May 26, 2022

BSE Limited ***Code: 532321***
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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 Investors' Call held on May 20, 2022**

Dear Sir / Madam,

Pursuant to Regulations 30 and 46(2)(oa) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, please find attached the Transcript of the Company's Q4 FY22 post results Investors' call held at 4:30 p.m. on May 20, 2022.

Please find the same in order.

Thanking you,

Yours faithfully,
For, **ZYDUS LIFESCIENCES LIMITED**
(Formerly known as Cadila Healthcare Limited)

DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2022.05.26 16:28:41 +05'30'

DHAVAL N. SONI
COMPANY SECRETARY

Encl.: As above

“Zydus Lifesciences Limited Q4 FY 22 and FY 22 Post Results Earnings Call”

May 20, 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: Ladies and gentlemen, good day and welcome to Zydus Lifesciences Limited Q4 FY22 post results earnings conference call. Please note that 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. Should you need assistance during the conference call, please raise your hand from the participant tab on your screen. Please note that this conference is being recorded. I now hand the conference over to Mr. Ganesh Nayak, Executive Director, Zydus Lifescience Limited. Thank you and over to you, sir.

Ganesh Nayak: Thank you.

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

I hope you would have gone through the quarterly results' investor presentation which we have posted on our website and filed with the stock exchanges.

I am pleased to share our performance for the financial year 2021-22 as we continued our efforts to fight the pandemic through our therapeutic products and on ground initiatives to support the healthcare fraternity. Though continued disruption in the supply chain and inflationary pressure impacted some of our businesses, our agile supply chain helped offset the impact meaningfully, thus ensuring reliable and timely supplies to our customers in the key markets. The year gone by turned out to be good for our branded formulations business in India as the business posted strong double-digit growth consistently. On the consumer wellness front, the business environment remained challenging due to COVID impact in the first half and the inflationary pressure in the second half. But importantly, the business retained leadership in 5 out 6 categories. Our US formulations business continued to grow the overall volume and maintained top 3 ranking in 60% of the product families despite increased competition and pricing pressure. On the innovation front, the year saw several important milestones achieved by us. Dr. Sharvil Patel will speak about them in his talk.

With that, let me take you through the financial numbers for the year gone by.

During the year, we posted consolidated revenues of 152.6 billion rupees, up 6%. Consolidated EBITDA for the year was 33.4 billion

rupees, implying an EBITDA margin of 21.9%. Excluding the impact of one-time COVID related inventory provision of 1.8 billion rupees, EBITDA margin for the year stood at a robust 23.1%. One-time inventory provision as mentioned above, input price inflation and continued pricing pressure in the US business impacted gross margins adversely. However, continued efforts on cost optimization and efficiency enhancement initiatives significantly helped contain the EBITDA margin decline. Profit after tax for the year was 44.9 billion rupees, up 110% year on year. Excluding the impact of COVID related inventory provision as mentioned above, profit from discontinued operations and certain exceptional and non–recurring items, our PAT grew by 12% during the year. Our balance sheet health improved significantly during the year with a negative Net Debt at 0.6 billion rupees as of 31st of March 2022 against 35 billion rupees as of 31st March 2021. As a result, our Net debt to EBITDA ratio turned negative and stood at minus 0.02 times as on 31st of March 2022 compared to 1.03 times as on 31st March 2021.

Coming to the quarterly financial numbers, during the fourth quarter of FY22, we posted consolidated revenues of 38.6 billion rupees, up 5% year on year. Excluding, COVID related revenues, the growth was 7% on a year on year basis. Adjusting for the inventory provision of 1.4 billion rupees made during the quarter, EBITDA was 8.6 billion rupees implying EBITDA margin of 22.3%, which is an improvement of 170 basis points on a sequential basis. Profit after tax for the quarter was 4 billion rupees. Excluding the impact of COVID related inventory provision as mentioned above, profit from discontinued operations and certain exceptional and non-recurring items, Profit after tax stood at 5.3 billion rupees, up 12% on a year on year basis during the quarter.

Over the last few years, our endeavour has been to strengthen our position in the Indian market, particularly in the branded businesses. In line with this, the salience of the India geography, which comprises of formulations and consumer wellness business has increased from 37% of the revenues in FY18 to 46% of the revenues in FY22. During the year, India geography business registered a healthy growth of 15% and posted sales of 67.9 billion rupees.

Now let me take you through the operating highlights for the fourth quarter of FY22 for each of our business lines.

Starting with our formulations business within the India geography,

The business recorded sales of 11.6 billion rupees during the quarter, up 14% on a year on year basis. Excluding sales of COVID related products, the branded business grew 19% on a year on year basis. Importantly, the growth was well represented by volume expansion as

well as better realizations. On a full year basis, the business posted sales of 48.1 billion rupees, registering a growth of 19% on an elevated base of last year. Excluding sales of COVID related products, the branded business growth was 21%. We gained market share in our core therapies of anti-diabetic, cardio vascular and gynecology during the quarter on a year on year basis. On the super speciality front, we continue to retain our leadership position in the nephrology segment. In the oncology space, we remain the fastest growing company in India. Our consumer wellness business posted revenues of 6.3 billion rupees with a growth of 6% during the quarter. Sales growth for the year was 7%.

Now let me take you through the performance of our US formulations business. The US business posted sales of 14.2 billion rupees during the quarter, down 4% year on year. On a full year basis, the business posted sales of 58.1 billion rupees, down 8%. During the quarter, we launched 4 new products in the US taking the cumulative number of new product launches for the year to 14. We received final approval for 5 new products during the quarter taking the cumulative number of approvals for the year to 28. Notable approvals include the receipt of final approval for Nelarabine injection which was granted 180 days exclusivity. Cumulative number of ANDA filings and approvals now stand at 420 and 312 respectively.

On the emerging markets front, the business posted sales of 2.8 billion rupees, up 10% on a year on year basis. Excluding COVID related portfolio, the business posted a growth of 29% during the quarter. Robust performance in key markets of Latin America, Philippines and Vietnam drove the overall performance of the business. However, the situation remained challenging for business growth in Sri Lanka in the light of ongoing political crisis. On a full year basis, the business posted sales of 11.9 billion rupees, up 17%.

On the operations and compliance front, our injectable facility at Jarod which is the erstwhile Liva formulations facility underwent a USFDA inspection during the quarter. The inspection concluded with 3 observations. We have received one new product approval and one site transfer approval from this facility post the inspection. As shared with you on previous occasions, we continue to remain vigilant towards our cost structure and undertake various measures to optimize the same and remain competitive. Advanced digital and analytics tools being implemented in manufacturing operations would enhance compliance and efficiency through simplification.

This concludes the business review. I would now request Dr. Sharvil Patel to take you through our strategic direction and material developments and initiatives in our innovation programme. 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. I would like to update you on our strategic direction as well as share material updates on the progress made by us on different R&D initiatives during the quarter.

Over the past few years, we have had a strategic review of our businesses as we continue to build sustainable, long-term growth drivers for the company. Certain loss making businesses like Nesher and Hercon in the US have been scaled down or discontinued as we continue to build pipeline and capabilities to improve our business mix in the US. We also want to position our speciality business as a rare and orphan disease focused organization and have been working on identification of bolt-on assets to leverage the common platform. To sharpen focus on key growth engines and to free up management bandwidth, the Animal health business divestment during the year also helped realizing optimal value for the business. These strategic decisions demonstrate an effort to streamline capital allocation, helped improve return ratios to ensure better stakeholder value creation.

I am pleased to state that given our strong financial position with net debt free status, supported by one-time gains from the divestment of India centric animal health business, the Board has approved the proposal for Buyback of shares at an attractive value to reward the shareholders.

We remain committed to build long term sustainable growth drivers for the company and that reflects in our continued investments on R&D as we continue to progress on the innovation front. We continue to augment our capacities across and realign our manufacturing network to be future ready across multiple technology and dosage platforms. We are leveraging automation and digitization to meet the highest compliance standards and optimize cost per unit incrementally. Our business mix will evolve over time to include more complex products with higher entry barriers, thereby enhancing our position in a competitive environment we all operate in.

I would also like to throw some light on the broad strategic direction for two of our largest businesses, which are US and India. We remain optimistic on the prospects of branded business in India and for both our businesses, formulations as well as the consumer wellness. In India formulations business, we continue to focus on enhancing our presence in high growth areas within the chronic and speciality

segment. Moreover, we have aligned our business strategy to build select pillar brands and focus on new product launches which will help us outpace the industry growth. Our biologics business is likely to sustain high growth momentum, cementing its position with one of the widest portfolios and fastest growing in respective categories. With few first in market launches like Exemptia and Ujvira, we remain excited with our pipeline and this segment will continue to bolster our growth in India. On the consumer wellness front, we are leveraging our R&D strength to launch new products which meet our consumer needs and ensure continued brand pool. Our distribution reach continues to expand and we aim to achieve healthy growth while expanding market share in each segment that we operate in and benefit from operating leverage, hence stronger profitability as we navigate the near-term inflationary pressures. While we have built up a formidable US generics business, backed by strong generics R&D efforts, we continue to focus on differentiated products, ensuring a balance between high volume and high value complex products. While this would scale up in times to come, we are calibrating our R&D spend judiciously and supplement it with business development and licensing efforts to improve the ROI and to ensure on time launches for commercial success. For the medium to long term, we also have been investing resources to evolve as a strong rare and orphan disease company. Our own NCE pipeline continues to progress well and we will invest in a phased manner to ensure that Saroglitazar meets its development goals for PBC and NASH indication that will translate into commercial success.

Let me also talk about some material developments on our innovation front. On the NCE front, we have launched a novel molecule Desidustat for the treatment of anaemia associated with CKD developed in-house, in India under the brand name Oxemia™ in March, 2022. This launch will further consolidate our leadership position in the Indian nephrology segment by providing first-in-class solution to the specialists. Desidustat is also being evaluated for global development and currently the molecule is undergoing Phase III clinical trials in China for the management of CKD. The global development of Saroglitazar magnesium, Phase II(b)/ III global clinical trials of the molecule to evaluate its efficacy and safety in patients with PBC and Phase II(b) trials for NASH and fibrosis and other indications are currently ongoing in the US market, in line with our current plans.

Coming to the biotech, we have submitted marketing authorization application to DCGI for Rituximab and submitted an application to initiate Phase III clinical trials for one more monoclonal antibody during the quarter. We have also received GMP approval for manufacturing facility from Mexican authority, COFEPRIS for 3 products during the

quarter. This will facilitate launching these products in the large opportunistic market of Mexico post their approval.

Coming to the speciality initiatives, after the acquisition of CUTX 101 (now branded as ZYCUBO), during the quarter, we entered into an agreement with BridgeBio Pharma Inc. to acquire NULIBRY™ (Fosdenopterin for Injection). NULIBRY™ is approved by the USFDA to reduce the risk of mortality in patients with molybdenum cofactor deficiency (MoCD) Type A, an ultra-rare, life threatening paediatric genetic disorder. With this acquisition, the Company further strengthens its paediatric rare and orphan disease portfolio. Commercialization plans for CUTX 101 for the treatment of Menkes disease are underway. The product is under a rolling submission and all modules of the NDA are expected to be filed during the current calendar year. We have undertaken various initiatives to create awareness for this disease which is a rare disease.

On the vaccines front, ZyCov-D received an EUA approval as a two dose vaccine for the eligible population in the age group of 12 years and above. The vaccine will now be administered on Day 0 and Day 28, improving the compliance profile.

Thank you, and now we will start the Q&A session.

Over to the coordinator for the Q&A.

Moderator: Thank you very much. We will now begin the question and answer session, anyone who wishes to ask questions 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.

First question is from Neha Manpuria.

Neha Manpuria: Thank you for taking my question. Firstly, just wanted to understand on our India business, we have seen good growth in the quarter even excluding COVID portfolio, could you give us a little color on, is this a reflection of our initiatives that we have taken and also how should we look at the growth for next year given the high base.

Sharvil Patel: Yes, we are very pleased to play an important role in the fight against COVID and that's been very good in terms of the overall business. But as we have recovered from the pandemic I am pleased to share that the India business has also started to register a healthy growth. Ex-COVID sales, India business grew by 19% for the quarter and 21% for the full year. This partially reflects the impact of our renewed strategy to focus on brand building. Also, the strong momentum of our novel

products like Lipaglyn, Bilypsa and Oxemia will further add to this growth. On the super speciality front, our biologics business continues to maintain strong momentum with major products leading in that category in terms of growth and in terms of patient enrolment. From the therapy focus standpoint, the chronic and the semi chronic will give us a higher thrust as we aim to strengthen our footprint in therapies like cardio vascular, diabetes, gastro intestinal, gynaecology, respiratory and also in the speciality segments like oncology and nephrology. So, as I highlighted earlier I think our endeavour is to outpace the industry growth sustainably now and we are clearly seeing the path to achieve that.

Neha Manpuria: Understood, and in the reported numbers for the quarter is there any contribution from vaccine?

Sharvil Patel: No.

Neha Manpuria: Okay, understood. And second you know the COVID inventory write-off if I understood it correctly this is all sitting in the gross margin, right, so if I were to adjust that, our gross margins seem pretty strong despite the price inflation, erosion we have seen in the US. Could you help us understand what's benefitting that?

Nitin Parekh: There are 3-4 different factors, one is the business mix itself in terms of the growth that you have seen in India business, another is foreign exchange fluctuation which is partly helping us in terms of realization. And also, our supply chain stockings have various inventories before the price increase due to inflation, on the other end some of our business like Zydus Wellness was able to take price hike as well. So, 3-4 major factors which contributed to this.

Neha Manpuria: So how should we look at this sustainable gross margin for next year?

Nitin Parekh: So gross margin, Neha, would remain a function of business mix to some extent but I think in terms of EBITDA, we are pretty confident of maintaining 20% plus EBITDA margin.

Neha Manpuria: Understood, thank you so much.

Moderator: Thank you. Next question is from Bino.

Bino: Hi, just a clarification on generic Revlimid launch, now that we are close to it, could we confirm if we will be part of the next wave of launches or would there be somebody in between, launching in between the first wave and us.

Sharvil Patel: We expect to launch this product in the next wave of the generic launches subject to the final approval being in place. So, I think we are

backwardly integrated on the product and beyond that I don't think we can add more color to it, but we will be planning for the launch.

Bino: Okay, great. And we have seen US FDA inspections coming across in facilities, you have any heads up on Moraiya?

Sharvil Patel: We are prepared to be inspected by the USFDA any time and we hope that re-inspection happens in the current year, as you said the resumption of inspections have started in India. As I also earlier have mentioned that majority of our high value products excluding transdermals have now been site transferred to alternate facilities. So, from the risk mitigation perspective, it is good, however there are still a number of products which would potentially be launched from this site post clearance and we await the FDA to come and inspect.

Bino: Okay, great. One last question on Asacol, between the last call and now have you got any incremental information about any competition entry, potential competition entry?

Sharvil Patel: No, we don't see any on the immediate basis any potential entry, right.

Bino: Okay, thank you, I will join back in the queue.

Moderator: Thank you. Next question is from Pritesh Vora.

Pritesh Vora: Hello, sir. Can you hear me?

Sharvil Patel: Yeah.

Pritesh Vora: So how do you see the India business going from here, I mean which areas we are targeting in India business, what is the outlook on India business?

Sharvil Patel: I think I covered some part of the answer earlier already on the India business. So it is 3 things, right, on India we have seen a strong growth. It is driven all across the segments for us. The future growth, we believe, will be driven by the chronic and sub chronic categories for the company. And novel products like Lipaglyn, Bilypsa and Oxemia will significantly add to further growth. And we are seeing strong momentum on our biologics business which will maintain its growth trajectory which will lead to better growth and also better patient enrolment that is what our ambition to do that. So, we believe that we are poised to grow and plan for a better than market growth with some of these initiatives that we have taken across the important TAs that we have mentioned earlier. So that's our current expectation.

Pritesh Vora: And my second question is about the API. We are seeing some kind of degrowth, large degrowth on quarter on quarter as well as the Y-o-Y degrowth so what is happening there in the API side?

Sharvil Patel: I think going forward I think the growth will come, I think it is also base effect, during the COVID period I think we have lot of business that got, that was created, so I think we were sitting on a good base. So, I think going forward we will see some growth coming back but it is more of a base effect.

Pritesh Vora: All right, sir, thank you very much.

Moderator: Thank you. Requesting everyone before asking the question please introduce yourselves and your company's name, thank you. Next question is from Anubhav Agarwal.

Anubhav Agarwal: Hi, this is Anubhav from Credit Suisse. One question, Sharvil bhai, on this product Nulibry, how big this drug could be in let's say in 2-3 years and how much you have paid for this for the US market.

Sharvil Patel: So, Nulibry targets an ultra-rare orphan disease, so the patient population that is there is very small. In Europe, this is a little bigger where there now about 1800 patients there but in US we believe there will be 2-3 patients every year who will be added to the ongoing program. So it is a very rare disease, it is a disease that is terminal in terms of children who have very high seizure rates and they don't survive. The payment for this is not anything significant at all. As I said it is a rare disease, as I said our company's philosophy is that we are committed to working on rare and speciality diseases where there are unmet needs and no medicines for. We have picked up this juvenile or new born area to work on and that's why there are these 2 drugs both Nulibry and CUTX 101 which would be going for the paediatric population. But the patient numbers always will be very very small because these are very rare, ultra rare diseases.

Anubhav Agarwal: Thank you. The second question is on Oxemia. What is the pricing that you have launched in the Indian market, that's one. And secondly, just from a patient perspective, I think the patient needs to take it on alternate days. But for how long does a patient who has CKD disease have to take it?

Sharvil Patel: So, it is a chronic treatment, it's not acute in nature. It has to be taken by CKD patients for almost throughout their lives. And, I don't have the exact pricing, so I can't give you the exact Rupee value on the tablet right now. But, our endeavour is that, today the class of treatment is an injectable, which is Erythropoietin, which has also side effects and you have to inject multiple times. So, this is an oral treatment to that and we believe we will see a lot of conversion from the current mode of treatment. Especially new patients who are not on dialysis will also see a significant opportunity in terms of this product. So, we believe that markets like India and other emerging markets like China have a

great potential with a large population of patients who have renal deficiencies and who have problems related to anaemia, so there is a lot of opportunity for that. And, the gross margins are good on this molecule, much better than the company's gross margins.

Anubhav Agarwal: Have you already commercialised this or are you about to commercialise this?

Sharvil Patel: We have already launched this in March and very good traction from the first month.

Anubhav Agarwal: And the last question – just a clarity on your vaccine contract of 1 crore doses. Since you haven't sold much, is there going to be some commercial opportunity from this 1 crore dose contract from the government, or that may not materialise?

Sharvil Patel: So, currently, there is no demand there from the government. So, we have not been able to fulfil that order because there is no demand for the vaccine in the adult population. What we are working on is to get our approvals. we already have approvals, but we are waiting for the final approval for 12 years and above. And, the opportunity that we are now currently targeting is exports and also the private market. And, if there are procedures that change with mix-n-match and booster and other things, then we might see some opportunity there.

Anubhav Agarwal: And lastly, for the US business, can you just give us some outlook? Do you expect fiscal 2023 to be a flattish year? I'm assuming that Asacol competition comes, maybe in the next quarter or the quarter after that… so do you expect that to be a flattish year or a growing year?

Sharvil Patel: We expect on the US business, there would be a price erosion in the mid to high single-digits, and that's what we are expecting. I think, what is going to help the US business to grow is going to be new launches. We are currently assuming for FY23 a single-digit growth for the year, but there are lot of variables to it and we have to see how everything goes. But, we have a good pipeline of ANDA still pending approval. We have some high impact products that we want to launch in the 2nd half of this year. And, if all of that goes well, we'll see single-digit growth for the full year, but the better 2nd half than the 1st half.

Anubhav Agarwal: Thank you.

Moderator: Thank you. We will keep two questions at a time because of the time constraints and there are many people who need to ask questions. The next question is from Prakash Agarwal.

Prakash Agarwal: Hi, thanks for the opportunity. Good Evening to all. First question, again a follow-on on the US. So, I'm looking at my last notes where you

mentioned that it is flattish or a partial decline is possible. Now we are talking about single-digit growth. Is there anything changing in your assumption? Do you think the competition is away in Asacol, or do you think the launches are chunky? If you could throw some light there?

Sharvil Patel: So, while we continue to see price erosion and some part of base erosion, we believe that there is some upside to Asacol in the 2nd half, and also two high-value launches that we believe can do good. So, because of that we believe that we can have a high single-digit growth.

Prakash Agarwal: And the follow up to that is the other Mesalamine product Pentasa. Is it stuck due to Moraiya?

Sharvil Patel: I don't think we give updates on to be launched products; I don't think we can give you that. But, we are working on other Mesalamine franchise products.

Prakash Agarwal: And secondly, on EBITDA margin guidance of at least 20%, if any colour could be given on the current gross margin or how we are seeing the input prices? We hear that packaging, freight, etc all have gone up, as also mentioned by various companies. So, what is the strategy here? Do we see that we take a lot of cost cutting measures? How are we going to address these high inventory cost issues?

Nitin Parekh: So Prakash, I think it works on several different measures. While we continue to work on cost optimization initiatives by different programs in manufacturing, supply chain as well as marketing and other aspects, other than that wherever feasible, we are also taking price increases to pass on at least part (if not full) of the price increases in various commodity items.

Prakash Agarwal: Okay. I'll join back in the queue.

Moderator: Thank you. The next question is from Sameer Baisiwala. Sameer, please unmute yourself.

Sameer Baisiwala: Sorry, can you hear me now?

Moderator: Yes.

Sameer Baisiwala: A very good evening. I don't know how you want to answer this, but just thinking, do you think the upside from Revlimid v/s negative from Asacol HD competition, how does that two factors stack up?

Sharvil Patel: So, I think it's very difficult to say when the competition is there in Asacol. As I said, currently there is an upside because the competition is delayed. Revlimid is going to be a good sizeable opportunity from our point of view, so that's a positive for the business. And, we do have one more high-value launch. So, I think, that's the current update I have for

the current FY23, beyond obviously our high-value filings and first to file products that we have for the future.

Sameer Baisiwala: Okay, thanks. But, if both were to get launched on the same day, which is Revlimid launch and the competition in Asacol HD, are the two comparable, that's what I'm trying to get at. Don't need to quantify it.

Sharvil Patel: No, obviously they are not comparable.

Sameer Baisiwala: The upside from Revlimid is much higher?

Sharvil Patel: No no, we can't comment on that because we have not launched the product. Until we know about that and the pricing and all of that, it's difficult to answer that question.

Sameer Baisiwala: Okay sir, no worries. And just on Nulibry, what's the thinking behind taking this asset? It doesn't look like any meaningful commercial opportunity, maybe a lot of hard work. You will build this whole infrastructure. So, why get into something like this?

Sharvil Patel: So, I think our philosophy for the company going forward is that we would be working on therapies and areas where there are unmet medical needs. If you look at our current portfolio of Zydus also, when you look at Saroglitazar for the treatment of PBC which is also an orphan disease in the US where there are no full line treatment for that. If you look at Desidustat and when we're doing work on chemotherapy induced anaemia, again, it's an orphan area. So, I think what we have decided to play is that, create a niche in this space of orphan and rare diseases. I think, as a responsible pharmaceutical company, we also want to make sure that while we do that, we also work on some of the neglected diseases or very rare diseases where there are no available outcomes. And, I think, both of these molecules have tremendous importance in terms of extending the life of young patients. So, I think, we looked at all of that and we decided to do that. Commercially, it is still meaningful for the size and scale of the company we are, and we do get premium for being able to provide the medicines for this. And, this business will slowly scale up, it's not something that can scale up overnight, but it's a very sticky and continuous business with very little threat on genericization.

Nitin Parekh: And Sameer, over a period, I think, it will a basket of such products which will make a meaningful difference using the common platform.

Sharvil Patel: And so, if I just give you an example on just Nulibry also, even if we are recruiting 2-3 new patients every year, it's still a good business model for us.

Sameer Baisiwala: Okay, great. Thank you so much. And, one final question is on ZyCoV-D. What's the outlook? I heard your commentary and it's good to see two-dose getting approved. On the previous call, you mentioned you can do 3-5 crore doses for the full year. Now, how does it look like? Is it a meaningful, commercial opportunity for this year?

Sharvil Patel: No, I don't see it immediately being so. I think our efforts are going to be to work on exports and the private market. If the plan of vaccination changes in terms of mix-n-match and other things, in terms of booster, we can see some opportunity. But, we are not now talking about doing 3 crore doses, because there is no demand currently for 3 crore doses. What we are also working on, is the multi-variant vaccine for this because we are working with multiple strains to be put into one vaccine, but that's a little longer-term development for this. So, that's the current update.

Sameer Baisiwala: Okay, thank you.

Moderator: Thank you. The next question is from Dipen Sheth.

Dipen Sheth: Hi. I hope I'm audible sir?

Moderator: Yes.

Dipen Sheth: Dipen from Buoyant Capital. Many of the questions that I wanted to ask have already been answered, so I'll take a slightly high-level issue that I'd like to raise for Sharvil to answer. We have raised a significant amount of resources on the balance sheet now, and we are literally pretty cash rich. I would guess that you are not going to let this ammunition remain idle for too long and you have a certain strategy intent with it. Or, would you be thinking in terms of returning it to shareholders? So, a little bit of a buyback and all that is fine, is there a concrete thought process here that over the next 1-2 years you want to put it into something which could be value accretive in some way? Is there any thinking around these lines? And if so, what is it?

Sharvil Patel: So, I think what you said is correct. As we are looking to build our speciality footprint and extend it both in India and US, and also look at some other global markets in terms of partnerships. So, I think some part of our investments will go into the build up of our speciality business and R&D associated with it for some of the products that we are developing. Second, we'll always look at some opportunities in India in terms of brand acquisitions that we want to look in terms of adjacencies that we want to create. There would be some capital investments now for enhancement of biosimilars and some vaccines, especially the global WHO prequalification vaccines like MR and TCV which we have committed to, and we are seeing good visibility to that.

And, some investment on oral solids for our US. As I said, we are looking optimising our network to make sure that the next facility we build is best in class in terms of cost. That's the current work that's going on.

Dipen Sheth: Okay, I'm hearing you. Thanks.

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

Prakash Agarwal: Hi, thanks for the follow up. I don't know if I missed it, but what are we guiding in R&D in terms of percentage to sales?

Nitin Parekh: About 8%.

Prakash Agarwal: So, my next question is on… Saroglitazar, last time we had indicated that the filing is expected by calendar 2024. Do we stick to that and do we see a ramp up in cost in fiscal 2024-25?

Sharvil Patel: So, Saroglitazar, yes we are still looking to file this in 2024 and commercialise it in 2025, and the clinical work is ongoing. These clinical programs for both PBC and NASH are going to be spread over 3-4 years, because NASH is a potential 2027-28 filing and launch. Our current view is, around 8% of revenue would be spent on R&D over the next 3 years.

Prakash Agarwal: And, would you say that your share towards NCE and innovative pipeline is increasing already v/s generics investments on the R&D side?

Nitin Parekh: It's almost the same. I think about 2/3rd is in generic and 1/3rd is in NCE.

Prakash Agarwal: I'm asking from a filing standpoint, once you are in fiscal 2024-25, would that share partly change or would you be at similar levels also? I mean, would the generics focus be there?

Sharvil Patel: The generics… I think we would not be having significant growth in absolute spend, I would say, on the current base. And, the base investments on obviously biologics and NCEs will grow. So, there would be some change towards that. But, I think at this base of generic investment, with some incremental growth, we should be okay.

Prakash Agarwal: Okay, perfect. And one clarity – there was a comment that there were no vaccine sales for the quarter. Is that correct?

Nitin Parekh: It's very insignificant. There is some sale, but not anything meaningful.

Prakash Agarwal: Okay. And the inventory write off is not related to vaccine, it is related to the COVID related drugs, would that be correct?

Nitin Parekh: No, it includes everything, including related to vaccine.

Prakash Agarwal: And lastly, on the overall strategy, there was a comment on big picture cash utilisation. So, the extra buck, where is that getting deployed? So, NCE is one area where you are increasing focus, but on an M&A side, India v/s US?

Sharvil Patel: I think in both markets we want to do acquisitions. US, on the speciality side, and in India, it's on the brands.

Prakash Agarwal: Okay. But, you would have looked at these assets which have gone. In the last 6 months, there's an aggressive M&A that's happened in India.

Sharvil Patel: Yeah, so I think more than businesses, we are looking to acquire brands, that's of more interest to us. Some of them have not been meaningful for us.

Prakash Agarwal: Okay, great, thank you.

Moderator: Thank you. The next question is from Vishal Manchanda.

Vishal Manchanda: Thanks for the opportunity. This is Vishal from Nirmal Bang. With respect to your orphan drug portfolio in the US, I wanted to understand how are you handling the diagnostic challenge because these are ultra-rare diseases. So, how do you get to reach to the patient?

Sharvil Patel: So, that's a very important part of the question. I think, the hard effort that is being put in for both the molecules is new born screening, and we are working on developing the assays for the deficiency that we want to see for both CUTX and Nulibry. And, new in born screening assays are being under development with different universities, and that's how in the future we'll be able to find more patients. So initially, we will find patients more by talking to the doctors and making them aware of the disease and the complications related to the disease. And, at the same time, work on new born screening assays which we'll also have to work on to make it part of the state plans and the government plans to make sure that they are part of the screening process.

Vishal Manchanda: And how long can this development of assays can take?

Sharvil Patel: The assays, we are hopeful we can do it over the next 3-6 months, but to get it enrolled into the programs for new born screening would be long-ended effort. It would be a state by state effort over a period of time.

Vishal Manchanda: Right. On the Copper Histidinate drug for Menkes disease, do we have a number on how many newborns get diagnosed every year? Or, would that number not be available?

Sharvil Patel: I don't have it off hand. But we have all that data… if you visit our website also, you'll see a little bit on that. But definitely, I can provide

you offline the prevalence, the diagnosis and what are we looking at. And, these are all ultra-rare diseases, so, as I said, for one of the products we are looking at 2-3 new patients. In this we are talking about 10-12, that would be enough.

Vishal Manchanda: And, the annual cost of therapy can be a few lakh dollars?

Sharvil Patel: Yes.

Vishal Manchanda: Okay, thank you. That's it from my side.

Moderator: Thank you. The next question is from Surya Patra. Surya, you can go ahead and ask your question. Okay, we'll take him again. The next question is from Anubhav Agarwal.

Anubhav Agarwal: One clarity on the personnel cost. From a 1H average to the 2H average, we are seeing a reduction of 50 crores. Is that just an absolute reduction in the personnel cost or is this just an expense getting booked in other line items?

Nitin Parekh: So, one reason was, because we discontinued operations of Nersher and Hercon, the people cost related to that is now no more there.

Anubhav Agarwal: But you know, the personal cost was lower in the 3rd quarter also. So, we were doing about 650 crores in 1Q and 2Q, now in the 3rd quarter we're doing about 585 and now 600 crores. And this discontinuation naturally you would have done in this quarter, I guess?

Nitin Parekh: No, it was done in September. There were few people still left and gradually they have been terminated. But, we'll get back to you with exact numbers if you want further details on that.

Anubhav Agarwal: But, the full cost saving advantage of the discontinuation of Nesher has flown in now in this quarter?

Nitin Parekh: Yes.

Anubhav Agarwal: Okay, thank you.

Moderator: Thank you. The next question is from Nitin Agarwal. Hi Nitin, please unmute yourself.

Nitin Agarwal: Thanks. On the US business, what is the share of speciality business as it stands today after the discontinuation of Nesher?

Sharvil Patel: So, we don't currently have any speciality business in any significant manner. So, it's not anything meaningful right now because we discontinued one of the products. That was the only speciality business we had.

Nitin Agarwal: And aspirationally, any focus which is there in orphan drugs, in this new strategy that you're building out, where do you see this number in say 3 to 5 years?

Sharvil Patel: So, our effort is going to be to make the business profitable and grow it sustainably. As I said, the way to build on the orphan, atleast ultra-rare orphan side is to slowly build on to the patient flow. And, these treatments are lifelong. So, you incrementally build the value on this, and that is going to be the expectation from the management to do so in the US.

Nitin Agarwal: In the past, you've talked a lot about complex injectables being a very critical driver for the US business growth. Can you provide any colour on how the next couple of years are looking like from a launch perspective on the injectable side?

Sharvil Patel: So yes, injectables is going to be an important segment of growth for the US generics business for us. Today, we have a mix of more simple products that we have started to commercialise after approvals and some complex products like Liposomal Doxorubicin, Enoxaparin, Fulvestrant and the Nelarabine injection where we are exclusive generic player. So, slowly we are building on to this launch pipeline where we have a good number of filings. We also have filed the first complex product in terms of the pen device combination product, and more products are likely to follow. So, that's how we're building on the pipeline of complex products for the US.

Nitin Agarwal: And, from a size perspective, when do you see that to become meaningful for your business, because right now it's primarily orals.

Sharvil Patel: Sorry, can you repeat the question?

Nitin Agarwal: I mean, the business currently is largely oral solids. When do you see injectables probably getting a 15-20% of the business?

Sharvil Patel: Injectable business overall will be part of the… I mean, it will never be a larger sum of the orals business, but it will become an important part of the business. So, I think it's a sum of three parts, right? We're talking about our orals, including complex orals. We're talking about transdermal as one franchise and injectables. So, these three franchises will aid to the overall growth and the aspiration that we have for the US generics business. I think, we generally look at it as a portfolio of businesses. While injectable is one part of it, we're not segmenting one for the other.

Nitin Agarwal: Got it, thank you. The last one, since you mentioned transdermal, what is the thought process on the transdermal launches?

Sharvil Patel: So transdermals, I think the important stage gate for it is the inspection for Moraiya facility and then the clearance for Moraiya. Once that happens, we would see a rollout of transdermals. I think the business of transdermals, once we're able to roll it out and take some share, it's more sticky business. So, that's what we're looking forward to.

Nitin Agarwal: Okay. Thank you and best of luck.

Moderator: Thank you. The next question is from Surya Patra. Surya, please unmute yourself. Okay, I think he's facing an issue. The next question is from Sameer Baisiwala. Sameer, please unmute yourself.

Sameer Baisiwala: Done it, thank you. Sir, looking at your last slide, Slide 14. For fiscal 2022, you had roughly 240 crores of income coming from FX fluctuations. A lot in other operating income, some in other income. And you have another 75 crores coming from profit on sale of investments. So, we're talking roughly 310-315 crores, sort of one-off, and this was not there in fiscal 2021. So, if you could talk a bit about it. And, in your opening remarks when you had excluded all one-offs while telling us the net profit for fiscal 2022 which was a 12% growth YoY, did you exclude all of this or was this part of this?

Nitin Parekh: No, it was not excluded. So, foreign exchange fluctuation has two components. One is, a normal movement of dollar and the other is because of the forward contract that we have entered into on our receivable, and we have got the forward premium for that which also gets classified here as a part of other operating income. And, on profit on sale of investments, it is related to our surplus cash deployed for liquid funds, overnight funds etc. So, that is the income, which could be… that's a part of interest income, here it is on profit on sale of investments. That is on surplus cash.

Sameer Baisiwala: Okay, I get it. So going forward, these incomes may come on the same line or may be part of the business income, but should be continuing as you go forward?

Nitin Parekh: So, profit on sale of investment kind of income would remain. Depending on the instrument that we invest in, maybe interest income, maybe it might continue like a mutual fund investment income, except to the extent of cash that we are now planning to use for the buyback program.

Sameer Baisiwala: Okay. And, for the FX part?

Nitin Parekh: Yeah, I think the Rupee continues depreciating and we have continued our forward contract for the existing receivables. So, that benefit will continue.

Sameer Baisiwala: Okay. Thank you very much sir.

Moderator: Thank you. We will take the last question from Vishal Manchanda.

Vishal Manchanda: Thanks for the opportunity. Can you share your biosimilar numbers for the quarter?

Sharvil Patel: No, we are not giving individually the numbers. But as I said, the biosimilars overall business is on a good trajectory, and it's scaling up very fast, and it will become an important line of revenue for the overall India business.

Vishal Manchanda: Or else, if you can share the YoY growth for the biosimilars?

Nitin Parekh: It's much better than overall India…

Sharvil Patel: It's significantly higher than the other India business.

Vishal Manchanda: Okay. Thank you.

Moderator: Thank you. I would now like to hand the conference back to Mr. Ganesh Nayak.

Ganesh Naik: Thank you very much and look forward to interacting with you again during the next conference which will be in July/August. Thank you and good night.

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

END OF TRANSCRIPT