May 23, 2024

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

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

Sub: **Transcript of the post results earnings call held on May 17, 2024 pursuant to regulations 30 and 46(2)(oa) of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 ("the Listing Regulations")**

Dear Sir / Madam,

Pursuant to regulations 30 and 46(2)(oa) of the Listing Regulations, please find attached the transcript of the Company's Q4 FY24 post results earnings call held on May 17, 2024.

Please find the same in order.

Thanking you,

Yours faithfully,
For, **ZYDUS LIFESCIENCES LIMITED**
DHAVAL NARENDRA SONI
Digitally signed by DHAVAL NARENDRA SONI
Date: 2024.05.23 15:23:22 +05'30'

**DHAVAL N. SONI**
**COMPANY SECRETARY**

Encl.: As above

# “Zydus Lifesciences Limited Q4 FY24 Post Results Earnings Call”

**May 17, 2024**

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

**Moderator:** Welcome to Zydus Lifesciences Limited Q4 FY24 Earnings Conference Call. Please note that all participants' line will be in listen-only mode and there will be an opportunity for you to ask questions after the opening remarks. Please note that this conference is being recorded. I now hand the conference over to Mr. Ganesh Nayak, Executive Director of Zydus Lifesciences. Thank you and over to you, Sir.

**Ganesh Nayak:** Good evening, ladies and gentlemen. Welcome to our post results teleconference for the fourth quarter and the financial year ended March 31, 2024. For today's call, we have with us Dr. Sharvil Patel - Managing Director, Mr. Nitin Parekh - Chief Financial Officer, Mr. Arvind Bothra - Senior Vice President, Investor Relations and Mr. Alok Garg - Senior Vice President from the Managing Director's office.

To begin with, let me give you an overview of the performance for the year. During the fiscal 2024, all our key businesses demonstrated strong performance through the year. Overall, we delivered a healthy double-digit growth during the year in-line with our expectations along with improved profitability. I am happy to inform you that we achieved the highest ever operating profit and margins during the year. Our branded formulations business in India grew faster than the market and registered double-digit growth during the year aided by healthy volume growth and new product launches.

On the Consumer Wellness front, the FMCG sector witnessed gradual improvement in demand during the quarter with an uptick in demand also in rural India. Most of our portfolio has seen demand recovery which was further fuelled by the demand of summer led brands like Glucon-D and Nycil in anticipation of a good summer.

We achieved an important milestone in our US formulations business during the year. Revenues of the business crossed US$ 1 billion for the first time on the back of strong, double digit growth. The base business achieved sequential growth every quarter through the year on the back of volume expansion and new product introductions.

International markets business, which comprises of Emerging markets and Europe, also delivered double digit growth with all key markets contributing to growth during the year.

In order to stay competitive and serve our customers in a cost-efficient manner, we continuously analyse the spend base and

identify and implement various ideas across functions to improve efficiencies in our operations. We could improve our profitability in the range of 50-70 basis points in the past on account of such initiatives and we expect similar improvement going forward as well.

On the back of our diversified portfolio of products and focused execution efforts, we expect all our businesses to sustain healthy growth.

With that, let me take you through the financial numbers for the year gone by. We recorded consolidated revenues of 195.5 billion rupees, up 13% on a year-on-year basis. The business delivered robust operating performance with an EBITDA margin of 27.5%, which is an improvement of 510 basis points over the previous year. Consequently, the consolidated EBITDA for the year grew by 40% to 53.8 billion rupees. Net Profit for the year stood at 38.6 billion rupees, up 97%. Our balance sheet strengthened further with a net cash position of 8.6 billion rupees as at 31st March 2024 against the net cash of 5.5 billion rupees as at 31st March 2023.

Coming to our quarterly performance. we ended the fiscal 2024 with a robust performance. Revenue stood at 55.3 billion rupees during the quarter, up 10% on a year-on-year and 23% on a quarter-on-quarter basis. We registered the highest ever operating profitability during the quarter with an EBITDA margin of 29.5%, which is an improvement of 440 basis points on a year-on-year and 500 basis points on a quarter-on-quarter basis. EBITDA for the quarter stood at 16.3 billion rupees, up 30% on a year-on-year and 48% on a sequential basis. Net Profit for the quarter was 11.8 billion rupees, up 299% on a year-on-year and 50% on a sequential basis.

Now, let me take you through the operating highlights for the fourth quarter of FY24 for our key business segments.

Our India geography, which comprises of formulations and consumer wellness business, accounted for 40% of the total revenues during the quarter and grew 8% year-on-year. Our branded formulations business in India grew faster than the market during the quarter as well with 8% year-on-year growth. Portfolio of key pillar brands and innovation products were the key growth drivers. During the quarter, we gained market share in derma and the anti-infective therapies. On the super speciality front, we retained the leadership position in the nephrology segment, while in the oncology space, we remained amongst the fastest growing companies in India. Contribution of chronic

portfolio has increased consistently over the years and stood at 41.2% as per IQVIA MAT March'24, an improvement of 360 basis points over the last three years. The consumer wellness business recorded revenues of 7.8 billion rupees, up 10% on a year-on-year basis. The personal care segment, which comprises of Nycil and Everyuth brands, registered yet another quarter of strong growth. Performance of food and nutrition segment improved with mid-single digit growth during the quarter. We continued to witness gross margin expansion with an improvement of 377 basis points on a year-on-year basis for the quarter driven by calibrated price increase taken earlier and efficient hedging strategy for key commodities.

Now, let me take you through the performance of our US formulations business. The business accounted for 47% of the consolidated revenues during the quarter with revenues of 25.2 billion rupees and delivered robust 37% growth sequentially. As mentioned earlier, the base business continued to expand sequentially during each quarter of the current fiscal on the back of volume expansion and new product launches. We launched 5 new products and received approval for 12 ANDAs, including four tentative approvals during the quarter. We filed 20 ANDAs, received approval for 46 new products, including 5 tentative approvals and launched 29 new products during the year.

On the international markets front, growth momentum built over the last several quarters continued as the business delivered double digit growth for yet another quarter with a healthy demand across key markets. Overall, the business posted revenues of 5 billion rupees, up 13% year-on-year.

During the quarter, we received the EIR from the USFDA for our API Ahmedabad facility which was inspected by the agency during the preceding quarter. Two of our injectable manufacturing facilities located at Ahmedabad SEZ and Jarod near Vadodara were recently inspected by the USFDA and were issued certain observations upon completion of inspection. We are closely working with the USFDA to implement necessary corrective actions.

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

**Sharvil Patel:** Thank you, Mr. Nayak. Good evening, ladies and gentlemen. It is a pleasure to have you all here on the call today. We are pleased with our performance during the quarter and the year. All our key businesses are focused on enhancing the value proposition to their customers by fulfilling their diverse healthcare needs. We look forward to expanding our presence in existing therapies and markets and explore newer avenues to serve our customers better and generate greater value for all the stakeholders.

On the India formulations front, we continue to channelize our efforts and resources towards strengthening our position in focused therapy areas through multiple levers. Our innovation engine continues to offer novel solutions to our customers and satisfy their unmet healthcare needs. Various strategic interventions done in the past have helped our branded formulations business to deliver double digit growth over the last couple of years and we look forward to building onto this momentum.

On the US formulations front, we have built a comprehensive portfolio spread across dosage forms by leveraging our in-house development capabilities as well as exploring partnership opportunities. In the specialty space, acquisition of LiqMeds has augmented our capabilities to deliver novel solutions to the patients while in the rare disease space, we have now a meaningful presence with two commercialized products and one product under filing stage. We expect our US business to sustain the growth trajectory going forward. This will be driven by large product portfolio, strong customer relationships, a network of regulatory compliant manufacturing facilities, an agile supply chain and an efficient cost management.

On the international markets front, we are focusing on growing the business in chosen therapies areas across key geographies by leveraging our global R&D portfolio of differentiated and niche generics as well as speciality products. In Europe, we are working towards strengthening our retail presence in France and Spain through portfolio expansion, improving cost proposition and increasing pharmacy coverage. We also commenced our UK operations during the year where we wish to expand by leveraging our global R&D portfolio.

Our innovation pipeline across different areas progressed well and achieved important milestones during the year. Success of our innovation efforts is evident from the increase in number of patients over the years who benefited from the affordable and accessible

treatments options delivered by our innovation engine to fulfil their unmet healthcare needs.

With this, let me talk about some of the material developments on the innovation efforts during the quarter.

On the NCE front, we completed the recruitment of patients for Phase II(b)/III clinical trials for Saroglitazar Magnesium for PBC indication for the US market. The trial will study the effects of a molecule relative to placebo over 52 weeks across 100 sites. The Phase II(b) clinical trial of Saroglitazar Magnesium for NASH indication for the US market is advancing as per the plans.

Recently, the National Medical Products Administration of China accepted the new drug application of Desidustat made by China Medical Systems holdings Limited (CMS). Earlier, in 2020, we granted an exclusive license for Desidustat to CMS for China, Hong Kong, Macau and Taiwan markets. Phase III clinical trials in China have demonstrated positive results. The primary endpoint of the haemoglobin mean change from baseline to the period of weeks 7 to 9 has indicated that Desidustat is more effective than placebo in increasing haemoglobin levels.

Coming to our key development program ZYIL1, the WHO's International Non-proprietary Names (INN) recently approved "Usnoflast" as the recommended name for the molecule. Usnoflast is under clinical development for four indications at present - Amyotrophic Lateral Sclerosis (ALS), Parkinson's disease, Cryopyrin-Associated Periodic Syndromes (CAPS) and Ulcerative Colitis.

For ALS indication, Usnoflast is undergoing Phase II clinical trials. ALS affects approximately 31,000 people in the US and on an average, 5000 new patients are diagnosed every year with this disease in the US. Over 30,000 people are estimated to be living with ALS in Europe, while in India, approximately 75,000 people are living with ALS. People with ALS have a median survival of approximately two years from diagnosis.

The USFDA granted the approval to initiate Phase II clinical trial of Usnoflast in patients with Parkinson's disease. It is estimated that there are over 8.5 million people worldwide suffering from Parkinson's disease with 1 million suffering from the disease in the US. Each year 90,000 new cases of Parkinson's disease are reported in the US.

On the CAPS front, we are the first company to establish Phase II proof of concept for Usnoflast in CAPS patients. Results of the study

were published in the 'Clinical Pharmacology Drug Development'. Usnoflast holds an orphan drug designation from the USFDA for CAPS indication.

We have initiated Phase II proof of concept study of Usnoflast in patients with UC (Ulcerative Colitis). It is characterized by irregular chronic immune response that creates inflammation and ulcers in the mucosa of the large intestine or rectum. In the year 2023, the prevalence of Ulcerative Colitis was estimated to be 5 million cases worldwide.

In the biotech R&D space, during the quarter, we initiated Phase III clinical trials for one product. We completed pre-clinical tox study for one monoclonal antibody and submitted the report to RCGM.

On the Specialty and 505(b)(2) development front, Sentynl Therapeutics, our wholly owned subsidiary, received marketing authorization from the UK MHRA for NULIBRY for the treatment of patients in Great Britain with Molybdenum Cofactor Deficiency (MoCD) Type A; an ultra-rare life-threatening genetic disorder. It is the first and only treatment in Great Britain for patients with genetic disorder. An early access program is in place for NULIBRY for eligible patients who meet the specific criteria. Through this program, healthcare professionals can request for the product, if it is not commercially available in their country.

Recently, Sentynl Therapeutics Inc. acquired world-wide proprietary rights to Zokinvy® from Eiger Biopharmaceuticals for the treatment of Hutchinson-Gilford Progeria Syndrome, an ultra-rare, fatal, genetic premature aging disease that accelerate mortality in young patients. Zokinvy® is the first and only treatment approved by the USFDA for Progeria. The product is also approved in EU, Great Britain and Japan for the same indication.

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

**Moderator:** Thank you very much. We will now begin the Question and Answer session. Anyone who wishes to ask a question may raise your hand from the participant tab on your screen. The participants are requested to use headphones or earphones while asking a question.

The first question is from Kunal Damesha.

**Kunal Damesha:** Hi. Good evening and thank you for the opportunity and congratulation on good set of numbers. Sir, can you highlight what would be our broader outlook for FY25 in terms of revenue growth? And also, I think, EBITDA margin, earlier we had suggested that we'll

do EBITDA margin north of 27% but 27% is something we have done in FY24 itself. So, do we expect to do higher EBITDA margin?

**Sharvil Patel:** So, we expect all our businesses to register good double-digit growth. At the aggregate level, we expect high teens growth. This is obviously after assuming competition in Asacol in FY25.

On the EBITDA margins front, I think, assuming we have competition in Asacol, we expect to comfortably maintain FY24 margins of 27.5% in the coming year and we will make our best efforts to continue to improve those margins.

So, yeah, those are the two main observations I have on this. And plus, I would say, we still continue to have a robust pipeline of launches with 30+ launches that we planned for FY25.

**Kunal Damesha:** Sure-sure. And in terms of R&D expenses, any outlook that we want to share now that we have enrolled patient for PBC trial. Does that mean that there would be a step jump in the R&D for FY25 or it would be more like business as usual?

**Sharvil Patel:** I think with revenue growth that we expect and also there will be growth on R&D, I think we are still giving guidance of around 7-8% for FY25.

**Kunal Damesha:** Sure. And the last one with your permission, Sir. On the acquisition of Zokinvy. From here on, whatever that product is doing, what would be our strategy to grow that? You know revenue, would it be more on getting…So, is it that we are not able to reach, the drug has not reached all the patients that are available? And is it more like geographic, you know, adding more geography in terms of launch and all? What would be the strategy with that product?

**Sharvil Patel:** Yes. So, I do think we believe that, with our current capability that we have in the rare disease space, we believe that we will be able to find better ways of, I mean, we'll do better execution on finding new patients first obviously in the US. But we also see the opportunity in other markets with the registrations and access programs being created for this to get more patients there. So, we do definitely see an opportunity to grow this in FY25 and FY26.

**Kunal Damesha:** Sure. I have more questions, I'll join back the queue.

**Sharvil Patel:** Thank you.

**Kunal Damesha:** Thank you.

**Moderator:** Thank you. The next question is from Neha.

**Neha:** Yeah, thanks for taking my question. Sir, on the US pipeline, based on your commentary that you would launch about 30 products. If I look at the pending pipeline that we have, it seems like it's around the 50-60 number. So, should we assume, as we go ahead, the number of launches sort of moderate because we're doing more high value launches? Or should we see the filing momentum materially pick up? What's the strategy to sort of augment this pipeline in the US?

**Sharvil Patel:** So, we still expect to file 25-30 plus ANDAs in FY25. This year we had filed 20 but we will see that uptick happen by at least 5 to 10 more. We are also actively pursuing partnership opportunities for in-licensing important products in the US and recently we obviously announced one but we are seeing success on that in terms of finding more opportunities.

And going forward, as I said, we still hope to launch 35+ products in the US in FY25. So, I think from that point of view we still will continue to have a robust pipeline of products that we have filed and to be filed. So, I think we will still achieve 20-25 plus launches consistently. But obviously this year we'll see higher launches. I mean, coming year we'll see higher launches.

**Neha:** Got it. And how many of these launches, you know, a rough breakup of what you're planning in 25 would be injectable, non-injectable? Just trying to assess the risk given two of our facilities have been inspected. I know we don't know the outcome yet and you're doing your best but how much of this is injectable versus non-injectable? Any colour there?

**Sharvil Patel:** So, currently, we believe, four maybe four products, that we may believe may get delayed. That's our current estimate.

**Neha:** Okay-okay. Got it. Second is on the India business. Now we've started seeing some momentum pick up in the India business. I'm talking about the formulation business this year, particularly in the last few quarters. Should we assume that the growth trajectory for India would be now at a higher level or what we saw last year is the momentum that we will maintain for the India business?

**Sharvil Patel:** So, as I said, we do expect double digit growth but definitely we will like to grow ahead of market depending on how the market shapes up in FY25. But currently our expectation is to grow in double digits for India business, which is mostly aided by obviously our proprietary and differentiated products which are specifically high value. And also, with the efforts that have been put on certain specialty and chronic segments, we will see better momentum for our growth booster brands that we have allocated.

So, I think, that focused segments plus the proprietary and new differentiated techno products that we have, we believe we can deliver double digit growth.

**Neha:** Understood. Sorry, one other question on the US market. On Asacol, you know, you said the guidance includes competition in Asacol. So, you know assuming that there will be competition this year in first half, second half? I mean, do you have any colour on that or this is just being conservative?

**Sharvil Patel:** Yeah, I think, to be on the conservative side, it is always prudent to assume we will see competition. So, that's what we always, when we are giving guidance, we are talking about guidance with the competition on Asacol.

**Neha:** Understood. Thank you so much, Sir.

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

**Surya Patra:** Yeah, thanks for this opportunity Sir and congrats for the strong set of numbers. Sir, my first question is on the margin improvement sequentially what we have seen. If I just adjust for let's say some Revlimid kind of a number out of the total reported, it looks like that your base business has seen the gross margin which is highest ever. And if this is the case, back to back, even third quarter gross margins were significantly better for the base business adjusted for Revlimid. So, what is driving this? Or it is largely to do with the consumer business doing better than expected?

**Sharvil Patel:** So, yes, one part of the reasons for the gross margins is we saw an improvement on the gross margins for the consumer business. But, overall also, we have seen improvement in gross margins with better efficiencies and inflationary pressures reducing. So, I think both of them have aided and, obviously, it's also to do with product mix. As new product sales becomes larger part of the overall business, the gross margin profiles are much better there.

So, I think all of that. So, the product mix, the wellness business seeing the inflationary pressures ease and better pricing realization and obviously the mix of markets that we have has led to that benefit of improved gross margins.

**Surya Patra:** So, in that case, so what is the sustainable, means whether this is a sustainable one or we can grow up on this? That is one. And, secondly, the spike in the other expenses also what we are witnessing in this quarter. Is it also largely led by the consumer business contributing significantly?

**Nitin Parekh:** So, gross margin without special products is sustainable. And with continuous efforts in terms of cost rationalization, normal price increases that we can take in consumer business, we are able to take care of inflation in terms of input cost. So far as other expenses are concerned, for the quarter, the increase is partly because of one-off expenses to the extent of about 50 crores and largely because of the seasonality of Consumer Wellness.

**Surya Patra:** Okay. This 50 is one off?

**Nitin Parekh:** Yes.

**Surya Patra:** And this is relating to what, Sir?

**Nitin Parekh:** There are different items.

**Surya Patra:** Okay. My second question is about the US business. So, obviously we have seen a kind of a strong sequential improvement, obviously also led by special products. But on the base business front, how should one think about? And while you are talking about sustaining the momentum there in the US market as well and all that. So, what is the nature of the products? Means while you are saying 30 odd products pipe-line for this year, any special products or any kind of a key product opportunities that you are targeting? If you can highlight selective few which will give some confidence about the sustenance of the double-digit kind of performance in the US business?

**Sharvil Patel:** So, I think, there are couple of things. One is obviously the new launches will scale up, as I had spoken of. So, both the new launches that we will do and the last year's launches that are scaling up including the products like in the transdermal space. The LiqMeds specialty US business also is scaling up meaningfully. There is also good contribution that will come in from the animal health business as well as the recent acquisition of Zokinvy which will start getting realized in a quarter from now.

And if you say very meaningfully, recent, obviously, we have launched Mirabegron, which is obviously a very significant launch by the company.

**Surya Patra:** And we have exclusivity kind of thing in both the strengths Sir, for Mirabegron?

**Sharvil Patel:** Yes. From our best knowledge, right now, on one strength, we have one more competitor and on the larger strength, we are exclusive for now.

**Surya Patra:** Okay. Okay. Sir, third question was about, sorry, it is a continuation to the Revlimid point. So, is it fair to believe, Sir, Revlimid is going to have a kind of improved contribution in the next FY25?

**Sharvil Patel:** Yes.

**Surya Patra:** Okay. And regards the business diversification, see, in fact now, having seen a kind of a sequential progress and improvising our positioning, presence, growth, all that in the domestic side, which now, along with the consumer account almost 40% and US more than 45%. So, these are two growth drivers in the recent past but going ahead, for your future progression and all that, are you really thinking about either business diversification in terms of geographically or you think that okay, you can enhance the depth of the business in the existing areas only or existing market only and hence can possibly think about sustaining the growth going ahead? What is your plan going ahead?

**Sharvil Patel:** So, I think, the two large markets, US and India, I think we are strategically well placed to continue to grow them strongly. So, that we are very confident on. Our developing market or emerging markets business is also scaled up meaningfully over the last five years with good growth and profitability and that business unit will continue to explore more market opportunities to enter into with the differentiated portfolio that now we have globally. So, that we will see some expansion.

But as I said, overall, we are well placed with the portfolio and the future pipeline to see meaningful opportunities in both US and India, which are our largest markets.

**Surya Patra:** Okay. If you permit me, Sir, one more question. So, how to think about this China Desidustat opportunity, Sir? And what is the kind of arrangement that would be, because obviously size wise it is a much bigger and larger market? And if we get a kind of a preference in terms of getting the product introduced into their reimbursement list, then it can also kind of a meaningful opportunity and what is the kind of arrangement that you would be having in terms of revenue sharing? Some sense and some visibility about this, because it could potentially be a really positive surprise for our overall performance.

**Sharvil Patel:** So, China is a very, very large market, is probably no. 2 in the world in terms of franchise. The current approved products in China are already clocking very significantly large value. So, we believe that if everything goes well and we get approval from the Chinese regulatory authority and with the very strong commercial partner like CMS, we will see good benefit, I mean good significant traction for Desidustat

to become a very large global product for us and it's a royalty-based partnership that we have. So, once everything happens, once we're able to commercialize, we can definitely then speak more about it, but it looks, it's a very positive sign and if everything goes well, it would be only a two-player market kind of thing, which will offer great opportunity for Desidustat.

**Surya Patra:** So, it's manufactured by them?

**Sharvil Patel:** No, it's manufactured by Zydus.

**Surya Patra:** Okay. Sure. Yeah. Thank you, Sir. Wish you all the best.

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

**Saion Mukherjee:** Yeah, hi. Thanks for taking my question. Sir, just one clarification to start with. Your guidance for next year is consolidated high teen growth or double-digit growth, I just missed that and also on the margin, you're expecting it to be flat with Asacol HD competition or you expect it to improve for next year?

**Sharvil Patel:** So, I think on a conservative side, if we see Asacol competition, at the basic, we will definitely maintain FY24 margins, but if we see scale-up of our new critical launch that has happened right now and with other benefits, we will work towards improving it further. In terms of growth, yes again, I think critical launches will play an important role in the growth. So, from double digit to high teens will all depend on the successful launches, one which we have done and few we hope to do. So, if that all goes well, we do hope to see better growth.

**Saion Mukherjee:** And Sir this number that you mentioned is on a consolidated basis, at overall company level, double digit to high teen is what one can expect?

**Nitin Parekh:** Saion, just to clarify, Nitin here. What we told, all the businesses will register a double-digit growth and at aggregate level, we expect a high teens growth.

**Saion Mukherjee:** Okay, understood. Sir, this Mirabegron launch, I mean, what's your expectation of competitive intensity going forward? Do you have a view there?

**Sharvil Patel:** Our current best estimate is we do not expect, in the near term, any more competitive intensity. So, it will be currently, in one strength, two players and on the higher strength, single player market.

**Saion Mukherjee:** Understood and Sir finally, before I join back, on the specialty and innovation piece, there are a lot of moving parts as we see today. So, from a next three years perspective, can you just lay out what are the

key milestones we should watch out for, the meaningful ones and also how should we think about the cost structure here with respect to R&D spend, sales and marketing efforts on the cost side and investment side from a next three-year perspective?

**Sharvil Patel:** So, for FY25, our R&D spend, we will be around 7% to 8%, is our current guidance. On the key milestones, I think, there are 2-3 critical milestones. The first, which is for our lead candidate Saroglitazar. So, we finished our recruitment for PBC indication. So, one year from now, we will have a readout on the results and if we see positive results, which we hope, then we will be filing it in the US for NDA application and probably six months to one year from then, we would see a commercialization of that. If we are successful with good data, FY26, we will see commercialization expenses get built in for the launch and FY27 more meaningfully. Beyond that, as I said, Desidustat will be the next milestone for approval in China and really kicking that off. Third would be our Zycubo, which is CUTX101, going through a rolling NDA filing and potentially quarter four of FY25, potentially seeing an approval and launch. And then, there are obviously multiple product launches that we have planned for in India, day one launches, which will be meaningful. So, I think all in all, these will be part of the plans for at least FY25 journey.

**Saion Mukherjee:** Sir, the experience of Desidustat in India, is there any color, the numbers look a bit low. I mean how do you see that ramping up in India and what are the issues that we're facing in India currently?

**Sharvil Patel:** In Desidustat in India, we have seen excellent results. So, I think it is one of our best new launches. So, we don't see any concern and for it to become, you know the 100-crore plus franchise soon, is definitely the goal. So, there is actually seeing very good traction on Desidustat. We don't have any growth issues in that market.

**Saion Mukherjee:** Okay. That's great. Sir, one last, if I can Sir, any color on vaccine, any major uptick you see, WHO approval or export opportunities over the next three years and if you can give some granular details on timeline there?

**Sharvil Patel:** So, I think FY24, the key milestone for vaccines will be first to get pre-qualification for MR, TCV and renew the rabies pre-qualification that would be the most important part. If that goes through well, we will see immediately opportunity on rabies in a meaningful manner. Post that, I think more it is a calendar year 26-27 for MR & TCV global public tender market opportunity, which would be very meaningful. Currently, I would say the immediate opportunity for MR will be the India vaccine tender opportunity that is coming up which we would like to participate and see if we can succeed and our flu vaccine and

other vaccines continue to scale up meaningfully. So, I think all of that is going well, but as I always have said that it is more FY26-27 where you will see major scale up of the vaccines business. Also, we don't speak always because it's not really a vaccine, but our rabies immunoglobulin, which is the dual monoclonal antibody is getting registration across India and other places in terms of getting into the usage and that will also see some improvement over the next two to three years.

**Saion Mukherjee:** Okay, Sir. Thank you, Sir.

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

**Bino:** Hi, good evening and congrats on a great set of numbers. Just couple questions, Sharvil bhai, just following up on the previous question, Mirabegron competition, what is preventing it? Is it the patents that are still in force which will run until 2030 or is there some FDA related exclusivity?

**Sharvil Patel:** No, it is to do with litigation, IP.

**Bino:** Understood. Today morning, you announced this distribution agreement with MSN. Earlier, you have done one with Synthon as well. Just for our understanding, you know, in this kind of distribution agreement, so, what is the sort of profitability that we get? Is it just a distribution margin around 10% or is it significantly better?

**Sharvil Patel:** No, it's a profit share arrangement.

**Bino:** Okay and so it should be much better than a typical distribution agreement?

**Sharvil Patel:** Yeah, yeah. It's equal profit share.

**Bino:** Okay, understood. Have you launched Zituvio, Zituvimet already?

**Sharvil Patel:** Sorry?

**Bino:** Zituvio, Zituvimet, the Januvia 505(b)(2), have you already launched it?

**Sharvil Patel:** Yes, we have launched Zituvimet and Zituvimet IR will be the next one which has also got approval. We have had good success. It's a tough launch in terms of making a branded launch in the US market, but we are seeing a good traction on it and we see, over the next five years it being a meaningful product for Zydus.

**Bino:** Great. One last, if I may please. This year 24, we saw that Revlimid was a bit episodic, more in 1Q and 4Q. Is it going to be similar in 25 as well?

**Sharvil Patel:** Yeah, Q1 will be higher than Q4.

**Bino:** Q1 and Q4, okay. Great. Thank you very much.

**Moderator:** Thank you. The next question is from Nimish Mehta.

**Nimish Mehta:** Yeah, hi. I hope we are able to hear it. Just one question on the US generics market. I mean, you know from the data that we have; we see that there has been some significant erosion, price erosion in the month of April. How do you see that, I mean and what is the impact on our portfolio?

**Sharvil Patel:** So, I don't know overall. So, we have had, I mean I think our base portfolio is stable and as I said they have been highly genericized and I think, overall we have seen a good traction on the business. So, I think as I always say the market is not changed, it is always going to be a large consolidated buying, which if hyper competition comes in, there will be price, the escalation and depending on where the product is and competition is, that will continue, but with the new products and certain capabilities that we have in supply chain resilience and how we have a strong customer insight as well as supply service levels, I think we are seeing good sticky business. So, but I think fundamentally nothing has changed in the market. It's still hyper competitive if there are more competitors. But as I said our discipline has always been to not sell products without making margin and that is helping us.

**Nimish Mehta:** Yeah, okay, but I mean, have you seen some fall in pricing on the base business that's what I'm trying to understand. I understand, I mean the new products and the other strategy that we use for getting the business, but has the base business?

**Sharvil Patel:** No, there's only, we don't have a heightened price erosion. It's normal price erosion that is there, but nothing different from the earlier quarters.

**Nimish Mehta:** Understood. If I may, you know one question on the domestic business as well. I mean if I'm not wrong, most of the large companies including ourself have been focusing now more on the generic - trade generic business in the domestic business. So, you know, can you let us know what is the trigger and if that expands, will that also not require a lot of capacity? I mean because you know it's a volume business and it's not typically a value business? Just your thoughts on that. Thank you.

**Sharvil Patel:** So, the trade generics business is generally a little different trade channel that utilizes this opportunity. I think, for us, we are more I would say measured in our approach towards the trade generics business. We are not, the way we are launching the products, is we only focus more on the branded side of our business and with the portfolio that we already have in trade generics and some of the portfolio that we miss because we don't want to build it, in the branded side, we have that trade generic offering, but by and large, I think our focus is more towards the branded side. Trade generic is more opportunistic for us.

**Nimish Mehta:** So, you don't see a significant growth in that `category, which I think other companies are looking at?

**Sharvil Patel:** I think the category is showing growth. It is also gonna be hyper competitive and price challenge, but there is growth definitely there. But as I said, for us, our focus right now is more on the branded side and the specialty and the proprietary side of the business. This is more of an opportunistic business.

**Nimish Mehta:** Okay. Okay. Thank you very much.

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

**Bino:** Hi, thanks for getting me back again. Just two follow up questions. One, there are these two biotech products, one in phase 3 and one just completed phase 1, are these biosimilars and are these also being developed for the US market?

**Sharvil Patel:** So, the biosimilars, currently our strategy is only focused towards India and emerging markets. One of the phase 1 molecule is our proprietary molecule that we started. We are starting a phase 1 and 2.

**Bino:** Understood. Second, there was a recent tentative approval you got for Prevymis, Letermovir. I believe there is an exclusivity which is preventing a final approval, but that exclusivity gets over I think in November or so this year, is that a near term launch?

**Sharvil Patel:** So, unfortunately, I'm not 100% clear when that launch will be, but we can come back to you separately, if we have a clear view. Currently, it is not launched for sure.

**Bino:** Okay. Thank you very much.

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

**Harsh:** Yeah, thank you. Am I audible?

**Sharvil Patel:** Yes.

**Harsh:** Yep. Thank you. Good evening. 2-3 quick questions. I joined the call a little bit late, so maybe repetitive, but one on LiqMeds, the small molecule portfolio. I think so, we had mentioned that a large growth driver would be the US market. So, just from that perspective, anything for us to keep in mind in terms of important timelines and would FY25 see any catalyst just from that business per se, of that segment per se and any launches or partnered assets from that portfolio would get categorized under the number of launches that we already report for the US market?

**Sharvil Patel:** Yeah. So, I think LiqMeds, the important thing is that we have today six marketing approvals for the specialty 505(b)(2) side of the business. In UK, we have 13 products that have been supplied out of the 15 that we have approval. Number of products that we still have waiting approval, there are two more specialty products waiting for approval and another 15 in UK, which are waiting for approval and we will see some of these approvals come through. Recently also, we saw one approval come through and this is the more specialty side of the business in the US. The scale up, we'll definitely see in FY25 also from the last year and going forward, we are also seeing meaningful scale up because these are branded businesses, especially in the US. So, once the scale up happens, they will be sticky with very good profit margins.

**Harsh:** So, should we assume like 3 to 5 approvals cum launches in FY25 just from this portfolio roughly?

**Sharvil Patel:** More.

**Harsh:** Okay. Okay. And in terms of the margin guidance that we had called out, in case of Asacol competition and on that part, we had mentioned that the important launch that we have done recently, the scale up of that is also pretty important along with other launches. So, should we assume another high value launch in second-half of FY25 which is very similar to the profile of Myrbetriq to that extent?

**Sharvil Patel:** So, I think as I said, I would say the significant scale launch right now has been Mirabegron, but we have to see how do we succeed in that going forward, but yeah, we have still a lot of products that will come for approval, which will add to the value growth for the organization. So, yeah, overall FY25, as I said, we still continue to believe that we'll see double digit growth in spite of Asacol competition in the US.

**Harsh:** Sure, and just from our understanding perspective. You have given the guidance in case of the Asacol competition. Directionally, if you

were to call out a best-case scenario, let's say without Asacol competition, where should we think about the range of margins per say, just very directionally?

**Sharvil Patel:** So, without Asacol competition, obviously we will see very significantly, much higher margins than what we have currently during the last quarter. So, that is the best estimate. I think there are so many moving parts. It's difficult to say, but, now, last quarter we did 29.5% margin. If Asacol competition is not there, it is definitely potentially possible to achieve that.

**Harsh:** Sure, that's helpful and one last if I may squeeze in, I might have missed this, but have we launched Vascepa in fourth quarter?

**Sharvil Patel:** We have launched Vascepa, I think recently, but we don't have scale manufacturing capacity yet, which we do to third party. So, once we are able to scale up our manufacturing which will require at least two more quarters, then we would see more capability of ours to take any meaningful business, but right now we don't have capacity.

**Harsh:** But this is not to do anything with the API supply issue per se, right? So, you're just getting in manufactured through a third party?

**Sharvil Patel:** Yeah.

**Harsh:** Okay, Sir. Thank you. Thank you.

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

**Saion Mukherjee:** Yeah. Thanks for taking my question again. Sir, just one question on acquisitions. You know the cash balance is rising and with very high value launches that we've seen and we continue to see, I think that's going up. You have done some buyback, but still I think the cash balance will keep rising. So, when you think about acquisition prospects, we haven't seen Zydus doing much in India unlike many of your peers and then you are investing in specialty. So, do you have some size in mind or what exactly you would be looking at? Are you okay doing $500-$600 million acquisition? If you can give some color what's available? What you're willing to invest? How you're thinking about inorganic opportunities in general?

**Sharvil Patel:** So, I think our first priority will be to diversify our business in the healthcare space. So, it's more to do with the market entry in different kind of geography if we get an opportunity, but large part of what we want to focus on is specialty. So, one is our own pipeline and then potentially see an opportunity. If we are successful with our own pipeline to coming to approval to find opportunities to acquire and scale that up meaningfully. So,that will be I think our first wish list

to build orphan disease business. The second obviously which we are already committed to is our rare portfolio of businesses. So, we acquired Zokinvy and we hope we can continue on both our internal pipeline, but more importantly continue to find opportunities in the rare disease space for acquisition. We do hope to enter more markets which are meaningful either directly or potentially again with the differentiated pipeline like LiqMeds that we have. So, those will be the first priority of products. In India, we are looking, we will look for brand, you know more brand businesses or brands which can help us overall in terms of it being accretive to the current business that we do. Again, something that is differentiated would be nice. We do like the OTC space also. So, we will look to see what we can do with that both in Wellness or in Pharma. So, I think those are some of the areas that we are looking at. So, I would say the ticket size will not be the constraint that will look at, but depending on the market and the opportunity, we want to make a profitable business in those places. So, in the US, our first expectation is how do we quickly scale up and become profitable on the specialty front, provided our current assets see the light of day and if that happens, then that will be the focus for the company.

**Saion Mukherjee:** And Sir, different geographies you mentioned, which geography you would be interested in?

**Sharvil Patel:** So, I think Europe is something that we need to figure out, right and whether it is some part, building a rare disease or specialty part of the business beyond the trade generics that we do. Also look at certain niche therapy areas and see if we can look at some opportunities to do something there and lastly also look at the hospital franchise that is there in Europe. So, those will be some areas that we continue to look at and overall as I said our mission now is to make sure that we build patient centric businesses. So, medicines is one part of being patient centric, but also how do we build businesses that are beyond just medicine and making sure that we are looking at companion diagnostics care and other areas that are important for treating chronic diseases. So, those are some of the areas that we want to continue to pursue. So, in oncology segment, we have already built a strong companion diagnostics business with our current business with both Guardant and the other onco product that we have for diagnosis for breast cancer. So, we're looking to scale those kind of opportunities further and build a meaningfully different business I would say.

**Saion Mukherjee:** Great Sir and just one last if I can ask on the GLP-1 opportunity. How you see Zydus position there? You have made filings in the US. So, what are your expectations and if you can talk about the capabilities

that Zydus has developed here and when can we see you know any meaningful contribution from this portfolio going forward?

**Sharvil Patel:** Yes, I think the meaningful capability is to obviously develop a peptide capability to obviously characterize the peptide capability to create a drug device combination and have the capability of both; obviously the drug part, but also the device part. I think those are the capabilities that we have now built. On the commercialization part, I think we will prepare for launch of the GLP-1 whenever the patents are over and we are preparing for market by market launch depending on the patent expiry.

**Saion Mukherjee:** Great, Sir. Thank you.

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

**Nitin Agarwal:** Hi, Sir. Thank you. Thanks for taking my question. Sharvil bhai, you know given the way the commentary has been, F25 and also F26 look to be very, very strong years for us given that we will continue to have tailwinds from Revlimid, possibly our gAsacol as well as even Mirabegron for now. You know how should we look about, you know the year after that, post FY26 onwards? Are we looking at potentially a largish cliff coming in the earnings as some of these big ticket opportunities begin to fade away or do you think there is enough in the pipeline to take care of you know sort of substitute some of these high growth opportunities?

**Sharvil Patel:** So, specific to the US, I think as I said, beyond this, I mean we at least have two to three other products where we believe we have sole exclusive launches available in the years after 26. So, we do still see a very healthy opportunity for the company to be able to launch meaningful launches with differentiation or sole exclusivity.

**Nitin Agarwal:** So, we should not be, we should not look at a situation potentially that we have a largish cliff coming through for the business on the high peak that we do in FY25 and FY26?

**Sharvil Patel:** Yeah. Currently, I think obviously it all depends on IP landscape and other things, but we have secured some 180-day exclusive launches beyond the ones that we have spoken of.

**Nitin Agarwal:** Okay, Sir. Thank you so much.

**Moderator:** Thank you. The next question is from Amman Vij.

**Amman Vij:** Yeah, hi. My question is on our peptide portfolio. So, if you can talk about how many products have we filed till today?

**Sharvil Patel:** Which portfolio? I'm sorry, we didn't get your question?

**Amman Vij:** Peptide portfolio.

**Sharvil Patel:** Currently, we have I think two peptides that are in advanced stages, filed and to be filed and we continue to have a portfolio of another two products that we hope to file. So, I would say that is the current portfolio that we have.

**Amman Vij:** Sure. When are you expecting the first approval for these four products?

**Sharvil Patel:** FY26.

**Amman Vij:** Okay. So, no contribution for FY25 at least?

**Sharvil Patel:** No.

**Amman Vij:** And Sir, these are for US markets or even for other markets?

**Sharvil Patel:** We would like to commercialize them in other markets also, but what guidance I was giving you is obviously the US market.

**Amman Vij:** Okay, okay. So, can we assume that other markets might come sooner than FY26 as well?

**Sharvil Patel:** There's a patent landscape to many of the peptides. So post patent, yes, they will be launched.

**Amman Vij:** Sure, and my final question is do you think these four products will be a small contributor to us or a meaningful contributor say in FY26 or FY27?

**Sharvil Patel:** I think it's a little too early to say this, but important markets are opening up like India, like Brazil, and more. So, we'll have to see how do we do there. So, we hope that they will be important, they will definitely be important launches the way the attention has been given by the organization, R&D, manufacturing. We hope they will be commercially successful in these markets.

**Amman Vij:** And Sir, do we have any FTF filings on any of the dosages for the same?

**Sharvil Patel:** Yes, and on Sema, we are first to file.

**Amman Vij:** Sema, we are first to file. One particular dose or is it all the four doses?

**Sharvil Patel:** On the diabetes indication.

**Amman Vij:** On the diabetes indication. Okay. Thank you, Sir.

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

**Ganesh Nayak:** Thank you very much and look forward to interacting with you during our next Investor and Analyst Conference. Thank you and good night.

**Moderator:** On behalf of Zydus Life Sciences Limited, that concludes this conference. Thank you for joining and you may now disconnect your line and exit the webinar. Thank you.

***END OF TRANSCRIPT***