

**“Zydus Lifesciences Limited Q1 FY 23  
Post Results Earnings Call”**

**August 10, 2022**

**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 Ltd. Q1 FY23 Earnings Conference Call. Please note, all participant lines will be in the 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 Limited. Thank you and over to you sir.

**Ganesh Nayak:** Good evening ladies and gentlemen. Welcome to our post results teleconference for the quarter ended June 30, 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 would 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 Q1 FY23 consolidated financial performance.

We registered revenues of Rs. 40.7 billion, up 2% year on year. Excluding COVID related revenues, the growth was 11% on a year on year basis. EBITDA for the quarter stood at Rs. 8.33 billion down 14% year on year. EBITDA margin for the quarter stood at 20.5%. Net Profit for the quarter was Rs. 5.18 billion down 12% year on year. We remain vigilant on managing our costs well and improving efficiencies across the value chain to meet our aspirations of achieving 20% plus EBITDA margin for FY23 as we aim to grow across all our key businesses.

Before I dwell into the operational highlights, I would like to draw your attention to key points related to our two key geographies, viz. India and the US. Our India geography which comprises of the Formulations and the consumer wellness businesses, now accounts for 46% of the total revenues and grew 12% year on year adjusted for COVID related revenues in the formulations business last year. Our US formulations business which accounted for 40% of the total revenues grew in double-digit on a sequential basis aided by volume expansion in existing products and new launches.

Now, let me take you through the operating highlights for the first quarter of FY23 for each of our business lines.

Starting with our formulations business in India geography, the branded business grew by 9% year on year, excluding revenues from COVID related products, generics portfolio and divested products. Overall, the business recorded revenues of Rs. 11.3 billion, down 17% year on year on a high base. Secondary sales growth remained robust for the period signifying healthy demand trend. We gained

market share and improved ranking in our core therapies in the cardiovascular, gynaecology, respiratory and pain management therapeutic areas during the quarter on a YoY basis. Lipaglyn is now ranked as the 66<sup>th</sup> largest brand in the Indian Pharmaceutical Market during Q1 FY23, improving by 13 positions versus Q4 FY22. Lipaglyn is our first indigenous New Chemical Entity launched in the market. We continue to retain our leadership position in the Nephrology segment while in Oncology, we gained multiple ranks and are now amongst the top two players in India. Our Consumer Wellness business recorded revenues of Rs. 6.9 billion, up 18% year on year. Timely onset of summer and improved distribution reach helped us re-recruit the consumers for summer heavy brands like Glucon-D and Nycil. This helped us achieve double-digit growth in these two marquee brands.

Now, let me take you through the performance of our US formulations business. We recorded revenues of Rs. 15.6 billion with 10% growth on a sequential basis. Price erosion during the quarter was almost entirely neutralized by volume share gains in the base portfolio and launch of new products. We received 7 new product approvals (including 1 tentative approval) and launched 8 new products during the quarter. Approvals for the quarter include one 1<sup>st</sup> cycle approval. We filed 8 ANDAs during the quarter including 3 filings which are designated as CGT which is Competitive Generic Therapies. On the emerging markets front, the business maintained its growth momentum and recorded double-digit growth. Overall, the business posted revenues of Rs. 3.2 billion, up 14% year on year. The growth was broad-based across most of the geographies. The USFDA inspected our Moraiya Formulations facility between 26<sup>th</sup> of July to 5<sup>th</sup> of August, 2022, which concluded with four Form 483 observations. None of the observations were related to data integrity. The company will submit its response to the regulator within the stipulated time. We have put up a new oral solid dosage facility in the Ahmedabad SEZ (SEZ 2) to cater to the requirements of the US market. During the quarter, we successfully completed the qualification and took the first exhibit batch from the facility.

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

**Sharvil Patel:**

Thank you Mr. Nayak. Good evening ladies and gentlemen. It is a pleasure to have you all on the call today. As we continue to evolve as an innovation driven life sciences company, our focus remains on building businesses with sustainable growth on a long-term basis. We continue to invest resources organically and inorganically in this

pursuit and endeavour to enhance shareholder value in the process. Let me share with you the strategic direction for two of our large businesses which is India geography and the US geography. As mentioned earlier, our branded formulations business in India grew by 9% year on year. In the near term, the aim is to grow in line with the market. In the medium to long-term we intend to outperform the industry growth sustainably. This will be achieved by expanding our presence in chronic therapies, introducing new molecules in focus therapies, expanding the presence in institutional segment and leveraging our innovation pipeline including the IP protected novel molecules and biosimilars. We will leverage digital technologies to improve our decision-making and to optimally utilize our resources to expand reach and availability, thereby improving the health outcomes for our patients.

The Consumer Wellness business regained its growth momentum driven by strong traction seen in its marquee brands. We aim to consolidate our position and sustain the momentum by expanding the distribution network, launch of new variants to meet consumer preferences and in turn, emerge as a formidable consumer wellness company.

The US formulations business witnessed healthy rebound highlighting our strength in execution. We look forward to commercialisation of our differentiated pipeline, supported by our business development efforts. Our specialty portfolio is likely to scale up over the medium to long term, and we want it to become a niche and a sustainable growth pillar.

Our philosophy to invest in people to build the businesses has received external validation as well. We received two noteworthy recognitions recently. The first being the Most Preferred Workplaces by Marksmen in association with Economic Times and India Today, and the second being amongst the Best Workplaces in the Biotech and Pharmaceutical Industry 2022 by The Great Place to Work.

With this, let me talk to you about the material developments on the innovation front.

On the NCE research front, as you are aware, our phase 2B/ phase 3 global clinical trials of Saroglitazar Magnesium to evaluate its efficacy and safety in patients with Primary Biliary Cholangitis, which is PBC, and phase 2B global clinical trials of the molecule for NASH/ fibrosis indications are currently going on for the US market. During the quarter, we completed the hepatic impairment studies in NASH and normal PBC patients, the results of which will be submitted in the near term. Clinical trials of Saroglitazar Magnesium in the US are ongoing

for indications of PCOS and NAFLD also. We completed the phase 1B trial of Desidustat in the United States for Chemotherapy Induced Anaemia (CIA) in cancer patients. The pre-IND meeting with the USFDA is scheduled in the current quarter to seek further guidance.

During the quarter, we completed recruitment of patients for our phase 2 clinical trials of ZYIL 1. The molecule is targeted at Cryopyrin Associated Periodic Syndrome which is CAPS, a rare indication. We are planning to initiate global pivotal clinical trial for this molecule in the near term. This marks our third NCE in our global development.

In the Biotech space, we received marketing approval for the drug substance of biosimilar of Adalimumab from the Russian regulatory authority. We continue to file new products in many of our emerging markets and enter new markets through partnerships to ensure long term sustainable growth for this business.

On the Speciality front, our wholly own subsidiary Sentynl Therapeutics Inc. commenced commercial supply of Nulibry during the quarter. Recently, Nulibry received positive opinion from the Committee for Medicinal Products for Human Use, the CHMP, for Nulibry for the treatment of patients with Molybdenum Cofactor Deficiency (MoCD) type A. The brand also received Industry Innovation Award, 2022 from the National Organization for Rare Disorders in the US. Sentynl continues to run various programs to expand awareness and early diagnosis of the Molybdenum Cofactor Deficiency (MoCD) type A and Menkes disease, both of which are life threatening paediatric genetic disorders.

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

**Moderator:** Thank you very much. We will now begin the Question & Answer session. Anyone who wishes to ask a question may raise your hand from the participant's tab on your screen. Participants are requested to use headphones or earphones while asking the question. Ladies and gentlemen, we will wait for a moment while the question queue assembles. First question is from Neha. Neha, please unmute yourself.

**Neha:** Thank you for taking my question. My first question is on the US business. We saw a very strong growth quarter on quarter. I know, in the opening remarks you mentioned volumes, new launches. If you could give us little more colour on what we are seeing in Asacol and in terms of volume expansion? Are there any one-off product supplies that we have seen or is this a sustainable base that we should grow on?

- Sharvil Patel:** So, we don't have any one-offs in these overall numbers. We did see a sequential growth on the business because we continued to gain volume share on the base portfolio, and also the new launches helped. So, despite the pricing pressure that do continue in the US, because of base volume growth and new product introductions, we were able to deliver on this growth. And, going forward, I think we currently have a sustainable base which we hope to grow forward.
- Neha:** And, is it fair to assume that the Asacol pressure that we were seeing through last year, that is stabilised now?
- Sharvil Patel:** Yeah, so there was no pressure on Asacol, it was just an inventory. The inventories would have been high during COVID which would have normalised. But, Asacol has been steady in terms of its share.
- Neha:** Understood. My second question is on the cost. If I were to look at our employee cost or even SG&A ex. R&D, there seems to be a fair bit of increase quarter on quarter, not so much on the SG&A but more on the employee cost. I'm assuming there's some amount of increments here or is this the base that we should be looking at? And on SG&A, has our SG&A spend, sales & promotions spend in India fully normalised?
- Nitin Parekh:** On employee cost Neha, QoQ may not make a lot of sense, possibly year on year makes sense. That's because in April, we gave the increments and incentives, including one-time performance rewards. So, about 8% impact is on account of increments and performance bonuses only, and about 2.5% impact is because in the last quarter i.e. Q4 of FY22, we had actuarial gain because on a yearly basis that exercise is done, even twice a year also. In September again, it will be done. So, that's the reason about 2.2% changed occurred because of that and 1.5% is due to new recruitments also.
- Neha:** Understood. And, these new recruitments would be in India sir?
- Nitin Parekh:** Yeah across, but largely in India.
- Neha:** Got it. And my last question is on the India business. I know there was COVID base, but our decline seems to be higher than some of what our peers have reported. In the ex-COVID base, are we seeing improved tractions from the initiatives that we have taken in India? If you could give some colour there?
- Sharvil Patel:** So, I think, for us, as we have also stated, last year corresponding quarter we had significant sale of COVID related portfolio, which obviously was largely driven by Remdesivir. But without that, we have had a 9% year on year growth. And, if you look at the latest AWACS data for July and all, we are tracking better than the market. So, I

think we are on track to grow as per the market in terms of our current efforts. And, the key drivers from whatever work we have done in terms of our earlier initiatives continues, and we are seeing some traction there. But, as we go forward, our efforts on institutional business, our efforts on the chronic segments that we want to leverage and more importantly, our strong IP protected business that we are trying to create, all will drive sustainable growth for the domestic business for us.

**Neha:** Got it, thank you so much.

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

**Moderator:** Mr. Surya I'm sorry, your voice is not clear.

**Surya Patra:** Is it audible now?

**Moderator:** Yeah, you can go ahead.

**Surya Patra:** On the gross margin front, I just wanted to understand, what has led to sequential 3% kind of decrease? Is it while the domestic branded business has performed well, is it that the volume?

**Arvind Bothra:** Mr. Surya, your voice is not clear, we are not able to get that. Can you try to get back on the line? There's some disturbance in the line that we're not able to hear properly.

**Moderator:** I think he has disconnected. The next question is from Prakash Agarwal.

**Prakash Agarwal:** Hi, am I audible?

**Moderator:** Yes.

**Prakash Agarwal:** Thanks for the opportunity. I just missed one comment on the US business. There is a sequential improvement. Is it that the volume has improved or we have had some good launches? If you could elaborate on that, that's my first question.

**Sharvil Patel:** So, the growth in the US is both we had a base business volume growth and a new product growth also. So, it's a combined effort.

**Prakash Agarwal:** But, is there anything you would want to call out in terms of any new product which would have contributed? That's because, most of the other companies have reported a sequential decline with double-digit erosion in the base business. So, did we experience that? And if not, what is our base business erosion and what are the key new launches we had which contributed?

**Sharvil Patel:** So, ex. Mesalamine, we saw an overall growth of 8% quarter on quarter on our US revenue, and this was mainly driven by volume growth. There was a price erosion of the impact of 2.5% which was offset by new launches.

**Prakash Agarwal:** Okay, fair enough. And, how do you see the remaining 9 months for us on the US side?

**Sharvil Patel:** So, our current best estimate we believe is that our base business is currently on track and we believe we can grow from that. This is the current base that we have, and we'll improve on the run rate as we continue forward in the coming quarters. And, we do have some important launches that are also phased in 1 or 2 quarters.

**Prakash Agarwal:** My second question is on the complex injectables. In the past, we have spoken that in the 2<sup>nd</sup> half of fiscal 2023-24 we should start seeing this. What is the update on that? How many filings we have and when do we start seeing the monetisation?

**Sharvil Patel:** I think when I'm talking about the US business, which we believe can continue to grow, it is also backed by our launches on the injectable side. In terms of very large complex injectables, the process of approvals and launch will obviously be much later on. But, with the current portfolio, we are seeing still good traction in terms of growth.

**Prakash Agarwal:** Sharvil, the question was on complex injectables. Are we still under development and due for filing by the end of this year? What is the update there?

**Sharvil Patel:** No, we continue to file complex injectables every year. We have a pipeline of at least another 5-6 molecules which are highly complex, which we still hope to file. But, we are filing 1-2 complex injectables every year.

**Prakash Agarwal:** Okay, fair enough. And lastly on the margin front, I understand there has been inflation, I understand freight, etc is very high. Is there any outlook you're sharing on the margins? The adjusted margins are 18.5%.

**Nitin Parekh:** We already talked about 20% plus margin for the year.

**Sharvil Patel:** I think last time I'd given an idea that we believe that we would be 20% plus margins. We hope to sustain these margins for FY23 by optimising all our efforts that we're doing. Also, between quarter on quarter, it's a question of business mix that happens. But, we are still confident that our 20% plus EBITDA margins we should be able to deliver for FY23.



**Prakash Agarwal:** And this is core margins. Like to like today is 20.5% or 18.5%?

**Sharvil Patel:** 20.5%.

**Prakash Agarwal:** So, this is reported margins?

**Sharvil Patel:** Yeah.

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

**Moderator:** Thank you. The next question is from Kashish Thakur. Kashish, please unmute yourself.

**Bino:** Hi, can you hear me? This is Bino.

**Moderator:** Okay Binu, yeah you can go ahead.

**Bino:** Just an update on a couple of questions, couple of products in the US. Any further update on Revlimid launch? You already have a tentative approval. Are you looking to launch in the coming quarter?

**Sharvil Patel:** Yes, we are looking forward.

**Bino:** Okay thanks. And second, I believe you have a settlement launch generic Trokendi in coming January. Is that correct? Are you looking forward to launching that?

**Sharvil Patel:** So, I think every product when we come closer to that, we will talk about those launches because I think it will be little too early and I think it's not good to talk about them right now.

**Bino:** Great, no issues. You've got a final approval for Jardiance I guess a couple of weeks back or a week back. Would you confirm if you have a 'first to file' exclusivity in that? Is it shared? What is the outlook there?

**Sharvil Patel:** I don't have the immediate update, but I can get back to you as to whether we have any exclusivity or not on that.

**Bino:** Okay, great. One final question, if I can add. In Moraiya facility, in the other facility you've got an approval. Although you had some 483 observations without a reinspection. Would you be able to, do you think you would get an approval for Moraiya without a reinspection despite these 3-4 observations that you have got now?

**Sharvil Patel:** I think, linking observations to a reaudit is not the right thing. I think, when we had our observations that were there for Liva, that were addressed in an appropriate manner in a stipulated time, and the facility was found to be acceptable and we continue to get our approvals. Moraiya, we will respond within the stipulated time that

we have with the agency and work with the agency for whatever will be the next steps. But, I think, to link observations to reaudit is not the right way to look at it.

- Bino:** Okay, got it. Perfect! Thank you. I'll join back in queue.
- Moderator:** Thank you. The next question is from Vishal Manchanda.
- Vishal M:** Thanks for the opportunity. On your Adalimumab biosimilar approval in Russia, could you share what's the market size there and give some colour on the competition?
- Sharvil Patel:** So, we are the first. On the competition front, I think we'll be first or second generic in that market. So, there would be one more generic, maybe. And, in terms of size, I don't have it with me, so maybe we can give that to you once we find out, because we don't have all that data, but we'll come back to you with what is the market opportunity size for Adalimumab.
- Vishal M:** Okay. Would this be a tender opportunity or would you need to promote it and hence you would need a partner in Russia?
- Sharvil Patel:** No, it would be sort of a tender opportunity.
- Vishal M:** Okay. And, do you think it's going to be meaningful?
- Sharvil Patel:** From our emerging markets business point of view, yes.
- Vishal M:** And, any other geographies where you would be expecting biosimilar approvals on the emerging market front?
- Sharvil Patel:** So, I think our next big market opportunity we're looking at is for the Latin American markets where we believe the opportunities could be sizeable, and there we are also expecting 2-3 approvals.
- Vishal M:** Is Brazil one of them or would you look at Mexico, Columbia and other markets.
- Sharvil Patel:** On the immediate basis, Mexico, Columbia and Venezuela markets.
- Vishal M:** Okay. And one on Lipaglyn, is the growth on Lipaglyn primarily on account of the liver indication approval that you got last year?
- Sharvil Patel:** I think that has aided to the growth. We have two indications, but yeah, the NAFLD indication will be the strong growth driver going forward.
- Vishal M:** And there is still large headroom there in that indication?

- Sharvil Patel:** Yes yes, it's a very large 4,000-5,000 crore plus market, so it's a good opportunity.
- Vishal M:** Okay. And, any colour you would like to share on Desidustat launch in India that has happened.
- Sharvil Patel:** So, the launch has already happened and we are tracking. For these types of products, we are tracking prescription and patients to make sure that we are able to provide the treatment options that they desire and follow through with them. So, the initial beginning is good, but it's still very early days. But, the interest from the medical community is very good because this is a replacement of an injectable product which can tremendously benefit in terms of both patients on dialysis or not on dialysis.
- Vishal M:** Would you also be able to target the iron sucrose market with this product Desidustat, or just the erythropoietins?
- Sharvil Patel:** It's mostly the erythropoietin.
- Vishal M:** Okay. Thank you.
- Moderator:** Thank you. The next question is from Sriman. Sriman, please unmute yourself.
- Sriman:** Hello Dr. Sharvil, can you hear me?
- Sharvil Patel:** Yes.
- Sriman:** Dr. Sharvil, I just want to know, we had an agreement with a Korean company Enzychem Lifesciences. Are we getting any revenue on the technology that you have transferred to them?
- Sharvil Patel:** We currently aren't getting any revenue. We are in the phase of tech transfer, which then will be followed by a regulatory inspection in their facilities, and then potentially launch in the market that they are targeting.
- Sriman:** Okay. But, initially it was told that 80 million doses will be manufactured somewhere in 2022. So, are we still in the process of transferring the technology only?
- Sharvil Patel:** The technology transfer has happened, but it will have to go through a WHO approval process. So, once that happens then. So, I think on the immediate basis, I doubt they will be able to produce so many doses this year. But, once they are through with some of the other regulatory approvals, maybe they can. But, it's a very fluid situation, but at least they are continuing with the regulatory filing.

- Sriman:** So, whatever revenue we are going to get is only based upon the production or irrespective of the production?
- Sharvil Patel:** No, based on the production and sale.
- Sriman:** Okay, I see. Thank you doctor. Those are my questions.
- Moderator:** Thank you. We request everyone, before asking the question, please introduce your firm name. The next question is from Sameer Baisiwala.
- Sameer B:** Hi, thank you. This is Sameer from Morgan Stanley. I dialled in five minutes late so I might have missed it. Sharvil bhai, any thoughts on the potential Asacol HD competition?
- Sharvil Patel:** I think, again, it's always difficult to predict. But as per our latest understanding or estimate, we believe the competition may not be there before Quarter 4 of this calendar year; but that would be our best estimate.
- Sameer B:** Okay. And, in the context of Revlimid you said that you're all set to launch next quarter. Are you referring to Q2 fiscal or Q3 fiscal?
- Sharvil Patel:** So, we will be launching as and when the approval is there. So, we have a tentative. We are obviously waiting for our final approval. And then, we will launch in the next wave that it is planned for. Exact dates and months I can't give you, but it is in the near term.
- Sameer B:** Okay wonderful and Sharvil bhai you mentioned that there are some more high value launches in the second-half anything that you can share on that?
- Sharvil Patel:** I think it's difficult to give a product wise detail, but it is a combination of products that we want to launch which will be important for in terms of our new product launches other than Revlimid.
- Sameer B:** Okay and finally, how does fiscal 24 look like for US pipeline?
- Sharvil Patel:** So, we continue to file 30 to 35 + ANDAs in the US. We believe we have a pipeline through which we will make 30 to 35 new launches every year and so we're from our current expectation point, we're still very buoyant about the next couple of years for US launches and we have also obviously factored in the incremental competition that will come with Asacol, but with what we have planned we hope that we'll be able to grow our business despite that in FY24.
- Sameer B:** You'll grow your business despite the Asacol competition in fiscal you said 23?

- Sharvil Patel:** Fiscal 24 and 23 also, but fiscal 24.
- Sameer B:** Which is in the full year impact. Okay got it yeah. Thank you so much.
- Moderator:** Thank you. Next question is from Devang Shah. Devang, please unmute yourself.
- Devang Shah:** Hi Sir. good evening. I'm from DD Enterprise, it's my private firm. I'm the shareholder in the company. Sir, my first question is the recent USFDA visit was there, was it a surprise visit or it was invited by the company? and the second one is like now the observations are there, so if we demark the observations within a stipulated time, so after then once again visit is going to be there or like they can approve and the Moraiya facility can get a full clean chit on the USFDA?
- Sharvil Patel:** So, I think from the latest updates with the US FDA most of the inspections that do occur now are surprised, so that's I think the stated way the audits had happened. So, these are not planned audits, but surprise audits that happen for all plants in India and globally. Beyond that, I think what I had said that from our observations point of view, we will respond in the stipulated time given to us and because the site is under OAI, we believe we would have some discussion before that it would be very difficult for us to say what would be the next steps, but we do believe that we can respond to these observations in the stipulated time.
- Devang Shah:** Okay and Sir the other question was like are we full on track for achieving the 18% or the 20% margin for the current year also? and the second question like in the US many other pharma companies got the sales or the margin pressure due to the price decrease in the US, so does we got impacted on that basis or not?
- Sharvil Patel:** So, we have stated that for FY23, we will have 20% plus margins from whatever we think for ourselves and in terms of US, yes there has been price erosion for us also, but because of volume expansion as well as new product launches, we have been able to still grow quarter-on-quarter.
- Devang Shah:** Okay Sir, that's all from my side. Thanks a lot.
- Moderator:** Thank you. Anyone who wishes to ask a question may raise your hand from the participants tab on your screen. Next question is from Naveen. Naveen, you please unmute yourself. Okay. We'll go to the next one. Next question is from Prakash Agarwal.
- Prakash Agarwal:** Hello.

**Moderator:** Yes, Mr. Prakash.

**Prakash Agarwal:** Yeah, can I go ahead?

**Moderator:** Yeah.

**Prakash Agarwal:** Yeah. Just one on the presentation that you have put in talks about forex, so I'm just trying to understand how sitting in other operating income to the extent of 108 crores, could you elaborate and sorry if you've already done that? I joined a bit late.

**Nitin Parekh:** Because that refers to the sales, that on the sales, when we book the sales, we book at going rate on a particular date when we realize obviously the rate is changed, so that is a part of the sales only and that is why that is classified as other operating income.

**Prakash Agarwal:** Okay and in terms of hedges, do we carry any hedges and at what rates?

**Nitin Parekh:** So, we have some forward contracts that we have entered into. One is for the loan that we have given to own subsidiary and it was more in terms of trying to get the arbitrage opportunity between rupee interest rate and the forward cover rate, so they were more certain in terms of the gains otherwise we don't have any kind of forwards.

**Prakash Agarwal:** Okay and everything is natural hedge basically, the cost and that.

**Nitin Parekh:** Yes, yes, yes.

**Prakash Agarwal:** Okay and second question is for Sharvil on the R&D side with two large programs in the US when do we see the inflection point in terms of cost increasing or we will have a fine balance in terms of R&D budget of 7% to 8% that we are having?

**Sharvil Patel:** For us, we expect that R&D investments to remain on an average of around 8% of revenue over the next three years. There could be some lumpiness, but the best guidance for us would be that around 8% of revenue over the next three years.

**Prakash Agarwal:** Okay and lastly on the India business, I think you mentioned ex. of COVID sales, it's 6% and or 9% and are we over that lump now going into Q2?

**Sharvil Patel:** It is 9%

**Prakash Agarwal:** Domestic formulations.

**Sharvil Patel:** Yes. Ex. of COVID it's a 9% year-on-year growth.

**Prakash Agarwal:** Okay and moving forward for this quarter, on a like to like basis, reported basis we see a normalized growth right?

**Sharvil Patel:** I think we would have had some sale in July, but by and large it would be a normalized growth.

**Prakash Agarwal:** Okay which we expect for the remaining nine months to be double digit plus mid-teens or something?

**Sharvil Patel:** I think we'll grow as per market is our best estimate right now.

**Prakash Agarwal:** Okay lovely. Great. Thank you.

**Moderator:** Thank you. Next question is from Harit Ahmed.

**Harit Ahmed:** Hi. Thanks for the opportunity. My first question is on biosimilars, when I look at our peers, most of them have one or two assets at least at various stages of development in the regulated markets while our focus so far seems to be on the emerging markets. So, can you elaborate a bit on your thought process and the different strategies that we are adopting when it comes to biosimilar regulated market?

**Sharvil Patel:** Yeah, so today from our point of view, our strategy we believe is currently we have a pipeline of 13 marketed products in India and 9 biosimilars that are under development. From the commercial standpoint, we're currently wanting to be a strong meaningful player in India and followed by that a good presence in some of the key emerging markets, which we want to build for. For the developed markets, the outlay on the clinical spend and the regulatory timelines, including IP timelines and all are very long and for that we have decided that for some of these, we will be looking at a much later launch timelines of maybe 27-28 and beyond. So, currently our immediate focus is only India and emerging markets, but meaningfully we are developing one or two products from the global development point of view including developed markets, but they're far later in terms of the horizon.

**Harit Ahmed:** Got it and one question on your guidance of 20% margins for FY23 and you also talked about a generic Revlimid launch in the near term and you also talked about your expectation of further competition in Asacol HD only towards the end of the year, so with generic Revlimid contributing for almost half the year and looking at our 1Q margins of already at 20% don't you think there is upside to this guidance of 20%?

**Sharvil Patel:** No, so if all of those things work out as planned, yes there is definitely an upside, but I think looking risk adjusting to whatever we believe in terms of the business mix and also the volatility that exist, I think we

believe that to sustain 20% plus margins is comfortable, but obviously there could be upsides depending on market dynamics or competition changes.

**Harit Ahmed:** And last one on the segment, which you classified as alliances in your segmental breakup of revenues, what exactly is the nature of this business? who are the partners here? and which are the geographies to which we supply under this?

**Sharvil Patel:** So, these are long standing joint ventures or partnerships that we have had. One is with Pfizer and it's a manufacturing partnership for some exclusive products for Pfizer to commercialize for them in the different markets, which has been a longstanding partnership and the other one is partnership with Takeda, which is for intermediates and APIs for their global requirements and use both for the off patent molecules and for their patented molecules.

**Harit Ahmed:** So, the Takeda partnership is part of revenue, it's not accounted as an associate, it's included as part of our revenues.

**Sharvil Patel:** We are a 50:50 joint venture there.

**Harit Ahmed:** 50% okay.

**Sharvil Patel:** 50%.

**Harit Ahmed:** Alright. Thanks for taking my questions.

**Moderator:** Thank you. Next question is from Damayanti.

**Damayanti:** Hi. Am I audible?

**Moderator:** Yes.

**Damayanti:** Okay, hi. This is Damayanti from HSBC Securities. So my first question is now Moraiya has seen FDA inspection, so can you update us on your transdermal opportunities, how should we look at them whether you need to redo your some of studies, which you have done earlier or like when we should be expecting first launch post Moraiya clearance?

**Sharvil Patel:** So, in Moraiya, we have 5 products that we have filed for transdermals. 4 out of the 5 products are being held for approval because of the warning letter, which means that all other product related queries and regulatory queries have been resolved. So, once we are able to clear our regulatory compliance on Moraiya, we believe that we can have approvals for about four products, exact timeline would be very difficult to give because first we need to clear



our regulatory hurdle and then go through the product clearance space.

**Management:** Just one clarification, alliance is actually referred to certain out licensing deals and a global contract manufacturing because we don't include now sales of the JVs.

**Damayanti:** Okay. So, Dr. Sharvil, out of 5 you are confident that once the warning letter is lifted for the facility, you should be getting approval for those products in reasonable time frame?

**Sharvil Patel:** Yeah, because it is only stuck for cGMP clearance, so once we get that clearance, we believe they can move into the clearance phase, but exact timelines I can't predict that yet.

**Damayanti:** Sure, and my second question is few quarters back, we used to discuss opportunities from vaccines, can you update on that segment please?

**Sharvil Patel:** Yeah, so on the vaccines front, we have two, so currently we believe there are three important vaccines, which we have already commercialized and have good value to be created. One is the rabies vaccine, which we already are in market for multiple years, then we have the typhoid conjugate vaccine and the quadrivalent flu vaccine. These are vaccines where we want to build for business. Also, recently with our approvals on the MR vaccine also we believe that between typhoid conjugate and the MR vaccine, this will be the critically large opportunities for us for both India and once WHO prequalified, for the other global tenders that come out for these two vaccines. Followed by that I think there are niche vaccines like the varicella vaccine, hepatitis E vaccine, which are much longer term in nature, but those are also important vaccines for our development and on the private market side, the quadrivalent flu vaccine is a good vaccine because it has -- we are the only Indian generic on that, so it helps us in terms of differentiating.

**Damayanti:** Sure and any number in terms of sales expectation, which you'd like to share like 2-3 years down the line how big this business can grow if everything goes as per the plan?

**Sharvil Patel:** So, we expect significant contribution from this vertical around three years down the line when a couple of vaccines like the TCB and MR are WHO prequalified and we are able to participate in the global tenders.

**Damayanti:** Any numbers, which you'd like to put?

- Sharvil Patel:** No, we aim for a 10% to 15% market share to be taken in these vaccines, but the number is not estimatable right now because it will depend on the timing and the pricing and the quantities.
- Damayanti:** Sure. Thank you. I'll get back in the queue. All the best.
- Moderator:** Thank you. Next question is from Anubhav Sahu.
- Anubhav Sahu:** Thanks for the opportunity.
- Moderator:** Anubhav, we are not able to hear you. Can you please?
- Anubhav Sahu:** Hello, is it better now?
- Moderator:** Yeah, it's better, but it's still not clear.
- Moderator:** Anubhav, can you come back again fixing this audio?
- Anubhav:** Okay, okay Sir.
- Moderator:** Yeah. Till that time, we'll take the next question from Surya Patra. Yes, Mr. Surya, please unmute yourself.
- Surya Patra:** Yeah. Sorry. Sir, thank you for this opportunity and the first question is on the domestic sorry US business Sir. The sequential growth, sequential as well as year-on-year growth what we have witnessed, is it by any chance led by the volume push at the cost of realisations?
- Sharvil Patel:** No.
- Surya Patra:** Okay, because what I'm trying to understand here is that the sequential correction in the gross margin while for consumer business it is a strong season and for the domestic formulation business as you mentioned that the branded business has done well and US is also progressing right, then what would have impacted the gross margin so more than 250 basis points sequentially?
- Sharvil Patel:** I think one, before Nitin Bhai gives you an answer on the gross margin, in the US our business model that we have been strictly following is that we don't sell products at losses or at very low margins. We are very clear every product has a clear P&L and we are driven by making sure that every product P&L is healthy or at least profitable, and so I don't think we make those compromises on product by product by looking at portfolio. So, that is just the clarification in terms of we don't do business in that manner for volume other than that the overall mix point of view Nitin Bhai will take that.
- Nitin Parekh:** So, Surya, there are three things. One is that domestic formulations business in reported terms in this quarter has a degrowth of about

17%, which obviously is a high gross margin business and the proportion of business affects that is one part. Secondly, you talk of Zydus Wellness, so Zydus Wellness obviously has a much higher growth in this quarter being a season, but Zydus Wellness on a business portfolio basis also has a lower GC than my overall GC, and third is that especially business like Zydus Wellness is affected by input cost also like a milk price and palm oil price apart from some other cost increases including let's say freight inward cost.

**Surya Patra:** Okay, okay. Sir is it possible to give some color on what kind of outlook that one should have on the GC side, gross margin side?

**Sharvil Patel:** I think we can give an EBITDA kind of outlook which we have clearly said that we'll be 20% + for FY23. I think gross margin is a question of product mix and business mix, which keeps on varying and gross margins to net margins also varies, so I don't think, I think that is the best way to assume the current next two to three quarters.

**Surya Patra:** Sure Sir. Second question is on the domestic formulation business. So obviously we are seeing a kind of generally trend of moderation for the industry from the high waves of COVID now, so and simultaneously we have seen many of the leading Indian peers are either expanding field force or kind of a building something like that on the field force side, so there is, if this is a kind of a trend then there is an enhanced competition likely to be, so given that scenario what is the general outlook for the industry as well as for you for the domestic business that you were anticipating?

**Sharvil Patel:** I agree to that extent that Indian branded generics has always been very competitive, there is a high degree of competition in the category and I think every company has a strategy in terms of what they try to follow. For us, I think on the short term side, we want to grow as per market because there is so much volatility that exists, but in the mid-term, our plans from our investments that we're making, we believe we will grow better than market in the coming years and that's mainly driven by obviously our differentiated portfolio that we have both on the small molecule side, which are IP protected as well as the biosimilars, our entry into first in India launches for off patent molecules which has happened in the diabetes and cardiovascular space, which has allowed us to gain good traction in these two therapies and a continued effort on some of the therapies like respiratory, women's health and others where we're trying to reinforce our position where we are there. We're also utilizing capabilities on the digital side to expand our reach both in terms of the patient-doctor reach as well as the distribution reach for many of our established brands and also build on to the growing organized

sectors in terms of hospitals, the tenders that are there and also the e-commerce players who are able to take some share in the segment. So, all of that will lead to our plans for the growth or the growth drivers for the domestic business.

**Surya Patra:** Okay. Sir just one more question on the finance cost side. So having seen the deleveraging throughout last year, still the finance cost seems flat, it has not corrected, anything on that side whether it is because of the consumer business contributing a significant chunk in this quarter that is why the number looks elevated or this is a kind of run rate, so basically the benefit of the financial deleveraging that is not visible?

**Nitin Parekh:** So, Surya what has happened that only towards the end of the quarter we repaid some debt, but that is what you'll be able to see in gross debt position between two dates, two quarter ends, otherwise we were using that as a treasury, so there is an increase in other income that you can see, which is largely related to interest income and some profit on sale of investment like mutual funds investment, so on the net basis because we found that we were having a low interest regime, it made sense for us rather than to repay the debt to use that as a treasury income because in overall terms, we found that as a beneficial position. Obviously, things are now going to change with increasing interest rates.

**Surya Patra:** yeah. Okay, sure. Just last one single Sir, on the Moraiya side what is the current utilization of that facility Sir?

**Sharvil Patel:** Moraiya it's a very well utilized facility and as I had always said other than transdermals, we do have launches, but not too many launches now planned out of Moraiya, so most of our future launches are out of our other facilities in SEZ and our future SEZ 2 facility. But Moraiya is a well utilized facility about 65%-70%, but it varies depending on the products.

**Surya Patra:** But if the US thing happens, then in terms of the profitability whether it will have a kind of meaningful say?

**Sharvil Patel:** I think the transdermals is the only one which is meaningful for us beyond that it is a business as usual.

**Surya Patra:** Okay, okay. Sure Sir. thank you. Wish you all the best.

**Moderator:** Thank you. Next question is from Saion Mukherjee.

**Saion Mukherjee:** Yeah. Am I audible?

**Moderator:** Yes.

**Saion Mukherjee:** yeah. I have a few questions. Firstly on the US business, can you share like what has been the price erosion year-on-year for your portfolio and have you seen or have you discontinued any product, have you come to a stage where the profitability has corrected so much that you've decided to discontinue, so if you can throw some light as to how many of such products you've discontinued?

**Sharvil Patel:** I won't have each product idea, but definitely if the products are becoming unviable, we are leaving the market if we do not see any price improvement and we have done that consistently. In fact, historically I can talk we had left the Atenolol market, we had left Losartan, we had left HCQ, and the markets turn, whenever the markets changed favorably, we were able to quickly enter these markets. So, I think as I said earlier, we run US business with each product as a P&L on its own and not as a portfolio, so we do get out of markets or don't go for any share if the margins are very low. So, that's my overall view. I can tell you quarter-on-quarter we have had a price erosion of 2.5%.

**Saion Mukherjee:** Okay and Dr. Sharvil on the specialty efforts that you're making in the US, before Saroglitazar gets approved over sometime, how should we think about the scale of this business you have couple of rare disease assets, do you think you need to add more to sort of make it sustainable? Any thoughts on the scale and profitability of this business from the next say 2-3 years perspective?

**Sharvil Patel:** So, from the investment point of view, there would be further investments over the next two to three years. Currently, we have two assets in the ultra-rare disease front, which is the Nulibry and CUTX assets. These are important assets for the company in terms of creating a place in terms of a pediatric orphan exclusive kind of products that we want to build towards, which will mean that we would continue to further license more products in this space. We first had done CUTX101. Immediately in the next few quarters, we were able to get Nulibry. I think we have become a good partner in this field because this is a very niche unique field to be in where you have to actually go and find patients, so I think for a future opportunities in this, we would look to be an active licensing partner and then slowly scale this business up. None of these molecules on its own will become very large, but I think we can build optimum business on the super specialty front through this Sentyln engine. For the Saroglitazar, I think currently we believe that we are 24 late filing then 25 launch. So, we are building towards that and this year phase 2B results will be out by end of this year, where we would be able to then see how aggressively we can push for a faster phase three and also the opportunity that we can get.

**Saion Mukherjee:** Thanks, Dr. Sharvil and on the ultrarare disease, so what is the optimal number of products you think you should have on this, you have currently 2, is it like 4, 5, and other opportunities you're seeing in the market and do you see a good possibility of adding more products over the course of the next year or so?

**Sharvil Patel:** So, we are seeing one or two opportunities right now and we are evaluating them in the pediatric space. So, there are opportunities that are there. There is a lot of impetus globally on pushing for medicines for this ultrarare diseases. So, I think those will continue, but in the short-term, we are seeing about one to two opportunities that we are actively looking.

**Saion Mukherjee:** Okay, okay, and finally one last question on the domestic market, you have a trade generic presence. Some of the peers are talking quite positively about this, so what are your thoughts, you're not pursuing this as an opportunity if you can share your thoughts on trade generics in India?

**Sharvil Patel:** No. Trade generic, we are as you rightly said are present in trade generics. Trade generics definitely will be one avenue of growth, which has a completely different distribution kind of network that exists and we do believe that as the market shifts or grows, we will also be able to capture growth there. Also some of the very legacy old brands, which don't require a lot of sales promotion anymore are potential for being also driven by the trade generic side either on the SKU level or the brand level, so all of those things that we continue to evaluate and we believe it will become a good business, it will account for 8%-10% of our overall revenue and we potentially can grow. So, we will remain present in this category.

**Saion Mukherjee:** Okay and how large is it today currently?

**Sharvil Patel:** It's about 7%.

**Saion Mukherjee:** Okay. 7% of the India formulation sales?

**Sharvil Patel:** Yeah.

**Saion Mukherjee:** Okay. Thank you. Thanks a lot.

**Moderator:** Thank you. We'll take the last question from Naveen.

**Naveen:** Can you hear me Sir?

**Moderator:** Yeah.

**Naveen:** I just wanted to know what is the revenue outlook from your new Ahmedabad SEZ plant?

- Sharvil Patel:** So, the new Ahmedabad SEZ plant has just started taking exhibit batches, which will then go for a USFDA audit when possible, and then commercialization, so there's no revenue driven out of that facility and it will be at least three years out before we see substantial manufacturing happening.
- Naveen:** Okay Sir. Thank you.
- Moderator:** Thank you. I now hand the conference over to the management for the closing comments.
- Ganesh Nayak:** Thank you very much and we look forward to interacting with you again in the month of November with our quarter 2 results. Thank you and have a nice evening.
- Moderator:** Thank you. On behalf of Zydus Lifesciences Limited that concludes this conference. Thank you for joining us and you may now disconnect your line and exit the webinar.

**End of Transcript**