Suven Life Sciences Limited

Q1FY19 Earnings Conference Call
August 17, 2018

Moderator Ladies and gentlemen, good day and welcome to Suven Life Sciences Limited Q1 and FY19 Earnings Conference Call. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing "*" then "0" on your touchtone telephone. Please note that this conference is being recorded. I now hand the conference over to Mr. Rishab Barar from CDR India. Thank you and over to you, sir.

Rishab Barar Thank you. Good day, everyone and thank you for joining us on this call to discuss Suven Life Sciences Results for Q1 FY19. We have with us Mr. Venkat Jasti – Chairman and CEO, Mr. Venkatraman Sunder – Vice President, Corporate Affairs and Mr. Subba Rao – CFO.

Before we begin, I would like to mention that some of the statements made in today's discussions may be forward looking in nature and may involve risks and uncertainties. Documents relating to the company's financial performance have been mailed to you earlier. I would now request Mr. Jasti to share his perspectives on performance his outlook going forward. Over to you, sir.

Venkat Jasti Thank you, Rishab. Thank you everyone for joining again for this conference call on the results for the quarter ending June 2018. You must have received all the data by now. As you could see the revenue growth has happened based on the last year same quarter we are up by about 36% on growth, 30% on PAT and EBITDA is by 30+%. But if you see quarter-on-quarter of course, there is a decline in the growth and also decline in the PAT by 37%, decline of EBITDA growth also by 33%. So this type of fluctuation will happen based on the product mix and also the changes in the order-book positions. And with respect to this, I need to bring up one small thing that is the issue with the raw materials from China which compared to generic players our effect on the pricing and the availability is limited to few items. But the same few items are affecting us with delay sometimes in the deliveries. Fortunately, in the first quarter, we have a positive Rs. 25 crore pre shipment that has happened for the speciality chemicals which is supposed to be in second quarter. Similarly, such possibility of preponement or postponement that may happen. So, quarter-on-quarter, the parameters will not be same, and we do not have to look [quarter-on-quarter basis] at like that but at the same time you can see year-on-year basis, we would like to maintain about 10% growth on core CRAMS, or you can say 10% to 15% core CRAMS.

With respect to the innovation, things are going very well [comparatively] with SUVN-502. We just had a conference call yesterday [with our CRO involved in study]. We would like to inform that 500 patients have been enrolled. Only 40 patients more to go and we expect that within the next couple of months that they

should be enrolled and that will leave us to sometime in June-July of next year to have the topline data of this molecule. And with respect to the qualitative aspect of our molecule the third Drug Safety Monitoring Board (DSMB) met during this last month and they have gone through the adverse event occurrence and they found not even a single serious adverse event related to the drug. They have just asked us to continue the trial as usual without any changes, which is a very good news because since 2003 there is no new drug which has been launched. The main reason [for no such new drug] is not only the problem with the efficacy, but also the problem [90% of the cases] of side effect profile. In that aspect we are faring very well, and we are very happy about our trial so far. Things are going very well but only time will tell how the efficacy will prove to be in our favor or not. Only next year, sometime in June-July we will know about it. And with respect to the second molecule SUVN-G3031 we have focused on for a new indication which is **Narcolepsy** [excessive day time sleep disorder].

As I was talking about the second molecule SUVN-G3031, even though it is meant for the cognitive disorders along with other indications, we have finalized with our Key Opinion Leaders for a new indication called Narcolepsy, that is excessive day time sleep and this is an orphan indication and we will be finalizing the protocol in the next couple of months and hope to start the trial before the end of fiscal for certain [but would like to start before the calendar year itself, if possible submitting the data are to be FDA] and in all when we compared to the SUVN-502 trial and it will [expected to be] be half the cost and also the time will be less than 2 years in total. That is what our expectation is and with respect to the third and fourth molecules, SUVN-911 and SUVN-D4010, they are undergoing the long term safety toxicology in order for us to move into the Phase-II proof-of-concept. So, the way things are moving up every year we should have a new molecule that bring into proof-of-concept Phase-2. I think with this I will stop here and take questions.

Moderator Thank you very much, sir. Ladies and gentlemen, we will now begin the question and answer session. The first question is from the line of BV Bajaj from Bajaj Shares. Please go ahead.

BV Bajaj Q1 FY19 results are much better if you take Q1-on-Q1 and if I look last year's 2017-2018 financial, your revenue growth was around 15% and by going Q1-on-Q1 consolidated it is giving impression that margins are being expanded if you take Q1-on-Q1. So, going forward my simple question is because of deliveries what you have explained do we cross around Rs. 800 crore revenue for the financial year 2018-2019. That is my first question.. And second question especially to Mr. Sunder. On that EMA, I mean Europe revised the guidelines which are applicable from 1st of September 2018 on dementia. So, regarding the biological changes of this disease and early appearance are diagnosis about 10 to 20 years early. So, do we fit, does our research fit in these revised guidelines? This is my second question.

Venkat Jasti Mr. Bajaj, we cannot give you any guidance on the numbers because I said it is only 10% to 15% core CRAMS growth and the quarter-on-quarter as I said one quarter is up and one quarter down. We said the same thing what you are saying but at the end of the year it will normalize out and as I have mentioned to you earlier also at AGM the success of the molecule will be known to them and only after that we will know whether we will get the supply arrangement or not. So, since the visibility is less than 6 months, I may not be able to comment anything further on the percentages of growth with actual numbers. With respect your second question, I think for those people who may not be understanding the new thing is guidance for the Alzheimer's disease. Since it cannot be treated, [and] more or less, it is only a systematic treatment and nor any drug is being discovered since 2003. There are new guidelines that are coming up in Europe and also in USA. The new thinking is that we should have started the drug much before the symptoms

appear. That means based on the age or something like that. And in that case SUVN-502 is in a much better place since our molecule works solo by itself and if you are talking about prophylactic then SUVN-502 with its safety margins, we will have a thumbs up. So, we are very happy that this thing comes in but [at this time] it is not there yet. They are still thinking up like existing, [like what we are doing on top of the 2 molecules], we are putting our molecule for the safety, I mean this is for the indication of the moderate Alzheimer disease. So, as far as the safety is concerned which we are very well placed and [for efficacy] we need to wait for the data that comes in June-July next year.

BV Bajaj So, really we fit in the revised guideline and now reference on deadline.

Venkat Jasti We are much better.

Moderator Thank you. The next question is from the line of Rashmi Sancheti from Anand Rathi. Please go ahead.

Rashmi Sancheti First question is related to the core CRAMS business. Sir, if I remove your launch supplies also launch quantity supplies still core CRAM business has shown a growth of around 54% during the quarter. And but you are giving guidance of just 10% to 15%. So, you think that in the subsequent quarters CRAMS sales would go down?

Venkat Jasti You cannot go by one quarter. I mean, when I was saying normal growth and it can happen like last year if there is a success, I mean the growth can be about 32%-35% also can happen. But on a year-on-year basis, I cannot give you any guidance and quarter-on-quarter also as I was alluding earlier. If you see this quarter instead of last compared to the last year same quarter the specialty chemicals we sold about 25 metric tonnes more, I mean Rs. 25 crore more because we reshipped them because they required it. So that there was a good inroads last quarter; at the same time because of the shortages sometimes, the delivery maybe delayed by 1 or 2 months. That means it may go into the next quarter. So, there will be up and down that can happen, so I cannot tell that it will have this 50% growth on quarter-on-quarter basis. These are all the aberrations**,** so we need to take into consideration but at the end of the day we are saying 10% to 15% normal growth and based on the success [at customer end] of the molecules we will see, you can have like last year about 30% to 40% growth.

Rashmi Sancheti And on specialty business do you think that it will be giving a flat growth because this quarter again specialty sales are also high?

Venkat Jasti Yes as I said it see, since we have built up the inventory they have taken the inventory; As Rs. 25 crore worth of inventory which was supposed to go in the second quarter went in the first quarter. So, as of now the guidance is same as last year.

Rashmi Sancheti And on gross margin front, you said that the impact from the Chinese environment is very limited. So, can you just quantify like how much percent impact we have seen during the quarter and how much is due to the adverse product mix?

Venkat Jasti As of the first quarter we have not much impact maybe because our imports itself is less than 20% of the raw materials but we are seeing some impact in the second and third quarters on the delays in supplies and also the increase in the prices. So, we will not know that, until it's done.

Rashmi Sancheti So, can you just guide us like on a full year basis what kind of gross margins should we see?

Venkat Jasti It depends on the raw material pricing, some of them but at the same time the EBITDA level is [expected] standalone plus 30%.

Rashmi Sancheti What are you guiding on an EBITDA level on a consolidated basis?

Venkat Jasti Let me tell you, it is only on the standalone I can tell you because I cannot crunch the numbers now and at the end of the year the only we will know. On the consolidated base I do not know but on standalone it is plus 30% EBITDA margin.

Rashmi Sancheti And on R&D front, what kind of R&D have we spent on SUVN-502 during the quarter?

Venkat Jasti During the quarter we spent about Rs. 1.69 million.

Rashmi Sancheti In the last concall you mentioned that you will be spending, I mean you have budgeted R&D for the other molecules which will be entering Phase-2 at around $12 million or something. So, in this quarter have we spent anything?

Venkat Jasti No, as I was telling you, that we are yet to finalize the protocol and have submitted to the FDA. So, we will not be spending any money until that time for that product. It will come in the fourth quarter maybe.

Moderator Thank you. The next question is from the line of Sriram Rathi from ICICI Securities. Please go ahead.

Sriram Rathi Just 2-3 questions. First on the speciality chemicals, initially you are talking about that we are also working for new products. So, basically in the future is there any decline because of the genericization we can compensate for the same, so? Any update on new products that you have been working on?

Venkat Jasti Yes, as I said it [earlier], I cannot give gudelines on this within 3 months, because I said it will be 2020, sometime in that time period the opportunity comes both the products which we are working and not until that time.

Sriram Rathi So, is this is the same customer, or it is a different customer?

Venkat Jasti Different customers, one for same customer one for the other customer.

Sriram Rathi And sir, how much has been that royalty from Taro in this quarter?

Venkat Jasti I think it is Rs. 1.81 crore.

Sriram Rathi On the commercial supplies, I think you gave guidance initially for a Rs. 90 to Rs. 100 crore of revenue. So, that remains intact for us or?

Venkat Jasti Annually we hope to, I said, I did not guide it. I said we hope to receive the same thing it may push back into the next year also, we do not know. But we do not know yet and we hope maybe 60-70 is possible but 100??, I do not know yet.

Sriram Rathi And sir in this quarter this Rs. 18 crore of revenue is from commercial supply, so which molecules have contributed?

Venkat Jasti It's depression and diabetics.

Moderator Thank you. The next question is from the line of Hareesha Kakkera from B&K Securities. Please go ahead.

Hareesha Kakkera Sir, why are our other expenses up by 70% this quarter, Y-o-Y?

Venkat Jasti Yes, the impact is basically because of we have a CSR expenditure which has come into quarter which is close to about Rs. 4.22 crore, that is the impact actually. If you take that off it is more or less equal to the previous quarters.

Hareesha Kakkera And on the SUVN-502 front like what is the EAP that you have received recently?

Venkat Jasti Yes, EAP means Expanded Access Program what it means is that when patients finished initial trial of 6 months they will have a one month washout period and they will go home, I mean they will not be using our medications any more. And after that what happens is some of the patient's relatives like either daughter or son or wife whoever they maybe, they keep coming back to the Doctors, some people, not all of them saying that I think my father or mother were doing better. And they are taking SUVN-502 [this is a 3 arm study with SUVN-502 50mg, 100mg and placebo] along with other medications [base medications like Donepezil and Memantine] I think they are deteriorating, so can we have the access to that product again? For that we need to have a permission from the FDA and as the safety is well established, FDA has given permission. We have applied and got permission but only 10% of the patients who have gone through this trial can be given this medication for another 6 months. Again, this is on a compassionate basis under the expanded access program. We have enrolled 10 patients already on the expanded access program. What it tells you indirectly is that this must be working on some of the patents. That it is practically significant or not we will not be knowing until end of the trial. Sometimes it can be placebo effect also, as some people feel better when they take medications. So, we cannot induce anything from this, like guarantee that this is going to work. But it is a positive sign along, without any the safety concern.

Hareesha Kakkera Do you have any idea like in this segment how many drugs till date could actually receive an EAP, I mean how many have actually applied for that during the investigation process?

Venkat Jasti Not many while we do not see in this they have done one more trial I think they have that expanded access program after the Phase-2 finished.

Venkat Jasti It is the probably that Phase-2 may be this is the one-off. This is one of the rare things that happened during Phase-2. Usually happens after Phase-3 or sales.

Hareesha Kakkera And sir the new drug by Biogene and Eisai, I mean which has recently cleared Phase-2, so would it be a competitor to our SUVN-502?

Venkat Jasti First of all they have not really finished Phase-2;, there is only one thing that is, one of the filed doses that is working and secondly it is meant for the not for the moderate Alzheimer's, it will be certainly mild Alzheimer disease. So, this is not a competitor but the sentiment on this molecule, because it is the disease modifying molecule, the sentiment will be much better. So, that may affect the valuation [for SUVN-502] but not a direct competitor.

Moderator Thank you. We move to the next question from the line of Ranveer Singh from Systematix Shares. Please go ahead.

Ranveer Singh Question related to that formulation business, how many ANDAs have we have filed? And what is your status of our formulation facility? So, are we ready with rolling out these ANDAs from our facility there?

Venkat Jasti No, we just filed as I mentioned last quarter, one more ANDA on Suven's name and 2 more ANDAs on the customer's name. And it takes 12 to 18 months before you can see any kind of approval and all that takes place. So, as far as the facility is concerned with a out layout of about Rs. 70 crore to 80 crore we just started, and it will be up and running only by the next year, this time with validations. So, more or less it coincides with hopefully the first approval of the ANDA filed.

Ranveer Singh So, by end of FY20, can we expect at least couple of ANDA rolling out or validation starting?

Venkat Jasti I think it could happen.

Ranveer Singh Just a clarity on our R&D pipeline. If for example, SUVN 3031 goes to Phase-2 then we will be putting these molecules under a subsidiary like we did for SUVN-502 and if so then how much R&D expenses will go away? If I say, 2 of molecules are in Phase-1 later stage and leveraging to our Phase-2. So, what percentage of R&D use actually go away from a standalone number?

Venkat Jasti There is no R&D at this time required for the SUVN- G3031 at the standalone. It is only the proof of concept clinical trial has to be done which is around $12 to 15 million, I think 12 million may be the right figure and that will go into the subsidiary, wholly own subsidiary. And that is what happens, it will be over a period of 18 to 24 months.

Ranveer Singh And third question, if I could. In speciality segment I just wanted the clarity because you talked about a problem from China. So, it was availability or was it pricing? So, what I wanted to understand with in a specialty segment whether we could have got more revenue but due to availability problem from China or there is no such issue actually?

Venkat Jasti This sometime is there, typical in nature and the products which are supposed to go in April and May timeframe. I mean usually we build up these inventories. I think you ask because most of the time about our inventories levels and I do this, because I cannot make one whole requirement in one lot and I have to keep building inventories. With respect to the China issue, I am not sure whether they did not get from China and hence they get from us. If that is the case they would have told us ahead that time may need more material which they did not tell me yet. So, I cannot comment on that basis. But with respect to the core CRAMS, the availability is the problem, more than the pricing. Pricing is also a bit of concern but because of our margins we could absorb those things. But sometimes the availability is delayed by a month or two, which will delay the production schedule which may consequently delay our delivery schedules. That is what I was trying to explain everyone about the typical problem we have in CRAMS based industry.

Ranveer Singh That was mostly related to CRAMS, not a speciality chemical?

Venkat Jasti Yes.

Moderator Thank you. The next question is from the line of Manushi Shah from Research Delta. Please go ahead.

Manushi Shah I just wanted to make sure if I heard correctly. Are you going to increase prices for your intermediate as well? The intermediate manufactured by Suven?

Venkat Jasti Are we going to, sorry, can you please repeat your question?

Manushi Shah Increase the prices for intermediates manufactured by Suven?

Venkat Jasti Not necessarily depending on how much the price increments that happened then we may be able to ask the things, but up to 5% will not have any say, I mean then depending on the nature of the price increases then we can ask for it. That is why I said the small increases we can take care of it because of our margins but otherwise, if it is a huge increase then we will certainly look for it and see what they can do for us.

Manushi Shah So till now you have not increased price of any intermediate?

Venkat Jasti No.

Manushi Shah And what is your dependence on China for the intermediate launch?

Venkat Jasti I said it is less than 10%.

Manushi Shah And from CRAMS, how much is from intermediate and how much is from API? If you can just give us split in percent or roughly.

Venkat Jasti There are no APIs for us. These are all CRAMS intermediates.

Manushi Shah So, CRAMS is all intermediate?

Venkat Jasti Yes.

Manushi Shah Sir, generally can you just give an outline that do you see a possibility of like price increase or what percent of price increase for companies making intermediates in house or like just a broad scenario?

Venkat Jasti No, I said it is all depending on our raw material price increases and based on that we will reach out to our customers and explain it to them and we may be able not price increases, there may be a separate check for that. But so far that thing has not come to our pipeline.

Manushi Shah You said something about delivery, can it be repeated?

Venkat Jasti Yes, what I am saying is when the delivery is there, you said the main problem as the price increases, price increase is also a problem but at least you get the material even if the price increases. But the delivery sometimes from them to us is delayed by a month or two, then my production schedule is get affected and my delivery is get affected. That way suppose, if I have some orders planned for by quarter 2 if it is not postponed to quarter 3, my revenues goes down, right? That is what I was trying to say.

Manushi Shah So, is that just for less than 10% of China intermediate?

Venkat Jasti Yes but 10% can affect, right? One product delay also can affect price.

Moderator Thank you. The next question is from the line of Cinderella Carvalho from Kotak. Please go ahead.

Cinderella Carvalho Sir, just want to understand our number of projects have moved from 113 to 115. So, what is it that is helping us here and how is the buoyancy of the R&D projects market? And again, we are seeing if I remove the commercial portion we are seeing around Rs. 90 crore run rate for our core CRAMS. So, what is it that is driving this and if you could help us with some majors that we can track along the side which will help us understand this better.

Venkat Jasti Yes. The core CRAMS, the traction is multiplied now-a-days compared to older days and that is why you see this growth patterns are happening and also, happens sometime [which is based on, even though I may have more number of projects sometimes] a few of them will give you much better margins and volumes because of the product mix. So, it keeps changing and this quarter we have value-added products in the mix and that is why you have the bottom-line and the topline growth has happened. So similarly, more number of products maybe there but of theuy are all in Phase-1 stage supply, then the volumes will be less and also the profitability is less. It keeps changing.

Cinderella Carvalho We understand that the moment from Phase-1 to Phase-2 would be more lucrative for our kind of business. But what I want to understand is like are there any key pointers that can help us understand like if there is some indication that you can give based on the Phase-1 currently that we have. Are there any such opportunities that you expect to move or according to your assessment may have a chance to move faster? And apart from that even on the new phases that we are getting as we add newer projects what is the level that we can reach like presently we are at 115.. How fast can we reach to our 150 level or what are the challenges in reaching there? So, any color on that side?

Venkat Jasti No, I mean getting huge number of changes as we could see some year-on-year may be 10 to 15 new products are net addition, even though the mix about is about 40%, it is moved from one stage to next stage to another stage, dead or something like that. The number of projects achieved is much higher than what is the number of net additions here. Getting the additions is much difficult because globally R&D has prioritized to few number of projects to run through compared to earlier days. But at the same time whatever they have started they want to continue on a seamless manner until it will happen. Before, it was not the same case, even though it passes a certain phase ,sometimes the prioritization may not have happened. So, that is not the case now. The continuation is taking place. So, it is very difficult say which factor, that this time it is what we are getting and what is the product mix and what are the factors at the innovator level, is the one that gives us the opportunity to go or move forward.

Cinderella Carvalho And, for clarification we said 10% of our raw material is dependent on China, is that correct?

Venkat Jasti Yes.

Cinderella Carvalho I mean we understand that you must be taking some internal measures to avoid delays and delivery because that has been our key focus area which is being on time in terms of delivery. So, any color that you can provide are we looking at some other sources or are there any challenges in that terms that we can face during coming 3 quarters?

Venkat Jasti Yes, we always look for 2 sources [vendors] at least when you are depending outside the country. But the problem is that some people take, what you call, work

in the L3 and all the stuff they promise and suddenly they are supposed to deliver in say the end of July and suddenly they come back and say and it could be delayed. So, whatever reason they will say it will be delayed by about 50 days-60 days, something like that, and nothing we can do about it. The reason mainly is twofold – one is they have their own problem with the environmental angle suddenly they are being closed and even though we order way ahead of time these things can happen. We are seeing one product already being delayed even though it is just 10%. One product can affect the whole cycle if it is an early start then it is affecting all the stages and if it is delayed start, at least you can cover it somehow. So, things are happening, and I think it will happen and the likelihood we may get bumped into next quarter or something like that, is so likely.

Cinderella Carvalho Sir, any color on the depression molecule that we have received a repeat order? Any clarity we have for next coming 3 quarters or something or maybe another quarter at least?

Venkat Jasti No, maybe diabetes we have indications that they may be required in both quarters, something like that. But not on the depression molecule.

Moderator: Thank you. The next question is from the line of Darshan Shah from Multi Act. Please go ahead.

Darshan Shah Sir, I wanted the breakup of our revenue of Rs. 200 crore into core CRAMS, commercials, speciality and others.

Venkatraman Sunder Yes, the core CRAMS is about Rs. 91 crore, commercials Rs. 18 crore and speciality chemicals Rs. 65, contract technical services Rs. 11 crore.

Moderator: Thank you and the next question is follow up from the line Rashmi Sancheti from Anand Rathi. Please go ahead.

Rashmi Sancheti Just want to know the CAPEX guidance for FY19 and 2020?

Venkat Jasti Yes, as you know we have in Pashamylaram that speciality block we are supposed to build with Rs. 120 crores outlay. Rs. 50 crores has been already spent and another Rs. 70 crores is spending, that will be more or less fully spent during the fiscal. And with respect to the formulation development around Rs. 70 crores will be spent within the next 12 months. And third thing is, Vizag we started a brand new multi-purpose plant which will be Rs. 70 crores to Rs. 80 crores, just started the work that also will be spent within the 15 months. In total, we have about Rs. 220 crores plans for it will be running for the next 18 months. And all the money will be spent from the accruals only, no loans.

Rashmi Sancheti And the major part of the CAPEX would be spent in FY19 itself, right?

Venkat Jasti Split. May be 60-40, 60% this year and 40% next year, right.

Rashmi Sancheti And what about the tax guidance for FY19 and 2020, the total tax guidance?

Venkatraman Sunder Yes, it will be around similar to last year around 32% to 33%.

Moderator: Thank you. The next question is from the line C. Srihari from PCS Securities. Please go ahead.

C. Srihari My questions pertain to your NCEs. Now, considering that for SUVN-502 you expect a read out within the next 12 months. Could you please give us some kind

of an indication of what kind of a milestone you may expect if it gets out-licensed? And for SUVN 3031 you are planning to start trials for Narcolepsy, so could you please give us an idea about what is the overall market size of this therapy and how many products are there currently?

Venkat Jasti SUVN-G3031, for Narcolepsy. There are about 2 to 3 products [in this category], one product has various other indications and also one product there along with Cataplexy. The sales of those molecules are around $700 million to $1.3 billion each. The market size [estimated] would be around $4 billion to $5 billion because Narcolepsy is a part of the indications along with Cataplexy and some other indication put together. The estimate is, any new molecule that comes out will be having is $750 million to $1 billion peak sales. With respect to the SUVN-502, we do not know because there is the depth of the molecule and there is no molecule that was discovered, developed for the Alzheimer since 2003. The last molecule out-licensed is, to Otsuka by Lundbeck and that time they have the news of upfront payment of $150 million and downstream payments around $680 million, out of which they might have received [our guess] about $300 million. But the product failed in Phase-3 [as per the news release], so we cannot tell that, at this time, but our hope is to have is a positive data. This business [please understand] is either it is 0 or 1. So, let us have the 1 first, before we guide ourselves with the numbers. So, number has no meaning unless it has a positive result.

C. Srihari Just to confirm is that, the upfront was $150 million in milestone payables?

Venkat Jasti Yes, upfront payment [by Otsuka to Lundbeck, based on news reports]

Moderator Thank you. The next question is a follow up from the line Cinderella Carvalho from Kotak. Please go ahead.

Cinderella Carvalho My question also pertains to the innovative pipeline that we have. So, absolutely closer to the 500 number. So the understanding that we have is June or July we should have the final data out. So, the plan as of date still remains in terms of looking forward for a partner if it comes in the positive direction or any change over there?

Venkat Jasti There is no change. This product was looked at by 8 different companies, speciality pharma, big pharma and everybody and they keep looking for the updates on this and they are waiting for the data. So, if the data is positive then there is no problem of out-licensing it. And there is no change in our thought process of not out licensing or anything like that.

Cinderella Carvalho Yes, the efficacy that you read out in terms of beginning of the call, you highlighted that the efficacy report in terms of SUVN-502 from one of the agencies has come much which is again favoring the continuation of the trial.

Venkat Jasti No, not the efficacy. We are saying the Drug Safety Monitoring Board has recommended to continue the study as usual since there is no serious adverse events related to the drug. With respect to the efficacy I will said, we will know only after the trial is over and the blind is broken, and the data is read out. What I said is that, an indirect indication is there that they may be efficacious because some people who finished clinical trial has come back and asking the doctor to resupply the medication since they feel that it is working. So, for that requirement we have taken an expanded access program permission from the FDA to the 10% of the trial undergoing people, which people are already taken that expanded access program. So, it indicates that it is working but whether it is statistically significant, or it is a placebo effect, we do not know until the data is read out. So, I never said efficacy is there. It is only a possibility.

Cinderella Carvalho In terms of the 3031, the trials would likely start only say next year. Is that a correct understanding?

Venkat Jasti Yes. But before the fiscal.

Cinderella Carvalho It might just be the fourth quarter?

Venkat Jasti Yes.

Cinderella Carvalho And this Phase-2 trial would run for 2 years, is that a correct understanding, 18 to 24 months?

Venkat Jasti The duration unlike the Alzheimer's where it is 6 months plus one month wash out, this will be 6 to 8 weeks trial. But getting the patients is a challenge in this, because most of the patients are the young adults like 18-year-old and mostly the girls are the most affected people in this. And the only advantage for us is unlike other Narcolepsy molecule which are habit-forming molecule, ours is a non-habit forming in nature. So, that will give us, may be a better opportunity to enroll but the enrolling is the one that takes the time at the duration of the trial. And so we expect 18 to 24 months duration.

Cinderella Carvalho So after this, like Phase-2 we have said around $ 12 million of cost that we estimate for this particular trial to go?

Venkat Jasti Yes.

Cinderella Carvalho So, if we complete this Phase-2 also do we have any further plans as of now or as of now are we just trying to complete Phase-2?

Venkat Jasti No, the other plans are always there, either for the out licensing or for continuation into Phase-3.

Cinderella Carvalho Similarly SUVN-502?

Venkat Jasti Similar to the SUVN-502. We preferred out licensing, so that the expenses we do not buy them, and the risk is also shared by us and them hopefully. And marketing wise we are not that savvy in those aspects.

Moderator Thank you. The next question is from the line Siva Rajendran from Capital Guards. Please go ahead.

Siva Rajendran We know drug discovery is a pretty long-term business. It will take 8 to 10 years and we have a pipeline of NCEs, right? So, now that you are in your 70s, right? You still have more product years, but have you started looking into succession planning in so on started mentoring to have a pipeline of leaders to fill your shoes?

Venkat Jasti So, indirectly you are telling me to retire?

Siva Rajendran I just want to have some color on like. I know your daughters are into some roles, right?

Venkat Jasti Yes, for anything there is a succession plan already in place, in the sense they may not be active as you could see it. But they are learning their ropes. My second daughter is taking care of the US operation for the CRAMS side of the business and my eldest daughter who is physician by herself is looking after the clinical

development of the NCE molecules. So, we have both divisions are taking care off. They are learning their ropes now. They are both in situated in USA.

Siva Rajendran In case of any worst case or any difficult results coming out of 502, right? Will it have any negative impact on other pipelines?

Venkat Jasti No, see you are going with a zero and based on that only you are planning all your activities and of course, that is for the continuation purpose, but your hope is still have one (1) all the time. So, as of now for the next 3 years I have all the molecules that can go to the next levels without any dilution or borrowings whatsoever with the existing cash and the accruing cash.

Moderator Thank you. The next question is from the line Charulata Gaidhani from Dalal & Brocha. Please go ahead.

Charulata Gaidhani My question pertains to the R&D expenses going forward with trails starting the number which is at Rs. 58 crore in FY18. Where do you see that going forward?

Venkat Jasti Yes, it will be in the same range as far as the standalone is concerned around $10 million of it that is all.

Charulata Gaidhani And consolidated basis?

Venkat Jasti Consolidated basis it has the other $ 4 million to $ 5 million we will add in the next fiscal year for the SUVN-G3031 plus continuing maybe $ 7 to $ 8 million of the SUVN-502 which will be spilled into next year.

Charulata Gaidhani So, around $ 12 million more?

Venkat Jasti Yes, $10 to $12 million.

Charulata Gaidhani Which will come in FY19? …

Venkat Jasti That is FY20 numbers I gave you, FY19 we will be around $ 6 million, $ 6 to $ 7 million.

Moderator Thank you. The next question is from the line of Vainatheya B. T, an individual investor. Please go ahead.

Vainatheya B. T My question is regarding your expanded access program. Are they also monitored after a particular step? Do they also have a wash out period and will that expand into beyond June 2019 or July 2019? Will that expanded program delay the results of SUVN-502?

Venkat Jasti There is no relationship, this is an expanded access program on a compassionate basis. It will not since, there are no side effects FDA has given a permission, that means we are not going to monitor them at all. We are only going to supply them, and it will be only for the 6 months from the dates they start. So, it will not have any effect as it will not be taken their data into consideration or any monitoring we have done on those patients.

Vainatheya B. T But as a company are we allowed to monitor them as this one as to see for our benefit what is the efficacy of that expanded access program?

Venkat Jasti I mean, we do not want to do that because it will muddle up the things and because that will not be what you call regulatory compliance and we do not want to take that into the system. We are only giving you on to the expand on a compassionate basis. [We do not collect or analyze the data]

Vainatheya B. T And second portion, our maximum revenue is in foreign exchange. So, do you see Rupee at 70 enhancing the revenues Suven?

Venkat Jasti That is what with small expansion is going out of the raw material sourcing, it should work out positive for us, yes.

Vainatheya B. T Are we hedging by any chance, our input cost against the dollar like you said material from China where we have to or, SUVN-502 program where we have spent money for sure on the clinical trials. So that it also enhances the expenditure if you compare it on the rupee front. So, are we into hedging the current year?

Venkat Jasti See, we keep this money in our program and we do not convert it and we use same thing for all the imports and also for the clinical trial program. Whatever is converted is the one that we going to get as a benefit in the rupee. Otherwise, that is the indirect hedging, you can say.

Vainatheya B. T And my last and final question, regarding this Rs. 220 crores which we intend to spend up to say the next 18-20-24 months. These are, to maintain this current program of you said that there are some new guidelines which has to be maintained to get the new research products the CRAMS business pouring into Suven. So, is it only for the maintenance part or we are also looking into expanding some of them into specialty chemicals and getting some more revenue or adding some other chemicals to obtain more revenue? That was my last question, sir.

Venkat Jasti This will be enhancement not only on the regulatory front but also on the capacity front. So, it will have a positive effect on the revenues also, eventually.

Moderator Thank you. The next question is from the line Afzal Mohammed, an individual investor. Please go ahead.

Afzal Mohammed What I understood from the call is some of the patients are coming back to you and asking for more of 502 molecule, right? under EAP. So, what I can infer from that is the molecule is efficacious. So can you throw some light on the efficacy of the molecule?

Venkat Jasti No, I cannot tell you what the efficacy is. It is presumed that it will be efficacious that is why they are asking for it. But I said in my call whether it is statistically significant enough, we do not know yet. Sometimes, I mean even people see since they are taking the medication they feel better also, whether it is a placebo effect or it is a product effect, we do not know until the data comes out. So, we cannot tell at this time. But it is a positive sign, is not it? But how far is it going to translate into real possibility we do not know yet because since 2003 there is no new molecule developed in this segment. So, it is a high attrition rate and the high bar to pass and we are hoping with the highest 50 mg as tablets so far, with this positive indication, it is as a positive thing. But you never know until the data comes out.

Afzal Mohammed And most of the patients were coming back and they are dementia patients or Alzheimer's patients?

Venkat Jasti First of all, patients who are enrolled in our trial are the Alzheimer's patients. Those are the only people who can come and ask for medication, not any guy from the

road. [cannot ask to supply medications]. Those people who have taken this medication from 6 months and for wash out period [of one month] they are the ones who are approaching us saying that it might have been good to continue that is why they are coming but not be fresh patients.

Afzal Mohammed And do you also intent to pursue that molecule for dementia patients who do not have Alzheimer's?

Venkat Jasti As per the product is concerned we are only talking about the moderate Alzheimer's patients in the inclusion and exclusion criteria, then they enroll in the study. We do not do anything other than that at this time. This is a proof of concept study. So, you have to only [give to] intended population which is moderate Alzheimer's disease.

Afzal Mohammed So one last question sir, how is your molecule 502 differentiated from other molecule?

Venkat Jasti If it comes to the efficacy in the animal models, when that molecule cannot work on isolation it has to be on top of the Donepezil, then it is efficacious. Whereas, Suven's molecule by itself without any added investigational drug, which is efficacious, that is one thing. And comes to the receptor-based activity Suven-502 is 5-6 antagonist it is 100% pure. There is no liability attached to whereas other molecule has some liability which may have a negative connotation, it may be. So, these are the 2 differentiators that we have to see this, safety and efficacy.

Afzal Mohammed And one last question, when do you expect to complete the trial?

Venkat Jasti Next year by this time.

Afzal Mohammed About a year, so your enrollment is complete, right it is almost complete now?

Venkat Jasti The enrollment will complete from the next couple of months after that 6 months, the drug taken after that one month wash out period than 2 months of data cleaning and analysis.

Afzal Mohammed About 9 months from now?

Venkat Jasti 9 to 10 months.

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

Venkat Jasti Thanks, everyone for tuning in. And as I said in my commentary that all in all things are going well qualitatively and quantitatively and as of now from both CRAM side of the activity and also on the innovation side. But there are challenges for us with quarter-on-quarter performances based on the deferment, we have done the non-availability of raw materials coming in time and some kind of a price increases all this effect. But overall year-on-year basis we expect the core CRAMS growth to be 10% to 15% and specialty chemicals is going to be flat. And barring any positive surprises, that we will try to maintain 10% to 15% growth. If projects move from phase to phase faster, effectively there they can be a better top-line growth and better margins. And hope that will happen like last year and hope that continues for the commercial supplies also will continue. Since, we do not have the visibility of more than 6 months I cannot give more than this as guidance at this time. And again, thanks for tuning in and hope to catch up with you in 3 months' time. Thanks a lot.

Moderator: Thank you very much, sir. Ladies and gentlemen, on behalf of Suven Life Sciences Limited, that concludes this conference call. Thank you for joining us and you may now disconnect your lines.

Please note: We have edited the language, without changing the content, wherever appropriate, to bring better clarity.