



November 19, 2024

Listing Department  
**BSE LIMITED**  
P J Towers, Dalal Street,  
Mumbai-400001

**Code: 532321**

Listing Department  
**NATIONAL STOCK EXCHANGE OF INDIA LIMITED**  
Exchange Plaza, C/1, Block G,  
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Mumbai-400051

**Code: ZYDUSLIFE**

Sub: Transcript of the post results earnings call held on November 12, 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 Q2 FY25 post results earnings call held on November 12, 2024.

Please find the same in order.

Thanking you,

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

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

**Encl.:** As above

**Zydus Lifesciences Limited**

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**“Zydus Lifesciences Limited Q2 FY25  
Post Results Earnings Call”**

**November 12, 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 - HEAD, INVESTOR RELATIONS, ZYDUS LIFESCIENCES LIMITED**  
**MR. ALOK GARG - MD OFFICE, ZYDUS LIFESCIENCES LIMITED**

**Ganesh Nayak:**

Good afternoon, ladies and gentlemen. Welcome to our post results teleconference for the quarter ended September 30<sup>th</sup>, 2024. For today's call, we have with us Dr. Sharvil Patel, Managing Director, Mr. Nitin Parekh, Chief Financial Officer, Mr. Arvind Bothra, Head of Investor Relations and Mr. Alok Garg from the Managing Director's Office. Let me now give you a broad overview of the developments during the quarter.

I am happy to inform you that we delivered strong double-digit growth during the quarter on the back of sustained growth across all our key businesses. Our India branded formulations business continued to outgrow the market with 10% year on year growth driven by healthy volumes and contributions from new products. The consumer wellness business continued to see robust demand in all categories. The US formulations business continued its upward journey with a robust year on year growth driven by volume expansion and new products launched over the last 12 months. The international formulations business comprising of the emerging markets and Europe, also delivered strong growth on the back of resilient demand across markets during the quarter.

With that, let me take you through the financial numbers for the quarter gone by. We registered consolidated revenues of Rs.52.4 bn, up 20% on a year-on-year basis. EBITDA for the quarter was 14.6 bn rupees with a growth of 28% on a year-on-year basis. Our operating profitability continued to improve as the EBITDA margin for the quarter stood at 27.9%, which is an improvement of 170 basis points on a year-on-year basis. Improvement in EBITDA margin was despite 185 basis points year on year increase in our R&D spend. Net profit for the quarter has gone up by 14% on a year-on-year basis despite increase in tax expenses due to certain one-offs and stood at 9.1 bn rupees. We had a net cash position of 25.9 bn rupees as at 30<sup>th</sup> September 2024 as against the net cash of 8.6 bn rupees as at 31<sup>st</sup> March 2024.

Now let me take you through the operating highlights for the second quarter of FY25 for our key business segments. Our India geography, which comprises of formulations and consumer wellness businesses, accounted for 38% of the total revenues during the quarter and grew 10% year on year. As mentioned earlier, our branded formulations business in India grew faster than the market during the quarter with 10% year on year growth. The business outpaced the market growth both in the chronic and acute segments. Portfolio of key pillar brands and innovation products registered strong volume growth, driving the overall performance during the quarter. We launched 12 new products

(including line extensions) with 4 first-in-India launches. The business grew faster than the market in key therapies of Cardiology, Gastro-Intestinal, Respiratory, Anti-infectives and super specialty therapy of Oncology. On the super specialty front, we continue to hold leadership position in the Nephrology and Oncology therapies. Contribution of chronic portfolio has increased consistently over the last several years and stood at 41.8% as per IQVIA MAT September 2024, an improvement of 400 basis points over the last 3 years. Our consumer wellness business recorded revenues of 4.9 bn rupees, up 12% on a year on year basis, primarily led by strong volume growth of 8.4%. Both the personal care segment and the food & nutrition segment performed well, driving the overall performance of the business.

Our US business accounted for 47% of the consolidated revenues during the quarter with revenues of 24.2 bn rupees, up 30% year on year. We launched 4 new products during the quarter. We filed 8 additional ANDAs and received approval for 9 ANDAs (including 3 tentative approvals) during the quarter.

On the international markets front, all key markets delivered robust growth during the quarter despite ongoing political and economic challenges in some countries. Overall, the business posted revenues of 5.4 bn rupees, up 20% year on year.

On the operations front, the USFDA issued an Establishment Inspection Report (EIR) with a VAI status to our transdermal formulation facility located in the Ahmedabad SEZ against an inspection conducted in the month of July, 2024. During the quarter, the USFDA issued a warning letter to our injectable facility located at Jarod near Baroda. We are working closely with the agency to implement necessary corrective actions and preventive actions for early remediation of the facility.

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

**Dr. Sharvil Patel:**

Thank you Mr. Nayak and good after-noon ladies and gentlemen. It is a pleasure to have you all today on the call. We are pleased with our performance during the quarter and the first half of this fiscal year. All our business continued their momentum from their previous fiscal and delivered healthy growth numbers. We are on track to achieve our aspirational growth and profitability for the fiscal year of 2025. We remain committed to augment our innovation efforts to drive long term growth across all our

businesses and generate improved outcomes for all our stakeholders.

On the India formulations front, our branded business delivered double digit growth on the back of strong execution. Our sustained thrust on innovation led by our patient centric approach has enabled us to build a healthy pipeline of novel and differentiated products and solutions aimed at fulfilling varied unmet healthcare needs of our patients. Consumer wellness business continued to witness healthy demand across categories, indicating sustained consumer preference for our brands. Our R&D capabilities continue to be on the forefront, helping us to launch new products and extensions to capitalize on emerging consumer trends. The recent acquisition of Naturell (India) Private Ltd., a leading player in the healthy snacking category, which is a fast-growing segment, will enable us to offer more product choices to the health and wellness conscious customers.

In the US, we have built significant capabilities to enhance patient care and treatment options in the form of comprehensive generics products portfolio, specialty play through LiqMeds acquisitions and investment in rare diseases space. This, coupled with strong customer relationships, a pool of manufacturing facilities with capabilities to produce diverse dosage forms and an agile supply chain will ensure sustained growth trajectory for the US business going forward.

On the international markets front, the focus remains on growing the business in chosen therapy areas across key geographies by leveraging our global R&D portfolio of differentiated and complex generics as well as specialty products.

During the quarter, we forayed into animal free fermentation-based protein business by forming a JV with Perfect Day Inc. through the acquisition of 50% stake in Sterling Biotech Ltd. The JV will establish a state-of-the-art manufacturing facility that will cater to the global markets. It will accelerate the production of high quality and eco-friendly protein products, reduce environmental impact and cater to the growing consumer demand for fermentation-based and ethically sourced nutrition. Post the formation of the JV with Perfect Day Inc., we entered into a business transfer agreement with the JV to acquire its API business. This business has a fermentation-based product portfolio with the capacity to produce 1600 kilo litres of API and hence, a very good strategic fit for us.

Our innovation pipeline across different areas continues to make progress and achieve desired milestones. With this, let me share some material developments on the innovation efforts during the quarter.

On the NCE front, our data monitoring and follow-up is going on post completion of patient recruitment for the Phase II(b)/ III clinical trial of Saroglitazar Magnesium for PBC indication and also the Phase II(b) clinical trial of Saroglitazar Magnesium for the Metabolic Dysfunction Associated Steatohepatitis known as MASH indication for the US market. We completed Phase II(a) clinical trials of Usnoflast in India for Amyotrophic Lateral Sclerosis (ALS) indication during the quarter. The molecule was well-tolerated in a 12 week, Phase II(a) trial with target levels achieved in both plasma and Cerebrospinal Fluid (CSF) of ALS patients. It showed favourable trends towards reduction in Neurofilament Light Chain, an established biomarker of neuro degeneration in the CSF of ALS patients. Improvement in ALS function rate scale (ALSFRSR) and slow vital capacity were also observed. We initiated a Phase II proof of concept trial of Desidustat in partnership with the ICMR in patients with sickle cell disease. The partnership marks a pivotal step towards developing new therapies for combating sickle cell disease.

In the biotech R&D space, we completed patient recruitment for a Phase III clinical trial for one of our biosimilars and the follow-up has also been completed. We also completed pre-clinical tox studies for one of the biosimilars and applied for clinical trial permission to the review committee on genetic manipulation.

On the vaccines front, we completed Phase II clinical trials for Hepatitis E vaccine during the quarter. Recently in the month of October, Typhoid Conjugate Vaccine, which is known as ZyVac TCV, received in-principle acceptance from the WHO. With this acceptance, ZyVac TCV is now eligible for the purchases by the UN agency. Thank you and now we can start with the Q&A session. Over to the co-ordinator for the Q&A.

**Moderator:**

Thank you very much Sir. We will now begin question and answer session. Anyone who wishes to ask a question may raise your hand from the participant tab on your screen. Participants are requested to use headphones or earphones while asking a question. The first question is from Kunal Dhamesha.

**Kunal Dhamesha:**

Hi Sir! Thank you for taking my question. The first question is on the tax expense. Nitin Sir mention that there are some one-offs.

So, can you highlight or quantify the one-offs and how should we expect the ETR to pan out for the rest of the FY25?

**Nitin Parekh:**

So, effective tax rate for the year would be 24-25%. One-off refers to one provision in terms of one time MAT credit taken last year, which reduced the effective tax rate and also, in this year, the R&D spend in different entities across globe, where the tax rates are different, that has pushed the rate little bit. But this is only quarter phenomena. For the year as a whole, it will get equalized to around 25%.

**Kunal Dhamesha:**

Sure Sir. Thank you on that and just continuing on the R&D expense, which was obviously meaningfully above our range that we have suggested. So, how should we think about R&D? Is it some one-time trial cost which is factored in this quarter and should we expect normalization from here and what's the outlook beyond FY25?

**Dr. Sharvil Patel:**

So, as I said, R&D spend on quarter basis, is difficult always to estimate but the guideline for the full of FY25 is around 8% of revenue, is what we believe will be our R&D and going forward also, I think, currently at least for the near future, we are looking at same percentage.

**Kunal Dhamesha:**

Sure Sir, and one last with your permission. On the guidance, we had suggested something like high teens topline growth guidance and year on year improvement in EBITDA margin for FY25. Are we still sticking to that? Is there an update there?

**Dr. Sharvil Patel:**

Ya, ya, we are ahead of our estimates.

**Kunal Dhamesha:**

So, is there a new estimate or new guidance that you would like to give or we should.....?

**Dr. Sharvil Patel**

No, no, we are comfortably, we should be able to achieve the estimates.

**Kunal Dhamesha:**

Sure Sir. Thank you. If I have more questions, I will join back the queue and all the best.

**Moderator:**

Thank you. Next question is from Neha Manpuria.

**Neha Manpuria:**

Ya, thanks for taking my question. Just on the 2 acquisitions that we announced. The first one, as a part of the wellness business, how big is this business that we acquired and any other details you can give? The second one is on the Perfect Day JV. Is this for the CDMO piece that we are setting up this facility? By when can

we expect commissioning of this facility as a part of the JV that would help please?

**Dr. Sharvil Patel**

On the consumer health front, the business that we acquired of RiteBite Max Protein and its range of products is about 130 crores in annual revenue and obviously it allows us to play in the healthy snacking and we have always indicated that we would like to play in the protein malnutrition/nutrition space. So, this gives us a good area to enter. The brand is obviously a market leader in its category with strong growth and continues to be a leader also in all segments, whether it is general trade, ecommerce, modern trade also. So, we are quite excited with the opportunity. With respect to our joint venture related to Perfect Day, it is going to be, I mean in a way, you call it as a CDMO because it is going to do development also. So, it is not only manufacturing but develop and manufacture large scale fermentation of the protein isolate of milk, which is the whey. We do believe that this will be a large global opportunity with large global consumers, who have already tested and have looked at making this as a part of their resilient supply chain. So, we see this as a tremendously large opportunity to have an animal free derived protein product which can also have a significant ESG benefit.

**Neha Manpuria:**

By when can we expect the commissioning of this facility? Any capex that you would want to highlight on the manufacturing facility?

**Dr. Sharvil Patel:**

Ya, I think, more details we can give over a period of next couple of quarters but we do hope to start the construction of the facility in the next 2 months.

**Neha Manpuria:**

Ok. And my second question is on the gross margins. Obviously, we have seen the benefit of our US pipeline reflect on the gross margins. If we were to look at the gross margins of the base business, is there anything that is materially changed between, from last year to drive this significant improvement besides the high value launches that we have in the US, in the gross margin? What's the sustainable level of gross margin that I should look at beyond this year?

**Dr. Sharvil Patel:**

So, on the US, as I said, it's all because of the portfolio. So, one is the base business which continues to still grow despite the different challenges that we hear about in the US but one thing which is good, is our base business continues to grow. We are quite disciplined when it comes to, how do we do business in terms of financially. Are we making sure we are doing the right product at the right price and right margin? So that continues and



it's quite healthy. And we still continue to have a lot of near-term opportunities over the next 1-2, 2-3 years, where we are going to have major big launches. So, we are looking to obviously continue to build our portfolio in the US and continue to make sure that we not only continue our base business but also have products where we will see exceptionally good returns also.

**Neha Manpuria:** Understood! And these opportunities would be as large as Mirabegron was for us in the next 1 or 2 years?

**Dr. Sharvil Patel:** So, Mirabegron will still continue for the coming financial year and post that, as we have always said that, in FY27, we have 2 large major launches. So, we would continue to see an uptake in the business until FY28-29.

**Neha Manpuria:** And Sir, last one, Mirabegron, any comment on the turn in events when it comes to litigation? What should be the timeline and if not the timelines, what are the events that we should look for, your view on what's going on, on the litigation front?

**Dr. Sharvil Patel:** Ya, so I think, litigation is always unpredictable. So, I think it is not something imminent. It is at least a few quarters, 1 or 2 quarters out. I don't think we will have anything more credible in the short term from our best estimate.

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

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

**Bino:** Hi, good afternoon. Just a follow up on Myrbetriq. Sharvil bhai, can we get some idea, quarterly Myrbetriq run rate, is it pretty much the same q-o-q, in Q1 and Q2, and will it continue similar going forward?

**Dr. Sharvil Patel:** Sorry. Can you repeat the last part? I didn't hear you well.

**Bino:** Yeah, Mirabegron. My question was, is the quarterly run rate similar for Q1 and Q2, and is it likely to be the same going forward for the next few quarters?

**Dr. Sharvil Patel:** I think the run rate is going up. The conversion is also going up. So, we would start to see better numbers.

- Bino:** Okay. Coming to Asacol HD, the competitor has launched the product I believe. What are you seeing on the ground, any price erosion, market share loss, etc.?
- Dr. Sharvil Patel:** Yeah, so, we are seeing competition in the market and currently what we are seeing, I mean, as per our assumption, we are, I would say in a good place, in terms of what we assume would be market share loss and also price loss. So that is our, as per our estimates, and you will get to see that impact in quarter 3 this year. Also, yeah, the speed of it has been a little slower. So, that has been good for us. Speed of conversion has been slower.
- Bino:** Yeah. Understood. One last question on Revlimid, generic Revlimid. So, you have this revenue bulked up in Q1 and Q4. So, I assume, Q4 of this year, we will see again and possibly Q1 of next year. So, but coming into FY 26, you know, the exclusivity is lost before the Q4 of FY 26. So, should we assume that the generic Revlimid run rate would be roughly half plus some volume increase as per your agreement in FY 26 versus FY 25? How do we think about it?
- Dr. Sharvil Patel:** No, we get more share in FY 26. So, we are still hoping to achieve, I mean, I don't think there'll be any drop in revenue.
- Bino:** And all that will be booked in Q1?
- Dr. Sharvil Patel:** Q4, Q1 is our, always our expectation.
- Bino:** Yeah, but in FY 26, before Q4....
- Dr. Sharvil Patel:** Yeah, FY 26 will only be Q1.
- Bino:** Only be Q1. Still, there won't be a Y-o-Y drop.
- Dr. Sharvil Patel:** No.
- Bino:** Understood. Thank you. I'll join back to queue.
- Moderator:** Thank you. The next question is from Surya Patra. Hi Surya, requesting you to unmute and ask your question.
- Surya:** Yeah. Thank you, sir. Thanks for this opportunity and congrats for the good set of numbers. My first question is on the gross margin again. See, this quarter, obviously we have not seen the benefit of the Revlimid and Revlimid is a kind of a sizeable opportunity, what we have witnessed in the previous two quarters. And although that is not there, though there is some benefit of Mirabegron is visible, but the gross margin is remaining as it is like Revlimid contributing gross margins. So, what is driving this or this quarter?

Because you are also indicating Mirabegron q-o-q would not be significantly large enough. So, what is driving this, sir?

**Dr. Sharvil Patel:** So, obviously Revlimid is down versus the last quarter but the uptick on Mirabegron continues. So, I think I did say q-o-q there is an uptick, not stable. So, we see an improvement but in quarter 3 we will see obviously the impact on Asacol, which was less in this quarter. So yeah, that is the current state and again, as I said, quarter 4 will again become very large because of generic Revlimid.

**Surya:** Yes. And whether you have indicated about Mirabegron FY 26 remaining a kind of strong year as well, sir?

**Dr. Sharvil Patel:** I mean, it's always based on litigation and what happens. But as with our best estimate today, if it continues, it will remain important.

**Surya:** Okay. So, regards the US business, see since long that we have been talking about a series of kind of complex product opportunities, including the in-licensed ones. And just in your opening remarks also, you mentioned about key complex product opportunities in the near future. Could you give some sense about the kind of pipeline opportunity that we are talking about?

**Dr. Sharvil Patel:** Yeah, so I think, some obviously we have already spoken of like the Palbociclib generic version or the Riociguat also, which is also settled. So those are more sure and finite in terms of launches. Beyond that, in terms of our partnership, we have also spoken about a large franchise that we're trying to create on the 505(b)(2) and generic injectable side. And we announced recently if you had read also, we announced a gadolinium, you know.

**Dr. Sharvil Patel:** Similarly, we are seeing a few more 505(b)(2) that we are looking to file and launch immediately. So, I think we have a healthy pipeline of In-licensing products, which we will get to see. On Cabozantinib, obviously the judgement was not completely, it's partly good, partly in not in favour. So, that appeal will continue, and we'll see how that goes. But despite that, I think on the BD&L efforts, we are seeing significant traction in being able to license high value or limited competition or even 505(b)(2) with patent life kind of products. And that is only getting better. So, I would say, over the next three years, we would see a significant value from the BD&L opportunity beyond what we are obviously filing ourselves in terms of first to file and day one launches.

- Surya:** Sir, is it possible to share some more colour about the Vivit pharmaceutical in-licensing and sir, you mentioned about this gadolinium and MRI injectable?
- Dr. Sharvil Patel:** So, as I said, it's right now for two of the products. And upon approval, we will commercialise these products. And we have created a capability of a sales team in the US to be able to do some of these things also.
- Surya:** How big this opportunity could be, sir? It is a genericized opportunity. It is a kind of NDA opportunity.
- Dr. Sharvil Patel:** It's limited competition. I don't think there is a generic version today in the market.
- Surya:** Okay.
- Dr. Sharvil Patel:** Exact size of the opportunity, I won't be able to today give you an estimate, but it will be niche but valuable.
- Surya:** Okay, just last one question, sir, about the animal health business, what we have been aspiring for and taking some interesting strides on that front. So, could you give some sense of what is the kind of over the next three year period, let's say how important and how sizeable this could be?
- Dr. Sharvil Patel:** So, as I said, for us, US, we have decided that we are going to make, we have focus on US. So, we have three, four legs of growth that we are targeting in the US and participating in a larger ecosystem. One is obviously the generics business, where we are large at, scaling up injectables, which is our second area that is scaling up, also launching competitive generics where you are late to market, as well as also now animal health products. And we are creating a complex, I mean, products which are good, valuable where we are sort of first generic into the market, like we are on the brand side or on the generic side, human generic side, also launching complex technology driven products in the animal health space. So, that will be the other leg of growth for us. And finally, obviously on our rare and speciality product is the final area where we are seeing a significant scale up on Sentynl coming up and becoming in the next two years, valuable and also obviously our own pipeline of our NCE molecule, which will be more future driven. So, it's a basket of business that we will do. Specific only to the animal health, is has done very well. It's ahead of our estimates on margin and has done good. So, we hope to continue to invest behind it and build it. As I said, we are a serious player in this. Not only do we do R&D, we also do manufacturing

and then obviously sell. So, we have built an end-to-end capability and Zydus generally builds the end-to-end infrastructure to be more relevant and long-term player in the US. So, we hope to remain a long term committed player in the animal health space in the US.

**Surya:** Sir, thank you. Wish you all the best.

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

**Kunal:** Hi sir. Thank you for the opportunity again. I just missed the name of the second product, which could be important for us in US apart from the palbociclib. Can you please share that?

**Dr. Sharvil Patel:** Riociguat.

**Kunal:** Riociguat. This is the brand name or....?

**Dr. Sharvil Patel:** Molecule.

**Kunal:** Okay. Sure, sure. And sir, on the typhoid conjugate vaccine, where we have received the WHO pre-approval. If you could share, I mean, something on the total addressable market and how are we planning there? And you know, what else do we have in the pipeline, you know, to kind of make this business more sustainable?

**Dr. Sharvil Patel:** Yeah. So, I think currently on TCV, UNICEF is, obviously with the approval on prequalification, we can participate in the UNICEF tenders. UNICEF is the largest procurer of TCV Vaccine. And over in this coming year, obviously, we will participate in the annual tender. The annual tenders generally range from 80 to 150 million doses. So, we hope to take a small percentage of that share, and that could be very meaningful and sizeable for the organization. Beyond TCV, we are also looking forward to also getting our MR vaccine qualified very soon. So once that happens, that will be also an opportunity for the UNICEF tenders. But beyond that MR, there is also an India tender coming up very soon and we are hopeful we will also participate in that tender. So, I think, finally, I would say that in terms of meaningfully scaling up vaccines, we are going to start to see that from FY 26 and FY 27.

**Kunal:** Sure sir. But do we have any, you know, like aspirational target in mind that we want to scale this business to some number based on the pipeline that you have right now?

**Dr. Sharvil Patel:** So, as I said that the opportunities are very large because when I talk about just for TCV, it's a 80 to 150 million doses tender

volumes and over a period of 2 to 3 years. So, I think, as I said, from our revenue and what revenue we have today, it will be quite meaningful. But the scale up, I think we can only talk about once we win certain tenders. But these are not small tenders. And the competition is only between one or two or three players. So, we believe that we can definitely take a small part of that tender meaningfully and become sizeable.

**Kunal:** Sure. And sir this tender you said it's for 2 to 3 years. So, is it up for a renewal now in this year?

**Dr. Sharvil Patel:** Yeah, I think, we will see that in this coming FY 26 there will be a tender on TCV and then following year, probably MR.

**Kunal:** Sure. And sir one question on the US business. In this quarter, would you have seen any negative pricing action on Asacol? The market share loss might be more visible in Q3, but is there any shelf stock adjustment that we would have taken in our revenue for Asacol?

**Dr. Sharvil Patel:** I think larger impact you will see in quarter 3, but yeah, we would have taken some in quarter 2 also.

**Kunal:** Sure, sir. And beyond, you know let's say FY 25, for FY 26, any key products? Because Palbociclib and maybe the other product that you talked about is slightly longer-term opportunity. But from FY 26 perspective, would you like to share any key products that we might be having in our pipeline?

**Dr. Sharvil Patel:** Yeah. So, if FY 27 and 28 obviously are the two years where you will see the other two. In FY 26, we have obviously our internal pipeline of products that is going to be important. We will see quarter 1 Revlimid also, which will be important. And then we are going to see a full year of the 505(b)(2) or on the whole Sitagliptin franchise, which would be quite meaningful. And we can talk about it more in the fourth quarter. But we believe that will be a very important and significant value creator for the, as an important class for 505(b)(2) with success. And then, as I said, we do have some impending launches on the injectables front. Also, a 505(b)(2) injectables if we succeed. So, there are quite a few products that are lined up for FY 26. But I would say the bigger chunk of products will come in '27 and '28. But we are still seeing FY 26 also in terms of maintaining our current base of business.

**Kunal:** Sure, sir. Thank you and all the best.

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

- Harsh Shah:** Yeah. Good afternoon, sir. So, my first question is on the overall direction of the business. You have partially answered the question. Could you just.....?
- Dr. Sharvil Patel:** Harsh, sorry, but we are finding it very difficult to understand you.
- Harsh Shah:** Is this better?
- Dr. Sharvil Patel:** Yeah. Yeah.
- Harsh Shah:** Yeah. Sir, part of the question you might have answered, but just wanted to get a bit of more clarity in terms of the direction of the overall business. For H1, of course, we have overshoot on the guidance but now, as we stand today on the higher base of revenue with the peak of Revlimid almost behind us and then Mirabegron and Cabozantinib having its own challenges. How do you see FY 26 and FY 27 panning out in terms of growth and margin? If you can, you know, share some light on a bit of FY 26 and 27.
- Dr. Sharvil Patel:** So, our guidance is, FY 26 in the US, we will see growth over FY 25 and which is depending on whatever portfolio and this is despite Asacol competition. And that is our current guidance. And FY 27 and 28 are obviously meaningfully very large because we have large opportunities, where we have assured launches coming up where we are Day 1 exclusive. So, the trajectory from at least from this point of view and guidance is this. While Asacol of course, is the challenge, Revlimid will still be a good quarter 4, quarter 1 product, and going forward, Mirabegron still remains. It still is growing quarter on quarter. So, I don't see any slowdown on Mirabegron.
- Harsh Shah:** And on margin front, we will stick to 27% plus kind of a number, or we might see some erosion there?
- Dr. Sharvil Patel:** No, we hope to maintain our FY 25 margins, guidance of 27
- Nitin Parekh:** Guidance that we have given of 100-150 basis point over last year. That will continue.
- Harsh Shah:** Okay. Okay. And a bit of qualitative question. With the US elections behind us now and the talks about this new government coming in, do you foresee any major challenges, any major regulatory challenges from what has been the policy of the new government that will be coming into effect?
- Dr. Sharvil Patel:** I mean, I would not be the right person to answer that. But today, in the US, 60% of what is consumed in the US is made in India in

terms of prescription volume. So, I would say, we are in a good place to continue to build on that.

**Harsh Shah:** Okay, sure. Thank you so much.

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

**Bino:** Hi. Thanks for taking the question again. Just two follow up questions. One on the tax rate. For this year, you have guided to around 24 to 25%, but that is much higher than previous last two, three years consolidated tax rate. Of course, this year, this quarter, we had some one offs. But FY 26, will it come down back to around 20 - 21% which was earlier tax rate, or will it stay high at 24 - 25%?

**Nitin Parekh:** Earlier Bino, we got benefit of MAT credit available, but over a period of time, we have started utilising them. So, we will not be left with more MAT credit now. Also the benefit, which we have for backward area in Sikkim that also somewhere in '26 and '27 is not going to be there. So, we will be then, you know, coming into normal tax rate. Having said so, because while we look at the consolidated tax rate, it constitutes of different entities having different kind of tax rates and therefore you may find something here and there, 1% plus minus. But on the whole that is where guiding for 24 to 25% kind of effective tax rate.

**Bino:** Understood. Sharvil bhai, this Riociguat, is that your own product or a partnered product?

**Dr. Sharvil Patel:** Partnered.

**Bino:** Okay. And would you be the only, would it be a sole exclusivity launch?

**Dr. Sharvil Patel:** Yes.

**Bino:** Okay, great. Thank you.

**Moderator:** Thank you. Next question is from Rahul Jeevani.

**Rahul Jeevani:** Yeah. Hi, sir. Hope I am audible.

**Dr. Sharvil Patel:** Yes.

**Rahul Jeevani:** Yes, sir. Sir, on the Sitagliptin 505(b)(2) opportunity which you spoke about for next year. Sir, next year the Sitagliptin generic market also opens up in mid-2025 and there are already, let's say, around 8 to 10 generic companies who have tentative approval on the product. So, with the generic market opening up on



Sitagliptin next year, so, what kind of a traction do you think you would be able to garner for your 505(b)(2) product?

**Dr. Sharvil Patel:** So, two things. One is, it is not 25, it is 26, the patent. May be you can check and I also can check, it is not for 25. So, we have one more year. And we have as I have always said, yeah, so the opportunity we are seeing is obviously launching our branded franchise of Sitagliptin. So, we see FY26 will be the most meaningful year. But going forward, we have a long term contract with the US government for supply for 3 years which will continue even after genericization.

And also, because we are building part of the branded business, we hope that post genericization, some part of it we may be able to manage share. But leaving that aside, at least the government business is going to continue for a longer period of time and FY26 may be the larger opportunity on the retail side which may not be substantial in the next year. But for sure, the coming year will be quite meaningful which we can obviously explain more in Q4 also.

**Rahul Jeevani:** Sure, sir. And this government channel, how big is this on Sitagliptin?

**Dr. Sharvil Patel:** It is a valuable business for the company. It becomes a good molecule for us just on that business.

**Rahul Jeevani:** Sure, sir. And we would need to put up a sales force for this 505(b)(2) product or would you market it through the team which Sentyln might have.

**Dr. Sharvil Patel:** No, we don't need any marketing team. As I said, we can give you more flavor by Q4. But we are seeing some very good opportunity on it.

**Rahul Jeevani:** Sure, sir. Thank you. That's it from my side.

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

**Damyanti:** Hi, good afternoon. I hope I am audible?

**Dr. Sharvil Patel:** Yes.

**Damyanti:** Okay, thank you. My first question is, you mentioned about, like good launches lined up specially in '27 and '28. So, can you update us, will that include few transdermal products also which I think we have talked in the past? And if you can update us on what is the current portfolio looking like in terms of transdermal supply? How do you see scale up? And similarly, how do you see

your injectable portfolio building up over the next few years in terms of sales?

**Dr. Sharvil Patel:**

We have total of 8 transdermal filing so far. Out of which, we have 2 pending approvals left. Out of this, 1 is certain and the other 1 may not be certain. From our point of view, we just recently, I mean we already have the Estradiol combo pack that is already launched in the market. Before that, we obviously had already one transdermal launch. Recently, we did launch Scopolamine Transdermal patch. And going forward, we hope to add twice weekly Estradiol which is also approved but we need to add scale that up, and Clonidine as the future product. Beyond that, we also have some more hormonal patches that are under development and to be filed which will get launched. So, that's where we are on the overall transdermal business.

On the injectable side of the business, as I said, we continue to file complex drug device combination products in the US. Beyond that obviously, we are actively licensing injectable products whether it is in the contrast media range for radiology or some of the niche like the dyes that we have licensed where we launched Methylene Blue, in future, Indocyanine Green and a few more coloured dyes in the future. So, we have a whole host of differentiated niche products also in the injectable side which we will launch, beyond obviously the large drug device combination products that are also being filed.

**Damayanti:**

Sure. So, currently to your total US sales, I assume injectable sales are like very small in terms of contribution? Can you just give us how much is currently coming from these products?

**Dr. Sharvil Patel:**

As I said, I think, for us and I also tried to talk a little earlier, I think we are looking at the whole US when we talk about, we look at the whole portfolio and we don't differentiate like injectables, orals or all of that because we are running it as a portfolio of choices of products that we do. But I can definitely say that injectables in the next 3 years will obviously scale up from today's level and become more meaningful. But I think, for us, it makes sense for us to talk about the overall portfolio rather than dosage form because we don't do business like dosage form because it is very similar ways of selling.

**Damayanti:**

Just want to understand one more point in transdermals. What we understand, in these market, I guess incumbents have largely stable markets share, right, few incumbents and they have certain market share. So, you enter that market, is it like easier to take

market share from existing players? Here is it more gradual build up which you generally see?

**Dr. Sharvil Patel:** Yes, it is always hard to take market share, whether it is in any product because we want to take market share with certain margins. It is always a thin line in terms of whom you target and how you target. But so far, in the two products that we are selling we have had decent success.

**Damayanti:** Okay, that's helpful, thank you. I will get back in the queue.

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

**Moderator:** Hi, Nitin, your voice is not clear.

**Nitin Agarwal:** Excuse me one second. Hello, can you hear me?

**Moderator:** Yes.

**Nitin Agarwal:** Thanks. Sir, two questions, one is on the India business. Any thoughts on the business now? I think, for the last few quarters, we have been performing well in line and above the market. So, has the business now sort of turned around for good in your assessment and where do we see the business over the next couple of years? What will be the drivers for this business from here on?

**Dr. Sharvil Patel:** So, I think, as I said, our aspiration is to grow better than market. We are in many quarters now doing as market or even better as we have demonstrated and we hope to continue to deliver on stronger growth. There are 2-3 areas that is helping us. One is the portfolio re-organization and focus has helped us in terms of growth. So, our innovative portfolio as well as our growth booster brands have both done extremely well and as that pie of the business becomes larger and larger, that is contributing meaningfully. Beyond that, there have been important new launches that have been successful. So, not only have the existing products been doing well, but the new launches have seen very strong meaningful traction and they continue to also drive future. Also, now our branded, our specialty portfolio or chronic portfolio is now more than 41% of our overall business and that's also improving its share in our overall pipeline, which also is allowing us to have a more sustained growth. I think, all in all, all of these things are giving us confidence that we can continue to deliver better than market growth which is our aspiration.

**Nitin Agarwal:** Sir, in the domestic business, what proportion of business is really coming from your innovative products now?

**Dr. Sharvil Patel:** It is a good question. I don't think, right now, we have a breakup like that that we give out. But I think give us some time, we will start preparing a different overall innovative pipeline portfolio. But I think individual breakup, we don't give right now.

**Nitin Agarwal:** If we take that forward, sir, on the innovation portfolio, or the innovation R&D portfolio which is there, in the next couple of years what are the milestones to really watch out for?

**Dr. Sharvil Patel:** So, I think, the milestones would be market share obviously for Saro, for Desidustat, for also the biologics that we are launching and also some of the differentiated technology products where we are first to market. If it is competitive, obviously it is market share. But beyond that as I have always said, we do strongly believe that both Saro and Desidustat will obviously come in the top 50 but hopefully soon in the top 25 in terms of brands of the country and we hope to continue to build that. I think those kinds of rank of molecule will become more and more impactful going forward.

And as I said, when we are launching biologics and other products, we are now at least like I can talk about our Ujvira molecule. We have even higher share than the brand now both by value and volume. And also, if you look at the overall share in the oncology space, we are now potentially the largest Indian oncology player and growing the fastest in this area. Similarly, if you see Desidustat, if you see the traction that we are getting on Saro both by ourselves and our partners, we are seeing significant traction on these molecules. So, the innovative pipeline is definitely driving a lot of meaningful growth and creating larger house brands.

**Nitin Agarwal:** Sir, on this innovation pipeline, you know, from wherever you are undertaking global trials, what are the major milestones for you on the global approval perspective for these products?

**Dr. Sharvil Patel:** So, the nearest product of ours is Saroglitazar. We just finished recruitment for a hybrid Phase II/Phase III trial. And in quarter two of next year, we will have a read-out. That will be one important milestone.

Our Usnoflast in ALS will start a Phase II(b) trial. So, that is still a little while away but that will be the next milestone of starting the next clinical development journey.

And on Desidustat, we are doing a trial in Sickle Cell Anaemia and we are also looking for something in the US in the defence space, so that is the other important milestone if we are able to achieve.

Beyond that, I think, we have large Phase IV trials going on in India to show the safety and efficacy of the medicine and a lot of publications that will all drive better value for the brands.

**Nitin Agarwal:** And, sir, on the R&D spend increase which has happened, you said it is going to be sustained around these levels, you know, which are the major areas where the increased R&D spends are going towards?

**Dr. Sharvil Patel:** So, yeah, obviously some part, as I said for us about 60%, 55, it is half and half almost very soon, so half of it goes for development of whole complex generic, better than generic kind of portfolio. And the remaining is for biologics and NCEs and for US development. In that, the largest cost is developing Saro for US right now because we are doing a large Phase III and that will continue. That's the clinical development cost is one of the larger costs of the overall cost.

**Nitin Agarwal:** The last one, sir. On the emerging market, I think, you have had some pretty decent sequential growth in the business for the last few quarters now. What has really changed and how should we look at this piece, how should we look at this business going forward?

**Dr. Sharvil Patel:** I think very strong execution, very strong portfolio of global products that are getting leveraged in all of these markets. More focus on branded business which is allowing us both consistency and profitability growth. Right selection of markets, we also entered new markets now like UK, Australia and we hope to add tactically more markets including Canada and others. So, I think, it has been overall I would strong strategy which led to strong execution, and also going forward we are seeing enough momentum of product portfolio as well as market still continuing to do very well in spite of obviously currency challenges, some geopolitical challenges that we do face market by market. But the portfolio is allowing us to continue with the strong double digit revenue growth and more importantly profitability growing faster than revenue.

**Nitin Agarwal:** Thank you. And if could just finish the last one, sir. On the US market, I think just to get it correct, you said that even the Mirabegron will continue to be a major product in FY26 for us.

- Dr. Sharvil Patel:** I think, the current litigation continuing, it will still continue in FY26, but how long it is very difficult to predict right now.
- Nitin Agarwal:** Okay, sir. Thank you so much.
- Moderator:** Thank you. The next question is from Vivek Agarwal.
- Vivek Agarwal:** Hi, thanks for the opportunity. Sir, you talked about Palbociclib as one of the key products in '27-28. So, just want to understand two things on this product, is it going to be a capsule or a tablet, if you can clarify?
- Dr. Sharvil Patel:** Tablet.
- Vivek Agarwal:** Okay. So, in tablets, is it likely to be sole exclusivity or is it going to be like you are going to share with a few other players? How the things are going to be?
- Dr. Sharvil Patel:** Our best estimate it will be sole, but there can always be an AG.
- Vivek Agarwal:** Okay, thank you. Any colour on capsules?
- Dr. Sharvil Patel:** No, I don't have any other update on it.
- Vivek Agarwal:** Okay. Thank you. That was from my side.
- Moderator:** Thank you. The next question is from Kunal Randeria.
- Kunal:** Hi, good afternoon, sir. Sharvil bhai, you mentioned timelines for Saroglitazar. So, what would be the realistic timelines for US filing and launch? And how should we evaluate the potential considering that two players got approval this year and have a bit of a head start on you in the PBC indication?
- Dr. Sharvil Patel:** Yeah, we had always, I mean in our estimate we always assumed that we will be third I mean, if lucky third or fourth, but I think we could be third to the market. As I said the major milestone is our initial read-out of our data in the second quarter of next financial year. If everything goes well then, we will go ahead for submission of the NDA by third or fourth quarter, mostly the fourth quarter and then about a year from there the launch. So, maybe, our estimate is Q4 of FY27 would be the launch which would mean first quarter of the calendar year '27.
- Kunal:** Got it. How do you kind of expect the market to kind of take a turn because even these two products are fairly new. And I presume your product will also be like a second line treatment. So, how do you evaluate this market by the time you launch this product?

- Dr. Sharvil Patel:** Yes, I think, obviously many moving parts on this. Right now, you know OCA is under regulatory action right now. So, potentially these other products, I mean this class of products will become maybe then the first line of treatment from second line and the other part is it will all depend on our data. If our data is at par or superior obviously depending on that situation, we will know how we will fare. So, very early to comment till we get to see our data. But if we are at par or better obviously the commercial value is quite valuable. If we don't have sufficiently equivalent data, then obviously we have to look at how do we commercialize it.
- Kunal:** Right. And just one clarity on this and this will be the first indication for Saroglitazar in developed markets, right, MASH and others will come later.
- Dr. Sharvil Patel:** Yeah, this we are only targeting in US PBC right now.
- Kunal:** Got it, thank you and all the best.
- Moderator:** Thank you. As this was our last question I would like to hand the conference over to Mr. Ganesh Nayak for the closing remarks.
- Mr. Ganesh Nayak:** Thank you very much and have a nice evening and well wish you a Merry Xmas and a happy new year and look forward to interacting with you in the month of February for our Quarter three results. Thank you and good night.
- Moderator:** On behalf of Zydus Life Sciences Limited, that concludes this conference. Thank you for joining us. And you may now disconnect your lines and exit the webinar.

**END OF TRANSCRIPT**