Laurus Labs Limited

Q3 & 9M FY18 Conference Call Transcript

January 30, 2018

Karl Kolah: Thank you, Aman, Good Evening, everyone, and thank you for joining us today on Laurus Labs Q3 & 9M FY'18 Results Conference Call for Investors and Analysts.

Today we have with us Dr. Satyanarayana Chava – CEO; Mr. V.V. Ravi Kumar – Executive Director & CFO and Monish Shah -- Senior Manager, Investor Relations.

We will commence the call with comments from the management team, post that we should open the call for 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 call may be forward-looking in nature. The actual results may vary significantly from the forward-looking statements made. The detail statement in this regard is available in 'Laurus' Q3 FY18 Results Presentation' which has been shared 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. Satya: Thank you. Thank you, everyone for taking time joining this call today on our Q3 & Nine Months' FY18 Results.

I would like to take you through the key highlights of our various business divisions: Total revenue stood at Rs.479 crore for the quarter ended December 2017 and Rs.1,496 crore for the nine months ended December 2017.

Our growth in ARV was muted mainly due to delay in offtake from one of our key customers. Since the ARV business is tender-driven, we look at ARV business in an overall year rather than month-on-month or quarter-on-quarter. Even if we look at the

nine months ARV revenue, we did Rs.40 crore more than the last year's nine months revenue; that is very positive.

In Oncology, quarter-on-quarter, we did Rs.25 crore more than the previous quarter, and we did Rs.43 crore more than the last nine months. In fact, in the first nine months of this financial year, we did more than last year's 12 months numbers in Oncology.

Interestingly other products also showed significant growth. If you look at the Company's franchisee, we are known for ARV, Hep-C, Oncology and other CMO products. Except Hep-C business, for the 9 months we have seen an increase in all our therapy revenues

Significant revenue increase also happened in Custom Synthesis business. In the nine months we did Rs.28 crore more than the last year's nine months. Whereas Ingredients we saw Rs.9 crore less in the last quarter and so the entire year, the first six months we did Ingredients as per our initial budget.

As far as the ARV business is concerned, Q4 is looking very good and next year even looks very bright; we are going to commission one of our largest manufacturing plant for another ARV about 500 tonnes of capacity per year for Lamivudine which will be available for commercialization beginning July next year. Our incremental revenue from ARV will also come from the validations which we have conducted right now. We have successfully done validation for Lopinavir, we are about to do validations for Ritonavir. These are the additions for ARV business in the next financial year.

We are also happy to share that Units-1 and 3, we have received EIR from USFDA.

The main reason for our decline in the Q3 FY18 and lesser PBT than what we anticipated is from Hep-C franchisee. We have seen significant pricing pressure in the API as well as in the Formulations, and also please note that actually some of HEP-C formulations came under DPCO. So that more pressure on the pricing on our partner. we saw a drop of Rs. 70 crs from the entire HEP-C franchise. If we look at the Hep-C, most of the share we get from partner is above the PBT. So despite of Rs.70 crore less income from our Hep-C, actually we were able to grow a little bit in our nine months duration, that is a very positive for us.

When it comes to Synthesis business, we have built dedicated block for a partner, C^2 Pharma, which we inaugurated, and one trial batch was completed. That unit also is going to have commercial sale in this quarter and we expect to complete the validation during this financial year.

We are also happy to share that one new block for Oncology NCE also completed and we have started validations already. So, there is significant Capex invested in capacity expansion in ARVs, in Oncology, and in Custom Synthesis division.

Also in Formulations, we wanted to share that we have done eight ANDA filings either on Laurus name or a partner name. As part of our philosophy, we are taking these products global, -- we have filed two dossiers in Europe, one with WHO, one in South Africa, one in Canada.In fact, we already received approval from Canada for one product. All these ANDAs are vertically integrated which is our biggest advantage.

We got tentative approval for Tenofovir. We are about to get a final approval. We have commitments from key buyers in US. We have already shipped our material to US. So we will start shipping more as and when the final approval comes.

In Ingredients business, there is a decline in sales for the Q3 and nine months, but the pipeline is looking good. One of our key customers gave one new product which is under validation right now, and we expect to do one more CMO product for the same customer in Europe beginning of next financial year. In the Ingredients division although there was a decline of Rs.9 crore, we expect that to cover up in the Q4. In Unit-4 apart from creating capacities for Synthesis and API division, we also created capacity for Ingredients by putting up a natural extraction plant.

With that I would like to hand over to Ravi to share financial highlights.

V.V. Ravi Kumar: Thank you, Dr. Satya, and a very warm welcome to all the participants in the call. Our revenues were around Rs.479 crore against Rs.506 crore in corresponding quarter and we have in for nine months 4% growth on YoY basis.

As Dr. Satya explained, the major contributor for the lower growth is Hepatitis–C, and in nine months basis ARV showed a growth by 4%. In the Ingredients business though it was lower by Rs.9 crore, it will be compensated in Q4 FY 18 as we have enough orders. One of the particular product, was not dispatched in the third quarter for a customer in Europe, that will be dispatched in the four quarter, the deficit will be fulfilled in the fourth quarter time for the Ingredients business.

Synthesis is also doing good; both Aspen and non-Aspen businesses are doing good. One important point on the Unit-5 is that we started recovering the expenditure. We have started billing to the Aspen on the fixed expenses, though we have supplied first validation quantity in October 2017, still there are unrecovered fixed cost that are getting reimbursed.

In Q4, we have the production in pipeline and we are dispatching larger volume from the Unit-5. That also will be adding in Quarter 4 for Synthesis Aspen business.

As Dr. Satya said it earlier, and again, I want to reiterate, we have completed the capacity creation for one of the NCE potent molecules and the validation batches already begun.

With that our EBITDA for nine months, is in the similar range in terms of EBITDA margins. And of course, the third quarter, margins were at 20.3% against 22% of the previous corresponding quarter. Our borrowing cost has come down significantly for the nine months' time and the three months' time and we expect in the future further reduction in the borrowing cost, because our dollar revenues have increased. With one of our customers in India, we are billing in US dollar denomination instead of Indian rupees. So, our borrowings in the US dollar will go up and thereby our cost of funds will come down in the future quarters.

Our EPS came in at Rs.3.3 per share for the quarter and Rs.11.5 per share for nine months. In this year Unit-4 was also inaugurated. Expenditure for the Unit-4 operations has already been begun. that is an additional expenditure. If you look at the corresponding nine months between FY18 and FY17, the Unit-5 expenditure was borne by Laurus, now that expenditure has been recovered, but this year Unit-4 is being added to the expenditure side and then it is being charged to the P&L account.

We have incurred Capex of around Rs.292 crore. Total consolidated borrowings are around Rs.1,050 crore.

That is all from my side. Now I request moderator to open the lines for the questions. Thank you.

Moderator: Thank you very much. Ladies and gentlemen, we will now begin the Question-and-Answer Session. First question is from the line of Ranvir Singh of Systematix Shares. Please go ahead.

Ranvir Singh: A couple of things; one is related to ANDA. That eight ANDA file you said is all are with partners?

Dr. Satya: Four ANDAs filed on our own and four ANDAs filed with two partners.

Ranvir Singh: What you talked about NCE, wanted more clarity. Is C^2 Pharma an innovator or how that partnership relationship we have?

Dr. Satya: C^2 Pharma we are doing CMO of potent generic APIs. A block has been dedicated to them. There we have done trial batches, validations will be completed during this financial year, whereas in potent NCE is concerned, we are doing in a different unit, we are doing validations right now, and a partner is going to file an ANDA during calendar year.

Ranvir Singh: So Unit-4 will be dedicated for that NCE…?

Dr. S. Chava: NCE is done in Unit-3, C^2 Pharma, CMO we are doing in Unit-4.

Ranvir Singh: This is a high potent Unit-3?

Dr. Satya: We have high potent capabilities in Unit-1, Unit-3 and Unit-4.

Ranvir Singh: That facility would be for Cytotoxic products only.

Dr. Satya: Yes, you are right.

Ranvir Singh: This NCE which stage it is in currently?

Dr. Satya: Currently partner is doing Phase-3.

Ranvir Singh: We have been associated right from beginning?

Dr. Satya: We engaged with that company from the pre-chemical stages. That one molecule we are doing validation right now. But in Q1 next financial year we will do validation for one more NCE for the same partner. So they have a pipeline and we are their preferred CMO partner.

Ranvir Singh: Apart from this NCE, how many other NCEs we are working currently?

Dr. Satya: There are about more than 20 active programs right now and there are three APIs which we are commercially supplying, one is already approved in Australia and Japan, they have filed an ANDA in US, two of the APIs which we supplied, our

partner expects approval by end of this calendar year and there are several other intermediates that we are doing; one intermediate is where we are supplying to Japanese customer, already we sold commercial quantity and many other programs in Phase-2 or early phase.

Ranvir Singh: So all these programs are independent of Aspen?

Dr. Satya: Yes.

Ranvir Singh: We supposed actually that Velpatasvir will support the revenue even if the base product is falling under price control. Whether the contribution of Velpatasvir has been negligible or there is revenue that we can increase revenue from that side or we should take it as run rate now going forward?

Dr. Satya: Velpatasvir, we have launched in the last quarter, but revenues including Velpatasvir are on declining mode. So, I would say as compared to earlier run rate, current rate is less right now, and second is there is pricing pressure in the Formulations. The total revenues came down and then pricing also came down.

Ranvir Singh: When we will see Formulations revenues coming in?

Dr. Satya: In a few weeks we will launch our first product and we expect three more approvals during this calendar year from FDA. We have got approval in Canada and we expect to add one molecule in Canada. Two more approvals are expected by middle of 2018 from Europe. So, lot of activities are going on in Formulations. Apart from the various dossiers filed in the geographies we have also completed almost 10 validations, another 10 validations under progress right now.

Ranvir Singh: When the first ANDA is going to roll out?

Dr. Satya: In a few weeks from now. Our material is already shipped to US and we are waiting for final approval from FDA to ship it to the distributors.

Ranvir Singh: Most of the ANDA pending is related to ARV segment?

Dr. Satya: No, for ARV we got tentative approval, other than ARVs we have products in Diabetic and Cardiovascular segments.

Ranvir Singh: This is mix of all these?

Dr. Satya: Yes, Right.

Moderator: Thank you Next question is from the line of Aditya Khemka from DSP Blackrock Mutual Fund. Please go ahead.

Aditya Khemka: Firstly, in this product that you are supposed to get approval for, I understand our competitors have got approvals whereas we have not really got approval on day 181. Could you throw some light on, do we have CRL on the product or what was the reason to not get the product approval while our competitor got it?

Dr. Satya: There were 10 tentative approvals for these products, on 26th of January, five of them got final approval and remaining 5 did not get final approval. We were the last ones

to get tentative approval, there is nothing pending except to the FDA reviewing the label changes we have done between the tentative approval and final approval based on their guidance. Once the final approval is there, as we mentioned, we have already shipped materials to US in our third-party logistics firm, and once we get the final approval we will ship it to distributors. We have commitments from distributors already about offtake.

Aditya Khemka: This ANDA we are launching on our own, this one is not partnered?

Dr. Satya: This is our own ANDA.

Aditya Khemka: You said that out of eight filed, four are partnered and four are not partnered. Just wanted to have some understanding, so out of the four that are not partnered, this ANDA is one, the other three are they HIV products or are they cardiovascular-diabetes, what is sort of understanding between us and the partners as to which products will be on our own and what will you partner with them?

Dr. Satya: In the four ANDAs we have filed with partner, one is Diabetic which we expect approval in the next few months, and one was Cardiovascular, and two are ARV products. And we filed 3 non-ARV products, which are not partnered with anyone.

Aditya Khemka: In terms of your OPEX in the FDF business, if I understand currently, previously, our OPEX run rate was about Rs.20 to 23 crore a quarter, this quarter has probably gone up to Rs.30, 32 crore. Could you just help me understand what led to that increase in Finished Dosage Formulations OPEX?

Dr. Satya: We have done more bio-studies in the last quarter… more validations were done in the last quarter.

Aditya Khemka: So largely R&D expense?

Dr. Satya: Yes, R&D expenditure.

Aditya Khemka: So what has gone up in the R&D expense, not the sort of infrastructure spend on US market or anything like that?

V.V. Ravi Kumar: But Aditya, we are in similar lines for the FDF expenses for the nine months between FY'18 and FY'17.

Aditya Khemka: I am comparing the third quarter to the first two quarters of FY'18, just wanted to understand.

Dr. Satya: That is only R&D-related expenditure.

Aditya Khemka: Dr. Chava, you spoke of the HiPo facilities for Cytotoxic molecules. Help me understand here, I know, one of your other peers also has a HiPo facility down south, and they have a reasonable clientele in terms of contract manufacturing and development for their clientele. How difficult it is or how complex it is to have a HiPo facility -- what is the sort of capital intensity there, do we need capital commitment from the client before we set up the facility, is there any sort of entry barrier in this business?

Dr. Satya: Capital expenditure is a little bit more than the normal infrastructure, but what is more important is systems and practices are to be very stringent. If you look at even our Oncology API business, we are building these Oncology franchisee for not only generic but also for NCE programs, we can say, we have the largest oncology API asset in India. We can make oncology high potent products in four locations -- we can do in Kilo Lab, which is in Hyderabad, we can do in Unit-1 in Vizag, we can do in Unit-3 in Vizag, and we can do in Unit-4 in Vizag, so we can do in four locations high potent. That puts us as one of the largest high potent manufacturers in the country, which is also demonstrated in our numbers.

Aditya Khemka: Is there any sort of entry barrier in this business? You said the practices and the capital intensity are a little higher, but do you feel let us say in the next two, three years, there will be another four five players in India opening up HiPo Cytotoxic manufacturing facilities or do you feel that something that will take a lot of courage to do given that they may not have enough clientele or enough business for that, what is your sense on that part?

Dr. Satya: Here, the capital is not that expensive, but development cost, development time cycle and validation cost and operating cost are more expensive than other API. I do not think there will too many players coming into this capacity.

Aditya Khemka: Lastly on quarter-to-quarter sort of variations in getting orders, I understand yours is B2B business, so there will be quarters where the customers does not order or order gets delayed, that is completely understandable, but can you sort of, therefore help us and guide us for top line and EBITDA margins for FY'19 and even FY'20 if you can, because it becomes very difficult for us to model the business given so many quarterly variations, so, if you have any guidance on that, Dr. Chava, it will be really helpful?

Dr. Satya: One thing I would like to mention here is despite of our heavy expenditure on Unit-2 and Unit-4 where we are not generating any revenue, we were able to achieve more than 20% EBITDA margin. What is also interesting our Gross Margin increased by 1% between Q2 and Q3 FY18. So that is the quality of business we are doing. We have not lost any market share to any other API player in ARV or Hep-C. Despite of lower sales, we were able to increase our gross margin by 1%.

Aditya Khemka: Can you sort of give us any guidance for FY'19 at least in terms of top line growth and EBITDA margin that you think is a reasonable assumption for us to make?

V.V. Ravi Kumar: EBITDA margins will be maintained in the full year basis, we are not envisaging any reduction in the EBITDA margins. In fact, as growth is concerned, we are not telling any specific numbers, but we can achieve a double-digit growth on the top line.

Aditya Khemka: EBITDA margin same as FY'18 for FY'19?

V.V. Ravi Kumar: Yes.

Aditya Khemka: But my understanding was that, Formulations which we are going to start selling in FY'18-19, in FY'18 last quarter we launched this one product as and when we get approval, and FY'19 maybe two or three more products Dr. Chava was saying, so, ideally, our EBITDA margins should have expanded, given that we will have some commensurate revenue where we have OPEX right now.

Dr. Satya: FY'19 probably yes.

V.V. Ravi Kumar: I agree, but on a conservative basis, we have been guiding for small growth

Aditya Khemka: Before that we have two partners, right, we have Rising, we have Natco, and we have Dr. Reddy's. Rising and Dr. Reddy's both are for the United States. So I was going through your 'Investor Presentation', a minor question there, I think in Dr. Reddy's you said in the presentation, that there is a profit and cost sharing whereas in Rising, there is profit sharing?

Dr. Satya: In all the three cases, there is a profit and cost sharing.

Aditya Khemka: Are the economics of all three partnerships almost similar like 50-50 profit share?

Dr. Satya: You are right, cost and profit are shared equally.

Aditya Khemka: Lastly, on our US front end, that we have established, the team under Tom Versosky, what would be the cost that we are incurring on the US front end in million dollars per annum roughly?

Dr. Satya: Maybe next year we are planning to hire RA, QA and another sales guy. It will be between $1.5-2 million per year of front ending expenditure next year.

Aditya Khemka: And this year it is $1 million?

Dr. Satya: Little less than $1 million.

Moderator: Thank you. Next question is from the line of Abhinav Kumar from Canara Bank. Please go ahead.

Abhinav Kumar: Just wanted to understand on your Hep C business, there has been a kind of drop in the volumes. Can you just explain what has gone wrong?

Dr. Satya: When these formulations were launched there were a lot of patients who were waiting for cure for Hep-C. As and when the initial patients were out of the patient pool, so one is offtake came down, second, pricing pressure was also there and hence overall sales came down.

Abhinav Kumar: On ARV, are we expecting any new tenders to come out and how are we placed?

Dr. Satya: In ARV the new tender are coming in regularly. In the Q3 FY18 we had some shortfall because one of our key customers did not get any orders.

Abhinav Kumar: But any good tender coming up now?

Dr. Satya: Nothing significant that we are aware of.

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

Charulata Gaidhani: Hi! My question pertains to the Oncology business. There has been a good growth. Can we treat this as a run rate for the future?

Dr. Satya: Definitely yes.

Charulata Gaidhani: My second question pertains to Hep-C pricing. With the lower pricing and it is coming under the PCO, you think there will be overall margin impact because that was a substantial portion of the revenue?

Dr. Satya: If we look at three quarters of the current financial year although we have done Rs.70 crore less revenue from Hep-C, our profits were down only by Rs.11 crore when compared quarter-on-quarter, but nine months we were able to maintain profitability despite getting Rs.70 crore less revenue for Hep-C business.

Charulata Gaidhani: But I think the real decline happened in Q2 and Q3?

Dr. Satya: Yes, you are right.

Charulata Gaidhani: So going forward Hep-C should not see much growth, right?

Dr. Satya: It may not see much growth but we do not expect further decline also.

Charulata Gaidhani: So what kind of growth you think is sustainable going forward?

V.V. Ravi Kumar: Current level of revenue will be sustained

Charulata Gaidhani: In terms of EBITDA margins?

V.V. Ravi Kumar: We expect to maintain at the similar level of nine months and then the fourth quarter also there may be a slight marginal improvement.

Moderator: Thank you. We will take the next question from the line of Dheeresh Pathak from Goldman Sachs Asset Management. Please go ahead.

Dheeresh Pathak: The Tenofovir ANDA approval is linked to the February inspection of Unit-II?

Dr. Satya: No, we already got tentative approval and we have received EIR for that facility. We were the last company to get a tentative approval and then we put up an application for final approval second week of December and we got response last week that it is under review. Nothing is pending, only label change is going on, we may expect approval anytime.

Dheeresh Pathak: There is no profit share, right, this is not…?

Dr. Satya: This is our own ANDA.

Dheeresh Pathak: So there will only be marketing and front end related expenses, but all profit should be alright?

Dr. Satya: Yes, you are right.

Dheeresh Pathak: What is your fair share you expect to have in this molecule? Highly competitive it seems.

Dr. Satya: Molecule became very competitive, but we have some commitments from distributors, we have already shipped some quantities in the US, so we expect the good share but we cannot tell you right now.

Dheeresh Pathak: The Finished Dosage OPEX, that comes in the P&L has two elements, right – one is the R&D part to it and the other is the operating expense of the plants. So based on the data that you share in the presentation and what you shared in the prior calls, and if I have my numbers correct, I am just looking at the Finished Dosage Formulations OPEX part excluding the R&D part of it, that expense has gone up from Rs.12 crore in the June quarter of 2015 to now Rs.21 crore in December quarter and I do not think we have operationalized any new formulation plant or anything. So what is driving this? I am not looking at R&D expense of the FDF part, I am just looking at the OPEX element and there seems to be a material increase in the last two quarters and this number for the full year in FY'17 what you gave in the prior calls was Rs.31 crore, now the run rate is almost Rs.80 crore?

Dr. Satya: We have done more validations in the last quarter and we have also added close to 70, 80 new colleagues in the manufacturing and QA. These are two main reasons.

Dheeresh Pathak: Is it stabilizing at this Rs.80 crore per year now or you think there is more …?

Dr. Satya: I would say probably it will stabilize at Rs.100 crore OPEX.

Dheeresh Pathak: So validation you do not include R&D, only Bioequivalence you include in R&D, validation is part of …?

Dr. Satya: We constantly including the OPEX for the validation batches.

Dheeresh Pathak: Just in Hep C, you would not have expected DPCO and sharp decline, but at the time of IPO, ARV business you had guided for double-digit growth, that we have not seen and then in the previous calls also I have asked and you said that there are some tenders, Lamivudine you did not have. So can you just refresh again what has not played out from the time of IPO guidance on the ARV side volume growth?

Dr. Satya: If you look at nine months for ARV, we have grown by 4%, and in the Q4 numbers probably it will go beyond 4%, but next year what we are envisaging is that, we are adding significant capacity for a new API and two validations we are going to complete. So that will improve our ARV revenue significantly in next financial year.

Dheeresh Pathak: This 4% is not what we expected when you had come for the IPO road show and this is also not what you had guided. So what has not gone well in FY'18 for nine months 4% growth in ARV?

V.V. Ravi Kumar: What Dr. Satya is saying is overall for full year, it will be much more than 4% growth, #1. The shortfall is because of some of the intermediate for a particular product, we thought a couple of customers will take, but that got deferred. So that is the reason for the less growth when compared to previous year.

Dheeresh Pathak: So next year ARV should be double-digit volume growth and Oncology and Hep-C I am assuming would be stable, and Synthesis business also should be very high growth for us, right, because you are just ramping up from low base?

Dr. Satya: You are right.

Dheeresh Pathak: And then we have the Finished Dosage Formulations. So it should be a very good next year, right, but you sounded very subdued in your guidance when you said, "just low double-digit growth"?

Dr. Satya: In segments other than FDF we could be very confident because we know it very clearly. It is new approvals, new market, how much market share we get in FDF. So, we are a little bit conservative in projecting FDF sales. Otherwise the business looks very good for us.

Moderator: Thank you. We will take the next question from the line of Saravanan V from Unify Capital. Please go ahead.

Saravanan V: In terms of tax rates, we have seen some higher rates compared to last year. So, what would it be for the full year?

V.V. Ravi Kumar: Similar range we will have around 28%. The main reason for the increase is, as you are aware that Government of India has reduced weighted deduction for an R&D expenditure from 200% to 150%.

Saravanan V: Even the next financial year, this tax rate would be around this range, 28%?

V.V. Ravi Kumar: Around this range. Once we get profits from the Unit-5 and Unit-2, these two units are SEZ units, then the tax rate will change. So those profits will be exempted.

Saravanan V: So in FY'19 tax rate could be lower than the effective tax rate of FY'18?

V.V. Ravi Kumar: Very slightly, I do not think too much lower, but similar range we are expecting.

Saravanan V: In terms of Q4 of last year, we have some one-time sort of income because Q4 profits were around Rs.70 plus crore last financial year. So was there any one-off element there?

Dr. Satya: We supplied significant volumes of ARVs for European launches and we are also planning to refill the ARV APIs in Q4 again. So that is the only change, otherwise there is no one-time benefit.

Saravanan V: So even this Q4 of this financial year also you expect equally good…?

Dr. Satya: Yes, we started supplying again ARV APIs to Europe.

Moderator: Thank you. We will take the next question from the line of Aditya Khemka from DSP BlackRock. Please go ahead.

Aditya Khemka: Sir, you have filed eight ANDAs in the United States. If my understanding is correct, generally for these eight sort of Finished Dosage Formulations, that ANDA file could be submitted to pretty much any other country to get approval, if that country for instance UK, Europe, Australia, New Zealand or Africa. So my question is when we have spent the money to do the R&D work for these eight formulations, are we therefore also planning to submit these dossiers in other jurisdictions like the other countries that we enter in so that we can use our formulation capacity better.

Dr. Satya: Two of these products we have filed are in Europe, one with South Africa, one with Canada… in fact, one of the five that we have filed with FDA, we have filed with DCGI India also. So we are using that product for global development approach.

Aditya Khemka: My question is when we have filed eight in the US, why restrict ourselves to only two in Europe, one in Africa, one in Canada, why not eight in Europe, eight in Africa, eight in Canada?

Dr. Satya: There are two reasons –in US you can file after five years of launch after NCE exclusivity is over, whereas in Europe you have to wait for ten years, and in some cases we have to do different bios for different regions, for example in Africa, there is no market for some of the cardiovascular diabetic, only market for ARV. So wherever there is a possibility we are expanding our geographical filing for these products. When people are asking, we are not saying cumulatively we have filed 20 files, we are saying eight products we have filed, some in multiple geographies, some in US.

Aditya Khemka: Sir, you also made a statement in the 'Investor Release' where you said 20 validations have been done. Does this mean that your pipeline of ANDAs in US is about 20?

Dr. Satya: Yes, you are right.

Aditya Khemka: So there is 20 products that you can file in the US in the near future?

Dr. Satya: In our infrastructure we are geared up to do 10 new products filing every year, 10 products, what I mean, 10 product you may file in the US, 5 in Canada, 5 in Europe like that.

Aditya Khemka: So in US next year we can file 10 ANDAs and out of those 10 ANDAs whatever is applicable in Canada, Africa, Europe we will do those filings in subsequent chances?

Dr. Satya: Yes, you are right.

Aditya Khemka: When you say 10 validations per year, you are referring to the USFDA standard validation?

Dr. Satya: Yes, you are right.

Aditya Khemka: Given the way different business segments are going to evolve in FY'19, it seems that it should be a far better year than the confidence you are showing in your guidance. I understand the principle of conservativeness and I applaud it because that always should be there. But our point is that when you are sort of as conservative as you are currently in guiding, then in some ways it indicates to us that there may be risks to the segmental plans that you are telling us and therefore on an overall basis you are guiding still very conservatively to make sure that you do not miss it. So I just want to understand from you that in the different segmental plans that you told us how ARV can grow, how Hep-C can remain flat, how Onco can grow and all that, are there any material risk to those statements that you have made for these segments?

Dr. Satya: Fundamentally there is no risk that we see right now.

Aditya Khemka: My only point is therefore then it seems that you have been a little too conservative in guiding on the top line and EBITDA because then the picture does not add up because if I take those statements that you have made into an excel sheet and sort of do the calculation that you have just said, then it sort of feels that next year should be significantly better than FY'18 and not really just a low double-digit growth at flat

EBITDA margin? Maybe next quarter we will have more better discussion when you have the budget in place, but that is the point I wanted to bring up. Thanks again sir and all the best.

Dr. Satya: Yes. Thank you.

Moderator: Thank you. We will take the next question from the line of C Srihari from PCS Securities. Please go ahead.

C Srihari: My question was pertaining to the medium-term outlook for the ARV business. If I understand correctly for the first time a dual bill was approved by the USFDA. So can you please tell what kind of impact that would have on profit? I am referring to the Dual Pill combination recently approved for I think Glaxo and ViiV Healthcare combination?

Dr. Satya: Dual Pill has not been approved, that is for the maintenance in the US and Europe. I think that will never take into these emerging markets.

Moderator: Thank you. We will take the next question from the line of Nitin Aggarwal from IDFC Securities. Please go ahead.

Nitin Aggarwal: On your API business, there has been of late some concerns around the fact that there has been some increase in intermediate pricing from China. Is there a major linkage dependence on China and has there been any impact of intermediate price increase that you potentially foresee?

Dr. Satya: There were increases of intermediate prices from China but we are able to weather that very comfortably, it is also demonstrated that we improved our gross margin by 1% despite of that.

Nitin Aggarwal: So that per se is not really a concern for us when we look through the next year or so?

Dr. Satya: It is kind of a lost opportunity had there not been a price increase from Chinese guys we could have made more margins. Otherwise the price increase of intermediates is not hurting our margins right now.

Nitin Aggarwal: Secondly, on the Custom Synthesis business, although you talked about a little bit earlier in the call. When you look through the next couple of years, what are the milestones we should watch out for the Custom Synthesis business?

Dr. Satya: The commercial supplies of Aspen from Unit-5. Our Custom Synthesis, NCE supplies from Unit-3. Also, the High Potent molecules supplies from Unit-4.

Nitin Aggarwal: At what points of time, these supplies will become meaningful in numbers, any assessment?

Dr. Satya: Next year we will supply two validations products from Unit-3 and FY'20 we will start commercial supplies from Unit-4 to our partner. So FY'19 there is one trigger, the validations from Unit-3 and the FY'20 will be Unit-4 commercial manufacturing.

Nitin Aggarwal: How do you see the Aspen contract playing through in terms of scale up?

Dr. Satya: In Aspen contract Maybe we will fully commercialize all production what are there in the pipeline. So full potential for Aspen contract will be achieved by probably end of FY'19 or early FY'20.

Nitin Aggarwal: So Aspen would be essentially the big driver for the Synthesis business next year and thereafter you see the NCE business as well as the high potency business scaling up in the outer areas?

Dr. Satya: 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: Going back to the ARV business again, does the delay in offtake actually mean that it is more like dispatch issue and we can compensate for it in the next quarter or is it something to do with the issue that the formulations player is facing and then this business is just about gone for the future also?

Dr. Satya: No-no, there is no fundamental issue there, there is only some orders delay to our key customers.

Kunal Randeria: So we expect to make up for this in the coming quarters?

Dr. Satya: Yes, you are right.

Kunal Randeria: Just one more financial question; do we foresee any increase in debt in the near future?

V.V. Ravi Kumar: We are evaluating. Right now our long-term debt is only Rs.250 crore which will be payable in the next three years time. At this moment, we are at Rs.1,050 crore level debt. If at all we take, we take maybe another Rs.100 crore, not more than that.

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

Tushar Manudhane: Just on the Oncology NCE space, this would be the cost plus mark-up kind of arrangement right with the innovator?

Dr. Satya: It is not a cost plus model, it is a quotation-driven model…we give quotation based on our RM cost, our inputs and significant margins built in there, it is not cost plus model.

Tushar Manudhane: So basically it is not profit sharing, it would be quotation-based?

Dr. Satya: It is quotation-based.

Tushar Manudhane: So let us say whenever that NCE peak sales begin, ideally assuming it to be a billion dollar, that time how much would be the API sales for us and effectively how many years it would take like three, four years or more than that?

Dr. Satya: We do not want to predict how much sales it will get, but what we can predict is we expect depending on the positive outcomes in Phase-3, they will launch in FY'20, so our commercial supplies will start in FY'20.

Tushar Manudhane: With respect to the ANDAs where you are expecting three approvals spread out over CY'18, do we have target action dates?

Dr. Satya: For all of those, yes; one target action date by March, one in June, one in December.

Tushar Manudhane: Any status on Metformin?

Dr. Satya: Metformin, we got a new target action date in July.

Tushar Manudhane: But the query is with respect to Metformin, has that been resolved?

Dr. Satya: It went into the new site, otherwise everything else is resolved. There is no pending response from our side, everything is closed.

Moderator: Thank you. Ladies and gentlemen, that was the last question. I now hand the conference over to the management for their closing comments. Thank you and over to you.

Dr. Satya: Thanks, everyone for participating in this conference call and there were very insightful questions.

V.V. Ravi Kumar: Thank you.

Moderator: Thank you very much. Ladies and gentlemen, on behalf of Laurus Labs Limited, that concludes this conference. Thank you for joining us and you may now disconnect your lines.