi has already faced competition versus quarter four. Obviously it will come down. But then we have launched the other Topiramate, which will add value and then we have going forward, some critical launches in the next three months. So, we believe if we are successful in two out of the three also, it'll be good value.

Prakash Agarwal: So, on the US, we can still see high single digit growth despite a very strong performance in fiscal '23?

Sharvil Patel: Yes.

Prakash Agarwal: Okay. And there you're factoring in Asacol or not really factoring in Asacol?

Nitin Parekh: So, even after factoring Asacol, we still will have a single digit growth.

Prakash Agarwal: Okay, lovely, that's great. And secondly, on guidance performance. So last year, similar time, the guidance on R&D about 8%, we did around 7%. This year also, we are guiding about 8%. So, anything to read out there and what is the margin like, we could see better margin going forward or this with 8% R&D, 22 is a good margin to model?

Sharvil Patel: So, we are seeing maybe, in spite of building for 100 basis point increase in R&D, we are still building for at least another 100 basis point increase versus last year. So, that we are still seeing. So, we are seeing good improvement in margin going forward. That's the current best estimate that we can give. Many things have to work out and maybe we're being conservative, but hopefully that's what we will try and achieve even assuming some things go wrong.

Nitin Parekh: So, assuming there is no competition, Prakash on Asacol HD, in spite of higher R&D by 50-100 basis point, we expect margins to go up by 50-100 basis point.

Prakash Agarwal: That is great. Okay. Thank you. And lastly on India. So, we've seen good growth, double digit growth coming in. April was soft month. I mean, you read as an aberration or you think, too early to call or what is the number? Do you think industry and yourself will be double digit growth this year?

Sharvil Patel: See, it's difficult to, I think that'd be difficult to say I mean, whether we are in, it's obviously not going to, it will be, we hope it's double digit, but it could be anywhere between 9% to 12%, it is very difficult to predict where the growth of the industry will be because we have seen volume growth being a challenge on the overall industry. The other is also, we continue to have price challenges with NLEM and other things. If you look at even our growth in the last quarter, it would have been at least two percentage points more, had we not have the NLEM impact so which, we hope to nullify going forward by doing the right product mix and other areas, but those challenges will remain. So, I think it's difficult to predict. But having said so, I think our focus on critical brands, the new launches, and more importantly, our differentiated portfolio driving strong momentum in the market, I think, in the medium term will allow us to outperform the market.

Prakash Agarwal: Okay. Last one here, MR number, if you can share as of March?

Sharvil Patel: Field force 7000 plus.

Prakash Agarwal: So, this includes the managers or this is just the field force?

Nitin Parekh: Only field force.

Prakash Agarwal: Okay, and the full team Sir?

Sharvil Patel: Sorry, this includes managers.

Moderator: Requesting everyone to limit themselves to two questions. The next question is from Sameer Baisiwala.

Sameer Baisiwala: Hi, thank you very much. And good evening, Sir. A quick question on Vascepa, your thoughts about when do you plan to launch, are there any raw material availability issues and the market dynamics?

Sharvil Patel: So, Vascepa was a welcome approval for us. We had predicted a little much later approval but got in the first cycle. So, we are preparing for the launch. I can't give the exact date but we are

working aggressively to launch the product. On the supply side, I am confident we'll be able to get enough material which is the limiting factor in the market. And we are, we believe, we will have hopefully enough material to get good share.

Sameer Baisiwala: Great. And the second question is on the US launches. So, can you talk about the transdermals?

Sharvil Patel: Sure, so transdermals as I said, we, after successfully clearing our Moraiya facility, we have been in preparation for launching the products. We are planning for three launches. And those will be staggered from the July quarter onwards. So, in this financial year, we at least hope to do three launches from Moraiya.

Sameer Baisiwala: Okay, great. So, Sharvil bhai, if I have to summarize the US calendar, you got two REMS, three trasndermals, Vascepa. And I guess, all of them should be fairly meaningful, substantive. Anything else that we are missing out?

Sharvil Patel: We do have at least another five programs which have high value. So, if we're successful in three also, it should significantly be good.

Sameer Baisiwala: Okay, Sharvil, so this is quite a handful. And you still expect just a single digit sort of a growth for US that's surprising?

Sharvil Patel: We have to also plan for the negative side which is competition to products, right? So and the base is also quite decent. So small erosion also is a meaningful erosion.

Sameer Baisiwala: Okay, great. Now all the very best way for fiscal ’24. Thank you so much.

Moderator: The next question is from Kunal Randeria.

Kunal Randeria: Hi, good afternoon. Sharvil bhai, if I understand correctly, you will maintain a generics R&D spend at around the current level of Rs. 1,300 crores and the incremental spend will be on NCEs, right?

Sharvil Patel: No, Rs.1, 300 crores?

Nitin Parekh: So, we've told the total in FY24 will be 8% to 8.5%. And normally the additional amount would be more or less for innovation portfolio only, and not the generic portfolio.

Kunal Randeria: Sorry, so I was not asking just for ‘24. But it's a slightly longer-term kind of question in the next two to three years because you will have a lot of NCE spends coming up.

Sharvil Patel: So, there will be very little or no growth on the generic side because we have hit a base which is comfortable. So, the most, as I said, the future delta of growth that comes on research with the growth in revenue is all going to be towards the NCE and NBE portfolio.

Kunal Randeria: Yes, sure. And just one more, on the US side, what's the kind of price erosion that you are expecting? How are the competitors behaving because we have seen some shortages going up? We have seen some ANDA withdrawal by competitors. So just to get your thoughts on how the market is evolving for FY24?

Sharvil Patel: We always build for a single digit. I mean before we used to see very strong double-digit erosions. But we are building for a single digit price erosion because that's what we expect to happen in FY24 in the best estimate. Obviously in the last quarter, we haven't had any major erosion. But knowing the portfolio and knowing competition, we on a conservative side, we should assume mid-single digit price erosion.

Kunal Randeria: Right. And this price mid-single erosion is pretty much similar for all product forms, like oral solids or injectables or transdermals?

Sharvil Patel: No, if you are different, alone in the market, the erosions are significantly larger. When I'm saying that I'm talking for the whole portfolio, otherwise, the erosions could be significant, depending on how much, how exclusive you are in the market.

Moderator: The next question is from Cindrella.

Cindrella: Yes, thanks for the opportunity. My question is on transdermal, you said that you will be launching most probably three products in the coming year, can you highlight the competition scenario that you expect in this? And you have already highlighted that this will be meaningful launches for us? What kind of duration do we expect them to be a two-year long opportunity? How should we see it?

Sharvil Patel: So, it's difficult to predict how, what will be the competition. There aren't many transdermal developments going on. So, we at least believe that many of them have at least, I would say at least a two-year opportunity, but could be longer, but two years definitely.

Cindrella: Even for the REMS, two REMS product that we spoke about, even for them also, the similar scenario we can expect?

Sharvil Patel: No, that is I can't predict for the REMS because REMS are not transdermal. So those are two different technologies. So, REMS, I don't, I would say when we launch, we will still have limited competition, but it will be difficult to say there will be no competition in the medium term to long term.

Cindrella: Right. And when we look at pricing scenario in US, like not just for our portfolio, but overall industry, how do you see the US pricing today? And if you can segregate it on based on products like orals and injectables? Can you help us understand some colour, today how does it look?

Sharvil Patel: It's a very competitive market with a very consolidated buying. So, there's no fundamental shift that has happened in the structure of how the US business is. So, price erosion will continue to be there. As I said, the only way to explain it is when the portfolios mature, the erosion there is not severe, but obviously, if for portfolios where there is limited competition, with competition, you would see more price erosion. So, as I said, we estimate generally about single digit price erosion, it could be low single digit to high single digit, but that's the range that we are operating in.

Cindrella: And on the NCE side, what kind of investment do you expect over coming two to three years? Because as you witness now, talking about the entire investment going be on the IP side or the NCE side. So what is the plan over two to three years? And what all geographies like apart from US, any other reg markets, what kind of, what is your thought process on it if you can share.

Sharvil Patel: So, the NCE developments are global developments. So, they cater for the US and Europe. As I said, we are, when we're talking about the investment, it is overall investment. We're talking about 8% to 8.5% of spend, which will include generics and NCEs which would largely be for the clinical programs. So, as the programs reach the clinical phase, the investments go up. So, Saroglitazar is our largest current investment that is going on. And then in the future, we have ZYIL1 and which is entering Phase II and phase III in the future. A few more, but these are all orphan assets. So, the investments are over a period of three to four years. And they are I mean, from our estimate, in the current 8% to 8.5%, we can manage our R&D expenses with these two or three programs.

Cindrella: Yes, on the R&D side, I think we've been clear. On any other kind of investment do you think like on ground, teams preparations, all those you will need to invest or you're planning to do it now or maybe later when we are closer to the phases that's where you will decide?

Sharvil Patel: Generally, the investment starts one year before the launch and major, large investment six months before. So, our current assumption is that we will commercialize in calendar year '26. So, calendar year '25 will see major investments.

Cindrella: Okay, thank you so much and all the very best.

Moderator: The next question is from Neha Manpuria.

Neha Manpuria: Yes, thanks for taking my question. Sir, you mentioned high single digit growth for the US. Just wanted to clarify, this growth would be on the base that we reported in the quarter, I'm assuming, is that fair to assume?

Sharvil Patel: Over FY23.

Nitin Parekh: We are talking of growth in FY24 over FY23.

Neha Manpuria: In that case, even if I were to take the higher end range, we are assuming that our quarterly run rate would probably come off from what we've seen in this quarter.

Sharvil Patel: I said not for the next quarter immediately, but going forward, we have to also assume competition so.

Neha Manpuria: But okay, but given that we have a fair bit of launch, the transdermal launches, Vascepa etc. Are we being too conservative on this number?

Sharvil Patel: You have to understand base price erosion is also there, and we have to assume for that also.

Neha Manpuria: Okay, understood. My second question is on the injectable business. Could you give us some colour in terms of how big it is, what we are targeting, how many launches do we have planned for that? And what's the pipeline there?

Sharvil Patel: So, I don't have the break up like that. But I think for us, when we talk about the US generics business, we talk about whether it's oral solid, topical, transdermal or injectable. So, I think is a composite way of doing business. Having said so, there are good amount of complex filings that have happened on injectables. And we would, we hope to see at least one or two important launches this year, but many of the launches will be post '25, '26, where we will see highly complex products coming to market. So, it's still a medium-term opportunity not a short term. But currently it has a good base and there are shortages and other issues in the market. So, the growth and momentum is very good, but it will become sizable probably post '25.

Neha Manpuria: Understood. Thank you, sir.

Moderator: The next question is from Tarang Agarwal.

Tarang Agarwal: Hi, good evening and thank you for the opportunity. Couple of questions. Just a follow up from the previous participant. Currently, how big would your injectable business be? And what would it be in the previous year? That's one. And the second. I mean, you're generating sizable cash now. So, is there a possibility of you probably looking at growing your business inorganically? If so, where could we see this getting deployed?

Sharvil Patel: So, I think today we are not giving the dosage wise breakup. I think that is not something that in our guidance we are giving. So, we continue to talk about the US generics business separately, and that's the best guidance we can give. Having said so, I have explained that on the injectables front, the meaningful revenue in terms of the overall business will be post '25. But the momentum and growth is very good. With respect to the future investments, as I said, we have two important markets, India and US which we look at. US from the specialty point of view, where we want to build our presence. So that's one area which we look to find opportunities to invest in. In India, we are continuing to look for brand acquisitions, if available. So that's one area that we will look at. And we have been seeing very strong progress on our developing markets business, including Europe. So, we will and it's growing very well and it's becoming an important part of our business. So, we hope, I would say on an opportunistic basis if we can find some opportunities to leverage our portfolio there.

Tarang Agarwal: Thank you.

Moderator: The next question is from Nitin Agarwal.

Nitin Agarwal: Yes, I've seen that on the developing markets you just mentioned. So, from a growth driver perspective, what would be the driver of this, what is the strategy for growth rather in this non-US markets for us? I mean, it's largely going to be driven by biosimilars? Are there other elements of growth also that you are focusing on?

Sharvil Patel: So, biosimilars will add over a period of time to the business. But today, the business is strongly driven by branded business, branded generics business with areas focusing on cardio metabolic and CNS space. And as I said, we have a focus market strategy where we have the deep penetration in certain markets in which we have identified and the others we do through distribution, but a majority of our focus is to deepen our presence

in the markets where we are very strong. And those markets in spite of fluctuations in currency and other things have continued to deliver good growth and now are becoming profitable also. So, we will continue to drive those.

And it's to do with mostly new product launches, but mostly in the, CNS and cardiometabolic space.

Nitin Agarwal: Secondly on the US market, this new business opportunities that you sort of referred to, have you seen increased incidence of these opportunities coming through in the last few months? And how do you see this sort of as a consequence of what facility closures and all which have been happening because of FDA, recent FDA inspections, and do you see momentum in this part of the business increasing as we go along?

Sharvil Patel: So, the earlier question was related to where I would invest in the future and that was more to do with the speciality business which is not with the current businesses which are sort of generic. So, generic business I think on our own we do have a very rich pipeline, we are filling up the gaps or finding opportunities through BD&L opportunities and really have been able to license very difficult and good products from the generic point of view and complex genetics point of view. Beyond that, our effort will be to look at the speciality business and invest behind that and not in the current generics business.

Nitin Agarwal: And lastly, I think we mentioned earlier on the call that on Revlimid, the assumption is that the volumes will keep increasing. So, philosophically is it fair to assume, how should we look at Revlimid as a business? Revenue should be '23 numbers are like a peak number or number should actually increase to the next couple of years before they come off?

Sharvil Patel: Our current best estimate is with the volumes increasing, the numbers will go up at least for the next two years.

Nitin Agarwal: You mean '24 would be higher – '24 would be higher than '23 and '25 Probably should be higher than '24.

Sharvil Patel: Yes. And as I said, we do still expect quarter one sales of Revlimid also.

Nitin Agarwal: Thank you.

Moderator: The next question is from Vishal.

Vishal Manchanda: Hi, good evening. Thanks for the opportunity. So, on the two REMS as said that we are expecting to launch. Are you going to launch them as an authorized generic or under our own ANDA?

Sharvil Patel: Own ANDA.

Vishal Manchanda: Okay. And would you be able to share the indication of the two?

Sharvil Patel: No, we won't be able to do that. When we launch, we will update everybody.

Vishal Manchanda: Right. And a second one on the Menkes disease asset, any timelines for approval?

Sharvil Patel: They are in their rolling NDA stage. So, it's difficult still to give a timeline. I would be able to give better understanding maybe in two quarters, but not before that.

Vishal Manchanda: Okay. On the vaccine front, do you expect to file any more vaccines for WHO pre-qualification this financial year?

Sharvil Patel: We have two vaccines, the TCV and the MR. So those two will be going for WHO pre-qualification.

Vishal Manchanda: And the one that you filed this quarter was for which indication?

Sharvil Patel: TCV.

Vishal Manchanda: Okay, and the two that you're going to file are for?

Sharvil Patel: So, one we already have, which is the rabies then TCV typhoid conjugate and measles rubella. And then, we are also doing pre-qualification for some other products. But slowly, we will add more products. But these are the current plans.

Vishal Manchanda: Would you have a number as to how large the WHO market is for TCV?

Sharvil Patel: I can share it offline, but it's a very, very large market, but we can share it to you offline.

Vishal Manchanda: Got it. And just on the Africa and Europe business, which grew sharply this quarter, can we expect that kind of a run rate to continue for the rest of the year?

Sharvil Patel: Yes, it will have a strong double-digit growth.

Vishal Manchanda: And any colour on what drove the strong growth this quarter?

Sharvil Patel: It's a branded business, so it's quarter-on-quarter good performance, across the board.

Vishal Manchanda: Okay, and it was across geographies, not any specific space.

Ganesh Nayak: Correct.

Vishal Manchanda: Okay, thank you.

Moderator: The next question is from Naser Parekh.

Naser Parekh: Sorry, hi, am I audible? Hi, thanks for taking the question. My question is on oncology. So, across both Indian and US formulations, what would be your share of oncology and how is that growth going?

Sharvil Patel: So, in India, we are now a leading oncology player. Our aspiration is to be in the top three and one day achieve the number one rank, if possible. So, that's what we are aspiring for with the kind of access of medicines we are creating, which are largely driven by biologics and also some small molecules. So that's our aspirations. We are amongst the top five or maybe third, but we hope to be in the top few with adding more products to the basket. With related to beyond India, and US, US obviously, it's not a branded business, it's a generic side. So, we do have the three oncology sites, two injectables and one oral and we are using those sites to build for the US oncology business where we do have some day one launches planned. I would see if we just look at the oncology business, and US generics point of view, it's maybe three years out when we will see significant revenue uptake.

Naser Parekh: In terms of capacity either in India or US, we've seen lot of people obviously putting up oncology plans for the last one or two years. So just overall from a demand supply situation, how we are seeing the growth in that segment, what is your view, do you think that there has been increased capacity that we've built in which has built for the industry and in the next two, three years, that could create some kind of oversupply or there is just enough demand growth?

Sharvil Patel: I do. To some extent, I do feel there is over capacity, but they seem to be regulated, approved, I mean, plants that are approved in the regulated markets. So, I'm sure there is a little bit of excess demand, because the volumes are not very high in oncology. So, I think it'll depend a lot on the product mix and what type of products one company has, which will drive value, not the volume.

Naser Parekh: Okay, got it. Thank you so much.

Moderator: The next question is from Punit, and this is the second last question.

Punit: Yes, hi, thanks for taking my question. So I have one question on specialty innovations initiatives. So, in Saroglitazar PBC indication, there are two molecules that are ahead in terms of timelines. And both are PPAR agonists. So, by the time we launch, we'll be forth player in the entire PBC market and considering the rare nature of the market, how are you expecting the numbers to flow through?

Sharvil Patel: Yes, so on the PBC asset, our current business model assumes that we will be fourth or third. So, I think there'll be one PPAR and two others, but we assume we will be, in the worst case will be the fourth, in a good case we can be the third. And our business case is appropriate for that, I mean our investments are still very much appropriate for that scenario. The market is as you said, it's an orphan indication. But it is a sizable market, which is growing.

Punit: Understood. And my second question was on the Phase II trial we completed for ZYIL1. So, by when can we expect Phase II b/3 to commence?

Sharvil Patel: We're just finalizing that strategy. So, if everything goes well, we'll start in a quarter or maximum, five to six months.

Moderator: Thank you. The last question is from Ishita Jain.

Ishita Jain: Hi, just a quick one, relating to what the previous participant asked on the products in the pipeline. The NCE especially products like the NLRP3 inhibitor, are these partnered products or is Zydus doing it independently?

Sharvil Patel: We are doing it independently.

Ishita Jain: So, none of including Saroglitazar nothing is partnered.

Sharvil Patel: Yes, right now, all our development phase programs are done by Zydus individually.

Ishita Jain: Okay. That's great, just as short follow up. So, once we are like you mentioned that you will be, expenses will increase as we are closer to the launch date, will that also include expenses such as setting up dedicated field force once we are closer to approvals?

Sharvil Patel: Yes, I think in that earlier question, when they spoke about, I was speaking about the field force and commercial operations team, that we need to set up if we are seeing good data on Saroglitazar.

Ishita Jain: Understood, got it. And is this the same approach that is going to be used in the European market as well? Or there are we going to out licence?

Sharvil Patel: There's a higher probability we will out license in Europe.

Ishita Jain: Perfect. Thanks a lot. All the best.

Moderator: Thank you. As there are no further questions, I will now hand the conference over to management for the closing comments.

Ganesh Nayak: Thank you very much and have a good evening. And look forward to interacting with you again in the month of August for the quarter one FY24 results. Good night.

Moderator: Thank you. On behalf of Zydus Lifesciences Limited that concludes this conference. Thank you for joining us and you may now disconnect and exit the webinar.

END OF TRANSCRIPT