February 10, 2023

BSE Limited ***Code: 532321***
1st Floor,
P J Towers,
Dalal Street,
Mumbai-400001

National Stock Exchange of India Limited ***Code: Zyduslife***
Exchange Plaza, 5th Floor,
Plot No. C/1, G Block,
Bandra-Kurla Complex, Bandra (East)
Mumbai-400051

Sub: **Transcript of the Post Results Earnings Call held on February 3, 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 Q3 FY23 post results earnings call held on February 3, 2023.

Please find the same in order.

Thanking you,

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

DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2023.02.10 15:05:52 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

“Zydus Lifesciences Limited Q3 FY 23 Post Results Earnings Call”

February 3, 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

Moderator: Welcome to Zydus Lifesciences Limited Q3 FY23 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 the conference over to Mr. Ganesh Nayak, Executive Director of Zydus Lifesciences. Thank you and over to you, sir.

Ganesh Nayak: Good evening ladies and gentlemen. Welcome to our post result teleconference for the quarter ended December 31st, 2022. For today's call, we have with us Dr. Sharvil Patel, Managing Director, Mr. Nitin Parekh, Chief Financial Officer, Mr. Arvind Bothra, Sr. Vice President, Investor Relations and Mr. Alok Garg, Sr. Vice President from the Managing Director's office.

I hope you have gone through the quarterly results, investor presentation and the press release which are available on our website and also filed with the stock exchanges.

First of all, let me quickly run you through the Q3 FY23 consolidated financial performance. We registered revenues of Rs. 43.6 billion, up 20% year-on-year led by a robust growth across businesses. Our key markets viz. India and the US also registered double digit growth during the quarter. Reported EBITDA for the quarter was Rs. 9.6 billion, up 27% year-on-year and 17% quarter-on-quarter. EBITDA margin for the quarter stood at 21.9%, which is an improvement of 130 basis points on a year-on-year and 220 basis points on a quarter-on-quarter basis. EBITDA margin expanded in spite of a 180 basis points increase in R&D investment on a sequential basis as well as certain one-time REMS set up cost during the quarter for an upcoming US launch. EBITDA margin for the nine months of FY23 stood at 20.7%. Profit After Tax for the quarter was Rs. 6.2 billion, up 24% on a year-on-year and 19% on a quarter-on-quarter basis, led by improved EBITDA margin. We are confident of sustaining the growth momentum across our key markets led by strong product pipeline and focused execution efforts.

Now, let me take you through the operating highlights for the third quarter of FY23 for our key business segments.

Our India geography, which comprises of the formulations and consumer wellness business, accounted for 40% of the total revenues during the quarter, and grew 13% year-on-year. The India geography continues to deliver double digit growth in the current fiscal, adjusted for COVID related revenues in the formulations business last year.

The formulations business in the India geography sustained strong momentum and posted revenues of Rs. 12.3 billion up 14% year-on-year. Excluding revenues from COVID related products and divested brands during Q3 and for the first nine months of the current fiscal, the business delivered a robust growth of 16% and 12% respectively. Overall, we outpaced the market growth during the quarter. We gained market share and improved our ranking in gynaecology, anti-diabetic and nutraceutical portfolio during the quarter on a year-on-year basis. Our first new chemical entity, Lipaglyn continued to expand its reach by growing its patient base by 45% in 2022. It has now benefited almost 1.5 million patients since its launch. The brand was ranked as the 59th largest brand in the Indian pharmaceutical market during Q3 FY23, a gain of 35 positions versus Q3 FY22.

Our consumer wellness products business recorded revenues of Rs. 4.1 billion, up 8% year-on-year. Inflation, which hurt margins over the last few quarters, is cooling down in key inputs except milk, where it still remains high. However, we have taken appropriate price increases to counter this, the impact of which will be reflected from the next quarter.

Now let me take you through the performance of our US formulations business. The business accounted for 46% of the consolidated revenues during the quarter with sales of Rs. 19.3 billion and registered a robust 13% growth sequentially. Growth during the quarter was mainly led by volume expansion in our base portfolio as well as seasonality. The business delivered sequential growth during each quarter of the current financial year which is a healthy sign for business momentum. We launched 6 new products during the quarter. Recently, in the month of January 2023, we launched Topiramate extended-release capsules, the first generic player to launch the product. We filed 9 additional ANDAs and received 14 new product approvals including 3 tentative approvals during the quarter. Approvals for the quarter include the receipt of final approval for Estradiol transdermal system twice weekly. It is the first transdermal product approval from our Moraiya site.

On the emerging markets front, the business continues to deliver double digit growth as it posted revenues of Rs. 3.1 billion, up 15% year-on-year, excluding revenues from COVID related products. The business maintained growth momentum on the back of robust performance across key markets.

During the quarter, we filed our first ANDA from the newly constructed oral solids formulations manufacturing facility in our Ahmedabad SEZ known as SEZ II.

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 on the call today. We are pleased with our Q3 FY23 performance particularly with the fact that India and the US, the two largest geographies for us continued to deliver robust performance, led by the different strategic initiatives and focused execution. We remain committed to investing in our future to drive sustainable and profitable growth by building a diversified portfolio of differentiated products in generics, complex generics, biologics and NCEs.

Over the last two years, our various strategic initiatives in India formulations business that includes focused brand building initiatives, intense marketing efforts keeping patients' needs in the mind, expanding distribution reach, leveraging digital platforms, and driving our innovation pipeline of novel molecules and biosimilars have enabled the business to deliver steady double digit growth in the current fiscal year. Our aim is to outperform the market growth over time.

Our US formulations business, too, delivered good performance in all quarters so far, driven by timely launches of new products and volume gains in existing products. Our wide product pipeline and focused BD&L efforts lend good visibility on new products, which are critical to offset the impact of price erosions in the base portfolio and boost growth prospects in our US generics. Our nimble and agile supply chain and a network of regulatory compliant manufacturing facilities equip us to capitalize on opportunities which keep arising in the US generics markets. Going forward, we remain focused on adhering to highest quality standards across our manufacturing footprint and to monetize our deep product portfolio in the US generics business. We are taking calibrated measures to build out our speciality business over the medium term. Our goal is to improve health outcomes of patients in dire need of therapies to treat the rare and orphan diseases.

On the innovation front, we continue to make steady progress which help us move further in our mission to improve the patients' health in an affordable manner. Lipaglyn, our first NCE, continues to improve its rank in the IPM with addition of new patients. Bilypsa, which is the only available treatment for NASH indication has picked pace as it addresses an unmet medical need. Our biosimilars portfolio has made the treatments affordable and accessible for patients and has registered a strong volume growth consistently.

With this, let me talk to you about some material developments on our innovation front. On the NCEs front, as you all know, Saroglitazar Magnesium is currently undergoing Phase II(b)/ III clinical trial for PBC indication for the US market. During the quarter, we also received approval from the Ministry of Health of Spain, Iceland and Argentina to conduct Phase II(b)/ III clinical trials for PBC indication. This will help us recruit patients faster and complete our trials on a given time. So far, 54 patients have been enrolled for the clinical trials of Saroglitazar Magnesium in the US for polycystic ovary syndrome and non-alcoholic fatty liver disease indication. Currently it is the only ongoing trial in the world for PCOS and NAFLD indications. We initiated Phase II clinical trials in India for ZY19489, a novel potential single dose anti-malarial drug candidate.

Coming to our biologics and vaccines pipeline, we initiated clinical trials in India for biosimilars of two monoclonal antibodies in the oncology space during the quarter. We continue to add more programs to build a robust biologics pipeline to aid future growth. We have also received approval from DCGI to initiate Phase II clinical trial for one our vaccines during the quarter.

On the speciality front, our wholly-owned subsidiary, Sentynl Therapeutics, launched an early access program for Nulibry to improve global distribution network for the product and in turn, expedite delivery of life critical medications to the patients across the world. We filed a new drug application for one of our products in the areas of metabolic disorder through 505(b)(2) route.

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

Moderator: Thank you very much, sir. We will now begin the Question and Answer session. Anyone who wishes to ask a question may raise your hand from the participant tab on your screen. Participants are requested to use headphones or earphones while asking a question. Ladies and gentlemen, we will wait for a moment while the question queue assembles. The first question would be from Saion Mukherjee.

Saion Mukherjee: Hi, so just wanted to understand the domestic business growth. We have seen good growth now for some time. In your commentary you mentioned about market share gains in some of the areas like gynaecology, diabetes, nutraceuticals. But you know the bigger segments that you have cardio, anti-infectives, so I am just wondering you know, how the growth has come without those segments delivering. If you can give some more colour, just want to understand sustainability of this growth. And secondly on your

innovation molecule particularly Saroglitazar, how should we think about the penetration of the molecule. You have got approval for various indications here. You mentioned 1.5 million patients. So, what is the kind of peak level of patient volume and revenues that you are looking from this product. How should we think about that? Thank you.

Sharvil Patel: So, I think on the overall side first, the important thing is our secondary sales have shown a good double-digit growth and have grown faster than the market. So, I think overall we have shown strong growth. The other market shares on other therapies is not that we are down or anything, they are nearby to the levels of what the market growth has been but we are talking about where we have significantly gained share. With respect to Saroglitazar, Saroglitazar as I have already said is doing significantly well. It has jumped almost 40+ ranks to become the 59th product and we believe, as I always said we believe this product will become the top 25 products of India in terms of its capacity and can grow beyond that. It is just very initial days, we have got full indications of NASH and NAFLD and that will allow us to significantly expand the patient base. So, the product is growing very well and contributing well to the growth and the overall volumes of the business and as a strong patient assisted program that we run on Saroglitazar so that is helping us track the effectiveness of the molecule which will continuously aid the further growth of the product.

Saion Mukherjee: Sir, just one clarification if I can ask, my understanding is that this product is materially big in the diabetes and associated indications, and for the liver diseases NASH and fatty liver, it is not very large. Is that understanding correct? And incrementally is that going to change particularly fatty liver be a bigger indication. How should we think about that?

Sharvil Patel: So, there are 2-3 indications, one is that it works in the overall metabolic syndrome, if you first take the fats and triglycerides, it has a tremendous impact on that and the earlier indications were for patients who were diabetic and who had dyslipidemia. So, that is definitely a good market but the prescription size, prescription length and duration of that indication sometimes is not as long. With the indication of NASH and NAFLD, the prescription period is very long in terms of treatment protocols. You have to go for years of treatment to reverse NASH and NAFLD. So, that is one important aspect of this. And if you look at competing molecules they are significantly larger, these are not even approved indications for them. So, we believe that the NASH and NAFLD is a very big indication in India. There is a high amount of undiagnosed patients in

this area. We run the largest number of fibroscans in the country now. And we want to even double that down. So, with the strong level of diagnosis that we are running we believe that the patient pool is quite significant and early on we are seeing good traction on this.

Saion Mukherjee: Okay. Sir, my second question would be on the US, you know, there is a good growth quarter-on-quarter. Now you mentioned about some expenditure on an upcoming launch, you are putting some money on the REMS program. So, if you can share some colour on that launch. Is that significant? And in general, given the seasonality, etc., and contribution from Revlimid, how should we think about US numbers for the coming quarters?

Sharvil Patel: So, the US numbers, we believe for the coming quarters will continue to be strong with the launches of new products and specific to the REMS, that is an important program that we have initiated because we believe we will have a launch in the coming year and for that we had to go and pay for that REMS. So that has a good business plan and a good growth potential for that REMS program product. And with Topiramate (Trokendi) launch, also we will see further value addition to the US business. So, I think overall the business will track well quarter-on-quarter going forward, at least for the next 2-3 quarters.

Saion Mukherjee: Okay, thank you, sir, I will join back.

Moderator: Thank you very much. The next question is from Tarang Agarwal.

Tarang Agarwal: Hi, good evening. I have two questions. One, you spoke about for the US business you spoke about volume expansion. So, was it perhaps because of the current flu conditions in the US, or you see the overall market to be improving in terms of channel having de-stocked, that's one. The second is in terms of biosimilars you have got a broad portfolio, but the portfolio for the time being seems to be restricted to India and lesser regulated markets. So, how should we see your journey here in terms of trying to approach the developed markets. That's it for me, thank you.

Sharvil Patel: So, first to the US, the seasonality of the portfolio is only 5 million dollars so the overall contribution is not significant but it is there. The overall growth as I said has been driven by from three areas, the new products, the base business both have contributed meaningfully to the growth of the business, and higher run rate that we are now running. With respect to biologics and biosimilars always our strategy has been in India/some emerging market plan and currently we are tracking extremely well on India. And overall the business is

in good health in India both in terms of obviously our business in terms of revenue but also profits. And going forward once we get more approvals in developing countries we would see that number increasing. So, our strategy is only linked to these two geographies, the rest of the world and India. And that is where we want to build for it. And we have a lot of plans for more launches at least 2-3 new launches coming up over the next two years. So, the portfolio which is currently 14 will continue to expand.

Moderator: Thank you very much. The next question is from Neha Manpuria.

Neha Manpuria: Thanks for taking my question. Sir, we saw an increase in the R&D spend in the quarter which I understand is related to the progress on the pipeline. As we make more progress on the trials for Saroglitazar, how should we see this number. Could this trend up further, I know this is within our guidance range of 7 to 8 % but on an absolute basis how much could it trend up further as we make progress.

Sharvil Patel: For the R&D spend, we believe that our investments will remain in the 7 to 8% range in FY23. The lumpiness of this quarter, I mean R&D spends are not even all throughout the year so you see that. But our guidance for the current financial year remains intact. Going forward also, we have said that our R&D spends will be around 8 to 9% maximum in medium to long term. But currently we are comfortable at the 7 to 8% R&D spend range.

Neha Manpuria: Understood. And thereafter probably in the 8 to 9% range.

Sharvil Patel: Much later probably we will see I mean it is very difficult to predict 2-3 years down the line but short term we are looking around 8%.

Neha Manpuria: Understood. And my second question is the REMS one time cost that you have mentioned, would it be possible to quantify that how much of the other expense has increased because of this REMS cost?

Sharvil Patel: It is 8 million dollars.

Neha Manpuria: 8 million dollars, understood. And we don't see this, this is just a set up cost, we don't see this recurring.

Sharvil Patel: There is a recurring but it is not significant this is mainly the set up cost.

Neha Manpuria: Okay, got it, thank so much, sir.

Moderator: Thank you. The next question is from Bino Pathiparampil.

Bino: Good afternoon and congrats on a good set of numbers. Just one question on this 505 (b)(2) that you have filed you say that is for

metabolic disorder. When you say metabolic disorder, are you talking about the diabetes obesity sort of thing or is it genetic and sign deficiency sort of disorder?

Sharvil Patel: We have a portfolio in this, we had already filed one product in this and this is the combination product that we are filing. So, in this franchise, we will have maybe around 3 filings total. So, this is the second filing.

Bino: Okay, and is it like a peptide or something?

Sharvil Patel: No, it is a small molecule.

Bino: It is a small molecule. Okay, great I will join back in the queue, thanks.

Moderator: Thank you very much. The next question is from Kunal Dhamesha.

Kunal Dhamesha: Thank you for the opportunity and congratulations on a good set of numbers. First just a clarification, I think as far as I remember earlier we were pursuing NASH indication for Saroglitazar in US as well. Is it still continuing or we are kind of pivoting more towards NAFLD?

Sharvil Patel: So, currently the trials in the US, most immediate ones are PBC trials which we believe are the near term ones, and we are still continuing with the Phase 2 trials for NASH. And as we progress, on the key milestones on NASH we will come back to you, but we are also testing for other indications like PCOS and NAFLD also. But the NASH trial is ongoing.

Kunal Dhamesha: Sure, perfect. And on the PBC trial when do we expect in terms of read out or if you can share any progress in terms of the enrolment etc., where are we currently?

Sharvil Patel: So, we hope to finish enrolment in the next two quarters if everything goes right. And then after the follow through we hope late ’24/ early ’25 filing if we are able to achieve that timeline.

Kunal Dhamesha: Okay, perfect. And the second question on the same thing like earlier we were thinking about having a strategic partner. Is that still on the cards for these kinds of specialty R&D or we are going to do it on our own?

Sharvil Patel: Our current strategy on Saro for PBC is to do it on our own. But as we move forward and as we evaluate our timelines and competitive intensity, we will take an appropriate call. But currently, we are preparing for our own launch for Saroglitazar.

Kunal Dhamesha: Okay. And last if I may on the Revlimid side, would you I am not asking for a number, but on a qualitative directionally would the quarter 3 numbers be better than quarter 2 for us, or how should we think about it? And whatever trend we are seeing right now contribution - would that continue for the next two quarters?

Sharvil Patel: So, Q2 and Q3 were similar, Q 4 we will see higher numbers.

Kunal Dhamesha: Okay, perfect. And that is because of some player coming out of exclusivity etc., would that be the case?

Sharvil Patel: No, it is the way, there is a market share volume plan so accordingly we are able to take more share.

Kunal Dhamesha: Okay. Thank you. I will join the queue again.

Moderator: Thank you very much. The next question is from Damayanti Kerai.

Damayanti Kerai: Hi, good evening. My first question is on your Topiramate XR launch. So, you are the first one to enter the market. So, how do you see this opportunity in terms of competition over next 2-3 quarters?

Sharvil Patel: It is very difficult to estimate. But currently we are alone in the market and we still believe we hope that we still have the exclusivity but we are not seeing any immediate launches. Currently we remain exclusive.

Damayanti Kerai: So, you launch in January, so 6 months you believe you will be the only generic market.

Sharvil Patel: That we can't predict because FDA will not make a sort of decision until they see a next generic. So, because there are no next generic yet, FDA has not made that decision.

Damayanti Kerai: Okay, and my second question is now you have two transdermal approvals from Moraiya. What are the launch plan and when do you see meaningful pick up from these opportunities?

Sharvil Patel: So, if everything goes well, we believe we will launch at least two transdermals in the next financial year, and if we do better then maybe upto 3. Currently that is the plan and all three of them are meaningful launches.

Damayanti Kerai: Okay. And you have all required set up from Moraiya and you might not need to invest anything additional for these launches?

Sharvil Patel: We have already made the investments earlier.

Damayanti Kerai: My final question is your capex is currently trending at around 10 billion for a year so, where are the major spend happening?

Sharvil Patel: The major capex is happening on our expansion of our oral SEZ II facility, some expansion that happened in the ZTL, the transdermal area. We had a new line, injectable line that is getting commissioned. And also the new pre-qualified I mean new plant for MR for WHO pre-qualification which is getting ready now. And some API projects.

Damayanti Kerai: Okay. And how do we see capex trending for coming years, will it remain in similar range or you are like broadly done with some of the major spends?

Sharvil Patel: No, I think this kind of base will remain because we are investing for our growth in different areas, so that this kind of range will remain.

Damayanti Kerai: Okay, that's helpful. Thank you

Moderator: Thank you. The next question is from Surya Patra.

Surya Patra: Thank you, sir. Congratulations for the good set of numbers. Sir, my first question is on the domestic formulations business. Is it possible to share excluding this biosimilar and the NCE portfolio, what is the growth for the quarter and 9-month period?

Sharvil Patel: No, I don't think we are segmenting our business like that. When we push something, we are obviously doing it as a portfolio play. So, I think we don't do one business and then look at the other business.

Surya Patra: No basically sir, what sometimes back that we have been emphasizing about the new launches and means, basically the speciality and the mass, kind of, approach that we had some time back we had followed and discuss. So, now, since we are not talking that way, so that is why I was trying to understand, on the core portfolio…

Sharvil Patel: I think for us, we look at India geography and the formulation business as a whole. So, you know, the strategy and investments will depend on where we feel the maximum growth will be driven from. So, we don't bifurcate like that. But overall to say even the base business, which is or the established products business of the company has done better than market.

Surya Patra: Okay. Yeah, thank you. And the second question is on, let's say, on the Moraiya front, whether we have seen any kind of advantage in the current quarter from the Moraiya side. I'm not talking about the product launches, let's say in terms of the cost or something like that, or increment?

Sharvil Patel: No. Moraiya the main launches are the Transdermals which will come.

Surya Patra: Yeah, but in the cost front also there isn't, there isn't no saving, right?

Sharvil Patel: There is no saving.

Surya Patra: Okay and is it possible to discuss something more about the Revlimid outlook like how should we be thinking that or how meaningful it could be so not giving any number but at least of the overall kind of run rate, what we have been seeing even for our US business. So how meaningful this could be?

Sharvil Patel: It is going to be meaningful. And Revlimid as I said in the next quarters will be better than the preceding quarters.

Surya Patra: Okay, just last one question sir, see, obviously you are one of the largest integrated manufacturers of the formulation as well as APIs. And, obviously, currently the trend what we are witnessing bit challenging trend for even API business. So, could you share something your view about the pricing, volume trends in that API side to be specific?

Sharvil Patel: So, I think for us currently, a large part of our strategic initiative is for our backward integration, for our formulations, and driving our first to day, first to market launches and first to file. So, the API strategy that we are generally following is for largely driven for internal consumption. Having said so, we also want to expand in the other markets, but we're not a very large player in terms of third-party sales. There has been some, you know, slowdown overall in the market, as we see, because of last two years. But for us, the major critical part of the API business is for internal consumption. But we hope going forward, we will see growth coming back for us because we are on a lower base.

Surya Patra: Sure sir, okay, yeah. Thank you.

Moderator: Thank you very much. The next question is from Devang.

Devang: Yeah, hi sir. My first query is regarding the last quarters, we're seeing some of the pressures on the US markets, the pricing of the drugs. So, is it continuing in the current quarter or like is it, like what's the, for next few quarters what is the view for that?

Sharvil Patel: So, our view still continues, we see single digit price erosion in the US market and we are not seeing anything majorly changing other than this guidance that we have given.

Devang: Okay, and the second question is, like, the growth was seen as the mid teen high levels like that would be of nearby 18% or something near to that. So is it the continue with the same prospects or there

are going to be the changes in the coming quarters or something like that for the quarter four also, and for any two, three quarters.

Sharvil Patel: As I said at least, it's difficult to predict the full year but the next two quarters are looking better than the current quarter.

Devang: Okay sir, thank you very much.

Moderator: Thank you. The next question is from Sameer Baisiwala. Sameer, you are on mute.

Sameer Baisiwala: Yeah. Got it. Good evening, everyone. So, first question is on the working capital side, over the last nine months looks like it has gone up much more than the sales growth. So, if you can talk about it.

Nitin Parekh: Sameer, partly it's also because of the business mix with higher growth coming from US and US obviously has a longer working capital cycle compared to India business. And also, you know, the growth in emerging markets where also relatively compared to India business, the working capital cycle is higher. I think it's the business mix which is responsible, there are no other factors.

Sameer Baisiwala: Okay. Got it. And on transdermal from Moraiya. One is Estradiol, the second, you got PAI inspection in January. Is that correct? And the third one may come and that's over and above this. And what about I think…

Sharvil Patel: Yeah, so we got one Estradiol approval, and we had a PAI for three products. And that's the portfolio right now that has been inspected.

Sameer Baisiwala: Oh, I see. Okay. So, which means that you may have four approvals in a short order of time.

Sharvil Patel: Yes, it's potentially possible, yes.

Sameer Baisiwala: And you said, all four of them are going to be meaningful. Yeah.

Sharvil Patel: Three out of the four, at least, if I have to hedge.

Sameer Baisiwala: Okay, that's great. And, Sharvil bhai, what's the outlook for margins, you've guided 21-22 types, but you'll see this now change going forward?

Sharvil Patel: So right now, we are trending on the higher margins. And as you know, we have some exclusive products and all of that. So current outlook for the margins is looking much better at 21 plus, but I think for the full year, at least, we believe we will be better than the last year.

Sameer Baisiwala: Okay, great. And one final question and I have to ask this. So, in your assessment, in your outlook for US, how are you thinking about Asacol HD competition, sir?

Sharvil Patel: So, I think the good thing is obviously for us is that there is no competition right now. And with the new products that we are launching, where we have also sort of exclusivities as well as may be differentiation as well as some of the new launches, I believe, with that base will continue to grow and, we will, as I had always said, we will find ways to make up for the losses on Asacol. Also, I think that is already happening but we have not lost Asacol yet.

Sameer Baisiwala: Six months to 12 months is what you would guess, if you have to…

Nitin Parekh: Whatever number Sameer you want to take!

Sharvil Patel: It is very difficult to say but short term… I can only say first, at least the next quarter nobody's this there. Every quarter maybe I can add.

Sameer Baisiwala: Okay, got it, sir. Thank you very much. Good luck.

Moderator: Thank you. The next question is from Prakash Agarwal.

Prakash Agarwal: Yeah, hi. Good evening. Am I audible?

Sharvil Patel: Yeah.

Prakash Agarwal: Yeah, just trying to understand this upcoming REMS product better. So, there's a large investment that we have done. I mean, how to think about this product, could it be you know, a largish product, billion-dollar kind of product and would it have exclusivity, some colour would really help given we are making some large investments.

Sharvil Patel: It is not exclusive, it will have some limited competition, but it is meaningful in terms of the investments that we have made. And there is a setup cost but the revenue we currently expect, obviously made that investment assuming we are going to have better revenues.

Prakash Agarwal: Okay, and this is like first half calendar year kind of opportunity or it's…

Sharvil Patel: It's a definitely FY24 opportunity, maybe the second or third quarter.

Prakash Agarwal: Understood. Fair enough. And in the opening remarks, there was a mention of market share gains. So, any particular trends we are seeing and these are like little longer-term trends, are we seeing or is it like one two large orders which have triggered this or it could percolate to next many quarters.

Sharvil Patel: So consistently, we have managed our base business well, so that is our strategy. And with the disruptions in the market place, we believe that we will continuously strive hard to not only manage it, but also make sure we don't do it, I mean, do it profitably.

Prakash Agarwal: When you say disruptions, you mean USFDA issues with others or you mean other trends?

Sharvil Patel: Mostly is to do with the supply chain, yes.

Prakash Agarwal: Okay. Understood. And, you know, just wanted to understand transdermal opportunity better. So, there is already some answer on two or three of the four opportunities. And we have taken some time to get the approvals. So, I mean, is the market already matured, the ramp up is low, or there is definite position for the third and fourth player? How do we think about that opportunity over 6-12 months?

Sharvil Patel: No, in the next 12 months, our current plans are showing that these will be meaningful launches for us.

Prakash Agarwal: Okay. And just to sum it up, so what I understand is there are few large meaningful opportunities, which can, you know, take us to the, you know, a sizable step up, then, in terms of margins and R&D investments that we're doing. So, margins, you gave some colour, but I mean, does it take us to three-four hundred basis points higher, or we have a step up in R&D, which will keep the margins at the current levels?

Sharvil Patel: So, I think first let us complete the current year, maybe in the next quarter, we can give some better understanding. But as I said, R&D investments on the generic side is, sort of almost stable and you don't see any major growth on that. So, the investment that we'll be making will be on the NCEs and biologics which are gradually going to scale up. And the EBITDA margins, as you've seen, there's room for improvement, and we hope we can continue to deliver better EBITDA margin.

Prakash Agarwal: Yeah, I mean, it is quite evident, right. I mean, the step up, just trying to understand the scale of step up that we can see?

Sharvil Patel: Currently, our estimates are looking that there will be a step up, but we can't predict the whole years.

Prakash Agarwal: Okay, understood. And top two, three priorities, apart from NCEs, any other large investment are gaps that you see, balance sheet is pretty strong.

Sharvil Patel: No for us now, the main thing is to execute on the new launches, and continue to make sure what we are doing in India we are able to keep on executing well there and at the same time, grow these strategic brands that we have decided to do so.

Prakash Agarwal: Okay, lovely, great, and all the best. Thank you.

Moderator: Thank you very much. Next question from Vishal Manchanda.

Vishal Manchanda: Thanks for the opportunity. Hope I'm audible.

Sharvil Patel: Yes.

Vishal Manchanda: So, my question is on Oxemia, can you share any feedback in terms of how the product is being accepted in the market?

Sharvil Patel: So, the product acceptance is very good. Right now, we are seeing a lot of patients who are not on dialysis. Slowly, we would also want to add people who are on dialysis. So, it will be a gradual build up once you know, once we are able to do enough, work with the medical fraternity as well as the patients to show the better safety as well as the better care, I mean, better compliance that we can see with an oral product. Also, with the approval of the same, similar class of products by the USFDA. We also believe that some of the questions will get answered and we'll see better traction going forward.

Vishal Manchanda: Got it. So, the US approval will help you promote that drug better in India.

Sharvil Patel: Yeah, this class of molecules as the USFDA has approved it. Obviously, all products are not the same, but at least one small overhang will sort of reduce.

Vishal Manchanda: Yeah, so GSK got that approval a few days back?

Sharvil Patel: Yes.

Vishal Manchanda: Okay. And second one on Asacol HD. So, there's a settlement agreement in public that says, you pay a royalty to the innovator. So, since the patent has expired in November 2021, is the royalty still payable or that royalty has been discontinued?

Sharvil Patel: So, I don't think we can discuss the confidential agreement right now. That will be difficult to answer.

Vishal Manchanda: Okay. And third one on biosimilars. What was the growth you achieved in the nine-month FY-23?

Sharvil Patel: As I said, biosimilars is part of the branded generics business so I don't think we will give different numbers on that but definitely its trending better.

Vishal Manchanda: Better than the company growth? Is that…..?

Sharvil Patel: Better than the market growth.

Vishal Manchanda: Ok. You also launched a drug called Rucaparib in India which is a cancer drug. You are among the few players to have launched that. Is that a large opportunity for you?

Sharvil Patel: From the overall oncology play, yes, this will significantly add importance with the practitioners and the patients. And we also believe that we would be adding 3-4 more products which are unique so our oncology pipeline will continue to evolve in terms of being meaningful for all types of cancer beyond just the solid tumours.

Vishal Manchanda: Ok and just one final one on Can Assist which you in-licensed from a company for breast cancer basically. That's a diagnostic sort of a product. Has that been launched? How is the product shaping up?

Sharvil Patel: It has been launched and it's tracking very well and I think as I said for us most important strategic drive for the future is to how do we bring better value for the patients. So, this is our, one of our attempts that we can bring the right advice and right diagnostic and prognosis markers for the patients to make the right choice and for the doctors to make the right choice whether chemotherapy is required and if required, then what could be the chemotherapy protocols. So, I think it's a good step forward in terms of giving patients and the doctors better access and better decision making capability.

Vishal Manchanda: Patients have started to use this option to kind of go forward with the……

Sharvil Patel: The doctors will go through for the patient.

Vishal Manchanda: The doctor, basically the doctors use this option.

Sharvil Patel: Yes.

Vishal Manchanda: Got it. Thank you. That's all for me.

Moderator: Thank you very much. Next question from Ankush Mahajan.

Ankush: Am I audible sir?

Moderator: Yes.

Ankush: Sir, I had checked the list of drugs that we got approval from USFDA from the last one year. So there are few drugs like Sarifrazine, Mirabegron, lenalidomide and Brexipiprazole. Can you tell me the status of these 4 drugs?

Sharvil Patel: Revlimid as you already know it's launched. Many of the products that get approved have settlement dates for launch. So all products that get approved don't get launched on that approval date.

Ankush: When we can expect such drugs in the market?

Sharvil Patel: These are not in the short term. These are much later.

Ankush: Ok. Ok. Thank you sir. That's from my side.

Moderator: Thank you very much. Next question is from Kunal Randeria. Now we will move on to Neha Manpuria.

Neha Manpuria: My questions have been answered. Thank you.

Moderator: Thank you very much. Bino Pathiparampil.

Bino: Hi! Thanks for follow-up. Sharvil bhai, the products for which you have invested in REMS, is that transdermal kind of product?

Sharvil Patel: No, it's not a transdermal product.

Ankush: Ok, thank you.

Moderator: Thank you. Let's move on to Kunal Dhamesha.

Kunal Dhamesha: Thank you for the follow-up. I just wanted to understand if you could provide a number in terms of how much we are spending on this specialty products specially for Saroglitazar in US, at least for first 9 months so that we can better understand what is the P/L burn right now on this business which is not generating revenue as of now?

Sharvil Patel: So, overall 30 percent of our R&D spend is on all of these clinical programs that we are running of the total spend that we are doing.

Kunal Dhamesha: Ok, great. Second one, again going back to the REMS that we have done. Is it a shared REMS program which we will be sharing with other generic companies? The others also would have put in similar amount?

Sharvil Patel: I can't disclose all of that but it's a shared REMS.

Kunal Dhamesha: Ok. Or is it that we have put in higher amount but we get them later on to pay some kind of fees?

Sharvil Patel: It's a shared REMS program so I think you will be able to understand the meaning of that.

Kunal Dhamesha: Ok, perfect. Thank you.

Moderator: Thank you very much. Now we have question from Saion Mukherjee.

Saion Mukherjee: Thanks for the follow-up. Sir, on the transdermal, what is the total number of filings you mentioned with one approval already come in from Moraiya. You will have 4 approvals. Just wanted to know, what is the total number of pending approvals now on transdermal side?

Sharvil Patel: We have filed 9 products, out of which 6 are pending approval and one of them, we are not going to commercialize which is the approval for fentanyl patch.

Saion Mukherjee: Ok.

Sharvil Patel: And we do continue to file, we do have an expectation to file at least 2 more products in the immediate future.

Saion Mukherjee: Ok, 2 more products. And sir, I think a few quarters back, you mentioned around your partnership pipeline on injectables, certain exclusive products likely to be commercialized in calendar 2023, are you on track for those launches?

Sharvil Patel: Yes, we are hopeful that we will see at least 1-2 partnered product launches.

Saion Mukherjee: So those would be exclusive, the 180 days exclusive kind of products?

Sharvil Patel: Not exclusive, but at least some of them have no generics.

Saion Mukherjee: And when do you expect sir, 1st half or 2nd half?

Sharvil Patel: See, it's the approval cycle and these are complex products but definitely in this calendar year.

Saion Mukherjee: Ok. And sir, one last question on your R&D program, 30 percent of R&D you are saying on clinical program. So, this proportion is going to go up in the next few years, right?

Sharvil Patel: Yes.

Saion Mukherjee: So, is it going to be closer to 40-50 percent, anything you can comment on?

Sharvil Patel: Again, for 3 years, I don't have the exact thing but as you first guided to speaking, it will definitely go up as a percentage of the overall R&D spend. But now whether it becomes 40 or 50 percent, it's a

little too early to say but I don't think it will be a drastic jump because every year we are recruiting similar number of patients, so it will be gradual unless we are seeing some major thrust on any critical program. But most of our programs are in indication that are not requiring a lot of patients so we hope that we will be able to manage our R&D expenses.

Saion Mukherjee: Ok sir, I have just one last question, if you can take that? It is on M&A. I mean you have done M&A in the past in consumer business but we haven't seen much action on the formulation side and there are lot of assets which people are acquiring. What are your thoughts because there are gaps in your portfolio currently? Any thoughts on sort of plugging those through acquisitions?

Sharvil Patel: So, on the India business, I think our first priority that we believe is that we have our portfolio and the new pipeline of our own launches we believe are sufficient for us to deliver, better than market growth, that's what we are driving towards executing. We do have gaps but I think currently we believe that our own portfolio, concentrating on our own business would be more better. Having said so, we do evaluate all opportunities but I think many of them at the multiples don't make sense for us to do because the growth will be a challenge if they are more established. I think focussing on our new launches and the products that we believe are important like those 20 plus products I think can drive substantial growth that we want to drive for the medium term.

Saion Mukherjee: Ok sir, thank you.

Moderator: Thank you very much. Next question is from Surya Patra.

Surya: Hello!! Hello!!

Sharvil Patel: Yes, I can hear you.

Surya Patra: Sir, can you clarify what is the gross debt number that we are currently having right now? In fact, I think in the quarter, it seems that you have paid something as per the credit rating report. So, that's why.

Nitin Parekh: As on 31st December, gross debt was 1816 cr. and net debt is 604 cr.

Surya Patra: Ok, fine, thank you so much.

Moderator: Thank you very much. Next question is from Vishal Manchanda.

Vishal Manchanda: Hi. On Saroglitazar, on the ongoing trial in primary biliary cholangitis, since you are recruiting patients from Europe as well, does that mean you can do a global filing, if the trials are successful?

Sharvil Patel: Yes, for Saro, we have recruited across centres in US and Europe. So our initial plan is for the US market in terms of commercialization but we will also be looking at how do we take it through partnerships in other European markets.

Vishal Manchanda: Ok. Since it is phase II, phase III trial, so would you be separately reading out the phase II data or it will go into phase III and then you will share the data?

Sharvil Patel: So, phase II will continue into phase III. So the meaningful readout will be after the phase III is completed. So the patients continue into the phase III.

Vishal Manchanda: Ok. That should happen in FY25 – the readout?

Sharvil Patel: Yes.

Vishal Manchanda: Ok. And just one on CUTX101, is that approval due anytime now and is there any progress on that testing?

Sharvil Patel: The new born screening testing had some good progress and we hope by the time, we have an approval, we are at least near to getting that test through. The approval is still pending and because we have licensed in product where it is manufactured by the licensing partner so until they are able to get through with the filing and approval, we have to still wait. But the exclusivity gets only triggered after launch.

Vishal Manchanda: Ok. Understood. Thanks. That's all from me.

Moderator: Thank you very much. Next question is from Vibha Ravi.

Vibha Ravi: Hello, hi! So, this is with regards to SEZ 2, you spoke about a few projects. You said there is the new oral solid plant. Then there is expansion of the transdermal area and some API projects. Did you also mention this MMR vaccine plant for which you are seeking PQ from WHO?

Sharvil Patel: Yes, yes, that also.

Vibha Ravi: So what's the capex and what's the kind of expenditure for these projects here at SEZ 2?

Sharvil Patel: We are not breaking up individual capex. SEZ 2 is a meaningful capex overall in the overall scheme of things. But I said the overall 900-1000cr capex is broken up into these major factors.

Vibha Ravi: Ok. And by when do you expect this PQ? Do you have any kind of a clue there?

Sharvil Patel: This is little bit down the line. It is nothing in the immediate terms. The first PQ for us will be the typhoid conjugate vaccine and then we will do the filing for MR. So, it's definitely not in this calendar year.

Vibha Ravi: Ok, fine. Could you just talk a bit more about how significant you expect this vaccine? You have spoken a bit in the past about it. But do you see that given post covid, the importance of vaccine has shot up considerably? What are your plans and how big do you see this business growing?

Sharvil Patel: So, the business is, I just said for both the PQ vaccines which is the MR and TCB, they are a part of the global immunization plans including India immunization. The volumes that have been stated in terms of requirement are significant and large and as I said, we were looking at taking about 11 to 20 percent share of that. If we are able to be successful with the pre-qualification and meet the timelines of the tenders, it would be meaningful and profitable.

Vibha Ravi: Ok, thanks.

Sharvil Patel: Thank you.

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

Ganesh Nayak: Thank you very much and look forward to interacting with you again in the month of May for the last quarter results. Thank you and good night and enjoy your weekend.

Moderator: Thank you very much. On behalf of Zydus Lifesciences Ltd., that concludes this conference. Thank you for joining us and you may now disconnect your lines and exit the webinar. Good bye, thank you.

END OF TRANSCRIPT