

Dr. Reddy's Laboratories Limited  
Q3 FY'21 Earnings Conference Call

**January 29, 2021**

**Moderator:** Ladies and gentlemen, good day and welcome to the Dr. Reddy's Laboratories Limited Q3 FY'21 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the call, please signal an operator by pressing "\*" then "0" on your touchtone phone. Please note that this conference is being recorded.

I now hand the conference over to Mr. Amit Agarwal from Dr. Reddy's Laboratories Limited. Thank you and over to you sir.

**Amit Agarwal:** A very good morning and good evening to all of you and thank you for joining us today for the Dr. Reddy's earnings conference call for the quarter ended December 31, 2020. Earlier during the day, we have released our results and the same are also posted on our website. This call is being recorded and the playback and transcripts shall be made available on our website soon. All the discussions and analysis of this call will be based on the IFRS consolidated financial statements.

To discuss the business performance and outlook, we have the leadership team of Dr. Reddy's comprising: Mr. Erez Israeli - our CEO, Mr. Parag Agarwal - our CFO and the Investor Relations team.

Please note that today's call is a copyrighted material of Dr. Reddy's and cannot be rebroadcasted or attributed in press or media outlet without the Company's expressed consent. Before I proceed with the call, I would like to remind everyone that the Safe Harbor contained in today's press release also pertains to this conference call.

Now, I hand over the call to Mr. Parag Agarwal. Over to you, sir.

**Parag Agarwal:** Thank you Amit and greetings to everyone. I hope all of you and your families are keeping safe and healthy.

I am pleased to take you through our financial results for the quarter 3 of fiscal 2021. We had yet another quarter of good performance in terms of revenue growth and EBITDA margin, though the profits were impacted by impairment charge taken during the quarter.

Let me take you through these in a bit more detail. For this section, all the amounts are translated into U.S. dollars at a convenience translation rate of Rs. 73.01, which is the rate as of December 31, 2020.

Consolidated revenues for the quarter stood at Rs. 4,930 crores that is US \$675 million and grew by 12% on a year-on-year basis. Growth is primarily on account of new product launches across markets. Our North America Generics business grew by 9%, Europe business by 34%, India by 26%, Emerging Markets by 5% and PSAI by 1%. Sequentially, our revenues grew by 1% supported by volume pickup in India, Emerging Markets and Europe, however, impacted by price erosion in North American business and lower volumes in the PSAI business. During the

quarter, we recognized milestone received towards AUR102, one of the programs of our Aurigene Discovery business.

Consolidated gross margin for this quarter has been 53.8%, a decline of 30 basis points year-on-year and 10 basis points on quarter-on-quarter basis. The decline is primarily on account of price erosion and lower export benefits, however, supported by milestone income received towards AUR102 compound and productivity improvements. Gross margin for the Global Generics and PSAI businesses were at 57.6% and 25.3% respectively for the quarter.

The SG&A spend for the quarter is Rs. 1,439 crores, that is US \$197 million, an increase of 14% year-on-year and an increase of 10% quarter-on-quarter. The increase in expenses is due to investments made in sales and marketing in branded markets, digital capability building, higher freight costs and certain one-time expenses pertaining to this quarter. SG&A as a percentage of sales was 29.2%, which is within our normal range.

The R&D spend for the quarter is Rs. 411 crores, that is US \$56 million and is at 8.3% of sales. The product development activities continued normally during the quarter, including development of COVID-19-related products.

The EBITDA for the quarter is Rs. 1,185 crores, that is US \$162 million. EBITDA margin is at 24% and is closely tracking our aspirational target of 25%.

In this quarter, we have taken an impairment charge of Rs. 597 crores that is US \$82 million. The impairment has been taken primarily on three products related to intangibles acquired from Teva in the year 2016. These are for the gNuvaRing, Phentermine & Topiramate and Saxagliptin & Metformin. We do a quarterly impairment testing analysis and as part of it we concluded that the carrying value of certain of our intangible assets are not reflected of the current market realities and hence, in line with the requirements of the accounting standards we took this charge.

Consequently, our profit before tax for the quarter stood at Rs. 284 crores, that is US \$39 million.

Effective tax rate for the quarter has been 93%, higher due to non-recognition of deferred tax assets and losses arising out of impairment. We expect our normal ETR to be around 25% before the impact of impairment charges.

Profit after tax for the quarter stood at Rs. 20 crores, that is \$3 million. Reported EPS for the quarter is Rs. 1.19.

Operating working capital increased by approximately Rs. 600 crores, which is US \$82 million. There has been an increase of approximately Rs. 300 crores each in the receivables and the inventory. Increase in receivables was partially due to reduction in discounting of receivables and the balance is in line with the normal business trend. Increase in inventory was due to a planned increase in inventory for certain products to deal with any potential supply disruptions. We invested Rs. 287 crores, which is US \$39 million towards capital investment in this quarter.

The free cash flow was a net outflow of Rs. 58 crores, which is US \$8 million after payout for the brands acquired from Glenmark for the Russia and CIS markets. We had a net cash surplus as on 31st December, 2020 of Rs. 84 crores, that is US \$11 million.

Foreign currency cash flow hedges for the next 15 months in the form of derivatives for U.S. dollars are approximately US \$535 million, largely hedged around the range of Rs. 74.5 to Rs. 77.6 to a dollar. In addition, we have cash flow hedges of RUB 5,550 million at the rate of Rs. 1.0021 to the ruble, maturing over the next 15 months.

With this, I now request Erez to take through the key business highlights. Over to you, Erez.

**Erez Israeli:**

Thank you, Parag. Good morning and good evening to everyone. Hope you are having a happy, safe and healthy beginning of the New Year. The year of 2021 has started with the hope and visibility around life returning to normal after a significant healthcare crisis and socioeconomic disruption caused by COVID-19 in 2020. The vaccination program has started in several countries and we are continuing to contribute our bit in this fight against the global pandemic. Recently, after the approval from DCGI, we have initiated the Phase-III clinical trials of Sputnik V vaccine in India. The vaccine's efficacy is confirmed at 91.4% based on the data analysis of the final control point of clinical trials arm in Russia. We have also strengthened our partnership with RDIF and have been confirmed as the preferred marketing partner to enable the safe and expeditious distribution of the vaccine in India.

During this quarter, we continued in our growth journey and achieved highest-ever quarterly sales, healthy EBITDA margins and once again turned net cash positive as of December 2020. We saw healthy growth across our branded markets and Europe. While the market demand in India, Russia and other branded markets has witnessed sequential improvement over the last couple of quarters, it is yet to recover to pre-COVID levels.

We continue to progress well on our strategy of diversified business model and creating the right levers of growth from each one of our businesses. This includes building a healthy product pipeline, focus on productivity, improvement in marketing capability and strengthening our processes led by digitalization initiatives. The strong balance sheet position allowed us to continue to invest in the right set of opportunities for future growth.

Now, let me take you through the key business highlights in each one of our businesses. Please note that all references to the numbers in this section are in respective local currencies.

Our North America Generics business recorded sales of \$235 million for the quarter with a growth of 4% year-over-year and a decline of 5% on a sequential quarterly basis. While the new product launches momentum continued through the quarter, we faced incremental competition led pricing erosion in certain base portfolio products. Towards the end of the quarter, we also witnessed signs of COVID-driven slowdown in demand levels especially at the retail and hospital level impacting the sourcing.

We launched five new products during the quarter: Sapropterin Tablets, Cinacalcet, Succinylcholine Injection and the relaunch of OTC Famotidine Tablets in the U.S. and Daptomycin Injection in Canada market. Overall, during the nine months in current fiscal, we have already launched 22 products, including one relaunch. As we continue to maintain the launch momentum for the rest of the year, resulting in around 30 launches for the fiscal, we remain focused on ramping up of the market share across key recent launches.

Our Europe business recorded sales of EUR47 million, with strong year-to-year growth of 20% and sequential quarter growth of 9%. The growth was driven by new product launches seen across the markets. During the quarter, we launched three new products in Germany and one product each in UK, Italy, France and Spain.

Our Emerging Markets business recorded sales of Rs. 962 crores, with a year-on-year growth of 5% and sequential quarter growth of 11%. The year-on-year growth adjusted for the forex impact has been also in double digit. Within the Emerging Markets segment, the Russia business grew by 4% on year-to-year basis and 17% on the quarter-to-quarter basis in constant currency. The market demand has been gradually improving after COVID-related decline. We also saw similar improvement trends in our CIS market. Our business in China also continued to perform well in the quarter. During the quarter, we launched 27 new products across Emerging Markets. We also completed the acquisition of select anti-allergy brands from Glenmark for Russia and CIS markets.

Our India business recorded sales of Rs. 959 crores with a year-over-year growth of 26% and a sequential growth of 5%. The strong growth in the quarter was supported by gradual improvements seen in the market demand. The brands acquired from Wockhardt have also performed well. We are progressively adopting digital platform to improve connects with various stakeholders, physician community, patient and channel partners to expand access and leverage demand platforms. During the quarter, we launched seven new products in the Indian market. As per the IQVIA report of December 2020, we have been ranked number 9 for the month of December and 11 on MQT and MAT basis.

Our PSAI business recorded sales of \$95 million, with a year-on-year decline of 2% and sequential quarter decline of 17%. As alluded to you in the last quarter, part of the high-growth in the first half of the financial year was driven by a higher API procurements / inventory level carried by our customers in response to the COVID-related disruptions. This part of demand has largely been normalized. At a strategic level, we continue to believe that our PSAI business is well positioned to benefit from the evolving structural shift in the industry as we continue to invest into new product development and cost reduction initiatives.

On the R&D front, we continued to strengthen our pipeline of products across the markets, with focused R&D investments to our value-accretive assets. During this quarter, we filed 57 formulation products across global markets, including two ANDAs in the United States. As of December 31, 2020, we have 89 cumulative filings pending for approval in the USFDA, which includes 87 ANDAs and two 505(b)(2) NDAs.

We also filed 45 Drug Master Files globally, including five filings made in the U.S. We are also progressing with Phase-III trials for Rituximab and working on the next wave of biosimilar products which are at different stages of development. We remain committed to strengthen our products pipeline across markets as one of the key levers for driving our future growth.

As the uncertainty surrounding COVID progressively recedes, we remain focused on our key strategic priorities of building sustainable growth stories across various businesses, including inorganic moves and strengthening the pipeline to enable long-term growth.

With this, I would like to open the floor for questions and answers.

**Moderator:** Thank you very much. We will now begin the question and answer session. The first question is from the line of Shanti Patel from Shanti Patel Investment Advisors. Please go ahead.

**Shanti Patel:** The light on capacity utilization in respect of various verticals. And question number two, is impairment loss, how it is determined? And will it be reversed in future if situation changes, please throw some light on that?

**Erez Israeli:** Yes, so we had the triggering event of the launch of Nuvaring by Teva and we have worked in accordance to the good accounting practices, as we see the attributed base events for that. We are still planning to launch these products and there are no plans to reverse, but I hope and believe that we will launch these products and make money from them.

**Shanti Patel:** Capacity utilization, what is the capacity utilization in respect of the various verticals?

**Erez Israeli:** The capacity realization?

**Shanti Patel:** Yes, that is correct.

**Erez Israeli:** We have enough capacity for the various verticals, so I'm not sure I understand the question.

**Shanti Patel:** No. Capacity utilization means suppose we can produce 1,000 units. Today, we are producing only 900, so 90%. So that way, what is the installed capacity and how much we are producing, the ratio?

**Erez Israeli:** I got that and then saying again, we had enough capacity for all the verticals. The only place to say in which we need additional capacity is in the injectable area and primarily for the years of FY'23 and FY'24, as well as the biologics. We have enough for the growth in the oral solid.

**Moderator:** Thank you. The next question is from the line of Rashmi Sancheti from InCred Research. Please go ahead.

**Rashmi Sancheti:** If you can highlight what kind of growth, we are seeing in India business ex-Wockhardt integration?

- Erez Israeli:** Amit, you want to answer it?
- Parag Agarwal:** Yes. Rashmi, thanks for the question. Excluding Wockhardt portfolio, our base business grew at about 8% during the quarter.
- Rashmi Sancheti:** And, sir, for the nine months?
- Parag Agarwal:** For the nine months, also the business grew in single digits.
- Rashmi Sancheti:** Single-digit? Okay, sir. And, sir, related to the Wockhardt integration expenses in this quarter, is it going to continue in the subsequent quarter or this is one-off, and this will be only in this quarter? And whether if you can quantify, how much of that additional cost has come?
- Parag Agarwal:** Yes. So we have now successfully integrated the Wockhardt portfolio into our business. And what our P&L reflects are the normal ongoing expenses. So there are no one-off expenses pertaining to the Wockhardt business in our P&L this quarter.
- Rashmi Sancheti:** But that integration expenses, will it continue in the subsequent quarter or it is already over by third quarter?
- Amit Agarwal:** So Rashmi, this integration expenses, so there is nothing integration expenses. It is the field force like we have got from this business. So that is now part and parcel of our business, so that will continue. So it is on account of incremental manpower cost, S&M cost, the plant which came from Wockhardt, so those expenses. On a year-on-year basis, that's the reason we have mentioned. On a sequential quarter basis, that is not the reason. It was there in Q2 also. It is there in Q3 also.
- Rashmi Sancheti:** Okay, sir. Got it. And, sir, finally, on the U.S. business, are we going to maintain our 30 product launches guidance in U.S. for this entire year? We have already launched around 22 products.
- Erez Israeli:** Yes, it will be in this year.
- Rashmi Sancheti:** And, finally, last on the pricing on the base portfolio. Are we seeing a huge price erosion in double digit sort of or it is a mid-single digit price erosion? And with the traction in launches, will it go down or it would remain at the same level?
- Erez Israeli:** So it's not huge. And, of course, it differs from product-to-product. But it's more than it used to be in the other quarters for us. And I believe that the business will continue to do well also in the future.
- Moderator:** Thank you. The next question is from the line of Damayanti Kerai from HSBC Securities and Capital Markets. Please go ahead.
- Damayanti Kerai:** Continuing on the U.S. business. While we are seeing healthy number of launches, but on the filing side I believe it has been bit muted for last few quarters and we are also having around 87

pending ANDAs. And in the past you earlier expressed your goal about increasing your U.S. sales by 50% in next 3 years. So how do you see pickup happening on the ANDA filings front? And second question on the U.S. businesses, any update on Vascepa and Remodulin generic launches?

**Erez Israeli:** So, on the filing, I think you're going to see much more filings next quarter. It is in line with what we discussed in previous meetings. So we are in the same place, just in terms of the **inaudible** between the quarters, that would happen in Q4. As for Vascepa, we are preparing for the launch of the product. Sorry, there was another one?

**Damayanti Kerai:** Remodulin?

**Amit Agarwal:** Remodulin will be some time away **inaudible**. It will take some time for us.

**Damayanti Kerai:** And my second question is on the impairment part. So, for acquiring eight ANDAs from Teva, we paid around 350 million. And if I'm correct, we have already taken impairment of around 250 - 260 million due to change in market conditions. So, do you see like the remaining asset value can also like be impaired if we see further deterioration in the market condition?

**Erez Israeli:** We are not expecting additional impairments.

**Damayanti Kerai:** And my final question, how should we look at API business growth picking up from here? Obviously, 1H was very strong. But as you said it has normalized now, so how should we look at that part of business?

**Erez Israeli:** We are going to grow this business on both the external sales, as well as much more important for us is the backward integration. So we are working on both and we are going to see growth in the API in the future.

**Moderator:** Thank you. The next question is from the line of Kunal Dhamesha from Emkay Global. Please go ahead.

**Kunal Dhamesha:** So the first question is on the other expenses. So, I think in the opening remarks, our CFO said that there was some one-time expense that was included. So, can you throw some light on what was the nature of the expense and can you quantify it?

**Parag Agarwal:** Thank you for the question, Kunal. The one-off expenses that I referred to are primarily two, one is COVID-related freight expenses have been at the higher end, as you know, for the last few quarters, since COVID started. And we are not seeing any moderation in the rates yet. It's a very marginal reduction. And we do think as situation normalizes, and COVID comes under control, over the next few quarters this is going to reverse. So, that's one reason I mentioned as one-off. And secondly, we also have some one-off litigation expenses that we have recognized during the quarter, which are non-recurring in nature.



**Kunal Dhamesha:** So, if I see the quarter-on-quarter, last quarter our SG&A expense excluding D&A was around 983 crores and this quarter it is somewhere around 1,120 crores. So, can you attribute the entire increase to that because we have said that Wockhardt integration costs were already there in quarter two, so the entire thing is related to and the freight cost would also be there in quarter two, right? So then the entire difference is coming from the one-time litigation costs?

**Parag Agarwal:** No, that's not right, Kunal. Let me give you the shape of the increase. So, as I said in my remarks earlier, the largest increase is driven by investment behind sales and marketing in the branded markets. In markets like India and Russia, we have seen the market growth is showing some gradual signs of pickup and we want to make sure that we invest ahead of the curve. So, we have started, in a cautious manner, investing behind our brands in these markets.

The second thing that we are investing behind is our digital capabilities. We have a very ambitious program in place where we want to digitize our core, our quality systems, our manufacturing plants, the way we manage the entire process of product selection to launch and also we are digitalizing our front-end, the way we go to market, the way we engage with the doctor. So, I would say that investments behind brands and capabilities is a large part of this increase. And the rest, as I said, is some bit of freight. In this quarter, we have seen higher freight costs compared to the previous one. To some extent, it is also because of the higher air to sea shipment, partly COVID-related, but also partly the mix between air and sea shipments.

**Kunal Dhamesha:** So, do you think that this investment in the brands and sales and marketing will continue for like next 3, 4 quarters before it kind of normalize or how should we look at it? Like, is this the new normal of SG&A, like 1,100 crore?

**Parag Agarwal:** See, as you know, Kunal, we don't give any forward-looking guidance. So, at the same time, I would like to say that the investment in sales and marketing, we do expect it will continue. But I must also point out that we evaluate return on investment on a continuous basis. And if we are finding sales growth is being driven by the investments, then we continue, otherwise, we also try to tear it down. So that's one point I would make. And, obviously, the COVID-related expenses will gradually normalize.

**Kunal Dhamesha:** And the second question is a more of a housekeeping question. So, I think we took 156.5 million of impairment charge for NuvaRing in quarter three FY'20 and we took another 40 - 45 million this quarter, so that adds to around 200 million. But the purchase price allocation that we did for this product was around 185 million. So what am I missing here? Like did we capitalize some of the R&D expense that we did on the product?

**Parag Agarwal:** Yes. That's a good question, Kunal. The difference is because of the interest that has been capitalized in line with the accounting standards.

**Moderator:** Thank you. The next question is from the line of Nithya Balasubramanian from Bernstein. Please go ahead.

**Nithya Balasubramanian:** Sir, my question is a follow-up on the SG&A expenses. Sir, in the last quarter, at least in branded markets like India, China, Russia, assuming that all the clinics are open, but that's the back on the ground. So the kind of savings you probably realize in Q1 and Q2, most of the costs are likely to come back. Is that also partially the reason why it's gone up? And should we now assume that there are no longer any lockdown-related savings in the base anymore?

**Parag Agarwal:** I think, to a large extent, I would say, it is getting normalized, that's true, Nithya. I would not say we are back to pre-COVID levels. But yes, it is getting normalized, so that's a fair statement.

**Nithya Balasubramanian:** Sir can I take that, you mean it's likely to inch a little higher because it's not fully back?

**Parag Agarwal:** Yes, it will gradually pick up, but as I said earlier, we maintain a very tight control on our investments and we link it to sales growth. So, ultimately, these investments are linked to the growth that we can deliver. But yes, you can expect that gradually will go back to pre-COVID levels.

**Nithya Balasubramanian:** The second question was on some of the material products that we have filed in the U.S. or are likely to file. Sir, if you can give us an update on where you are on NuvaRing, Copaxone, I think you mentioned you refiled? Do you have a TAD date? If you can update us on those two products?

**Erez Israeli:** Yes. I'll do that. So, on NuvaRing, we submitted the response to the CRL in December. And now the ball is in the court of US FDA, so we will wait for the response from the FDA. And accordingly, prepare for the launch. As for Copaxone, we received the CRL and we are now addressing it. So this is the status of these two assets.

**Nithya Balasubramanian:** Sorry, Erez, I hope I got that right, you have got received another CRL on Copaxone and you are preparing a response. Did I hear that right?

**Erez Israeli:** Yes, correct.

**Nithya Balasubramanian:** Any timelines on when you likely to resubmit?

**Erez Israeli:** We are still testing, but I believe it will be within the next few months.

**Moderator:** Thank you. The next question is from the line of Vishal Manchanda from Nirmal Bang Institutional Equities. Please go ahead.

**Vishal Manchanda:** On the domestic side, is there a seasonal element to the Wockhardt portfolio kind, so this Q3 a large quarter for the Wockhardt portfolio or this is like normal across all the quarters?

**Parag Agarwal:** Yes. There is no significant seasonal element, I would say. As I said earlier, Wockhardt portfolio is performing well. It is exceeding internal expectations. And we believe that we will maintain growth at similar levels for this portfolio.

- Vishal Manchanda:** And second one on the Sputnik vaccine. So, just wanted to understand whether this could involve marketing and you would need to distribute it in the private market or will this be a sale to the government? And whether you would also be allowed to sell in markets outside India?
- Erez Israeli:** So, we are planning to go to both the government as well as the private market. Of course, in accordance with the guidance that will come from the Indian government about priorities and how do they see that. So this is still in discussion or will be in discussion also in the future. And what was the second part of the question, sorry?
- Vishal Manchanda:** Would you also be allowed to sell it outside India, maybe Emerging Markets?
- Erez Israeli:** Yes. So, we are discussing regarding various options to increase the collaboration also to other markets.
- Moderator:** Thank you. The next question is from the line of Neha Manpuria from J.P. Morgan. Please go ahead.
- Neha Manpuria:** If I heard the numbers correctly, you said that, excluding Wockhardt, our India business is growing about 8% in the quarter, which would imply that Wockhardt revenues are pretty much back to the peak sales level? Is that correct and if that is the case, how should we look at momentum from Wockhardt from here? What will drive incremental growth or what you're indicating in line growth for Wockhardt from here?
- Erez Israeli:** I believe that the Wockhardt products will continue to grow from here as well, Neha.
- Neha Manpuria:** And what would drive that growth Erez, since most of the low-hanging fruit is already there in the numbers?
- Erez Israeli:** I think that it was primarily our ability to invest behind this product and to full stock the activity that this product demanded. So, this is both the sales synergies as well as the cost synergies that we anticipated to have and it is working well so far.
- Neha Manpuria:** I'm not sure if I caught this in your opening remarks, but our working capital seems to have increased in the quarter, both receivable and inventory. Could you indicate, if there was anything specific here that you would like to point out?
- Parag Agarwal:** Yes, Neha. So, on receivables, approximately the increase is 300 crores. I would say roughly around one-third or slightly higher than that is because of lower discounting of receivables in the U.S. and that's because we are no longer finding it economical because of the drop in interest rates in India. So that's the fundamental reason. The second reason is an increase because of the normal sales growth that we see. And finally, the milestone payment that we had received from Aurigene is another driver. But overall, I would say, the receivables increase is due to the underlying business drivers.

On inventory, again, part of it is because of sales growth and the rest of it is a planned increase. We want to make sure that our safety stock levels are adequate and there is absolutely no disruption as we enter Q4. So, these are the reasons for the increase in working capital. I hope I've answered the question.

**Neha Manpuria:** Just one other clarification on the U.S. business, the price erosion that we saw quarter-on-quarter, was that related to any specific product or was it across assets and across the portfolio and that could probably continue?

**Erez Israeli:** It is more than the one product and so it's not specific. It's like the normal course of business, but it's not the entire portfolio. So, like always United States when competition is coming, we need to react to it if we want to defend than what happens in these cases.

**Moderator:** Thank you. The next question is from the line of Kunal Mehta from Vallum Capital. Please go ahead.

**Kunal Mehta:** Sir, my first question was on NuvaRing. So, just wanted to understand the rationale behind the write-down of the entire product because I think it's still a viable product and, of course, it was, from an earnings perspective, even you consider the five-year period, it's practically neutral because it just accelerates the amortization. But wanted to understand the rationale behind the writing down this whole product.

**Erez Israeli:** Well, the rationale is we have the triggering event with the launch of Teva, so change of course the model around this product. And as we address the CRL only now and depends, of course, on the time that we will obtain approval; in accordance with good accounting standards we had to depreciate this asset. But yes, you are right, we are still committed to this product. Hopefully, the FDA will approve the product and then we can launch it and make money out of it.

**Kunal Mehta:** Sir, the second question I wanted to understand regarding the Emerging Markets. So, I'm sure in the opening remarks you mentioned a lot of the filings which you have done this year, especially in this quarter also. Most of these are dedicated to the Emerging Markets, ex-U.S., I would say, ex-U.S. markets, including Europe and Russia, CIS, and the other Emerging Markets, also smaller ones. So, just wanted to understand, of course, there is a lot of understanding available to understand the U.S. portfolio in the sense, but on the Emerging Markets side, could you please give us an understanding of the new product launches which we have targeted over the next two, three years? I mean, any sense could you give us on, let's say, if we are targeting these markets to grow by, let's say, maybe 15% over the longer two, three years' perspective, then any target whereby what would be the contribution of the new product launches for these markets?

**Erez Israeli:** So, yes, so we are not giving targets. But I am expecting, especially on the institutional and hospital that this product will significantly contribute to the growth in these area. As you recall, when we discussed our strategy, we are taking our global products portfolio and try to find as many markets as possible in order to get much more dollar sales for investment in R&D, and

that's what we are doing. So, you're going to see more and more filings in the rest of the markets and most of the development that we are doing now, we are doing globally and not necessarily for a specific market. So, it's in line with the strategy that we have discussed. And I want to say it is the starting of the proof of this execution. We are going to file more and more.

**Kunal Mehta:** Understood. Just a last final question from my end, sir. I just wanted to understand the strategy which we have on the injectable side. Firstly, could you please give us a number of regarding from the outstanding portfolio of outstanding filings in the U.S. ANDAs, how many are on the injectables? And if you could break it down between complex and, I would say, rather simple ones on the injectable side? And, of course, you've mentioned in your 20F that from the U.S. business, roughly one-fourth comes from the injectable portfolio, I'm talking about financial year '20. So, I would say, any perspective on how we want to take this business ahead? Because I think considering the fact that a good portion of the off-patent products are now in this portion of the market for the next five years. So, any perspective on how we want to take this business ahead in the U.S.?

**Erez Israeli:** Yes, of course. Our injectables are global products. And we want to develop and most of our investments in that area is for global products, including the U.S. The impact on the U.S. is that more and more injectable products will be filed in the U.S. So, proportionally, the injectables will be higher than they used to be in the past. So, if you wish in the U.S. complex and injectables will grow and the simple **inaudible**.

**Kunal Mehta:** Okay, sir. So, if I have to say that 25% current contribution over the next three, four years this contribution will only move upwards in terms of the overall portfolio assuming that's the way we want to...

**Erez Israeli:** Yes. The weight of the injectables will be bigger in the future.

**Moderator:** Thank you. The next question is from the line of G Vivek from GS Investment. Please go ahead.

**G. Vivek:** Yes. Is my understanding correct, that the tailwind our pharma sector was having due to COVID is now weakening and are we back to the time of price erosion getting on weight severely, instead of the single-digit price erosion due to consolidation we faced?

**Erez Israeli:** You are talking about the United States?

**G. Vivek:** Yes. U.S. and entire world market, basically, the tailwinds due to COVID for pharma sector in India were responsible for very good performance in Q1, Q2 and that is now weakening.

**Erez Israeli:** So, it depends of course on the market. But we are not yet in the pre-COVID level or the pre-COVID behavior, there are still impacts of COVID in certain areas. For example, in the U.S. we do see still the certain products are affected by the ability of people to meet physicians and stuff like that. We do see that these products are softer than they used to be. In terms of price erosion, in the U.S., it's primarily related to competition. So when competition is coming, this is what is causing price erosion, it's not so much COVID impact. In the case of India, we absolutely see a

pickup but the Q3 was a quarter in which by and large the activities of India came almost to normality. We are not there yet, but we are almost there.

**G. Vivek:** Is the similar situation prevailing for injectables also or is it mostly for oral solid? Injectable also the price erosion is severe?

**Erez Israeli:** The price erosion is affected by both injectable and oral solid. It's not related to COVID. It is related to competition that is coming. It's in both segments in the case of the United States.

**G. Vivek:** And the good part for our Company was all our five plants were FDA approved and may be after some gap also. And now FDA inspection has again begun in India and any FDA inspection due for any of our plants in India?

**Erez Israeli:** We did not get any requirements from the US FDA yet. And in general, it's a good news that the US FDA is starting inspection soon. It's a great news, actually.

**Moderator:** Thank you. The next question is from the line of Nitin Agarwal from DAM Capital. Please go ahead.

**Nitin Agarwal:** Sir, my question was, we've had 24 new launches during the year in the U.S., but our run rate still is sort of continues to be below sub to around \$240 million per quarter run rate. So, in your assessment what will it take for us to really breakthrough to meaningfully scale up from these levels given the fact that number of launches clearly has not been a hindrance so far. We've done fairly large number of launches even this year.

**Erez Israeli:** So, as you know, it's the number of the launches and also the type of products that we are launching. First of all, I believe that the portfolio moving forward is attracting. And it should create a growth and actually, the product that hopefully, we are launching should give us the growth we are looking for. So it's not just the quantity, but it's also what you call the quality, the size of the product that are going to be launched. And some of the products coming up are interesting.

**Nitin Agarwal:** Okay. And secondly, on the gross margin, we've had a fairly sharp drop in the gross margin, the generic business this quarter, if you adjust for the license fee income. Now, how should we read this? I mean, is this the new normal to go with given the fact that the export incentives are no longer there and how should we sort of model in the generic gross margins now going forward, generic business gross margins?

**Erez Israeli:** Yes. Like we shared in the past, we are not managing the gross margin per se. We are actually managing the EBITDA and we are maintaining that we are staying and sticking to the 25% that we shared in the past and we are already in this neighborhood and planning to stay in this neighborhood or may be even lower for a while. Gross margin, it's a matter of mix of activities. For example, if we have a great product that will give us 50% gross margin, and it will be profitable with the right EBITDA, we will take it. So, we are not managing the percentage. We are managing the nominal gross margins. And in general, what we've said and we are still there,

that we will stay around the neighborhood of the gross margin that we were in the past. But we are not managing it per se. We will continue to take businesses if the profits are there and even if gross margin will be below this number that we have now.

**Moderator:** Thank you. The next question is from the line of Sameer Baisiwala from Morgan Stanley. Please go ahead.

**Sameer Baisiwala:** Sir, this is an important launch, which is Vascepa. So let me ask a question on this. I'm not sure how much you can talk. But would it be like your regular high-value launch, or would it be volume constraint like the first entrant with the lower margins and it should improve as we go along? So, any thoughts would be very helpful.

**Erez Israeli:** Yes. Sameer, I cannot tell you that. It's absolutely going to be an important launch for us, that's what I can say. But I am not going to discuss quantities or anything like that for **inaudible** reasons.

**Sameer Baisiwala:** Sir, can you confirm that this would be a regular high-value launch for you?

**Erez Israeli:** It should be a high-value launch for us, yes.

**Sameer Baisiwala:** Sir, second question on Sputnik V. Just if you can tell us, what's your sourcing plan for the vaccine? And second, is there any change to your earlier launch timelines and 100 million volume target, that would be great?

**Erez Israeli:** So the 100 is now 125 million, this is one update. And we are discussing more countries. Actually, we initiated already Phase-III in this 1600 and by March we hope we can submit to DCGI the emergency use authorization application. And if we will get, we can launch in March.

**Sameer Baisiwala:** And what about the sourcing plan? I mean, would you be taking it from your partner RDIF or would you also be doing some manufacturing?

**Erez Israeli:** So, a little bit from Russia and most of it from India with 2 partners.

**Sameer Baisiwala:** Sir, the other question is on the Aurigene outsourcing of AUR102. This is pre-Phase-I sort of out-licensing to Exelixis. So, it's a very early stage out-licensing. So, what's the thought process behind this? You could have taken it to Phase-II or even early Phase-III and then could have out-licensed?

**Erez Israeli:** Yes, Aurigene developed over the year's very interesting pipelines. Some of them, we are planning to continue to develop to later stage. Some of them, we are planning to monetize in early stage in order to allow Aurigene to be self-sustained in terms of risk reward management. So, I think that Aurigene has a very interesting pipeline going forward. So, those of what we want to keep and continue to invest, we will not monetize an early stage, we will do later.

**Sameer Baisiwala:** One final one, if I can. Parag, if I'm not wrong, you've mentioned that in the EBITDA margins sort of internal aspiration as 25%. And if so, if you did fill it and you are very close to that already. So, what's in your outlook for margins and what are the levers for that? Thank you.

**Parag Agarwal:** Yes. So, as I said, our aspiration indeed is to deliver 25% EBITDA on a sustainable basis. And while we are in the neighborhood of 25%, we are not yet able to consistently deliver 25% and we have a number of levers to get there. I think the biggest lever, obviously is topline growth and second is productivity that we are driving very hard across the value chain. I mean, I can talk about it in detail that we drive products re-formulation, the chemistry, how we can run our machines more efficiently, how to improve the yields, finding alternate vendors for our materials and so on. And also in sales and marketing and so on. So productivity is a big driver and we want to make it a habit. But I must point out that as we drive productivity, we also need to invest some of it back into the business behind our brands and behind capabilities. Digital capabilities I spoke earlier. So it's very important that we drive the levers that can potentially improve the margin, but we also invest behind the business so that we can give a sustainable growth in the future. So I would say that we are in the neighborhood of 25% EBITDA estimations. And I think you can expect that in the next few quarters we should be in that range.

**Moderator:** Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.

**Prakash Agarwal:** Just a follow-up on this, clearly, mentioned 25% over few quarters on a sustainable basis, but if I get my maths right, particularly this quarter, if you strip the licensing income then you are around 21% and you mentioned that there are some structural cost upgradation, which would happen or will continue over few quarters. So I'm just trying to get these two together that currently we are at 21%, last two quarters we're at 25%. There is a 400 basis gap here. Actually, we are not near 25%. So, if you could explain that? Or you want to say that the cost is truly a one-off here? So that would be helpful. Thank you.

**Parag Agarwal:** That's not right that the cost is entirely one-off. Let me clarify that, first of all, the impact of the Aurigene milestone payment is around 1%. We have delivered EBITDA margin of 24% during the quarter and even if our EBITDA margin is around 23% excluding the milestone payment, it is within normal range. I must also say that we do drive out-licensing in a number of our businesses, like Proprietary Products and Aurigene and Biologics business fairly regularly. So I'm not sure it is fair to exclude or include a milestone payment. As I said earlier, we are driving productivity and we are also investing behind the business. We are right now in the neighborhood of 25% margin and we will continue to drive that as our long-term aspiration.

**Prakash Agarwal:** And can you confirm, like the increase in expenses are recurring apart from the small one-off you mentioned and you can quantify that one-off please?

**Parag Agarwal:** I don't think I can quantify the one-offs. In terms of the increase in cost, as I said, it is an investment behind our brands. We do expect it to continue, but it is also linked to growth. So we have a process to manage return on investment and therefore, this went to growth. So, in



summary, I think this level of investment we expect to continue, but this is directly linked to the sales growth that we can deliver.

**Prakash Agarwal:** Secondly sir, on China, so I think with COVID, everything is muted. But what is the ground level action in terms of the filing momentum? How it has been in the last nine months? And is it started to pick-up and when do we see the next round of approvals for us?

**Erez Israeli:** So China is doing very well for us. We are also growing in China despite COVID. And we already filed 15 products and out of a list of about 100 products in the pipeline that we shared before. So we are very much on track with our plans for China.

**Prakash Agarwal:** Sorry, you mentioned 16 products filed and growing double digit. Did I hear that right, sir?

**Erez Israeli:** What I said is 15 and I did not say anything about the digit.

**Prakash Agarwal:** But we are growing in China despite COVID?

**Erez Israeli:** We are growing in China despite COVID and even nicely. And we already submitted 15 products on top of the products that we already have in the market.

**Prakash Agarwal:** Perfect. That is very helpful. Thank you. And, sir, on the API, PSAI business that we have. So, clearly, the first two quarters very heavy, you mentioned stocking supply disruption. So how do we see the outlook going forward given that in the last call we mentioned that it is strategically important to us and we want to invest in this business?

**Erez Israeli:** We would grow our API business. It will grow, may be not quarter-on-quarter but it will grow. It will grow and it's very important for us. And I want to increase also the level of back integration over time.

**Prakash Agarwal:** And it has two parts, if I'm not wrong, the API and the pharma services and then you carved out Aurigene out of it. So, I just wanted to understand the growth trajectory for each of the business?

**Erez Israeli:** Both will grow. We are not giving guidance, but both will grow.

**Prakash Agarwal:** Understood. And lastly, sir, on Pegfilgrastim, is there any update in terms of where we are in the overall approval scheme?

**Erez Israeli:** Which one, sorry?

**Prakash Agarwal:** Pegfilgrastim.

**Amit Agarwal:** That program is run by Fresenius, they filed the product. We haven't heard anything about approval, but we expect in FY'22, but we do not have any confirmed date.

**Moderator:** Thank you. Ladies and gentlemen, due to time constraint we will take that as the last question. I now hand the conference over to Mr. Amit Agarwal for closing comments.

**Amit Agarwal:** Thanks everyone for joining us today for the earnings call. In case of any further queries, please reach out to the Investor Relations team. Thank you.

**Moderator:** Thank you. Ladies and gentlemen on behalf of Dr. Reddy's Laboratories Limited that concludes this conference. Thank you for joining us and you may now disconnect your lines.