Dr. Reddy's Laboratories Limited Q2 FY 20 Earnings Conference Call

November 01, 2019

Amit Agarwal:

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 30th September, 2019. Earlier during the day, we have released our results and the same are also posted on our website. This call is being recorded. The playback and transcript 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. Saumen Chakraborty - 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 written consent.

Before I proceed with the call, I would like to remind everyone that the safe harbor language contained in today's press release also pertains to this conference call.

Now I hand over the call to Mr. Saumen Chakraborty. Over to you, sir.

Saumen Chakraborty:

Thank you. Greetings to everyone. Let me take you through the key financial highlights for the quarter. This quarter, we had certain one-off items impacting revenues, gross profit margin and SG&A, which I would cover as part of the respective section. Herein, all the amounts are translated into US dollars at a convenient translation rate of Rs. 70.64, which is the rate as of 30th September, 2019.

Consolidated revenues for the quarter are at Rs. 4,801 crores, which is \$680 million, registering a growth of 26% year-on-year and 25% on a sequential quarter basis. It includes an amount of Rs. 723 crores, recognized as revenue towards the sale of two neurology brands of our Proprietary Products business. Even after netting off this amount, revenue during this quarter has been the highest ever for Dr. Reddy's. This has been made possible by registering a good growth in the PSAI, Europe, Emerging Markets and India businesses. However, NAG performance could have been better.

Consolidated gross profit margin for the quarter is 57.5% with an improvement of 250 basis points on a year-on-year basis and 590 basis points on a sequential basis. Gross margin for the Global Generics business was 55.5% and for PSAI business was 24.6%. While the overall gross margin is benefited due to revenue recognition of the PP neuro brand, it was impacted due to certain one-offs, including, but not restricted to the impact of the voluntary recall of Ranitidine in the U.S. market. Adjusted for the one-offs, the normalized gross profit margin for the quarter is about 51.5%.

The SG&A spend for the quarter is Rs. 1,678 crores, that is \$238 million. As part of our quarterly impairment testing analysis, we concluded that the carrying value of the intangible asset is not reflective of the current market reality for three of the products namely, Tobramycin, Ramelteon and Imiquimod acquired from Teva. While the first two products faced increased competition

and substantial price drop during this quarter, we have taken a decision not to launch the third product. Accordingly, an impairment charge of Rs. 355 crores has been considered in the current quarter. Beyond the impairment charge, there have been additional one-off over Rs. 100 crores, including, but not restricted to the cost associated with the sale of two neurology brands. Adjusted for the one-off, the normalized SG&A spend is lower on a sequential quarter basis.

R&D spend for the quarter is Rs. 366 crores that is \$52 million and is at 7.6% of the sales for the quarter. The R&D spend is lower by 11% year-on-year, but higher by 1% on a sequential quarter basis. Considering the current state of activities, we believe that the overall R&D for this fiscal would be in the range of \$200 million to \$240 million.

The EBITDA of the quarter is Rs. 1,434 crores that is \$203 million, which is around 29.9% of the revenue.

The net tax for this quarter is a benefit of Rs. 326 crores due to recognition of deferred tax asset for Rs. 522 crores, primarily related to MAT credit. Pursuant to the recent amendments in the taxation laws in India, the MAT rate has been reduced from 21.55% to 17.47%. Consequently, during the quarter, the company has evaluated the recoverability of the unrecognized MAT credit and ascertained that it is likely to recover the MAT credit within the stipulated period as per Income Tax Act. Accordingly, the company has recognized a deferred tax asset of Rs. 499 crores related to the unrecognized MAT credit in the current quarter. With this development, the ETR for this financial year is expected to be less than 10%.

EPS for the quarter is Rs. 65.82.

Operating working capital increased by around Rs. 350 crores, which is \$49.5 million. This increase is attributable to an increase in receivables in line with the sales increase. The net working capital days has increased by four days against the last quarter.

We invested Rs. 108 crores which is \$15 million towards capital investment in this quarter. The free cash flow generated during this quarter was Rs. 874 crores, which is \$124 million. Consequently our net debt-to-equity ratio has improved further and is at 0.01 as on 30th September, 2019.

Foreign currency cash flow hedges for the next six months in the form of derivatives for US dollars are approximately \$300 million, largely hedged around the range of Rs. 70.20 to Rs. 73.95 to the dollar. In addition, we have balance sheet hedges of \$564 million. We also have foreign currency cash flow hedges of RUB 1,650 million at the rate of Rs. 1.0813 to the ruble, maturing over next six months.

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

Erez Israeli:

Thank you, Saumen. Greetings to all. We had a good quarter and are progressing well in implementing our strategy in the focus spaces we have communicated. In this quarter, we generated Rs. 874 crores in cash, which improves our financial strength and enables us additional

means to grow in the future. This quarter, we had number of one-off in the financial performance, but we believe this is not going to impact our strategy and our future growth.

Now let me take you through the key highlights across our businesses. Please note that all the references to the numbers in this section are in the respective local currencies. Our North America generics recorded sales of \$202 million for the quarter and declined by 1% year-over-year and 14% on a sequential quarter basis. The sequential decline was primarily driven by certain issues impacting the quarter such as (a) provisions related to nationwide recall of Ranitidine product due to NDMA impurities limits following FDA's caution note regarding the same. We now have completely suspended the sales of Ranitidine OTC and Rx product, and (b) logistics-related challenges leading to temporary disruption in supply, which have been addressed since. We expect the sales run rate to normalize from Q3 onwards.

During the quarter, we launched eight new products, including some first-to-market and limited competition products like Carboprost injectable, Pregabalin, Fosaprepitant injectable and OTC Guaif/Psuedo. Overall, we launched 13 products in the first half of the fiscal. While we continue to work towards ramping up our market share across the key launches, we are on track to launch more than 30 new products in the current fiscal.

Our Europe business recorded sales of \in 35 million with a strong year-on-year growth of 50% and sequential growth of 15%. This great performance was driven by increased contribution from new launches, coupled with base business performing well across all the European markets. We expect this business to continue to perform well during the balance of the year.

Our emerging markets business recorded sales of Rs. 820 crores with a year-on-year growth of 10% and sequential growth of 13%. Within EM segment, Russia business grew at 6% year-on-year and 2% sequential in constant currency. New launches and higher volumes contributed towards the overall growth, which were partially offset by lower realization in few of the markets.

This quarter witnessed a great milestone for our China business. As many of you may be aware, Dr. Reddy successfully emerged as one of the winner for the supply of olanzapine in the centralized drug procurement program, becoming the first Indian generic company to have prevailed in the new tendering process. This award is a testament to our focus and efforts towards building China as one of our key growth drivers for the company. We remain committed to building a healthy pipeline of products to enable us to support Chinese patients with more such opportunities going forward.

Our India business recorded sales of Rs. 751 crores with a year-on-year growth of 9% and a sequential growth of 8%. During the quarter, we launched five new brands. As per the secondary sales reported by IQVIA, we registered a healthy growth of 13.4% ahead of total market growth of 13.1% for the quarter ended September 2019. We continue to focus and strengthen our presence in India market.

Our PSAI business recorded sales of \$100 million with a year-on-year growth of 16% and sequential quarter growth of 54% with a strong quarter for the business and we expect to build on this momentum going forward.

On the R&D front, we filed one ANDA during this quarter and the filing run rate is expected to ramp up during the balance of the year. As of 30th September 2019, we have 99 cumulative filings pending for approval with the USFDA, including 96 ANDA and 3 NDAs. During the quarter, we have also filed eight drug master files globally. We continue to strengthen our product portfolio across all of our focus markets.

On the quality and regulatory front, we had several audits during the year, carried by USFDA and other agencies and I am quite satisfied with the overall audit outcome. We believe that we should be able to appropriately address wherever there are open observation from these audits. As regards to the API Srikakulam plant, what we call CTO-VI, we are expecting an inspection from the USFDA in the near future.

Our proprietary products business pursuant to the closure of the divestiture of our two neurology brands to Upsher-Smith, we recognized income of \$105 million during this quarter, representing the upfront consideration and discounted value of near-term milestones. Further, we are happy to announce that TOSYMRA brand for intra nasal Sumatriptan was launched by Upsher-Smith in the United States in October 2019. Going forward, we remain focused on addressing unmet and under met medical needs of patient suffering from critical and chronic illness globally. We are focusing on our core capabilities in R&D to build a self-sustained business that can consistently deliver high-value, globally relevant, differentiated products that provide meaningful health economic outcome to patients and payers. The NDA for DFN-15 which is oral celecoxib has been accepted by the USFDA and progress on all of our other R&D program is on track.

While we continue to progress well on the organic growth for each one of our focus businesses, we are also evaluating multiple inorganic opportunities, which can accelerate our growth journey further to reach more patient and create value for all stakeholders.

I am pleased with the shift seen in the organization behavior toward cost consciousness and higher prudence toward cash utilization. We are taking significant effort to improve on multiple health parameters in addition to financial performance and believe that we are progressing well in the right direction.

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

Prakash Agrawal:

Sir, two questions, one is on the U.S. business. Just trying to understand the reasons that you have cited in terms of the logistics, the price erosion, volume erosion and some bit on Ranitidine, if you could just break it down so that we know that if things wouldn't have happened, what would have been the normalized U.S. sales run rate? Would it be similar to last quarter, a tad lower or much lower?

Saumen Chakraborty: It will be a bit lower than the previous quarter, not much lower.

Prakash Agrawal: Okay. So are we quantifying the Ranitidine impact and the logistics impact, that would be really

helpful.

Saumen Chakraborty: Ranitidine will be quantified when we are releasing 6-K very shortly that you will find out there.

Others are not quantified.

Prakash Agrawal: Okay. And with respect to coming back to the normalized run rate, do we expect going forward

whether this new launches to ramp up coming back to Q1 run rate? Or how should we think

about the rest of the year?

Erez Israeli: We are planning to grow and we are not going to disclose specific numbers, as we normally do

not do. So but absolutely, the performance of this quarter was impacted significantly, the main difference by the factors that we mentioned. On top of this, we had a price decrease on some of the products, so it was not the only reason for that. These two issues naturally will not be there in the Q3 and at last, I believe that we will ramp up, so it's supposed to be better. Overall, we

are planning to grow in North America.

Prakash Agrawal: Okay. And, sir, second question on the key products. So if you could share any progress on our

biosimilar portfolio, which is the XenoPort, Rituximab and the PEG?

Erez Israeli: So on biosimilar, we're talking about rituximab, the trial is progressing well. On your first

question, just to add, and naturally on top of it, we see an opportunity with Suboxone. And there is a certain announcement that the AG will not be there, so naturally it has opened an opportunity

for us which we hope to exploit.

Saumen Chakraborty: So on XenoPort, I would tell you the status. We successfully completed the Phase 2b studies.

Now it really does support our belief that this will become the first approved oral prodrug of Monomethyl Fumarate class for treatment of moderate to severe plaque psoriasis in U.S. We are in active dialogue with the USFDA right now for crafting the way forward with respect to the

design of the Phase 3 trials.

Prakash Agrawal: Okay. And we are also developing Pegfilgrastim, right?

Saumen Chakraborty: That is Fresenius Kabi. We earlier had an agreement with Merck Serono which was acquired by

Fresenius Kabi, so they would have done ...inaudible.

Amit Agarwal: Yes. So Phase 3 was completed. They are preparing for filing. We do not know the date but they

should be filing.

Prakash Agrawal: Okay. And we do have economic interest, right?

Amit Agarwal: Yes.

Erez Israeli: Absolutely.

Anubhav Agarwal: First question is, can you just elaborate a little bit on this disruption which you mentioned related

to logistic issue? Is this Dr. Reddy's-specific issue or this was an industry issue?

Erez Israeli: Dr. Reddy's-specific issues. We had issue with the distribution of the products in the U.S. over

a certain period of time.

Anubhav Agarwal: But this was across the basket or this is very few products, you had the issue?

Erez Israeli: Across the basket, it was just issue in the way we distributed products. Nothing special and we

overcame it.

Anubhav Agarwal: But I'm just trying to understand, so the way it's worded in the press release, it looks like the

sales that were lower this quarter is the lost sales. So I am just trying to understand, let's say x

amount of dollar we showed as lower sales in this quarter.

Erez Israeli: We had less days that we could ship product. So naturally, it resulted, therefore the quarter, we

had lower sales.

Saumen Chakraborty: But you are right to interpret in terms of that since it has happened in the last month of the

quarter, we could not get back to the normalcy during the quarter. Now things have become

normal, so there have been some problem in shipping out of the warehouse during the last part

of the quarter.

Anubhav Agarwal: So I'm just trying to understand a very simple question that lets say, x million dollars was the

sales in each quarter. Over a period of 2-3 quarters, are we going to get 3x let's say over three

quarters, so or are we going to get 2x because of the supply issues?

Erez Israeli: We did not lose sales because of the supply issues.

Anubhav Agarwal: But are we going to get, in the next quarter, is this...

Saumen Chakraborty: Yes. Whatever, we could not ship in the last quarter, that part of the things we would have been

shipped in this quarter, in the month of October.

Anubhav Agarwal: So this quarter should show a higher sales for whatever we have done lowest in the second

quarter, right?

Erez Israeli: This quarter should be better than the second quarter, yes.

Anubhav Agarwal: Okay, and second question was on generic Suboxone. I just wanted to check that can our capacity

support, let's say if our market share were to double, do we have enough capacity to support

that?

Erez Israeli: Yes.

Anubhav Agarwal: And just one clarity on generic Febuxostat. We did not get approval of this product. We were

one of the shared generics. What was the reason that we did not get approval of this product?

Amit Agarwal: Which product Anubhav?

Anubhav Agarwal: Uloric as a brand, generic Febuxostat.

Erez Israeli: Okay. I don't have the detail, I believe that maybe it's because of the CTO-VI situation, but I'm

not sure about it.

Amit Agarwal: May be we can check and get back to you.

Neha Manpuria: Sir, first on the SG&A. On the 100 crores, I understand some part of it is transaction cost related

to proprietary brand sales, but could you give us some color on what the other one-off was? And should we see the SG&A spend continue to decline from the current quarter level, like you've

indicated or in the second quarter? Or this is adjusted for this 100 crores is the new level?

Saumen Chakraborty: So whatever we can disclose and we need to disclose, these are all to be there in the 6-K and

there will be certain areas where there could be specific confidentiality and other that we cannot speak so directly. But the crux of the thing is at a normalized level, the SG&A, actually we are improving. And this quarter, at a normalized level is lower than just the previous quarter, that means from the Q1, Q2 we have improved on SG&A, but because of the one-off it is looking

higher.

Neha Manpuria: Okay. So sir, if I were to look at our margin trajectory, given that a lot of our growth is now

coming from emerging market, India. Is it fair to assume that this growth should help improve

EBITDA margins? Is that the right way to look at our margins?

Erez Israeli: Yes. Over time yes.

Neha Manpuria: And when you say over time that would be couple of quarters or do you see that happening more

gradually?

Saumen Chakraborty: So you will have to first appreciate that over the last few years there have been continuous

pressure of price erosion. And at other hand, we have been continuously trying to improve productivity and have all the cost excellence program to neutralize the impact of so severe price erosion particularly in U.S. market. And we have been trying to keep the gross margin at that level. But at an EBITDA level, overall, since multiple things that we are doing, we have come to a level where we are not very far from the right kind of benchmark for the pharma industry, what kind of EBITDA we should be having. So that is what dropped for subsequent to the warning letter situation. I think we are recovering, and more or less we've recovered. And as Erez just said that if there is no other specific impact, which is dropping down, we hope to

continuously improve.

Neha Manpuria:

Understood. And my second question is on the use of cash, particularly after the cash flow in this quarter. You mentioned in the opening comments that you are evaluating quite a few opportunities. Again, are these focused on probably India, emerging market, if you could give some areas, where we're looking at deploying this cash in?

Erez Israeli:

No, absolutely. We are looking to invest in our spaces, in all the relevant spaces. The primary focus is on branded generic markets, India, in particular. This is the primary focus. At the same time, the efforts and the discussions are in each one of the spaces in order to support the growth that is required in the strategy. We are doing it with the following: one, it has to support the strategy. If something that will add capability, and it makes sense for economically and it's better for the shareholders, we will buy the capability then develop it ourselves. And it's complementary to the organic growth in that space. We will continue to be an organic growth company. So this is a complementary. But naturally, the fact that essentially, we have no debt and this is going to improve even further in the future. If we find the opportunity to increase shareholder value by having a good deal, we'll not hesitate to do so.

Damavanti Kerai:

Sir, can you elaborate a bit more about our progress in China? So are we targeting mainly the tender market or we are looking into other channels also? And any sales target, or any guidance we are having for China market in the next 3 to 4 years, if you can share that?

Erez Israeli:

Sure. So China is a very important market for us, it's one of our leading spaces. In China, we are working in the following channels. One, our regional channel that is primarily through our partnership or JV in China, KRRP. And this is selling and marketing of branded generic products. This is also progressing well and it is growing double digits, as we speak. In that space, we are 20 years now. And we'll continue to be in that space. What was opened up to us and I discussed it in a couple of investor meetings, given the new regulations in China, two channels are now open for us. One is direct sales of generic product if they are getting a GEA recognition. And when you do that, the idea is to partner, this is not through the partnership, this is where we partner a company that has relevant salesforce to this therapeutic areas, but we can compete on the slot of the innovator in that relevant hospitals. The third channel is this new procurement program. This is a relatively new development in China, which is probably going to be scaled up and in which, if we have product that means, we as Strategy will try to participate and win our share as well. And we want to grow in all three channels, not just in the last one. And we are happy that we had olanzapine is the first time that we enter into the third channel that I mentioned. We are already in other two.

Damayanti Kerai:

Okay. So any target we have in mind, is it set for near to medium term, where we would like to reach?

Erez Israeli:

Not something that we want to share because we are not giving guidance. But it's way, way, way higher than what we have now.

Damayanti Kerai:

Sure. And do you have any update for our key filings of NuvaRing and Copaxone from what we shared earlier? Or anything, any update there?

Erez Israeli: On NuvaRing and generic Copaxone, we are on CRL, and we are addressing it. We continue to

address it today. And we hope to file a response to that in the next few months.

Damayanti Kerai: For both the products? Or first, NuvaRing or...

Erez Israeli: For both products. We cannot yet commit to a specific date.

Abhishek Sharma: Sir, two questions. First, on China tender market. Olanzapine, I was just trying to understand the

dynamics of pricing it? How is the pricing for olanzapine in the tender market versus the private

market?

Erez Israeli: We are not sharing specific numbers naturally of pricing the product. But as you can imagine,

it's a tender process, so it was significantly lower.

Abhishek Sharma: And would that mean that you would sort of look at sort of much higher volumes through the

tender market? And is that how you're looking at it?

Erez Israeli: Yes. It is a higher volume, its lower prices but it's still very profitable. And you don't need to

have the sales and marketing efforts, you don't need to go to physicians and use sales efforts, like you need to do for example, in the second channel that I mentioned. So it's more like, if you

wish, other tender systems in other countries.

Saumen Chakraborty: So net profit is higher on that part.

Erez Israeli: Yes, net profit is actually higher.

Abhishek Sharma: The other question was on receivables. There's a sharp jump this quarter despite the fact that

there has been a dip in the U.S., so just wanted to understand with respect to that?

Saumen Chakraborty: On overall working capital front, I already shared that there is only four days increase in the

number of days. So we are not concerned about it. Whatever jump in this has happened, it is in

line with the sales.

Surya Patra: Just wanted to have some more clarity on the Suboxone. Recently in the opioid lawsuit

settlement, Teva, what has offered to supply and subsidized Suboxone tablet for a longer period. So what is the business dynamic with Suboxone, the films will be releasing? And whether that would really impact the opportunity what we are targeting. Anyway we have so far progressed in terms of a market share around 15% only in the Suboxone. So what is also has restricted our

penetration faster? Something on the Suboxone side that you can.

Erez Israeli: So firstly, I would like to address our market share on Suboxone is higher than 15%. The second,

the development that was shared by Indivior, I think even yesterday, about the potential exit of the AG, so naturally this has opened for us an opportunity that we are planning to pursue. As for

the Teva deal, naturally, we are not part of that activities. So I am learning about it, and we are

monitoring it in the same way as others, and once we will come, we will try to understand the outcome. I don't know what is the pace and how it will impact the market.

Surva Patra:

Yes is it right that earlier also it has been commented that way by industry people that hardly there is a difference in Suboxone tablet versus the film versus the sublingual. So is there any practical difference there? Or it is not and hence, there could be a kind of impact, if there is a subsidized supply by a large player?

Erez Israeli:

Naturally, the film is more advanced version and gives better outcome for the patient that are taking it. So that's why the film is growing versus the tablets originally. And in the natural course, so that this phenomena will continue. I don't have any visibility if any other developments in the market will happen. I cannot speculate on it.

Surya Patra:

Okay. And second thing, one clarification about this \$105 million what you have received from the disposal of the three brands. So initially, you were talking about in two tranches, like, 70-40. So that means it is clear that, okay, the entire of the 110 something like that is already been factored in this quarter, right?

Saumen Chakraborty:

Yes.

Surya Patra:

And regards the European growth, sir, how should one really look at. I think sequentially has improved significantly, but Y-o-Y it is still stronger double-digit kind of. So what is driving, whether it is on a relatively low base it is growing? Any sense on that front?

Erez Israeli:

Sure. First, for many years we were not performing well in Europe, and we made certain adjustments to the portfolio, to the team and to the activities and I think now we are starting to bear the fruits of them. Overall, Europe will grow significantly up. But the growth now is primarily due to launches of couple of very good products in various markets.

Surya Patra:

Okay. Just one thing, sir. Is it fair to believe that NuvaRing is a product opportunity for FY21?

Erez Israeli:

NuvaRing is an important product for us. And once we will get the approval and we will know, I absolutely hope so.

Sameer Baisiwala:

Sir, one question on China is to the extent that you are going to do local manufacturing out there, which I think would be a substantial part of your business. How does it make you more competitive than the other local Chinese players? And second, how do you bring to table India's cost competitiveness, when you're participating in Chinese market?

Erez Israeli:

Yes. Thank you, Sameer. We are making products now. We have a plant that is making product for China, primarily for the KRRP product, and we took a decision and we are implementing an expansion for that plant. So this will take some of the growth. On top of it, we are moving few products to a contractor to make in China. There are certain advantages for example, exemptions from certain tests when you do a bio study and make products in China, and we will explore

that. And some products we will sell out of our Indian facilities. So it's a combination of the three of them.

Sameer Baisiwala:

Okay, great. And sir, second question is on the U.S. pricing environment. My understanding is over last two quarters, most companies both manufacturers as well as your customers have come back to say that the base business price erosion is roughly about, somewhere around mid-single digit, call it 5% to 7%, but your commentary seems to be suggesting that it's much worse than that. Is it true? And is this anything specific to Dr. Reddy's?

Erez Israeli:

Yes. So it is not an overall market dynamics. It is a specific situation in products that faced new competition, normally for that particular product there is a double-digit decrease in price in which you can either protect your share or drop the product. And now, it depends what is the mix of those in your mix. In our case, for the quarter, it was relatively higher.

Sameer Baisiwala:

Okay. And going forward, for the base business price erosion, what's the outlook for your portfolio?

Erez Israeli:

The same like we discussed in the past. I don't see any specific outcome for the base. The main erosions, I believe, going forward will be on new launches that naturally, over time the price that we launch with will be different as more competitors will join the game.

Sameer Baisiwala:

Okay. And sir, just one final one from my side and that's about generic NuvaRing. I remember, in the last call you mentioned that until you get the full response from FDA and see the new queries from them, you would not know what's the timeline and what kind of complexity and what kind of work is required to be done? I'm pretty much sure that now you've got all that information if you can add any more color to what you had already spoken on the call that would be great, sir?

Erez Israeli:

We got the CRL, if I'm not mistaken, in August, right? In August. And it was related to some specs of the products that we had to address in certain testing. For that, we had to do some experiments and to buy certain equipments. This is the work that will take few months starting from August. And if everything is successful, we will address and answer the CRL and naturally, we are very keen on this product.

Ranveer Singh:

Sir, my question is related to the Proprietary Products thereafter divesting this three molecules, what is the outlook there? So what kind of investments we are making? And what we are doing actually there?

Erez Israeli:

Thank you. First, we still have a pipeline of products that we need to finish certain experiments and in order to further find the partner for that, and if there is licensing or divestiture. So we are looking for either get what you call long-term stream of revenue, which will be more of a licensing in nature of the product or divestitures which means relatively high level of upfront and lower level of royalties going forward. So both models we're pursuing on the project that we have. In addition to that, we are building this team to continue to develop product. This time,

less dependent on the U.S. market, but more globally, in which we want to continue to develop products for unmet need. Basically, if you wish the desire if they ask to have a meaningful stream of revenue from each one of this development, we can either develop directly partnering with a potential partner globally or do it after certain milestones, if there is an interest. The new model is pretty simple. Stream of revenue in, then it allows certain stream of revenue out and overall, this is going to be going forward a profit center for us rather than an investment for long term.

Ranveer Singh:

Okay. So what portion of our R&D is going towards this Promius Pharma?

Erez Israeli:

Relatively small portion of it.

Ranveer Singh:

And secondly, on Ranitidine, I think two events that we recalled and then we halted the sale, I think last week of September. So in this quarter, virtually, what we have factored in is recall value and then the discontinuance of sales. So what I wanted to understand that it's entire Ranitidine issue has been factored in this quarter or part of it is likely to come in subsequent quarter?

Saumen Chakraborty:

No. We have covered whatever is impact of voluntary recall, we have covered it fully.

Ranveer Singh:

Okay. So what I see that a few other regulators like Australia has given go ahead with Ranitidine in present form to some of your competitor. What I wanted to understand that the standard that USFDA came out for this Ranitidine. Is there any further submission or something is happening there to lower their standard to show that the Ranitidine, the content of NDMA can be permissible going forward?

Erez Israeli:

I don't know what eventually will be the right level of NDMA and where it will lead for us. By the way it's globally. So we'll not sell Ranitidine. We have one standard with that respect. We will not differentiate between countries as related to safety of patients. But overall, it will be interesting to see if there will be consideration about certain level that is possible to sell this product. And then it will have the relevant APIs that can meet that, we can always consider to go back. But right now, we are not aware of that API and that limit.

Ranveer Singh:

And the last one. I couldn't understand that sharp jump in SG&A, so selling and administration expenses. Could you give some light on it?

Saumen Chakraborty:

Sure. One, of course, is impairment effect, which we have taken during the quarter. And then I also explained that there are certain one-offs which have contributed to more than 100 crores during this quarter. And then of course, there is also this cost of sales associated with the PP neuro brand and that amount already we have declared in the press release. So overall, that's why the SG&A has gone up but I also said that, if you normalize the one-off, actually there is an improvement in the SG&A productivity.

Surya Patra:

Just one clarification that whether the Carboprost, which is F2F and the sort of exclusive product opportunity, whether we have gained meaningfully there by this quarter? Or the true benefit is yet to be seen?

Amit Agarwal: So this product, we have been able to get our market share, though it will ramp up further going

forward. But largely, market share wise we are there.

Surjit Pal: Could you please tell me, there were two events, One is your logistical challenge, one is your

recall of Ranitidine. Now these two events, will it lead to some bit of penalty payment going

forward as an overhead costs say, in H2?

Erez Israeli: No.

Surjit Pal: None of them will lead to any kind of penalty payments?

Erez Israeli: Whatever had the penalty was already booked in this quarter.

Surjit Pal: Okay. So if there is any penalty, you have already booked.

Erez Israeli: Whatever is related to any activities that related to that, including penalties was included in the

quarter.

Surjit Pal: As you guided initially on this fiscal, what could be your current guidance in terms of launch of

product in this year? And what could be the kind of growth we could expect from U.S. revenue

year-on-year?

Erez Israeli: So as I read in my script, we are still on track for 30-plus products for this fiscal. As for guidance

for sales, we're not giving guidance.

Surjit Pal: Last question is that regarding Suboxone and their interchangeability between tabs and films.

Do you think that this Teva deal could ultimately erode the sales of under Medicare, Medicaid program or some of the insurance formularies might be forcing the users to go for tablets from

films?

Erez Israeli: I mentioned it in previous question, we are not part of the discussion. I don't know what is the

Teva deal. I'm reading about it in the media. And I cannot speculate what will be the outcome

of that.

Nitin Agarwal: Saumen, on the SG&A, you talked about the adjustment of 100 odd crores in the current quarter

to get a normalized number. So does this reflect a full impact of the discontinuation of the

proprietary business from this quarter onwards?

Saumen Chakraborty: So, of course, when you say Proprietary Products business, there is no discontinuation of

Proprietary Products business.

Nitin Agarwal: The marketing part.

Saumen Chakraborty: There is a commercial arm including the sales and marketing from those neuro franchise now

that has been reduced, so that impact is there. That's helping in terms of SG&A reduction.

Nitin Agarwal:

Okay. Adjusted for that, that's probably reflected in this quarter. Now going forward, how should we really look at the SG&A base? I mean you have done a very decent job on this cost over the last 3-4 years. Do we still see an opportunity to keep SG&A in absolute terms at these levels, around these levels? Or one should budget in some amount of inflation as we go through the year?

Saumen Chakraborty:

So in the sales force part, this has been reduced in North America that is not one-off. So that is unrelated, so that is going to stay. So why should we adjust that. And anyway with the focus that we have for our productivity improvement and cost excellence has given us good results. But we believe that there is still further scope and we are continuing on that focus.

Nitin Agarwal:

Okay. And secondly on the U.S. business, in the current quarter, we had about 8 odd new launches and despite that you've sort of mentioned that even adjusted for the two factors you mentioned, the business was lower on a Q-o-Q basis, the margin is lower on a Q-o-Q basis. So in this context, when you look at the business and you had a reasonable number of launches, what will really be required to move the needle on the business from a revenue growth perspective in the U.S.?

Erez Israeli:

To sell more.

Nitin Agarwal:

Do we need some big blockbuster launches, by the time they come through, we will not have a meaningful delta on the U.S. sales, or how should one structurally look at this business. The way that this business is in the U.S. right now?

Erez Israeli:

We have a great portfolio. We just need to sell more of it.

Aditya Khemka:

Erez or Saumen, could you just talk about the gross margin. So your adjusted gross margin for the quarter you said is 51.5%. And if I remember correctly, when we were speaking after the FY 19 results, the range that you had cited for your gross margin, over the past several quarters was between 53% and 56%. So clearly, we are lagging our historical range of 53% to 56% gross margin?

Saumen Chakraborty:

So in the same quarter when I spoke, we also said that the way we put our business model, we expect to deliver north of 50%, but it has been fluctuating between these two. And yes, I agree, last couple of quarters, we are outside that range, and we are lower than 53%. But we'll hope to get back there, that's all I can say.

Aditya Khemka:

Sorry. I couldn't catch that last bit. You expect to?

Saumen Chakraborty:

I said we can hope to get back to this range, that's all I can say. You have to also understand, there have been impact of price erosions in USA and also in Europe. So we have been improving on our cost structures and all to be in that gross margin range. We are trying to do everything possible, but there is still scope for improvement we'll have to do.

Aditya Khemka: Sure. I understand. My only doubt there was that since we are now more inclining towards

branded generic businesses versus Europe and U.S. being more generic, generic businesses. So from that perspective, I believe our gross margin should have already started reflecting

improvement versus what it historically was?

Saumen Chakraborty: But see what happens in this quarter, we had much higher PSAI. The last quarter, PSAI was

lower. So when the mix changes that will also have its impact on the overall gross margin. So

there are multiple factors, which contribute to the overall gross margin number.

Aditya Khemka: No, that's fair enough. Just another clarification on Ranitidine. Were you selling Ranitidine in

Australia?

Saumen Chakraborty: No, we say that it is categorically *inaudible*. We have only one quality system which is global.

So we don't go by respective regulators, and there thing, if we have voluntary recall from U.S.

market that means we're not selling Ranitidine anywhere in the globe.

Aditya Khemka: No, my question was before the voluntary recall, were you selling Ranitidine in Australia?

Saumen Chakraborty: No. We were not.

Aditya Khemka: Okay. So sir, just last question then on R&D expenses. So could you help us with the budget

number there for FY 20, 21, anywhere you want to guide?

Saumen Chakraborty: FY 20, 21?

Aditya Khemka: Yes. Your R&D budget for FY 20 and 21 if you could or percentage of sales or an absolute

number.

Saumen Chakraborty: We have not even started our budgeting process for FY 21. So it may happen may be next couple

of quarters, we will complete that.

Aditya Khemka: And FY 20?

Saumen Chakraborty: FY 20, as I said today that given the current set of activities in most likelihood in this fiscal,

R&D will be anywhere between \$ 200 million to \$ 240 million.

Amit Agarwal: Thank you 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.