Suven Life Sciences Limited

Q2 & H1FY19 Earnings Conference Call Transcript
November 16, 2018

Moderator: Ladies and gentlemen, good day and welcome to the Suven Life Sciences Limited Q2 & H1FY19 Earnings conference call. As a reminder, all participants' 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 would now like to hand the conference over to Mr. Gavin Desa from CDR India. Thank you and over to you, Mr. Desa.

Gavin Desa: Thank you. Good day everyone and thank you for joining us on this call to discuss Suven Life Sciences Q2 & H1 FY19 earnings. We have with us Mr. Venkat Jasti, the Chairman and CEO; and Mr. Venkatraman Sunder, Vice President of Corporate Affairs as well as Mr. Subba Rao, the 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 now request Mr. Jasti to share his perspectives on performance and outlook. Over to you, sir.

Venkat Jasti: Thank you Gavin and good morning to everyone. On this as a starter, if you see this from the Quarter-on-Quarter basis our revenues are down by more than 50% and our net profit is down by more than 50% even though we have gone up by 14% on a half yearly basis.

Just a soft touch on the bottom-line [for half year]. As last time I have mentioned in call conference, the first quarter being a good quarter is because of Rs. 25 crore of pre-shipment of the specialty chemicals and also mentioned that the likelihood of delays or postponements of clients projects due to the non-availability of raw materials which happened for the second quarter which is why you see the double effect [of lower revenue and profit].

But it is kind of a rollercoaster ride for us as of now. But we hope to have the stability within the next two quarters because more or less we have secured the raw material for the shipments for the next two quarters. Again it can happen based on some of the information we are getting are which is likely to happen in the New Year. [However, we may face] some delays due to the raw material shortages.

We are unable to secure these raw material shortages from the local sources because there is no local supplies involved even though the cost is more. So this is real and even-out within three to four quarters is maximum and I hope not only for us but for everybody in the country which is what we are depending on what you call from the Chinese sources.

I will answer other questions with respect to the CRAMS side of the business when we have the question-answer session. With respect to the innovation we are very happy that finally we have achieved the milestone of enrolling the last patient and we are supposed to enroll 537 patients but because the patients who are in the screening whoever passes we must enroll them hence our number has raised to 563 which is good for us and it has happened on October 23.

The last patient out will be in May 2019 and after one month the database lock in happens in June 2019 and we hope to get the data [analysed] sometime in July-August timeframe. The topline data which will give us the indication how the drug has worked for the patients.

As we have mentioned earlier in the conference call that the safety is very well established and the drug safety monitory board met three times during the trial and they never had any questions on any side effects that have taken place.

All the side effects are not related to the drug. There is no serious adverse event related to the drug but there are serious adverse events because of other conditions they have. So things are going very well. I think we are waiting for the data to come out to have the what you call the efficacy data based on that then we will be having the monetization opportunity in third quarter of next year.

With respect to the second molecule we have finalized what you call which indication we should use that is for G3031 we are going to go for the excessive data in sleepiness and we are in the preparation for finalizing the protocol and trying to put the paperwork for the FDA which can happen at end of the fourth quarter and hope to start the clinical trial sometime in the first quarter of the next fiscal year.

And the other two drugs are going through the long-term safety toxicology like D4011 and 911; both of these drugs are going for the safety toxicology and one of them will move in to the Phase-2 another [by next] fiscal year. That is why as I said we have other molecules running in the pipeline which are moving in to the next level like POC; also for the cognitive disorders and every year we hope to have one new molecule going into the Phase-2 clinical trial.

So I think I will stop at this time and I will want to reiterate that this is kind of a rollercoaster ride will not be there jn the near future and we hope it will not be there in the next two to three quarters and we hope to achieve the last year's numbers as things stands.

With this I will leave the floor open for question answers.

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 Rashmi Sancheti from Anand Rathi. Please go ahead.

Rashmi Sancheti: This entire CRAM sales of Rs. 72 crore is it just a core CRAMS business or it includes any commercial quantity of those four molecules?

Venkat Jasti: No commercial quantity.

Rashmi Sancheti: This time no commercial quantity. And what would be the royalty payment from Taro during the quarter?

Venkat Jasti: It is only Rs. 1 crore and I need to bring to your attention; as you see that royalty of Taro is coming down because of the competition Taro is facing. And it will be in the Rs. 5 crore to Rs. 6 crore over the year. Those will be for the year compared to the Rs. 10 crore to Rs. 12 crore last year.

Rashmi Sancheti: On a full year basis post Q2 result what kind of guidance do you give for the core CRAMS business and do you think that we would be able to sustain FY18 margins on a consolidated basis or you need to reduce your guidance?

Venkat Jasti: See on a standalone basis we would like to achieve the numbers of last year. But on a consolidated basis because the cost of doing a clinical trial is going up since there is no other income generated in the subsidiary it will be less on a consolidated basis even though if we maintain it standalone as is consolidated will be less based on the amount spend that we have to do.

Rashmi Sancheti: So what kind of R&D we have spent on SUVN-502 and the new molecule that is 3031?

Venkat Jasti: **For G**3031 we are spending only about $1.5 million or so before the end of the year but SUVN-502 we will be spending about $6 million for this year.

Rashmi Sancheti: And how much have we spent in the first half?

Venkat Jasti: $4 million but total $10 million.

Rashmi Sancheti: So for 3031 you are saying it is $1.5 million. So that will come in the consolidated right, it is not included in the standalone?

Venkat Jasti: Right it is expensed out when it is spent.

Moderator: Thank you. We would take the next question from the line of Jay Modi from Emkay Investment. Please go ahead.

Jay Modi: This commercial revenue being zero is largely to do with the raw material short supply that we had, right?

Venkat Jasti: No, it has nothing to do with that. It is scheduling the order or deliveries which is in the third quarter and fourth quarter.

Jay Modi: But then since the molecules that we supply have already been commercialized for the last four years. Is it not that the revenue that we generate supposed to be a steady number?

Venkat Jasti: Nobody makes day in day out manufacturing. They will do it on a campaign basis. So you will make us deliver our request not on a monthly basis or not on yearly basis. Sometimes it may take 18 months campaign, sometimes may take a 12-month campaign or 24-month campaign depending on the nature of the product.

Jay Modi: Okay so on full year basis will our commercial launches generate revenue of Rs. 100 crore for us the same number that we had last year or it can still come down?

Venkat Jasti: No, I have not said. I said Rs. 60 crore to Rs. 70 crore. It may be that much or to Rs. 80 crore to Rs. 90 crore may be the maximum as of now.

Jay Modi: And our base CRAMS business on a full year basis would continue to grow at 15% for us?

Venkat Jasti: Yes, 10% to 15% on the base CRAMS..

Jay Modi: And specialty will be flat?

Venkat Jasti: That is flat, 5% this way or that way compared to the last year number.

Moderator: Thank you. The next question is from the line of Deepan Natha from Elixir Equity. Please go ahead.

Deepan Natha: In your news release you have said that updates on CRAM project total 116 CRAM projects are there. So how has that changed over the last quarter June 2018 and over September 2017?

Venkat Jasti: There are 5 new projects added and 4 have been gone. So there is a net addition of 1.

Deepan Natha: Is this Year-on-Year or Quarter-on-Quarter?

Venkat Jasti: Quarter-on-Quarter.

Deepan Natha: And what are the basic trends which are driving this CRAMS business I mean in terms of what are the kinds of scenarios where this business has a higher growth rate or the risk factors which result in this business having a slower growth rate?

Venkat Jasti: It is the status of the clinical trials and the success of the clinical trials that drives the growth of this CRAMS business, since we are in the innovation supply chain rather than the generic or the launched products. So that way whenever there is success when it most from stage to stage then you will get a new order. If it dies you lose the order. That is what it is. It is not about losing the order, you do not get an order [if the product has not moved from one phase to another phase]..

Deepan Natha: And in this quarter we have seen the services that is DDDSS that has shown good traction. What exactly is which activity which has formed part of this particular division and again what is driving that division to have reported better performance in the September quarter?

Venkat Jasti: This is on the services we provide to the innovators based on the efficacy data for their own molecules and it keeps moving up and down depending on the service which takes six months to do the then only give the report and then only it takes [the form as revenue]. Sometimes it can happen in three months so it is Year-on-Year basis and it will remain the same. But not much unlike the CRAMS business; the growth will not be that much [in this segment].

Deepan Natha: And just to reconfirm all the R&D expenses are being written off, right even for that new molecule everything is getting written off?

Venkat Jasti: Whatever we spend we write off.

Deepan Natha: There is no asset like intangible assets as far as R&D expenses are concerned?

Venkat Jasti: It has never been there.

Moderator: Thank you. The next question is from the line of Ranveer Singh from Systematix Shares. Please go ahead.

Ranveer Singh: I see that in this quarter because the commercial supply opportunity was not there so there is no question of the Chinese factor. But if and when that opportunity comes do you feel that the Chinese factor will impact our API side?

Venkat Jasti: It is not the commercial only that impacts what you call any export. It is also the other products which is whatever the manufacturer it has a raw material even Phase-3 molecules, in Phase-2 molecules there are materials.

Ranveer Singh: So my question is are we totally dependent on that or we have some internal sources or some other sources where we can de-risk this?

Venkat Jasti: I clearly mentioned before that there is no internal source available for some of those things and for us to develop those internal sources it takes time and and until that time there will be kind of a postponement that will happen and the customer knows about this ahead of time. If there is any possibility they will also help us to secure those raw materials. So this will be a two, three quarters like this will happen by that time we will have stability.

Ranveer Singh: So when we talk about normalization in subsequent quarters so what gives us confidence because Chinese situation remains there? So how would we able to make up the scenario we are currently facing?

Venkat Jasti: This is also like other people are trying to make these products. Some of the Indians have also started doing some of those raw materials and some of them we are also doing backward integration in a small way because it is not viable it is not cost effective. But why I said is this equalizes if you have three to four quarters with the same kind of run rate and this will continue.

There is no question of postponing anything because every day, time it is getting postponed so it becomes a norm and then it becomes a thing and half of it is we are getting a backward integration. So all those things gives us an indication that the levels of exports will remain constant.

Ranveer Singh: And just a clarity in core CRAMS what we capture is just a service revenue or some small quantity supplies are also like some gram or kilogram type of supplies which are also captured there?

Venkat Jasti: Everything is in manufactured based in core CRAMS which means services is the CTS revenue. That is the technical services. All the core CRAMS whatever we say it is a manufactured revenue.

Moderator: Thank you. The next question is from the line of Sachin Kasera from Lucky Investment. Please go ahead.

Sachin Kasera: Taro, what was the royalty income in FY18?

Venkat Jasti: Rs. 2.82 crore.

Sachin Kasera: And when you say Rs. 2.82 crore that was for the quarter or last year or for the full year last year?

Venkat Jasti: For six months first half. This quarter I said it is only Rs. 1 crore. Last quarter it was Rs. 1.82 crore.

Sachin Kasera: So it is like the same as last year flattish?

Sunder Venkatraman: It will be lower than last year. Last year it was about Rs. 10.86 crore for the whole year.

Venkat Jasti: This is only Rs. 2.82 crore right now. That is why I said around Rs. 6 crore to Rs. 7 crore maximum.

Sachin Kasera: Okay so first half to first half it is similar. Second half is when last year we had a higher income that will be much lower?

Venkat Jasti: Yes, that is right.

Sachin Kasera: Secondly, could you give us some update on the ANDAs or 505(b)(2) filings? what is the progress there?

Venkat Jasti: They are going as usual and the numbers are 2 for us and 2 for the customers who had done it and the others are in preparation and some more will happen before the end of the year. We expect three more to happen.

Sachin Kasera: Are there three more to happen in the second half?

Venkat Jasti: Yes.

Sachin Kasera: And all three would be our own or this will include some for customers also?

Venkat Jasti: Yes, it is a combination.

Sachin Kasera: And does that include any 505(b)(2) also these three?

Venkat Jasti: No 505(b)(2) at this time.

Sachin Kasera: And as of it is total first half you have filed anything sir?

Venkat Jasti: No, it is whatever we filed is what we have got the approval acceptance so that is why it is 2 plus 2.

Sachin Kasera: And sir, this cost on ANDA also do we take for the P&L or is that actually something we take through the balance sheet?

Venkat Jasti: No, I mean that is why I expensed it out as a regular thing. It is not in the regular R&D based. It is a commercial based.

Management: It is part of the raw material prices.

Venkat Jasti: Raw material; expensed out.

Sachin Kasera: That is not part of the R&D cost it is part of raw material and the normal staff cost?

Venkat Jasti: Yes.

Sachin Kasera: And sir lastly, what is the visibility on how much we are going to spent on the CAPEX this year and maybe in FY20?

Venkat Jasti: Out of the total of Rs. 270 crore ,Rs. 200 crore will be spent next 18 months.

Sachin Kasera: I missed that, can you explain that again?

Venkat Jasti: Rs. 270 crore is the planned CAPEX. That Rs. 70 crore is already spent and other things have been ordered but not money we spent but we will be spending another Rs. 200 crore within 18 months.

Sachin Kasera: So we can take FY2019 and FY2020 combined around Rs. 270 crore plus is that the better way?

Venkat Jasti: Yes.

Sachin Kasera: And sir, what will be the current utilization of the capacities what capacity we will be working at currently?

Venkat Jasti: 100%.

Moderator: Thank you. The next question is from the line of Jivan Pathava from Candyfloss Advisors. Please go ahead.

Jivan Pathava: Two questions. One is on your CAPEX side. So you said we will be spending Rs. 270 crore in all so what will be the kind of asset approximately what kind of asset turn we are expecting there?

What kind of asset turnover we are expecting on the Rs. 270 crore so how much of topline we can make out of the Rs. 270 crore approximate number?

Venkat Jasti: In our business model it never happens that way because these are the requirements we are foreseeing based on the customer feedback for the future and sometimes even they recover [shortly]. See one block is costing Rs. 120 crore that is the occupational exposure levels. That is the requirement coming for the new CRAMS projects. And there is no project as of today but it has to be constructed for us to achieve but we will be using this for other projects too. It will not be based on the amount of money we spend, you cannot guess estimate the value you generate.

Sometimes if you see in 2014 crore when we have spent only Rs. 30 crore for one block for one of the launched product. We recovered back within the same campaign. This Rs. 120 crore which we spent I can recover back within 18 months of time [if we get the order immediately]. And it can take two to three years sometimes. But I cannot extrapolate if it is Rs. 120 crore that I spend I get Rs. 150 crore turnover on that. It will not happen like that.

Jivan Pathava: And second question is on your so last quarter you said we got the USFDA permission for expanded access program for SUVN-502. Can you just share how many patients actually enrolled in that program till now?

Venkat Jasti: Yes, we have obtained permission for 50 patients. And so far 22 have enrolled.

Moderator: Thank you. The next question is from the line of Harisha Kakera from B&K Securities. Please go ahead.

Harisha Kakera: You were mentioning about the raw material shortages for the base CRAMS business. So am I getting it right that now we have procured the required raw materials?

Venkat Jasti: Within the next two quarters the orders what we have we have raw material sources secured.

Harisha Kakera: So ideally in the second half we would not face this issue is what?

Venkat Jasti: Yes, that is what I was telling you.

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

Shree Hari: My question is mainly pertaining to the research assets NCEs. Firstly if you could tell us what is the overall R&D budgeted for the all the assets during FY19 and FY20? And specifically, to 502; maybe you might have mentioned this earlier but you have been talking about the safety parameter so can you please highlight that aspect? And on 502 itself another question is if let us say you are not able to out-license it due to commercial terms are not really viable then what happens to 502?

Venkat Jasti: Let me go reverse to the last question first. It was discovered since 2003 (the last discovered product] in Alzheimers. [Since then no new drug on Alzheimers']. We are the one of the few that are left in the fray. If the data post the clinical trial [positive] there is no question of not getting and out-licensing deal done because the appetite is so much. So only thing is what happens is if the data is not what it is supposed to be like other molecules then it will go to the shelf. [Then] there is no monetization that will happen.

So it is a zero to one there is no in-between here. And there is another factor about not getting a good deal which is out of the question because the appetite is so much and the dearth of molecules since 15 years; so any positive data will give you certainly a deal. So that is the one question. With respect to the safety as you know in the Alzheimer's compounds or any CNS compounds which needs to take longer duration, the detrimental factor is mainly the safety first the efficacy is the secondary.

Most of the molecules die because of the safety aspect even though they are efficacious. In that case Suven is very well placed because we do not have any serious adverse event related to the drug during the clinical trial [so far] with three meetings that have taken place by the DSMB [Data Safety Monitoring Board, an independent committee setup to oversee the safety effects of the drug in human] there is nothing shown [safety concerns] and they have given a clearance to go ahead [and continue with the trial]. And that is why it is very well-established safety. Finally, where the spend is concerned I think Sunder will tell about the numbers on the R&D spent.

Venkatraman Sunder: **SUVN-**502, the total budget was $25 million of which we have spent about $17 million up to 30 September 2018 and then we are expecting at this point another $6 million during this year [say $5 million to $6 million during this year FY19] and there will be spill over of another $4 million to $5 million in FY20.. So we expect the total spend is likely to be around $27 million to $28 million with a cost overrun of $3 million on this project.

C Shree Hari: I wanted to know you have several molecules in various stages of trial. So all of them put together FY19 and FY20 what would be the research spend?

Venkatraman Sunder: As far as the clinical development program is concerned SUVN-502 is the only project that is running right now in Phase 2. SUVN-G3031 yet to start the Phase-2 clinical development program. That is what Mr. Jasti was telling us that once we get the budget, if we start actually we may spend about $1.5 million on that project for FY19. The budget what I was giving you on SUVN-502. Other projects are in early Phase and whatever the study is including pre-clinical studies we spent from the Indian budget for these projects.

This is what you would have seen actually for all our discovery [standalone financials]. We have spent about Rs. 28 crore up to 30 September 2018 now and it is likely to be about another Rs. 30 crore for about next six months. We expect around Rs. 60 crore approximately for this year total for all other projects which is expensed out in our standalone R&D budget.

C Shree Hari: So if I get it right then for FY20 as of now $4 million for 502 and $1.5 million for 3031 that is what have been budgeted for.

Venkatraman Sunder: That is correct.

C Shree Hari: Now one final question to Mr. Jasti. Do you have some kind of a flow for the outlicening and the milestone that we would expect?

Venkat Jasti: **At present our focus is to get data, if positive, it is good.** After that it is all the bargaining and we are not worried about that part now. Let us get the positive data that is what we are interested and focused on. And when that comes in automatically we can out-license; it is not a problem whatsoever.

C Shree Hari: Do you have a figure in mind like let us say below $25 million you would not be keen to out-license it?

Venkat Jasti: There is nothing like that. It depends on the nature and the time because next line we need to have a marketing based approach also. So we will be out-licensing. We cannot give a figure right now. The figure you are quoting is nowhere to be seen we are spending more than that. How can you see that kind of figure?

Moderator: Thank you. The next question is from the line of Devesh Vakharia, individual investor. Please go ahead.

Devesh Vakharia: The various products patents that we are securing from various countries does it form a part of the core CRAMS or is it something separate from that?

Venkat Jasti: It has nothing to do with the core CRAMS. It is all innovation and discovery. That is all the 22 [corrected to 38] innovations we have in place and various countries we have and as of now as you know there is no value for it in this country there is no value for any patents until the product is marketed then you get the exclusivity based on that.

Devesh Vakharia: So when do you expect them to start getting monetized?

Venkat Jasti: Only when the clinical trials are successful and if there are monetizing opportunities if everything goes well it will happen in the third quarter of next year.

Moderator: Thank you. The next question is from the line of Ashish Rathi from Lucky Investment. Please go ahead.

Ashish Rathi: Just wanted to check on the SUVN-502 the trial itself. I believe last time you mentioned that the side effect if it happens it is informed within 24 hours and the CRO will be informed. So I believe this whole how has it gone how much what is your reading on the side effects and how is the people basically what is the perception on it after the whole thing?

Venkat Jasti: Yes, I do not know where that 24 hour thing has come up but actually I was mentioning earlier the safest molecule ever tried so far in terms of the dose versus the maximum it can absorb and as I was talking about the safety is very, very well established because all the the side effects that have happened is due to other drugs or other indications they have but not due to the drug which we had given which is corroborated by the drug safety monitoring board which has the authority to stop the trial also based on the outcome.

And three times they met during the trial and they said it is very clear and they have no questions and they have given go ahead to run [continue] the trial. So the safety is very well established. That is what the main crux of the information is [that we were talking about].

Ashish Rathi: And like you said safety is the key parameter for reduction and other in efficacy?

Venkat Jasti: For the approval process by the FDA even though if it is efficacious if the safety is not there they will not approve. When the safety is there if it is half way decent molecule they may approve.

Ashish Rathi: And what I understood from your commentary is that the safety has been quite positively established during our trials for our products?

Venkat Jasti: We are waiting for the efficacy.

Ashish Rathi: Yes, it is efficacious or not will come to know?

Venkat Jasti: The efficacy only; what is the use. So it has to be safe but efficacious. But safety is important.

Ashish Rathi: Does USFDA taken into account that this whole EAP and 22 patients being enrolled for that out of 50 and the maximum. So can we say that these 20 are at least finding it efficacious that is why they are using it further?

Venkat Jasti: Say it again?

Ashish Rathi: This extended access program?

Venkat Jasti: Extended access program only activated six months ago. Not even six months, less than that. Till that time because already people who have gone out of the trial up to two years back and one year back they did not come back. The people who just stop the medication I mean finished their clinical trial they are the ones who ask for it. And before that it was not there. Since the efficacy is very well-established FDA has given us go ahead and accepted the expanded access program.

Since it is done within the last 5 to 6 months so they have taken 22 people who have finished the trial has gone into that. And we expect the other, 28 people into this when they finish the trial. I think the requests are many but they have to finish the trial before they access what you call the expanded access program.

Ashish Rathi: So like as of now for the safety your confidence appears to be decent because we have not seen any major safety issues but efficacy you are not absolutely sure as to what the outcome could be because you do not have anything in terms of a further lead to understand the efficacy of the product?

Venkat Jasti: Yes, it will be known only I mean in July timeframe.

Ashish Rathi: Any update on iron sucrose?

Venkat Jasti: No, no update on that. It is still going on.

Moderator: Thank you. The next question is from the line of Ritesh Bagwati from Rockstud Capital. Please go ahead.

Ritesh Bagwati: Sir, my question is pertaining to our blockbuster drug 502. Being a devil's advocate out here like God forbid if you fail to provide a positive efficacy data what happens to us like do, we have a plan B? I hope it does not happen but what is though the preliminary data so far has been positive one. That is my first question.

Venkat Jasti: What happens if it is not positive, it goes to the shelf. That means whatever money we had spent has not given us any revenue. If it is positive then we will have a number of players to work with to monetize it. And that depending on the day when we get the positive results if there is no competing molecule; this in a symptomatic treatment.

If something like a disease modifying drug the results comes in the same timeframe then the valuation will come down. But that will be known only later. So right now we have no idea what will happen. But it will be certainly monetized if the data is positive.

Ritesh Bagwati: But then does it not affect our core CRAMS business?

Venkat Jasti: Yes, naturally. [CRAMS has no connection with the outcome of this trial]

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

Cindrella Carvalho: I wanted to understand what you mentioned about the raw material scenario. We have secured this for the coming two quarters but how is this scenario presently for the industry and what is your reading about it and what might like you highlighted that in the next year or may be early next year you might face some issue. So what are our provisions? I understand we said that we are not going there is no internal or local source for it so I am sure we must be evaluating some other plans. So could you elaborate on all these points?

Venkat Jasti: Yes, I mean in general affecting not only Suven but all the industry and luckily for us being in the high value addition gain the increase in the cost also it is affecting us little bit but not that much compared to the generic players and where it is affecting real bad. And with respect to the next two quarters yes, we have as per the orders we have on hand we have the raw material secured.

Why I said that it may happen for the next year because some of the orders we have on hand when we asked for quoting the raw material sourcing only partially we could be able to secure and suddenly couple of players various other raw materials they got shut down. Now we are searching and checking for the other sources and also trying to do some kind of internal backward integration.

Not all of them are possible to do internal backward integration and we are also seeing how other players now slowly Indian players also started going into this direction. Hopefully within a year there will be some capacity building which will happen to develop these raw materials in India also. So this will be I think three to four quarters from now. There may be stabilization because some of the good companies in China are taking up the flag. Similarly, some Indian companies are taking up the flag.

It takes a year or year-and-a-half before you see any output coming in. Similarly we are there also because with R&D based additional quantity. So we are trying to develop backward integration. Bigger quantities we may not do it but smaller quantity we may be able to do it even though it is not cost effective but for the sake of supply chain security.

Cindrella Carvalho: And that internal development that we would be doing what you have highlighted so this may not be cost effective but you will be able to pass it on because you are doing it only for the supply continuity. Is that a correct understanding?

Venkat Jasti: Yes.

Cindrella Carvalho: And sir, if we come to the specialty chemical side of it I understand we have earlier said that we have some pipeline which we are working on. So would you be able to help us with what is the present status where are we which how many projects do we have as of now and in terms of where do we see them?

Venkat Jasti: I think last quarter also I said the opportunity to have in monetization of supplies will start sometimes in FY2020 for the new molecules under development. Three of them are there as of now.

Cindrella Carvalho: And even on the ANDA side we said that we have three more which we would?

Venkat Jasti: Four will come within the next six months.

Cindrella Carvalho: So that also we would be able to see in FY20?

Venkat Jasti: I think it takes time. One year or something like that before you can settle.

Cindrella Carvalho: And sir, coming to the SUVN-502 as I understand we have closed the trials.

Venkat Jasti: Not the trials, we have closed the enrolment.

Cindrella Carvalho: Yeah, I am sorry we have closed the enrolment, the recruitment is over and we are awaiting the data and there are lot of doubts about what happens but in terms of if you could help us understand how this molecule has been compared to the other drugs which were there or are still running. What is your understanding so far?

Venkat Jasti: See we were saying this for the last four years based on our pre-clinical data our molecule is much superior and it has much delta safety margins that means you need to take a 50 milligram even if you take 600 milligram there is no CNS side effect which is now proven after taking the drug safety monitoring board has reviewed the data for 380 patients or so something like that.

Whatever the safety deviations that have happened I mean adverse events that have happened have nothing to do with our drug. So it is highly safe. If you say how do you compare with the other molecules, if you see the competitor molecule they have 10% of the improved liver function abnormality which is the reason why

they have to cut down the dose. When they cut down the dose the efficacy has gone down.

So that kind of thing has happened. Our second thing that you need to understand is all other molecules have a liability at some other drug in relation to the main target 5HT6 antagonist whereas Suven molecule is 5HT6 antagonist. Based on all these things we are very well positioned if the data is positive have a molecule from this segment to go to the market. This is the only thing that will be left.

Moderator: Thank you. The next question is from the line of Deepan Natha from Elixir Equity. Please go ahead.

Deepan Natha: My question is regarding the Forex rate. So whenever the rupee depreciates as it had in the last quarter do you get the benefit of the rupee depreciation or you are expected it to pass on the benefit to your customers?

Venkat Jasti: Couple of customers who we will share 50:50 and some we get benefit. But at the same time we also when we are spending money we also spend now with dollars. We have some positive benefit out of the depreciation certainly.

Deepan Natha: And could you please tell us a little bit more about the two 505(b)(2) and the two ANDAs which you have filed which you expect commercial production in Fiscal 19-20 as to which are kind of specific segments that they are targeted at and what is so special about that ?

Venkat Jasti: See our molecules have nothing to do with any specific segment. It is the regular generic products which have gone in to and we do not take those blockbusters. These are all small value niche products not many people have come. Those are the things which we try to do. And some of these things will be I mean these will be sometime in end of 2019 we should start selling after the approval from FDA.

Deepan Natha: But is it going to be a major revenue earner for the company?

Venkat Jasti: I clearly mentioned maybe you may not have heard not this time but last time it will be $2 million to $3 million per ANDA net, that will be maximum.

Moderator: Thank you. The next question is from the line of Darshit Shah from Nirvana Capital. Please go ahead.

Darshit Shah: My question again pertains to SUVN-502. Sir, when we read in the past that there are lot of other companies who did clinical trials and to give this same info. Since you are tracking these players closely can you just highlight what was the reasons for all those company's drugs being rejected in the past? If you could throw some light on that.

Venkat Jasti: Okay what made us think that this will work because we do not know we thought it will work and as of now we do not know the efficacy data. As far as the safety is concerned it is very well established and with respect to the other drugs the main problem is even though they are efficacious because safety margins they could not get an approval.

And the safety is cured and we are waiting for the efficacy data and based on our pre-clinical trials we are confident that the efficacy data will also be good. But only time will tell I mean this is the highest attrition area where we are working and there is no drug discovered in this field since 2003. And we hope we may be the first one

to get into the market on this but it is the kind of target as we have based on the pre-clinical and the clinical safety margins.

Darshit Shah: Has anyone else been given the expanded access program in the recent times if you could recall?

Venkat Jasti: I do not think they have asked for it because expanded access program happens to many other drugs but in the 5HT6 antagonist nobody else has done it as far as I know at the Phase-2 level especially. Usually at the Phase-2 level it had never happened.

Darshit Shah: First time it has has happened in the same antagonist?

Venkat Jasti: Yes. So I have no knowledge for the drugs being given as an expanded access program.

Darshit Shah: Can you highlight how many drug in the similar space are going to complete Phase-2 trials next year?

Venkat Jasti: There are hundred trials going on and various indications and various stages and various types like symptomatic to disease modifying and various theories also being worked out. So we do not know how many will come out. But as far as 5HT6 is concerned we are only two or three left and one is Lundbeck which is still continuing the second study after taking the first study at the Phase-3 level. Next we are one in the line.

Moderator: Thank you. The next question is from the line of Gagan Thareja from Kotak Investment. Please go ahead.

Gagan Thareja: Couple of questions. First question, on your core CRAMS business if you could just sort give us some idea about your own appraisal roughly of the drug pipeline those innovative companies and consequently the impact it could have on the core CRAMS business for you? I mean just want to get an industry view first and to be able to then see for first Suven also whether with the current pipeline that the innovator companies have you see this business growing for you as an industry or it looks like it is a stable state business?

Venkat Jasti: It is in a growing Phase-right now in the sense but it all depends on the success of the molecules and the clinical trial also. In general if you compare with the five, six years ago the number of molecules that are in development is less but at the same time you need to take the cognizance that the molecules that are working now. See before they used to work two or three different molecules for same indication and after Phase-1 they may prioritize only one out of the three. After Phase-2 also they may prioritize one out of the three and some they kept on hold for backups.

But now what they are doing they cut down the number and focusing only one molecule and seeing even though I mean if it is passing stage-to-stage they are not stopping unlike before. So that means the continuation is happening. The traction is much better now and the second aspect of it is now they are cutting down number of players they are working with. They are working with those players who have the capabilities, the capacities and the commitments and long term relationships they have.

And also they are expanding rather than doing a part of the activities they are slowly expanding to multi activity kind of a thing. So in that process the number is going down and the players who are in the fields are getting a better out of it and of

course at the same time even though an opportunities in a continuous basis the continuation of the trial that means success of the clinical trial will drive us the growth. So it is a chicken or egg kind of a situation. But in general terms as you are asking it is in a positive way. It is in growth phase.

Gagan Thareja: So if I were to extend this logically to your specific case what it means is that the pipeline in Phase-1 may or not grow stupendously but you could have more transitions from one to two and from two to three. Is that correct?

Venkat Jasti: As of now one to two. But slowly they will turn into two to three.

Gagan Thareja: And the second question pertains to your SUVN-502 molecule. Recently in October there were studies from Kings College, London reported in translational psychiatry and nature which sort of indicated a new mechanism or rather which basically indicates that drugs targeting beta amyloid formation in the brain for Alzheimer's might not be the correct route simply because there is a feedback loop every time more **flakes** are destroyed by beta amyloid the production of beta amyloid seems to go up and they seem to indicate that an existing drug called Fasudil which targets the BKK1 protein is actually more efficacious in at least animal models of clinical trials that have been conducted.

Obviously you would have accessed the study. So I just wanted your opinion on what you think possibly an existing drug for other indications and all it requires is trials for indications on Alzheimer's. Do you see this has another promising sort of a molecule for Alzheimer's treatment?

Venkat Jasti: As you know everything looks rosy in the beginning. I said the same thing and the other people were saying the same thing. But the molecules that failed again being tested in a different hypothesis and for a different indication in the Alzheimer's itself. This is the second thing. This is modifying it what we are talking about the amyloid thing and all those stuff. That means curing and I can tell you honestly, they spent about $15 billion it in the last five years on that and everybody failed.

Only thing that is left out is the Biogen molecule. And how the yo-yo kind of thing has happened with the stock prices when they said yes and when they saw the data later and with a different kind of a series and they came down also. And that is the only thing left. Everybody has a theory and there are a hundreds of theories. The only thing that has worked so far not for long time though it is two to three years or three to four years maximum that is the quality for slight improvement.

That is the Donepezil, the Memantine, and all that stuff. That is symptomatic treatment. That is where we are in the game. Our molecule is a symptomatic treatment. So symptomatic treatments are the fastest if at all if the safety is established to go to the market and disease modifying is a decade away to start with. But I can tell you one more thing since there is no drug that is being discovered since 2003 and people are frustrated using a two of the known molecules, the existing molecules to get some results and since we are doing the clinical trial we get only those patients who are taking two drugs on top of that we have to put our drug and which is a challenging thing too.

But challenging both two ways. One is a safety aspect, that is the drug interaction that is taken care by our drug so far. No drug interaction and the safety is very well established as I was telling you earlier. But the efficacy we need to see. So disease modifying may be way long but symptomatic there are few molecules that can come in to within the next two to three years or four years.

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

Afzal Mohammad: Since you have completed the patient requirement for 502 and you said that you will be reporting the topline results by July-August. So what factors can delay this timeline?

Venkat Jasti: As far as the last patient going up the trial by May 23 is not going to be delayed. Either it is going to be delayed and the patient can be discontinued may be but not delaying that is our deadline anyway. From that time if the data cleaning and data lock will happen there can be maximum a month delay and the statistical analysis and all those stuff. Other than that certainly August we should have it as of now. I think we are 95% confident the data will come out. I mean how the data will look like we do not know but the data will come out sometime in August 2019.

Afzal Mohammad: Okay not in year end of 2019 calendar year?

Venkat Jasti: That is too far away.

Afzal Mohammad: So you are bidding based on the safety of 502 but how would you differentiate between safety of 502 and safety of the competitor molecule?

Venkat Jasti: Much better and as I said ours is a pure molecule and compared to the competitor molecule has a liability 5HT2A instead of 5HT6 also and also they have the liver function abnormality in more than 10% of the patients in Phase-2 and hence they have to reduce the dose in to Phase-3 which in turn has caused the non-efficacy. So whereas that way our safety there is no liver function abnormality to have a meaningful statistically significant and as I said no serious adverse event related of the drug. So that way it is highly differentiated.

Afzal Mohammad: So is there any tradeoff between safety and efficacy for 502 as opposed to competitor molecule?

Venkat Jasti: No, there is no trade off.

Afzal Mohammad: What indication do you think 502 will be more applicable to the entire dementia spectrum or particularly Alzheimer's?

Venkat Jasti: It is only meant or moderate Alzheimer's disease as of today.

Afzal Mohammad: But in case the efficacy data is positive would you be willing to expand?

Venkat Jasti: No, that will happen in Phase-3 depending on the innovator that comes in and collaborates with us. We can go in to various other things also.

Afzal Mohammad: Okay there is a clinical trial data that tells you something about whether you can expand this to other dementia spectrum?

Venkat Jasti: Yes, we know that it can be expanded because I cannot do so many clinical trials in one go being a small player. So we have to do what is the best indication that suits the best based on the available patient full and that is what happened. It is the moderate because people are already taking two drugs that means they are not in the mild category. They are already moderate. So the medication we are giving is only for the inclusion exclusion criteria when we are doing the recruitment takes this in to account it is only for moderate Alzheimer's patients; period.

Afzal Mohammad: So is there any addressable market size dollars you have in mind ballpark?

Venkat Jasti: If you go by the old data it has gone up to $5 billion per year maximum. But now with the heavy drugs have been there that time two or three drugs were there and it can go much higher. But by the time you may get some other disease modifying breakthroughs also we do not know. But anything can happen.

Afzal Mohammad: Okay it is quite a large range.

Moderator: Thank you. The next question is from the line of Ashish Kacholia from Lucky Investment. Please go ahead.

Ashish Kacholia: Sir, you have presented that some your clinical trial data and information that some recent clinical conferences and if yes, if you can just share what was the line of questioning from the medical professionals there?

Venkat Jasti: The only question is when the data comes out. Everybody is happy and we have presented the clinical trials on Alzheimer's disease and they are all asking when the data will come out.

Moderator: Thank you. The next question is from the line of Ranveer Singh from Systematix Shares. Please go ahead.

Ranveer Singh: My question related to another molecule which is 3031. Like on the SUVN-502 earlier we have to raise some fund to meet the expenses for entire Phase-2. So do you feel for this molecule also you need to raise some funds or we have enough resource right now?

Venkat Jasti: We do not need to raise any money for these innovative molecules until FY2020.

Ranveer Singh: Okay so even if the fund we raise for SUVN-502 that fund also can be used for any other molecule moving to Phase-2 that?

Venkat Jasti: They can and also the generation that is happening will fund all these activities until FY2020.

Moderator: Thank you. The next question is from the line of Ashish Rathi from Lucky Investment. Please go ahead.

Ashish Rathi: I wanted to understand from a layman perspective like you have already said safety profile is largely you are confident on this SUVN-502. My question is basically in layman term because this is a triple combination and we have already the two drugs which are applicable in the market today helping our cause of getting the efficacy.

So how the triple combination efficacy versus the double already been present there for the patient is being measured? Like is it required to be even a bit better and then we are granted the Phase-2 clearance or is there are measurement for it like it has to improve it by 100% for the safety versus efficacy reward to come in our favor? If you could just help us understanding this?

Venkat Jasti: Yeah, see we are taking patients in the moderate Alzheimer's disease. They are taking already two medications as you correctly mentioned. The measurement they call is ADAS-cog. There is a measurement. Day one there is a measurement say x number and what happens is when the trial is finished plus 2 has to happen the numbers. If that is not happened it is not efficacious. If plus 2 happens on the

existing day one with the medications they are on then it is a positive result. That is the way it works out.

Ashish Rathi: Could you repeat that, sir? What is the parameter sorry I did not get that?

Venkat Jasti: ADAS-cog.

Venkatraman Sunder: It is ADAS-cog 11 and suppose if the existing score is say about X it is expected that actually at the end of the trial actually to have an efficacy, at least for us to take the 2 point difference. And these patients are already on the medications of Donepezil and Memantine. So they are going to stabilized on those patients only we take it. So this is supposed to show an incremental efficacy at least 2 points. Then it is called efficacious.

Venkat Jasti: Yesterday's data when your inclusion taken place with day one's ADAS-cog number on that it has to be plus points after the dosing is over six months.

Ashish Rathi: And this ADAS-cog number for every patient is different on the day one?

Venkat Jasti: Yes. This is taken day one.

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

C Shree Hari: I mean if you say that the safety has been established is it possible that if let us say the drug is not as efficacious let us say below a certain limit then can the trials be stopped based on that? And secondly, if 502 get licensed out next year you will have a significant cash at your disposal. So have you firmed up any plans for how you are planning to deploy that?

Venkat Jasti: Yes, buy a lottery ticket and expecting that I will get a $10 million and do you plan anything? I mean there is nothing like a guarantee here. It is a zero to one game. We do not know the efficacy yet. How can you plan your expected money to spend? I mean when you get the money our plans will be formed within a day because we have so many things in place.

Nothing like a planning from meetings which we do not know. It is an unknown at this time and nobody can guarantee it and we have been saying it is a zero to one game and will remain same until August of next year then we can say yes, gone are alive.

C Shree Hari: Yes my second question was pertaining to efficacy.

Venkat Jasti: Okay let me tell you they would not stop the trail based on the efficacy base alone. Mainly they will stop the study if it is having a lot of side effects.

Venkatraman Sunder: Because they will not be studying the efficacy, being a blinded study.

Venkat Jasti: Yeah, this is a blinded study, nobody studies the efficacy part of it. It is only side effect, it should not affect unnecessarily the people complications which they do not have before when they have not taken their medications. So that way they do not start the study.

C Shree Hari: So basically the point I am getting to is that efficacy data is not available with anyone at this point of time?

Venkat Jasti: Correct nobody.

Moderator: Thank you. The next question is from the line of Devesh Vakharia, individual investor. Please go ahead.

Devesh Vakharia: With regard to Suven 502 if it is efficacious sir, is there any ballpark figure that you have in mind for the deal to monetize it I mean can you give some ballpark figure as to what is the monetary value if it is efficacious?

Venkat Jasti: I cannot guess estimate the numbers because it keep changing depending on the availability of other molecules and time on non-availability. But if you can go back and look into the data of it will like at the stage of Phase-2 they received upfront payment of $150 million with milestones of $850 million.

Devesh Vakharia: Sorry the second part was the upfront payment of $150 million and the next part?

Venkat Jasti: Milestones because then they have to do the milestones before the launch.

Devesh Vakharia: Can you repeat that amount?

Venkat Jasti: $850 million.

Venkatraman Sunder: That may be available on the web. This is about Lundbeck Otsuka deal they are available on the web. We may not have exact figures.

Moderator: Thank you. Ladies and gentlemen, this seems to be the last question for today. I would now like to hand the conference over to the management for their closing comments.

Venkat Jasti: Thank you everyone who has tuned in for the updates on our performance. As far as the CRAM side of the revenue generating is concerned this is the worst quarter ever during these last four years. Obvious reasons but we hope to fill the gap before the end of the year to have the same numbers as last year. And with respect to the innovation we are very happy that we are getting to the end of the trial within the next six months and the data within the next nine months' time frame.

And the second molecule by the time the data of the second molecule also will be in Phase-2 for the efficacy data and sleepiness and the other molecules are progressing in to Phase-2 release date. And hope to I mean qualitatively we are doing very good in innovation. Only time will tell whether the proof of the pudding is there or not. Safety is very well established for this lead molecule and we are waiting for the data. And I hope things will turn out to positive for us. And again thanks for tuning in and hope to talk to you three months later.

Moderator: Thank you very much. Ladies and gentlemen, on behalf of Suven Life Sciences we conclude today's conference. Thank you all for joining us. You may disconnect your lines now.

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