Laurus Labs Limited
Conference Call Transcript
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Siddharth Rangnekar Thank you and good afternoon to everyone joining us. I welcome all of you to Laurus Labs Q2 & H1 FY18 Call for Investors and Analysts. Today, we have with us, Dr. Satyanarayana Chava – CEO and V.V. Ravi Kumar – Executive Director and CFO and Monish Shah, Senior Manager - Investor Relations.

We will commence the call with comments from the management team, post that we shall open the call for a Q&A Session where the management will be glad to respond to any queries that you may have.

At this point, I would like to highlight that some statements that could be made or discussed on today's con-call maybe forward-looking. The actual results may vary significantly from the forward-looking statements made. A detail statement in this regard is available in Laurus Q2 FY18 Results Presentation which has been shared with you earlier and is available on the stock exchange website.

I would now like to invite Dr. Satya to address you with his overview of the strategic progress made and the outlook for the Company in line with the new initiatives planned. Over to you, sir.

Dr. Satyanarayana Chava Thank you everyone for being part of today's call with us. I look forward to sharing updates with you about our journey of transforming into a full-fledged pharma company.

At the outset, I would like to bring some of the highlights that we have said, so that we can set tone for the discussions today.

During Q2 FY18, the total revenue stood at Rs.539 crore, growing at 12.6% quarter-on-quarter and 4.3% year-on-year. The overall improvement was mainly driven by our significant growth in our ARV business on the back of higher offtake from our customers. There is also improvement from other API segment along with upside from our Aspen supplies in our custom synthesis business. The EBITDA for Q2 is at Rs. 119 crore, up by 15.2% quarter-on-quarter where we have seen better margins because of our product mix.

Our Q2 FY18 profit after tax also is at Rs.49 crore which is higher by almost 25% quarter-on-quarter. And the diluted EPS is at Rs. 4.6 per share.

Moving along, I am pleased to state that our Unit 2 where we make APIs and formulations received EIR from US FDA. Our intention is to capture the entire value chain across the product value chain. In our FDF segment, we filed 8 ANDAs with US FDA and one each with Canada, South Africa, WHO and also Europe. As you are aware, for the initial period, we partnered with Dr. Reddy's and Rising Pharma to develop, market and distribute our products on a partnership basis for US market and close up to the date of launch, we will share further details in terms of the market dynamics and expected contribution from this foray.

Out of this 8 ANDAs we have filed so far, two products already genericized, so we can market based on the approval we received and two products we will be gearing up to launch on the day one of the product patent expiry and four products where we will see opportunities in the volume in long run.

The environment for the US generics as all of you are aware is very challenging, but is stabilizing. And we look forward to building our presence in the segment through focused portfolio based on our API core strength while being completely backward integrated for these products, we target filings about 8 to 10 ANDAs every year in the therapeutic areas like ARV, Diabetes and Cardiovascular. That will put us in a strong growth over next few years.

Equally impressive is our scale-up in Synthesis business, although Aspen partnership gave us a good head start. Following the initial validations at dedicated units for Aspen, we expect to start generating revenue in this financial year itself much earlier than we anticipated. We are also witnessing good demand from our services to launch our CMO business.

The synthesis business had a good growth when compared to first half of FY17. As this contribution from these two segments start building in the coming quarters, there will be improvement in the earnings profile of the company and that will also diversify our revenue base from few API base to custom synthesis as well as our finished dosage forms.

The core generics operations is doing well as you are seeing from our performance during H1. Our EBITDA margins were constant despite our increased focus and spend on building new facilities and investment into finished dosage forms. The work is going on to develop not only the first line ARV products but also into the second line ARV products where we see about 10% of first line patients are being moved into the second line over a period of 3 years. So company is gearing up to improve our API portfolio in ARVs. As we move into developed markets commencing with EU supplies, as well as into other markets like US, the potential for growth in topline and also profits remain very strong.

The outlook for Hep C. franchise remains challenging, although we have seen improvements in volumes. However, we have seen significant pricing pressures as we understood from our partner and we expect the overall value will be muted for this segment. Interestingly, our focused approach in developing Oncology API resulted in good accretion to our margins. We are also very focused on our intent

to further expand our API portfolio meaningfully with new launches in Cardiovascular, CNS, Diabetic and Proton Pump Inhibitors.

The growth agenda in Ingredients business is taking shape as we make investments in developing capabilities, especially in the natural extractions. Given our complementary strengths in commercializing processes I am confident of this segment making a healthy contribution to our topline in the coming future.

Our investment into expanding our manufacturing base is on track and we expect to inaugurate new unit, Unit 4 in this quarter. Our Unit 2 expansion was completed, with that we have 5 billion units capacity. Our capacity expansion Unit 3 in oncology and other ARV products is also on track and we expect it to be commissioned in the Q1 of FY19.

With that, I would like to hand over to Ravi to continue the discussion on prospects and on the financial performance of the company.

V. V. Ravikumar

Thank you, doctor. A warm welcome to the Laurus Labs' second Quarter & Half Year earnings Call. Dr. Satya gave an insight in progress of the operational performance of the business and I will now update on the Q2 and H1 FY18 highlights.

So moving on to the company highlights, total revenue per quarter two grew up by 4.3% to Rs. 539 crore and in our API business, ARV segment saw a healthy performance on account of higher customer update. We can say that most of our customers have been showing lot of interest and their offtake to all the customers.

We expect to maintain the momentum for the remaining half of the year. In Hep-C, we had a volume growth, but some pricing pressure and also on account of entire launch quantities of Velpatasvir API were booked in the quarter one. So that is the reason there is a dip in the total revenue for the second quarter for Hepatitis, but the volume growth is still intact. The Velpatasvir combination is doing well.

In Oncology, we continue to have a robust growth. For our H1, we did about 45% growth and the order book is continuing. And our Synthesis and Ingredient business demonstrated a good growth and we met our expectations in the coming period. Probably in the synthesis side, we will see interesting proposal for the second half of the current fiscal.

The EBITDA was higher by 2.9% and our interest cost also lowered by 21% year-on-year. Though the total borrowings were higher, but the predominant factor is our cost of funds has come down. Our diluted EPS for the quarter is Rs. 4.6 per share. We have seen several new initiatives that are lined up in both businesses. In synthesis, we expect to see revenue from Unit 5 in quarter four, in fact this quarter itself we are raising an invoice precisely in the coming week from Unit 5. This actually we have expected only in the few quarters later, but we are dispatching this quantity.

In conclusion, I would like to state that expansion of volumes in generic API business, let us say ARV, Oncology and Hepatitis-C are likely to be healthy and are likely to lead robust cash generation. We are confident that our new initiatives in generic FDF and synthesis will augment overall performance. Our Unit 4

expansion is in progress. In fact, the facility will be inaugurated in the next week and the operation will begin in maybe 2 months' time. Revenue enhancement and cost efficiencies will lead to better profitability and strengthen our balance sheet and reward our shareholders from time to time while maintaining our investment initiatives intact.

With that, I conclude my opening remarks and I request the operator to open the forum for questions. Thank you.

Moderator Thank you very much. Ladies and gentlemen, we will now begin the question and answer session. We will take the first question from the line of Aditya Khemka from DSP Blackrock Mutual Fund. Please go ahead.

Aditya Khemka Can you just slightly elaborate on what exactly happened in Hep-C this quarter? It seems like our revenues Q-on-Q are down significantly in Hep-C. So just wanted to understand what the dynamics there are and how sustainable is the revenue stream that we are currently booking in Hep-C?

Dr. Satyanarayana Chava In the Hep-C business, new product launches happened in Q1. So we supplied significant volumes of Velpatasvir in Q1. There was a dip in our sales from Q1 to Q2. That was one reason, and the second reason was because of GST, the formulation sales were less by our partner. So we didn't sell much API in the Q2 as well. We believe that will improve in Q3 and Q4.

Aditya Khemka Okay. So this was basically an impact of the amount of inventory that we put in the channel in 1Q?

Dr. Satyanarayana Chava Yes.

Aditya Khemka Okay. And on the US plant side, you briefly spoke of it. 8 ANDAs to genericize two day one and four longer term products. Can you categorize? So I am assuming all of these are oral solids but can you categorize them between modified release or extended release and immediate release?

Dr. Satyanarayana Chava So far all 8 products what we have filed are immediate release. We haven't done anything in the modified release. But we have few projects which are under development with modified release solid orals.

Aditya Khemka Okay. That is good to know. And in terms of these two products that would be day one products, these are HIV products which will be day one?

Dr. Satyanarayana Chava Yes, there is no patent challenge. So will be on the day 1 of launch with many other people.

Aditya Khemka Sure. And in terms of your filing rate going forward, this year how many ANDAs have we already filed in the first half?

Dr. Satyanarayana Chava First half, we have filed 5 ANDAs cumulatively, but last year we filed 3, the first half we filed 5 and our rate as we explained previously, we expect to file between 8 to 10 ANDAs per year and we are very comfortable with that number.

Aditya Khemka Okay, understood. In terms of our custom synthesis business for Aspen, can you sort of elaborate a little on what are the really capacity utilization numbers that we are running there and therefore how should we look at that revenue stream evolving in the future because really we are putting up new capacity. So how much additional revenue could be generated by that new capacity?

Dr. Satyanarayana Chava In Aspen, we had two initiatives. One dedicated block was constructed in the existing unit and one new dedicated unit was constructed. The intermediate block in the existing unit is running at full capacity whereas the dedicated unit where we completed validation batches, that is the one where we are shipping soon from and we expect the facility will go full scale utilization in the next 12 months.

Aditya Khemka Yes. But I mean what are the kinds of asset terms we can expect from the business that we are doing with Aspen? Would it be in line with the historical asset terms that we have achieved with them, or would it be better or would it be lesser than the historical asset term with Aspen?

Dr. Satyanarayana Chava The asset turnover ratio will be little lower than our existing business, but EBITDA percentage is going to be very high. So we have an agreement where we will recover all the fixed expenditure and we get cost plus certain percentage. So it is very interesting business for us. We are not looking at asset turnover ratio or capacity utilization on that. On the day one itself in Unit 5, we are not incurring any losses right now. We are recovering all the expenses of Unit 5 from Aspen.

Aditya Khemka Got it. And last question before I get back in the queue. For the US business cycle in last time in FY17, we had elaborated that the Unit 2 plants and the operating expenses are about Rs. 100 crore. What was that number for first half of FY18?

V. V. Ravikumar We are in the similar line Aditya.

Aditya Khemka Rs. 50 crore roughly?

Moderator Thank you. The next question is from the line of Ranvir Singh from Systematix Shares & Stocks (I) Ltd. Please go ahead.

Ranvir Singh For ARV, what exactly has driven ARV part?

Dr. Satyanarayana Chava You know our major products are in the first line. So we saw significant growth in the first line APIs especially Efavirenz, Tenofovir and Emtricitabine. So these are contributed by all three APIs.

Ranvir Singh So when we said this run rate would be sustainable, so we are also assuming that few more products are getting added in this portfolio?

Dr. Satyanarayana Chava In the first line, we are adding only one product that is Lamivudine. We expect that capacity will be up and running in the Q1 FY19, whereas in the second line portfolio, we are going to finish validations for two APIs during this financial year and we expect some revenues coming next year. So next year ARV growth will be driven by the new product launches, Lamivudine and the other second generation products. So next year ARV growth looks interesting for us.

Ranvir Singh Fine. And in Hep-C business, you said that because the first quarter we had Velpatasvir inventory and the average run rate which we see in the first half, this will be sustainable, that is what you are saying?

Dr. Satyanarayana Chava See, if you look at the Q1-Q2 average, I am sure we are going to achieve the same number in H2 of this financial year.

Ranvir Singh Okay and I see that debt level has gone up. So what may be the reason?

V. V. Ravikumar We have taken an additional term loan of Rs.100 crore. The working capital limits also slightly increased because of the GST. So you know that all our facilities are EOUs, but the initial till the 30th September to even for an EOUs, we have to pay GST on import materials. So the rule was amended from 1st October. Because of that, there was an accumulation of GST amount, almost to the tune of more than Rs. 40 crore.

Ranvir Singh And just one more if I can that on EBITDA margin front we see, that despite this change in product mix last year versus this year, there has been higher ARV and lower Hep-C which we understood that in Hep-C normally we had a bit of margin but still we have maintained it. So just we wanted to understand that even if the revenue mix changes going forward, the higher contribution of Hep-C will change our EBITDA margin going forward or this is likely to be in this range?

Dr. Satyanarayana Chava See, your observation is very valid. So we had improved sales in our Synthesis business where our margins are significantly higher than our other businesses. If the Hep-C business goes up to the previous quarter in the next two quarters and our Synthesis business continue to show the robust growth, we expect improvement in our EBITDA margins.

Ranvir Singh So any ballpark number if you could guide for FY18?

V. V. Ravikumar Sorry, we are not giving any ballpark number.

Dr. Satyanarayana Chava But we can tell you, your observation is very good. So we expect the improvement in EBITDA with the improvement in sales in Hep-C as well as continued growth in our Synthesis business.

Moderator Thank you. We will take the next question from the line of Charulata Gaidhani from Dalal & Broacha. Please go ahead.

Charulata Gaidhani My question pertains to Hep-C. You said that the sales were lower because of the inventory clearing up in the channels, how much would be the volume growth and how much would be the price growth or price erosion in Hep-C?

Dr. Satyanarayana Chava See, volume growth will be driven by approvals in the new market. As our partner is getting approvals from Indonesia, Vietnam and other markets, market expansion is happening whereas there is stagnation in the domestic market. The volume growth will be driven by the approvals in the new markets whereas the price erosion in India will be compensated by the new markets formation. So we expect overall margins will be okay when you add the new markets and the existing markets.

Charulata Gaidhani Okay. And whatever price erosion has taken place, you should be able to make up on the margins with other product launches or through custom synthesis?

Dr. Satyanarayana Chava You are right.

Charulata Gaidhani Okay. My second question pertains to the ANDA filings, you said that two products you planned to launch on day one?

Dr. Satyanarayana Chava You are right. See, out of 8 ANDAs we have filed, two products we will launch as we get FDA approval, and the two products we will launch on the day one of the patent expiry and the rest of the four ANDAs we have to wait until the approval comes.

Charulata Gaidhani So when is this likely to be if you can give an idea of the time period?

Dr. Satyanarayana Chava We expect to be first two ANDAs where products are already genericized. One approval we are expecting, we will get in few months. The day one launch will happen in the Q4 of this financial year. Another genericized product launch will happen next financial year. Actually, we expect to launch all four ANDAs in the next year, two genericized and two day one launches in the next 12 months.

Moderator Thank you. We will take the next question from the line of Jeevan Patwa from CandyFloss Advisors. Please go ahead.

Jeevan Patwa I am looking at your total fixed assets, so you have around Rs. 1,200 crore of fixed assets. So out of that Rs. 1,200 crore of fixed assets, how much of asset is still not generating any topline?

V. V. Ravikumar Almost around Rs. 400 crore.

Moderator Thank you. The next question is a follow up from Charulata Gaidhani from Dalal and Broacha. Please go ahead.

Charulata Gaidhani My question pertains to the USFDA approval. What is the status on the approvals to the manufacturing units?

Dr. Satyanarayana Chava For both the API and Formulation Unit, we got EIR. The only delay is where our ANDAs are under review. Once the ANDAs are approved, we don't have any other approvals required. So we will launch on the day when we will receive ANDA approval.

Charulata Gaidhani So Unit 1 and Unit 3?

Dr. Satyanarayana Chava Unit 1 and Unit 3 were inspected by FDA in second half of August. There were two observations made. We responded to the observations already.

Charulata Gaidhani Okay, you have not got the EIR yet?

Dr. Satyanarayana Chava Not yet. See only August, EIR typically takes between 4-6 months.

Moderator Thank you. The next question is from the line of Jeevan Patwa from CandyFloss Advisors. Please go ahead.

Jeevan Patwa Just a follow-up question on what I asked, so whatever Rs. 400 crore not generating any topline, are we capitalizing that, so are we providing depreciation and interest on that asset or we are still not…?

V. V. Ravikumar Yes, we are providing a depreciation on that because we are carrying in validation batches in that asset and asset is being put to use, but there is no revenue generation yet.

Jeevan Patwa Okay and when we expect this to generate revenue, in the next 6 months?

V. V. Ravikumar What we are expecting is as Dr. Satya said, we will generate token of revenue in FY18, maybe reasonable revenue in FY19.

Moderator Thank you. The next question is from the line of Gagan Thareja from Kotak Mahindra Capital Co. Ltd. Please go ahead.

Gagan Thareja On this Rs. 400 crore of gross blocks which is still not monetized, what could be the potential asset turn, I mean sales turnover on this?

V. V. Ravikumar It all depends. Unless it is matured, all approvals come in, you will not get peak asset turn, but it will go slowly.

Gagan Thareja Peak could be how much sir?

Dr. Satyanarayana Chava Two types of investments you have to consider, one is we have invested into finished dosage form facility and also Unit 4, which we are going to inaugurate shortly, these two assets are not yielding any revenue. So maybe up to Rs. 500 crore assets are not yielding revenue, we are not giving any forecast. But if you compare our asset turnover ratio is more than one already.

Gagan Thareja The current asset turn ratio, I mean one which you have on your existing gross block is representative of what you could have on this gross block also? Is it fair to say that there will not be…?

V. V. Ravikumar It is fair to say but it may happen maybe in the next two years' time. It cannot happen in year one.

Gagan Thareja And on the OPEX side, although you might not be generating any revenues, are you incurring any cost above the EBITDA line from these facilities and what could be the order of these costs?

Dr. Satyanarayana Chava On non-revenue yielding assets, we are incurring almost between Rs. 4 and 5 crore of OPEX per month, where everything is expensed.

Gagan Thareja Okay. And is it possible for you to outline your CAPEX plan and therefore also how your debt to equity positions can move in the next 2 years?

V. V. Ravikumar The CAPEX plan as of today whatever we have been telling, is under execution. So the next year CAPEX plan, which is still at drawing board stage, we have not crystallized yet. So probably earlier we were talking about Rs. 350 plus Rs. 300 crore. We will be spending in the two years' time the similar number. As per the debt equity is concerned, we are not envisaging in additional debt at this moment. So as we said last time, apart from the existing working capital loan of Rs. 700 crore totally, we have already drawn about Rs. 60 crore by 30th September, the balance we will be drawn in this month. So Rs. 100 crore additional term loan we will take. Beyond that, we are not envisaging at this moment any additional loan.

Gagan Thareja So your CAPEX can be taken care of through internal accruals is what you are trying to say?

V. V. Ravikumar That is what the plan is at this moment.

Gagan Thareja And in the LMIC countries where you are market leader in ARV APIs, are you also looking at finished dosage formulation supplies for these ARVs or would you rather continue being an API supplier?

Dr. Satyanarayana Chava We have plans to go into LMIC countries with our own dosage forms, that is the reason we did have an ARV dossier filed with WHO as well as in South Africa.

Gagan Thareja And this could happen in the coming financial year or would it start in this financial year itself?

Dr. Satyanarayana Chava It will not be in this financial year, it will start very little in the next financial year.

Gagan Thareja Okay. Finally the UN AIDS program under this CHAI Foundation and I think the Bill Gates Foundation has come up with a $75 annual treatment of Dolutegravir combination in South Africa. This is post the declaration of reaching the treatment resistance to the current first line treatment already at 10% or so. Do you see this price point of the Dolutegravir combination as something that might lead to the penetration of Dolutegravir in the LMICs to grow and grow fast?

Dr. Satyanarayana Chava The LMIC countries, the WHO and other agencies indicate they are going to add about 2 million new patients into the treatment every year. So who are eligible for the new treatment would be put on Dolutegravir combinations, preferably. So this Dolutegravir combination will definitely do well in the future and it is not clear at this time how they are going to monitor the TB patients, with the Dolutegravir and Dolutegravir in the pregnant women, Dolutegravir in the prevention of mother to child transmission in the pediatric use, these are not clear, but eligible adult patients who will take the first line, the preference will be given to the Dolutegravir combination.

Gagan Thareja So in that scenario, are you already in a position to be an API supplier for Dolutegravir. Are there fixed contracts for that with either Mylan or Aurobindo which seem to be the two eligible Dolutegravir formulation companies?

Dr. Satyanarayana Chava We have few customers already who took validation batches for API. We have filed our DMF with FDA. We have filed our DMF with other agencies. It is

under review. It is approved by WHO. So we are fully geared up to capture the opportunity of Dolutegravir growth.

Gagan Thareja Would you consider going into formulations in Dolutegravir or would be an API supplier there?

Dr. Satyanarayana Chava At this juncture, we are evaluating, we are not clear.

Gagan Thareja Okay. And would it be fair to assume that you could replicate your Efavirenz success in Dolutegravir. I mean you had the most cost competent manufacturing process in Efavirenz. Could we look forward to you being able to replicate that success in Dolutegravir?

Dr. Satyanarayana Chava We hope so.

Moderator Thank you. We will take the next question from the line of Aditya Khemka from DSP Blackrock Mutual Fund. Please go ahead.

Aditya Khemka Sir you just said, there is Unit 1 and Unit 3 both are USFDA units, so is that correct?

Dr. Satyanarayana Chava Yes, both were inspected in August.

Aditya Khemka And Unit 1 and Unit 3, which one is formulation and which one is API?

Dr. Satyanarayana Chava Unit 1 and 3 are both for API. And Unit 2 is for API as well as formulations.

Aditya Khemka Okay. And this two observations that we have got, from which unit is that?

Dr. Satyanarayana Chava 1 and 3.

Aditya Khemka So the two observations are both 1 and 3?

Dr. Satyanarayana Chava Yes, you are right. Whereas for Unit 2, there we have API as well as formulations. We had no 483s and we got EIR already.

Aditya Khemka Okay. So when FDA audited Unit 1 and 3 both together in August, so they gave you one form 483 for both the plants or they gave you different form 483 for both the plants?

Dr. Satyanarayana Chava With FDA, both 1 and 3 have only one establishment number.

Aditya Khemka Okay. Understood. They are in the same campus basically?

Dr. Satyanarayana Chava It is not same campus, it is separated by a road. So FDA said you have one quality management, existing in each other, so they said let us consider this as one unit.

Aditya Khemka Understood. Make sense for them to do that. Okay. And out of the 8 ANDAs that we have filed, do we have the API for all of those 8 ANDAs?

Dr. Satyanarayana Chava All 8 APIs we are vertically integrated.

Aditya Khemka Yes, so out of those 8 APIs, how many come from 1, 3 and how many come from 2?

Dr. Satyanarayana Chava Only one coming from 2, and rest of the seven coming from either 1 or 3.

Aditya Khemka So for us, it is sort of critical to get the EIR of Unit 1 and 3 because then your seven ANDAs will not get approved till you get the EIR of Unit 1 and 3?

Dr. Satyanarayana Chava You are right. So inspection happened only end of August.

Aditya Khemka Sure, I understand the timeline. Sir, would you like to share the nature of the observations?

Dr. Satyanarayana Chava These are very procedural in nature. It is available in the FDA website. It is a very procedural in nature. We already responded to them.

Aditya Khemka And there has been no dialogue per se with the FDA regarding that form 483? We are just waiting for the EIR to come; there is no dialogue between us and the FDA?

Dr. Satyanarayana Chava No response pending from our side.

Aditya Khemka That is understood. And sir following the previous participant's question on Dolutegravir, you know it is very interesting to see, so Efavirenz obviously we had a novel process and you know chemistry process which helps us to achieve a certain cost which was competent. Dolutegravir, why I think the previous participant asked the question, obviously we hope to be the lowest cost supplier in every product, but is there any chemistry skill that we have, so by now while we have already filed our DMFs and filed with WHO and everybody for the API, the process that we will be using for manufacturing would have already been established, right? So in that process whatever cost you are able to envisage at a commercial scale, at that cost do you currently believe that you will be the most cost competent or you think you still are not aware of the cost that the other manufacturers are making?

Dr. Satyanarayana Chava In the case of Dolutegravir, no manufacturer produces very large commercial quantities. So the purchase prices of the key raw material from suppliers I think have not stabilized yet. So we will discover the right pricing of the starting materials maybe in the next 6 to 12 months and we have a new process for Dolutegravir, using that only we are manufacturing and we believe we will be one of the low cost manufacturer for that, for sure.

Aditya Khemka Understood. And the other question the previous participant asked, again I just wanted to pick your brains on that, when he said that whether we would want to be API manufacturers or formulation manufacturers, so obviously for us is that company it makes sense to always be the formulation manufacturer because we can garner more part of the value share, right, on that side. Unless it is our customers who are telling us, look I don't want formulation, give me API. So what would be the rational on either side? Why would the customer not want the formulation from us and just want the API?

Dr. Satyanarayana Chava The biggest challenge in ARV therapy is not formulation capacity. The biggest challenge comes from the API capacity. If you look at 20 million patients, everybody takes one pill a day, they need 7 billion tablets. Many companies in India have that capacity, but to treat 20 million patients assuming everybody takes a gram they need roughly 20,000 tonnes of API. That everybody may not be able to make. So the challenge here is API and not the formulation. That is the reason, nobody would like to outsource formulations manufacturing.

Aditya Khemka Understood because that is not really a challenge. But isn't it true that if you did it, you would probably be more cost competitive than let us say a Mylan trying to do it in-house or a Cipla trying to do it in-house?

Dr. Satyanarayana Chava You mean formulations?

Aditya Khemka Yes.

Dr. Satyanarayana Chava The manufacturing cost of formulations in the entire formulation cost of ARV therapy does not differentiate winners and losers. The winning tender having the API access makes them winner or loser, not the manufacturing cost of formulations.

Aditya Khemka Right. And sir, so I asked this question to every pharma company because you are seeing so much consolidation happening around in various aspects, be it contract manufacturers, be it generic companies, be it India, be it US, any plans that we have though I know we have organically expanded, but are we at all looking at acquiring any asset by taking a load up on our balance sheet because it sort of can support some debt. Any plans on that side, if yes, what sort of assets would we look at to acquire?

Dr. Satyanarayana Chava Right now, we are not aggressively pursuing. We have lot happening on our plate right now internally. Lot of CAPEX, lot of development, lot of market expansions. So not right now.

Aditya Khemka And is management bandwidth an issue at all, given that I obviously saw the slide on your presentation where your key management personnel looks obviously a very impressive theme but I was just thinking that given that we are engaged in 4-5 different verticals where dynamics are so different from each other, is management bandwidth becoming an issue internally?

Dr. Satyanarayana Chava We are not looking at acquiring companies not because of bandwidth, because of right fit. We don't want to acquire for the sake of acquisitions. We are opening our radar and watching and if there is a right fit we don't mind acquiring, but we are just scanning right now.

Aditya Khemka Last question from my side. All this 'Make in India' push from the Indian government and then saying that we need to sort of protect our API suppliers from Chinese competition, anything you are seeing on that front from the government, any sort of incentivization going on for API manufacturers to scale up?

Dr. Satyanarayana Chava I think if any API manufacturer want to depend on government subsidies, it is not going to be sustainable. There should be inherent strength in the company to counter these challenges, and then only they will be successful. Otherwise,

government cannot give support forever. So we are not looking at government support, we are self-sufficient in our intermediates and starting materials, we are putting our own efforts.

Moderator Thank you. We will take the next question from the line of Tushar Manudhane from Motilal Oswal Securities Limited. Please go ahead.

Tushar Manudhane Just on the CAPEX front, with the kind of increase in the formulation for US and regulated market as such, will the increase in the working capital, despite that do you think that the internal accruals would be sufficient to meet the CAPEX for the next two years?

Dr. Satyanarayana Chava Next year and onwards, definitely our internal accruals will be enough to meet CAPEX as well as increase in working capital.

Tushar Manudhane Would there be reduction in debt as well or the debt will be maintained the same?

V. V. Ravikumar We already taken in long term debt of Rs. 100 crore this year.

Dr. Satyanarayana Chava So total long term debt is as of now is Rs. 200 crore roughly.

Tushar Manudhane So that number will not be increasing significantly to fund the CAPEX?

Dr. Satyanarayana Chava With current envisaged CAPEX and working capital increase, we don't expect it will increase long term debt.

Tushar Manudhane And with respect to the South African tender, would it be up for renewal in first quarter next calendar year. So any color on the tender size or are we going to get into formulation, participate in the formulations now?

Dr. Satyanarayana Chava At this point of time when the South African tender opens, is not very clear and everybody says it will be in the next 6 months and we have no clear plans at this time to participate in the tender. All depends on what kind of therapies; what kind of combinations they are going to float tender is not clear at this time.

Tushar Manudhane Okay. And just with respect to the two products, may be like Metformin and Tenofovir, so out of these one, I mean the API is from Unit 2 or from Unit 1 and 3?

Dr. Satyanarayana Chava These APIs they are coming from either Unit 1 or Unit 3. For South African market, our APIs have already got approvals. So there are no new approvals required for South African market.

Tushar Manudhane No, this was for the US market.

Dr. Satyanarayana Chava Yes.

Moderator Thank you. We will take the next question from the line of Kunal Randeria from Antique Stock Broking. Please go ahead.

Kunal Randeria My question is on the oncology business, I believe some of the shipments were delayed from fourth quarter 17 to first quarter 18 and that is why we saw a very sharp jump in the last quarter, so again in this quarter I see that there is some quarter-on-quarter decline. So I was wondering if you could share your thoughts on this business, what we should look forward for the rest of the year in FY19.

Dr. Satyanarayana Chava See, in the FY17, whole year we had Rs. 107 crore of oncology sales. In the first half of this financial year, we already did Rs. 82 crore.

Kunal Randeria That is fine. So basically I think from fourth quarter 17 you moved from Rs. 25 crore to around Rs. 44 crore last quarter. This quarter we dipped to around Rs. 37 crore. So I was just wondering what we should look forward to for the rest of the year?

V. V. Ravikumar So as we said before, we will be doing a FY16 number in FY18. So there will be enough growth and then we will maintain this average of the H1 in the H2.

Moderator Thank you. We will take the next question from the line of Gagan Thareja from Kotak Mahindra Capital Co. Ltd. Please go ahead.

Gagan Thareja If I sort of reference some of your comments from the previous calls and what you said in this call again, in the previous calls you indicated that Dolutegravir volumes could be one twelfth that of Efavirenz and at the same time, the pricing could be higher. But if I take the additional input from the latest UN AIDS figures which as I said indicate annual treatment of $75 per person which would be probably lower than the current first line HIV treatment. And at the same time, you take the fact that the volumes will be lower in Dolutegravir given the dosage. Does it not make for the much smaller API market in this case than Efavirenz?

Dr. Satyanarayana Chava See, API market quantity wise will be less. But if you look at the therapy wise, they have to take Tenofovir, Lamivudine or Emtricitabine and Efavirenz or Dolutegravir. So if you look at the franchise wise, the first line franchise, people either will take Efavirenz or Dolutegravir. So the total value of the non-nucleoside inhibitor or integrase inhibitor will remain growing, from the current market. And with respect to the value of the regimen, we will keep on increasing because as two million new patients are being enrolled every year from this LMIC region, so the overall value will keep growing.

Gagan Thareja Okay, but then how do you reconcile the fact that Efavirenz combination treatment costs are probably $100-110-120 if I remember them correctly dollars per person per year?

Dr. Satyanarayana Chava Currently, the Efavirenz based triple combinations are sold less than $75 per year today.

Gagan Thareja So there has been a steep drop in the Efavirenz combination prices as well is what you are trying to say?

Dr. Satyanarayana Chava Yes.

Gagan Thareja In which case I mean and as I said if the UN AIDS is going to subscribe to Dolutegravir at $75, obviously the API as a percentage of the final combination

value cannot be indiscriminately higher than what you have in the Efavirenz combination, in which case given that theoretically the volumes are lower, it would seem that from a total value point of view, it might not end up being a bigger market and at the same time I would also reference to your comments, you said that the 2 million additional patients would preferentially be every year be put on Dolutegravir in which case the Efavirenz market stagnates, am I inferring correctly, that if I were to understand how this market evolves, when the Efavirenz based treatment would actually stagnate, incrementally volumes would go to Dolutegravir and finally the value of the Dolutegravir market would be dependent upon the therapy treatment cost on an annual basis per patient.

Dr. Satyanarayana Chava There are close to between 12 and 14 million patients in Efavirenz treatment right now and less than half a million patients on Dolutegravir treatment. The clinical data about the adverse events and all is not well understood. So everybody is watching how Dolutegravir will take market share. So people who are having lot of adverse effect events with Efavirenz we will move to Dolutegravir and Dolutegravir interaction with Rifampicin and pregnancy and mother to child transmission, those are not studied well. So there is a lot of flux in the regimen right now, but there is a trend towards switching to Dolutegravir and if new patients are put on Dolutegravir, as we mentioned there could be a plateau for Efavirenz volumes and Dolutegravir volume currently very close to zero, so that will go up significantly and we are fully geared up to take that opportunity as well.

Moderator Thank you. We will take the next question from the line of Dheeresh Pathak from Goldman Sachs Asset Management (India) Pvt. Ltd. Please go ahead.

Dheeresh Pathak When you said Rs. 400 crore of non-revenue yielding asset, of which Rs. 250-260 crore is formulation block, what is the balance?

V. V. Ravikumar Rs. 300 crore is formulation and for Rs. 100 crore we have an API facility also in the same premises, metformin facility.

Dheeresh Pathak This is that Unit 2 you said, API.

V. V. Ravikumar Unit 2 itself. As Dr. Satya said, apart from it, Unit 4 we are going to inaugurate soon and that is another Rs. 100 crore plus which is going to add to the asset which will not give any revenue maybe in the next few months' time, but probably Unit 4 may start little revenue quicker than Unit 2.

Dheeresh Pathak Unit 4 is the Synthesis?

V. V. Ravikumar This is new.

Dr. Satyanarayana Chava Unit 4 will add capacities to Synthesis division, API Generics as well as Ingredients division. So in the phase 1, we are creating 3 manufacturing blocks. One is for natural extracts for Ingredients, one is for Generic APIs, and one is for Synthesis division.

Dheeresh Pathak And that will get commercialized when, Unit 4?

Dr. Satyanarayana Chava Validations will start next month and billing will be done in this year itself.

Dheeresh Pathak When will you start charging the depreciation on this unit?

V. V. Ravikumar December '17.

Dheeresh Pathak And when did you file your DTG DMF?

Dr. Satyanarayana Chava DMF was filed last year and it was reviewed by FDA. We are answering those queries.

Dheeresh Pathak So is it like the two companies which have got approval, I think Mylan, Auro. So Auro is vertically integrated, Mylan is using…

Dr. Satyanarayana Chava Mylan is also vertically integrated on that. This is very early days for people to outsource APIs because nobody sold significant volumes right now to have capacity constraints.

Dheeresh Pathak So who is your partner who has done the final because your DMF will get triggered for…

Dr. Satyanarayana Chava DMF was accessed by two customers already apart from Aspen in South Africa.

Dheeresh Pathak So Aspen is one of them?

Dr. Satyanarayana Chava No, apart from Aspen, there were two customers.

Dheeresh Pathak Apart from Aspen, there were two. Who are the other two?

Dr. Satyanarayana Chava We cannot tell you right now.

Dheeresh Pathak Are they having issues with their formulation or it is your technical that your DMF that is holding up the approval for them?

Dr. Satyanarayana Chava No, it is in the regular queue. There is no significant hurdles for their approval as well.

Dheeresh Pathak But PEPFAR program, our understanding was accelerated?

Dr. Satyanarayana Chava We filed earlier and then our partners filed ANDAs recently. So we gave letter of access. DMF is being reviewed.

Dheeresh Pathak Where should be the expectations for the approval of the DTG?

Dr. Satyanarayana Chava We expect one partner will get approval maybe next 2-3 months. Other one will get maybe Q1 of FY19.

Dheeresh Pathak And when did you file the Lamivudine DMF?

Dr. Satyanarayana Chava Lamivudine DMF was filed with WHO 3 months back and with PEPFAR, we are going to file next month.

Dheeresh Pathak What is the capacity of Lamivudine?

Dr. Satyanarayana Chava Currently, we did file from a multipurpose facility, but we are creating very large capacity up where we can produce up to 500 tonnes per year.

Dheeresh Pathak And for DTG, you filed from multipurpose as well?

Dr. Satyanarayana Chava DTG, we have filed from one unit, but we have plans to file from Unit 4 also to augment capacity.

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

Dr. Satyanarayana Chava Thank you for your active participation and we always admire your understanding of the business and interesting questions you are asking us and thanks for your support.

V. V. Ravikumar Thank you.

Moderator Thank you. Ladies and gentlemen on behalf of Laurus Labs Limited, that concludes this conference call for today. Thank you for joining us.