



“Natco Pharma Limited Q1 FY2017 Earnings  
Conference Call”

**August 10, 2016**



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LTD**



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**Moderator:** Ladies and gentlemen good day and welcome to the Natco Pharma Limited's Q1 FY2017 Earnings Conference Call hosted by Edelweiss Securities Limited. As a reminder, all participant line will be in 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 '\*' and then '0' on your touchtone phone. Please note, this conference is being recorded. I now hand the conference over to Mr. Deepak Malik from Edelweiss Securities Limited. Thank you and over to you sir.

**Deepak Malik:** Thank you and good morning everyone. On behalf of Edelweiss I welcome you all for Natco Pharma's 1<sup>st</sup> quarter FY2017 conference call. Today we have with us the senior management of the company represented by Mr. Rajeev Nannapaneni - Vice Chairman and CEO and Mr. Rajesh Chebiyam- Vice President (Business Development & Corporate Affairs). I would like to handover the conference to Mr. Rajesh for the opening remarks, over to you Rajesh.

**Rajesh Chebiyam:** Thank you Deepak, good morning everyone. Welcome to Natco's Conference Call, discussing our Earnings Results for the 1<sup>st</sup> quarter FY2017 which ended June 30<sup>th</sup> 2016. As Deepak just mentioned joining me in today's call is Mr. Rajeev Nannapaneni, Vice Chairman and CEO of Natco Pharma Ltd. Just as a standard disclaimer before discussing our results, we would like to state that we may be making certain forward looking statements during the call, because forward looking statements inherently involve risks and uncertainties actual future results may differ materially from those expressed or implied by such forward looking statements. Let me also state that the material in the call with the exception of participant questions is the property of Natco and cannot be recorded or rebroadcast without Natco's expressed written permission.

Coming to the earnings detail, the company is pleased with these results for the quarter and is in line with our forecast. The company recorded consolidated net operating revenues of 325 crores for the quarter which ended June 30<sup>th</sup>, 2016 as against 223.7 crores during the same quarter last year reflecting an increase of about 45%. The net profit for the period after tax and minority interest on a consolidated basis was 47.6 crores as against 28 crores same quarter last year showing a growth of 70 %. The growth for the company was predominately driven by increase sales of its formulation business. I would like to just take you briefly through the segmental breakdown broadly. The API business recorded 40 crores, domestic did 8 crores and exports 32 crores. On the formulation side for the quarter we did 228 crores total, Oncology recorded 73, brand pharma did 134 crores, the third party did 21 crores, Exports including the profit share we did 51 crores. So if we look at Oncology we had compared to the Q1 of last year we recorded 17 % growth. Branded pharma, obviously we had a very low base during Q1 of last year so it exceeded 300 % growth. Exports also showed a growth of roughly about 30 %. Specifically, on Hepatitis C our brands, domestic for the quarter did 131 crores; third party did 13.6 crores and exports 3.6 crores. We are giving you a broad basis without getting into the specific details of the product but this is how the Hepatitis C franchise did for us. I will pause here now I think we will take questions.



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**Moderator:** Thank you very much sir. Ladies and gentleman, we will now begin the question and answer session. We have a first question from the line of Mitul Mehta from Lucky Investment Managers. Please go ahead.

**Mitul Mehta:** Just wanted to gauge some visibility on your US business in the second half, so my question would be one is on Copaxone, I was just going through the transcripts of Mylan which clearly mentioned that there was some query which came in and that was again fully answered So just wanted to understand that when did this query came and what was the nature of the query?

Second is, we recently got Tamiflu approval, so just wanted to understand when does the dispatches for Tamiflu start and I know you would not be able to share the agreement with Gilead but if we can get some color on that and my third question is on the Entocort, what we understand is that there are some issues on the API from whom we would be sourcing, so what is the current status on that, has there been any query on that and whether the facility has got cleared or you can just show highlight on this?

**Rajeev Nannapaneni:** Okay sure. Let me answer backward, I will start with Entocort. Entocort there are no formulation queries pending there was a API query that was pending we have answered the query already. So based on correspondence with the FDA, I think we understand that we will approval in second half of the year, in the second financial half of the year. I think that is our estimation. There are no regulatory issues in the API plant that we are aware of. Not that I am aware of.

Second question was on Tamiflu; as I said Tamiflu settlement agreement allowed us to launching before February 2017. The exact launch date we are bound by confidentiality so unfortunately I am not able to disclose what day but definitely we will see it in this financial year, I am unable to answer because of confidentiality.

And the third question you asked about the Copaxone, we have time and again received minor queries and I think we have answered all of them and we just waiting for approval and I think we go back to the early guidance that we have given. I think we are confident we will get the approval in this financial year.

**Moderator:** Thank you Mr. Mehta. We have a next question from the line of Afzal Ahamad from Karvy Stock Broking. Please go ahead.

**Afzal Ahamad:** Regarding Tamiflu in terms of inventorial levels how big is the stock pile of generic Tamiflu to enable you to supply in event of a flu outbreak in the US ?

**Rajeev Nannapaneni:** We have done everything which allows us to take care of the demand of the flu in the US and the launch will be as per the settlement agreement that we have with Roche and Gilead, so we are ready. I think short answer to it.



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- Afzal Ahamad:** Stock file is big enough to even in Flu outbreak case like, it happened in 2009?
- Rajeev Nannapaneni:** I have answered it, we are ready. We got again, I am sorry Afzal, we are being little opaque in the answer but the problem is that we are bound by confidentialities. I am only allowed to speak to a particular script that is why, we are ready and we can handle whatever demand and I keep saying the same line again that again we will be allowed to launch before the February 2017.
- Afza lAhamad** Alright, who do you think is closest to approval Cipla or SeQuent because both of them have a very old DMF?
- Rajeev Nannapaneni:** I am not aware of their approvals but presumably i think definitely post February there will see a lot of generic approvals. That is what I would estimate.
- Afzal Ahamad:** Okay and sir can you give me the spilt of Hep C portfolio, this quarter sales?
- Rajeev Nannapaneni:** I think Rajesh did it few minutes ago but just reiterate it again, Rajesh can you just say?
- Rajesh Chebiyam:** Yes, so we are giving the broad, so we are not giving the breakdown of individuals but domestic is 131 crores, I just mentioned third party 13.6 crores and exports is 3.6 crores.
- Afzal Ahamad:** So there is a dip in the third parties' sales from 33 to 13.6 crores, so what exactly led to that?
- Rajesh Chebiyam:** They are decided to do their own product. Earlier last year same time I think Mylan and Cadila where buying from us; there are not buying any more. It is not a huge loss but say because the margin was low anyway in that business; it is only a revenue drop; it is not a margin drop.
- Afzal Ahamad:** But the branded products is compensating for that for fall?
- Rajeev Nannapaneni:** I think what we look at is our own brand that does I think that is where the real money is so as long as it does well I am not too worried about the third party dropping out of it.
- Rajesh Chebiyam:** It also in line with what we had indicated in the prior calls also, we said the shift to more on the brand. Third party is more of a short term opportunity because they do not have the manufacturing license and the need somewhat so. Eventually everybody wants to make it themselves for the August season.
- Afzal Ahamad:** Alright and how much products have we launched in Canada?
- Rajeev Nannapaneni:** I think total 8 products we have launched in Canada.
- Afzal Ahamad:** How many additional you planned to launch in FY2017 in Canada?



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- Rajeev Nannapaneni:** Another 5 launches I think we are looking at.
- Afzal Ahamad:** Do you expect the Canadian subsidiary to become profitable in FY2017?
- Rajeev Nannapaneni:** Yes, I think the 1<sup>st</sup> quarter there was a small loss, but I think by the end of the year we should be able to breakeven and actually make some profits, so the whole year we are expecting to be positive.
- Afzal Ahamad:** Okay and how about the Australian subsidiary?
- Rajeev Nannapaneni:** Australian subsidiary just started recently. So we booked a loss this quarter of 1 crores I think if I remember right and it will take probably a year for it to breakeven and Brazil will continue to lose money even this year. We are hoping that we will make money in 2018 March, that is all our expectation.
- Afzal Ahamad:** You mean the API sales there?
- Rajeev Nannapaneni:** Not API, we have sub and API, so I am talking about the sub.
- AfzalAhamad:** And you expect any uptick in API sales in Brazil?
- Rajesh Chebiyam:** RoW has been a little weak because of the oil crisis and all and the commodity burst as you are aware so the uptake of RoW has been a little weak, I think that has impacted our API sales as you can see.
- Afzal Ahamad:** Okay just one last question sir. When you expect to launch Imatinib and Bendamustine in Europe?
- Rajeev Nannapaneni:** I think both are in this financial year in Europe.
- Moderator:** Thank you Sir. We have a next question from the line of Urvi Shah from Sharekhan. Please go ahead
- Urvi Shah:** I had a question regarding the other expenses, it is almost double. So if you could just explain what is the reason behind it?
- Rajeev Nannapaneni:** Sure definitely, what is happened is that, you have seen in our balance sheet Hep C sale has become nearly 45% of our sales as you can see right and what we have is we have a profit share arrangement with Laurus and a royalty payment to Gilead and both these expenses together I think came to about 33-34 crores this quarter. That is pretty much explains the other expenditure so I think we paid 26-27 crores to Laurus and I think 6-7 crores to Gilead, so I think that is pretty much the bulk of the expenditure.



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- Urvi Shah:** Right sir, so do we see this going ahead as well or was it one of kind of situation?
- Rajeev Nannapaneni:** No, it is not a one off.
- Urvi Shah:** It is ongoing?
- Rajeev Nannapaneni:** It is all linked with this sale. This is a sale we are going to maintained that is what why we have to pay that.
- Urvi Shah:** Exactly and sir, the raw material cost as a percentage of sales it is 28.5% this quarter versus 31 in the last quarter. So if you could, so basically the gross margins are improving because of the better product mix, so do we see this sustaining going forward as well?
- Rajeev Nannapaneni:** I think it will be maintained. But again raw material is not a true indication, so we need to include the profit share also that is indirectly capturing it, so...?
- Urvi Shah:** Because I assume that the next quarters obviously because we are having a generic Tamiflu launch, so the margins obviously are going to picked up. So that will be a 6 months exclusivity but apart from that also the base business margins is what we are expecting to be around 24%?
- Rajeev Nannapaneni:** It will get better but the how much money will be made will be depended on the market place right now, so it is hard to judge. I just want to correct you, we do not have 6 months' exclusivity, I think what we have is a launch date prior to the patent expiry. It is not 6-month exclusivity. Just wanted to correct it.
- Urvi Shah:** Okay, so we cannot timeline, I mean you would be guiding us on around timeline launch?
- Rajeev Nannapaneni:** What I am guiding you is saying that it is before the patent expiry and it is during the flu season. That is what we are saying, beyond that I don't want to say.
- Urvi Shah:** Right Sir.
- Rajeev Nannapaneni:** I actually want to correct you. I know there is some reports like that but I just want to correct you. Okay.
- Moderator:** Thank you Ms. Shah. We have a next question from the line of Nimesh Mehta from Research Delta Advisors. Please go ahead
- Nimesh Mehta:** Yes thanks for taking my question. First question if you can just bring down the other operating income which was fairly higher as compared to Q4?
- Rajeev Nannapaneni:** See of the other operating income 12 crores, 12.5 crores came from profit share and 1 crores and 43 lakhs came from third party job work, 2 crores twenty came as export incentives and



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10.89 lakhs came as raw material sales of a particular API which was shown as other income because it was made of a third party site.

**Nimesh Mehta:** Okay that so that last one 10.89 is that recurring, what is that nature of?

**Rajeev Nannapaneni:** It is a particular product that was sold to a particular customer which is manufactured at third party site.

**Nimesh Mehta:** Okay will that continue, going forward?

**Rajeev Nannapaneni:** No I cannot predict as per this is what happened this quarter

**Nimesh Mehta:** Okay and this profit share of 12.5 is largely from the US sale?

**Rajeev Nannapaneni:** We had some one time booking of profit because there was couple of failure to supply by couple of our comparatives, so that is why it was little on the higher side.

**Nimesh Mehta:** Okay, so what is the normalized number that we should look at on other operating?

**Rajeev Nannapaneni:** Usually 1 million typically a quarter but this time it came 2 million so it was double the normal number.

**Nimesh Mehta:** Okay great. The second thing I just wanted to know why do you feel that Tamiflu will have too many approvals let us say post February 2017, we do not see too many. So if you can just give throw some light on the competitive landscape?

**Rajeev Nannapaneni:** I like to be conservative; logically speaking on patent expiry we should expect more approvals. How many will come and all I do not know but I do not want to speculate too much but we should assume that they could be more than I say.

**Nimesh Mehta:** And what according to you is visibility of competitor as of now?

**Rajeev Nannapaneni:** I cannot tell you we are not privy to everybody's ANDAs position on each of the product. It is a presumable educated guess that this is what will happen.

**Nimesh Mehta:** Okay third, this new Hep C. product Eplusa, but not Eplusa the one before there has been some WHO tenders which has opened up and where I see a lot of companies participating in that but Natco is not a party to it, as in Natco has not participated. So one is that the big opportunity and if yes, then is there is any reason for us not being in that?

**Rajeev Nannapaneni:** We are working on the WHO filing; we have not completed the filings so I think other guys are completed it I think we are focusing more on the branded opportunities and WHO. WHO is typically done by the typical retroviral companies like Mylan and Hetero. I think generally we



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have never been in the retroviral business so we do not have the WHO pre-qualification Geneva inspection done in our factory, so we never had to do those products. So I think we have started the process so I think we will catch up, I think.

**Nimesh Mehta:** Is that a big market to cater to, even for the Hep C portfolio?

**Rajeev Nannapaneni:** The tenders are not so large as of now, I think WHO is doing a prequalification right now of the product I do not think WHO tenders Hep Care very large at this time. The anticipation is of the global **fund** increase, there could be to the larger opportunity is still **lies** in the branded business.

**Nimesh Mehta:** World over as well outside of India, as well?

**Rajeev Nannapaneni:** I am talking about specific to our license territories, ROW territories.

**Nimesh Mehta:** Okay understood and finally if you can just let us know the R&D cost this quarter that will be helpful?

**Rajeev Nannapaneni:** I think it is about 7%-8% of sale typically and we have done a little more extra R&D expense because we have to cushion our cash flow but about 7%-8% seems rough.

**Nimesh Mehta:** Is it likely to increase now that we are increasing the filing and typically we have not seen that increasing too much. Is it because we are partnered and thus get compensated, how is that?

**Rajeev Nannapaneni:** Usually yes. I think it does not increase too much because we partner it out but we are asking a little more higher profit shares than before so that respect our other income has dropped dramatically, earlier if you recollect few years ago our other income is to be very high. So we used to get reimburse for R&D. Now-a-days we are not getting reimburse for R&D the way we used to get in the past. So we are asking more profit shares. So I think that is indirectly impacting our bottom line. So we have foregone certain revenues so that we should benefit a higher profit share. It is an indirect impact, not directly.

**Nimesh Mehta:** So is it likely to remain at 7-8 excluding Tamiflu obviously or it will go up?

**Rajeev Nannapaneni:** It will remain on 7-8, so if we have more cushion then we will probably try to go after more projects. It is opportunities driven. I think if I see something interesting, yes we will probably just spend a little more.

**Moderator:** Thank you Mr. Mehta. We have a next question from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

**Nitin Agarwal:** On the Hep C portfolio when we look out the next 1.5-2 years and we know just based on the current rate, how do you see that portfolio playing through in the domestic market?



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**Rajeev Nannapaneni:** I think the Eplusa launch is one large piece of the puzzle that is left. So that we are pursuing the license, so if that happens that pretty much is most of the portfolios, so that is one critical item that we need to sort of get licensed for. Second is we need to get registrations and lot of the RoW countries that we have filed, so we are expecting some launches in some good RoW countries like Vietnam, Indonesia that are expecting approvals. So that will bump our earnings a little bit and that will be our second most important thing and third it is doing well, when will it peak I do not know, honestly I have no idea but our expectation is that I think we hit a number where it will probably settle around 600-700 crores. I am only speculating the scenario, I do not know, honestly this product has surprised us in every way. When I started off I thought 100 crores would be very good number and then I said 200 will be a good number but if you see annualized we are hitting almost 500-600, so everything has been a surprise. So we are hard to judge but it will probably settle around 600-700 if I were to make an educated guess but again there is always a surprise element.

**Nitin Agarwal:** So you have 600-700 crores, this is across India and RoW or only in India?

**Rajeev Nannapaneni:** RoW included also I think. We have done much better in India than we anticipated and in RoW we are not doing as well as India. In the end it is always price erosion that is happening in all markets, so I think that seems like a reasonable number accounting for all the price erosions and competitions going forward.

**Nitin Agarwal:** Fair enough and this new launch Eplusa how relevant will that be? Will again be hitting into some of the existing therapies or...?

**Rajeev Nannapaneni:** I think Eplusa would be used concurrently with the other therapies, I do not think it will eat into some. I will not deny it will not but I think all the products will have a place. Daclatasvir will have a place, SOF singles will have a place, SOF/Ledi will have a place for the genotype 1 and this will be a Pan-genotype but SOF plus Decla in my opinion is the cheapest combination so economically that will survive and Eplusa will be slightly more expensive than SOF plus Ducla , so that is why I think all of them will survive that is our feeling.

**Nitin Agarwal:** Thanks and secondly on the US, we talked about potential Entocort approval in the second half of the year and you still remain comfortable on Copaxone, if you just look a little out over next 18 next months what else could really fall in our way in terms approval?

**Rajeev Nannapaneni:** They are all summer contingent, so broadly I think the major approvals we are expecting in the next 18 months would be one is Azacitidine and another one is (Inaudible) 25:13 and another one will be Bosentan and if Copaxone IPR proceeding goes well and may be again that being contingent on IPR proceeding going well and getting 20 approvals and may be even 40, I mean there are lot of other patent issues in it, so it is little more complicated it is probably one contingent on some favorable patents outcomes and Doxil on the higher end but Doxil we do



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not want give any guidance as of now, it is too premature but if you play out 18 months these are probably broadly the big ones we are looking for in addition to what you have mentioned.

**Nitin Agarwal:** And Fosrenol, how do you see the market playing out?

**Rajeev Nannapaneni:** As of now there is no generics so if we get approval and we are on the early generics then I think we are in good situation. It is not a huge product as you know it is about 125 million, 140 million, I think.

**Nitin Agarwal:** And in terms of our filings how many we looking to file this year?

**Rajeev Nannapaneni:** About 7 is what our expectation is this financial year.

**Nitin Agarwal:** And how do you see in terms of quantitative, qualitatively what kind of filings will these be?

**Rajeev Nannapaneni:** I think half of them are Para-IV and half of them are relatively niche products.

**Moderator:** Thank you Mr. Agarwal. We have a next question from the line of Sriram Rathi from ICICI Securities. Please go ahead

**Sriram Rathi:** Just one thing you mentioned that Imatinib, we are expecting a launch in Europe and US both this year?

**Rajeev Nannapaneni:** No, I said only for Europe. The question was whether we expecting Imatinib for Europe. We are launching in Europe in this financial year but we are not given much numbers on this because it is a dossier business and it is not a great sales numbers that we should make huge impact on the earnings, so that is why it is not being as one of our top product and US as of now we are not giving any guidance, it is still under review and we have been in suits, so we are not giving any guidance on the launch here.

**SriramRathi:** Okay, luckily on Bosentan, are we expecting launch this year itself, in FY2017?

**Rajeev Nannapaneni:** Hopefully I think if everything goes well and I think before 2017 March is our expectation, I think if everything goes well.

**Moderator:** Thank you Mr. Rathi. We have a next question from the line of Samir Baisiwala from Morgan Stanley. Please go ahead.

**Samir Baisiwala:** Just quickly on this Imatinib we just mentioned for the US , is your case not dismissed?

**Rajeev Nannapaneni:** I am not able to recollect, top of my head I cannot recollect.



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- Samir Baisiwala:** Okay because that is what the court filing say and if that is the case...?
- Rajeev Nannapaneni:** I think if that is what it says I will just check with Lupin. I do not want to say something that I am not supposed to, so I will just check with them and I will clarify again. I think there were some discussions but whether it done or not I do not know I will just check and I will find out.
- Samir Baisiwala:** It shows the date as in January so it has been a while. That is fine. But if that is true then that means only thing that is blocking your launch is really the Doxil approval?
- Rajeev Nannapaneni:** I cannot answer that because let me check with Lupin because Lupin is handling litigation, let me check with them and I will come back to you, I do not want to say something I am not supposed to, okay?
- Samir Baisiwala:** Okay that is fine. I am not going there. The questions that I am trying to get to is, if your file is just about a year old with FDA then what is the reasonable time for us to expect the FDA review and I am just keeping the court case on aside that is not too material so would it take 2, 3 years from the time of filing or could it be done earlier?
- Rajeev Nannapaneni:** I am sorry Samir I cannot answer that, I need to check with Lupin and I will answer because typically these are legal documents so I want to be sure of what I am saying. Let me check with them and I will come back to you.
- Samir Baisiwala:** Okay, no worries. So on Copaxone 40 mg you just mention that it depends on IPR ruling then it may well fall in the 18 months' bucket. Would you not think that the separate court case, in the district courts on the same patterns, would that not be blocking you for a period of time and whatever happens in both these, district court as well as IPR the case will then go to appeal courts, so is it not 2-3 years out really that we are looking at?
- Rajeev Nannapaneni:** I think let us get the IPR verdict and I think then we will get more clarity on it. There are lot of moving parts in that product, so I need to check with Mylan and see what their strategy is, I think we will give more clarity in the next few, I think once we get the IPR verdict then I think we will reassess our situation and I will check with Mylan and tell you what our strategy is going to be. Personally you have asked that question point blank, I do not have an answer to that. I will check with them. I think these all as I said there are a lot of moving parts. Let us take one thing at a time, let us hear from the IPR first and then let me discuss with Mylan and I will tell you what the next step is going to be, it is not too far away, I think the August 25<sup>th</sup> is the timeline what I remember. Is that correct?
- Samir Baisiwala:** Two is for two patterns and for the third it is for September, if I am not wrong?
- Rajeev Nannapaneni:** I think but not too far away, not in other 3 weeks we will hear something in special and then we will give an official update on where we stand on various issues, okay?



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**Samir Baisiwala:** Okay, on Copaxone 20 mg, I am a little surprised, because Sandoz has been for a period of time now and but I think the market share is roughly about give or take 30%, so the penetration has not been all that great, so what is really impeding higher market share and when you/Mylan gets in there, would it be a very slow and low market share sort of situation or the other way around?

**Rajeev Nannapaneni:** It is still a great opportunity, I think with much smaller companies and lot of the bigger guys, so I would take those numbers of momenta any day, so having said that I think once we launch Mylan is a very good company and they are very excessive in their marketing and I think I am very confident that they will do a good job, the actual strategy and all I think will play out, I think once we will get the approval I think we will get more clarity on this. But I am still optimistic about the product.

**Samir Baisiwala:** And momentum members would be the upper limit for you for you in a way to think...?

**Rajeev Nannapaneni:** I do not want to say any numbers, it will be little premature. Let us get the approval, then you ask me that questions then I will be in a better position to answer.

**Moderator:** Thank you sir. We have a next question from the line of Karthik Mehta from Deutsche Bank. Please go ahead.

**Karthik Mehta:** With cash coming in from the approvals that you have and products which you will launch now how do you view to utilize that cash assuming we do not have any debt and if you have any areas of preference would that be in the Indian market, US market, any thoughts on this Rajeev?

**Rajeev Nannapaneni:** Yes sure. As of this year we have put a CAPEX budget of about 350 crores and obviously we were expected to spend about 280 this year and I think we can probably fund the whole thing comfortably with the cash flow except for some short term borrowing just to deal with the mismatch. But I think by end of March, I think more or less we will be able to fund everything cash flows. So we do not really need to borrow. As of now our net debt is zero. I think going forward even 12 months alone our net debt will continue to be zero. It actually will be a cash positive. A lot of the investment that we are doing is primarily to upgrade our API capability in Chennai and Hyderabad and we are spending a lot of money in our Vizag SEZ which will be online early next year and we are enhancing our domestic capabilities in Dehradun and Guwahati. So I have not put all my energy in the US this time. I think we have done, more like 60-40 allocation, 60% in US and regulated market and 40% market in India. I think we have been little more bullish about India. I think a lot of interesting opportunities in next few years even in India which we were allow us to go, it will take our domestic past 1000 crores. So this year we are going to touch because we are near 1000 crores in the domestic, may not touch thousand but we will probably be around 800-900 so I think we have some clear strategies will take us past 1000 in domestic.



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**Karthik Mehta:** So in terms of M&A, would you look at, I mean if it outside India would you look at, I am just trying to understand that, if you have to do any R&D or if you have any other product may be let us say like Revlimid, would you to do it all on your own or would you still seek a partner assuming you can take some risk now with the scale that you have now? So will all the upsides be...

**Rajeev Nannapaneni:** As of now the deals that we are doing at least for this financial year, we are doing partnership. But what we are doing now is asking for a higher profit share, earlier as I remember it should 70:30 is the loss, and we not doing 70:30, we are doing 50:50 now, but we are still doing the partnership approach especially in the US. The reason being lot of the launches are good 5-6 years away based on the outcome of litigation, so even if I do what you call 100% funding of it, I have not started doing it yet, I think to answer it, maybe I think once we have more cash maybe we will change our mind, but for now we are still doing a partnership mode.

**Moderator:** Thank you Mr. Mehta. We have a next question from line of Girish Bakhru from HSBC. please go ahead sir.

**Girish Bakhru:** First one again on Copaxone, just following up on the IPR. I know you will share detail more later, but according to you is the base understanding like all 3 patents have been overturned?

**Rajeev Nannapaneni:** Let's see just wait for the IPR, do not make me speculate it. Let us here the IPR and as I told Sameer it is only literally 2 weeks' way. Let us wait what happens and then I will tell you what we think as the next step forward. Okay?

**Girish Bakhru:** Okay and on Gleevec I know you said it is opportunity for Europe, in terms of API is it an opportunity for US this year?

**Rajeev Nannapaneni:** We had tied up with one particular customer we have launched. It is an opportunity but on API side it is not great opportunity. I think we already build the API already, it is probably not such a great opportunity.

**Girish Bakhru:** And on the product that you mentioned I somehow still do not hear Tykerb, where is that filing? I do not see the case also active any longer?

**Rajeev Nannapaneni:** They have not sued us yet.

**Girish Bakhru:** So there was never a case? I think there was a case against Natco on the product?

**Rajeev Nannapaneni:** I think best of knowledge I do not think we have been sued, again I will check my stats again. Typically, what happens is that the date is very far away, they do not sued right away.

**Girish Bakhru:** So you do not see it as a launch in a next say 24 months even?



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- Rajeev Nannapaneni:** Way out there, we gave P3 is on some very distance patent and P4s are extremely distant patent. So like top of my head I cannot recollect but from what I recollect, again I do not want to say something I am not supposed, I do not think we were sued, that is what I think Lupin told us, I will check with Lupin again. Lupin is our partner on this. I will check with them again.
- Girish Bakhr:** Right, on say Fosrenol and Tykerb where Lupin of course the partner, can you just comment if it is the profit sharing, 50% profit sharing should one assume?
- Rajeev Nannapaneni:** It is not like that, I think if they spent X amount, if they do not spend much legal I think it is 50-50, but our profit share goes down if the legal spends are more. I think that is the arrangement we have with them.
- Moderator:** Thank you sir. We have a next question from line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** Sir if you could help us understand the FDA status for your facilities?
- Rajeev Nannapaneni:** Of the 3 facilities we have 2 API sites and finished dosage site. I think the Hyderabad API site has a EIR and the inspection was I think nearly little less than 2 years ago and the API side in Chennai had an inspection I think about 6-7 months ago for which we are awaiting EIR and the formation side also had inspection I think about 4 months ago for which we are waiting for EIR, that is the procedure.
- Prakash Agarwal:** And these got the 483s?
- Rajeev Nannapaneni:** Both the types got 483s. I think I cannot remember exactly but I think the Chennai site are like 2-3 observation and I think the Hyderabad formation site are like 7-8 observations, but subsequently we got approvals from these sites. So we do not think there is any show stoppers I think we should get the IR shortly.
- Prakash Agarwal:** Okay, understood and you talked about CAPEX, so the Chennai and Hyderabad is you are adding more blocks?
- Rajeev Nannapaneni:** Correct.
- Prakash Agarwal:** And Vizag SEZ is the totally new one?
- Rajeev Nannapaneni:** That is a complete new formulation side, yes.
- Prakash Agarwal:** Okay and you would start filing from this next year onwards or something?



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- Rajeev Nannapaneni:** Yes, early 2017, we are first exhibit batch from that site, from the Vizag site.
- Prakash Agarwal:** Okay and you mentioned something on Dehradun and one more?
- Rajeev Nannapaneni:** Dehradun and Assam, Guwahati is where we make our domestic formulations, so those sides we are doing some CAPEX. So we are going on with the 40-50 crores CAPEX. Guwahati is about 25 crores and Dehradun is about 14-15 crores. We are augmenting our domestic capacity to account for its some new launches in the next 2 to 3 years.
- Prakash Agarwal:** Okay and how should we think about your new launches in India, I mean so far we focus on niches and done pretty well in terms of scaling of Hep C and stuff. You talked about taking new initiatives and new launches if you could throw some broad level highlight?
- Rajeev Nannapaneni:** As you know, in domestic we operate primarily in two segments, Oncology and Gastroenterology. So the idea now is we want to expand in to a new segment, so we looking at Diabetology or Cardiology, we are just weighing our options. But again as you know we like to do products where there is not going to be too much competition or there is some comparative advantage. So we are weighing different options. I think now the domestic businesses has hit a very good number now, I think we almost hitting 850-900 crores this year. So I think we are some smart ideas which will play out in the next 12 to 18 months and I am very positive that we can take this business to 1100 crores 1200 crores in the next 1.5-2 years.
- Moderator:** Thank you Mr. Agarwal. We have a next question from the line of Chunky Shah from Credit Suisse. Please go ahead.
- Chunky Shah:** On Eplusa, I just wanted to ask whether, do we have any head start in terms of approval earlier than other players or launching earlier than them and on Tamiflu, when you say you expect more competition do you expect it to be a 2-3 player market post the patent expiry or like a 4-5 player market?
- Rajeev Nannapaneni:** Eplusa is too early right now. But I anticipate I think the approval should happen by end of the year. But there will probably be a more competition in Eplusa because as long as we are in one of the pack I think I will be very happy, we cannot expect beyond that. Regarding Tamiflu and all I have no idea how many guys will come. So all amounting speculation but logic says that there could be some people but how many and all is hard to predict.
- Chunky Shah:** On the Hep C once earlier there have been two approvals, so this time we are expecting it to be more than 2 approvals from the DCGA?
- Rajeev Nannapaneni:** I would say so yes because people will be well-prepared. Reasonably that is an assumption to make.



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- Chunky Shah:** And December is the timeline, so have you already filed this product?
- Rajeev Nannapaneni:** We are getting ready.
- Moderator:** Thank you Mr. Shah. We have a next question follow on question from the line of Afzal Mohammad from Karvy Stock Broking. Please go ahead.
- Afzal Mohammad:** Regarding Copaxone 20 mg when is the last time Mylan replied to the query from the FDA?
- Rajeev Nannapaneni:** I think we get time to time queries. I think we have answered all queries. If you ask specifically when we got it, I cannot recollect on top of my head but I think the engagement on that is ongoing.
- Afzal Mohammad:** Ongoing okay, so the reply still pending you mean, from Mylan?
- Rajeev Nannapaneni:** I think we have answered everything but I will let you know in our next update as of now I do not think anything is pending.
- Afzal Mohammad:** Do you expect for an approval before the end of GDUFA which is September 2017 the 90 % of the cases FDA promises to act on the backlog ANDAs?
- Rajeev Nannapaneni:** I think I do not want to say anything about 40 as of now. Let me speak to Mylan get more clarity on this issue. As of now, if we do not have an approval on 20. So I do not want to talk about 40, so let us get 20 and I will speak about 40.
- Afzal Mohammad:** No I am talking about 20 mg?
- Rajeev Nannapaneni:** 20, I think we are awaiting approval as I said so I think waiting shortly, I think that is our expectation.
- Afzal Mohammad:** Okay and in domestic business do you want to move from small molecules to vaccines or because you will be having significant cash in the long term may be 3 years from now and since Natco is known for compulsory licensing, the first company to do a compulsory license, do you expect to challenge any of the major difficult to afford product such as Prevnar?
- Rajeev Nannapaneni:** Honestly, we do not have a capability to do vaccines or biotech. I think the ways we are done our investments we are awarded doing vaccines and biotech. There are couples of biotech deals have done but both of them are in-licensed deals from partners. They are not where we are actually put money setting up greenfield projects. As of now, no. If I change my mind I will let you know but as of now no, it is not in our horizon as of today and but what I still feel in India is there are some interesting niche launches that you can do where there are patent litigation and if we play smart and you are have a good position then there is some really good launches you can do in India as well.



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**Afzal Mohammad:** Okay and one last question Sir. Hep C exports have not taken any traction this year like only 3.6 crores in sales, so do you expect this to pick up in the end of FY2017?

**Rajeev Nannapaneni:** Yes, I think so. I think that is our expectation, yes correct. We are anticipating approvals so I think once it starts kicking in I think we should....

**Afzal Mohammad:** Which is major one sir? Are you still interested in Egypt?

**Rajeev Nannapaneni:** Egypt would not work. Egypt what happens is they do not have patent there and second is they liked the product we made locally and in third you need to compete with the Chinese and these other countries work better because they are all packed. See if we take countries like Indonesia for example, Indonesia has packing zone on the Hep C. portfolio, so when you come into the market saying that I have a licensing or the innovator then gives you access to market but in market like Egypt and all there is no entry barrier to for others to come in. So I had written off Egypt personally.

**Afzal Mohammad:** As anybody got in a patent like Indian manufacture in the south East Asian countries, Vietnam, Indonesia, Malaysia?

**Rajeev Nannapaneni:** Some people are getting permits, yes. Some people have got.

**Afzal Mohammad:** Okay have they launched, any idea?

**Rajeev Nannapaneni:** Some of them have launched

**Afzal Mohammad:** Okay you expect to launch like..?

**Rajeev Nannapaneni:** We also looking to launch in next few months, I guess.

**Moderator:** Thank you Sir. We have a next question follow on question from the line of Ravi Dharamshi from ValueQuest. Please go ahead

**Ravi Dharamshi:** I just had one question as we understand that the latest inspection was triggered by Doxil, so I was just wondering if there is any possibility that Doxil might come way earlier than, is there any accelerated program that can happen?

**Rajeev Nannapaneni:** Good question Ravi. I think I spoke to DRL on this issue, as of now we do not want give any guidance for Doxil. Too early to say anything right now. I think once you get more regulatory clarity I will give you some answer but the ANDA is being reviewed that I can tell you positively I think it is going well but it is too premature to speculate as of today. I will give you an update once to get more clarity. As of now no.



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- Moderator:** Thank you very much Sir. Ladies and gentlemen, will take the last two questions. We have a next question from the line of Sayan Mukherjee from Nomura. Please go ahead.
- Sayan Mukherjee:** Rajeev just one on Copaxone, you know the thing is there has been considerable delay and in the interim moment about approval there have been a new guidance. So when you say that you are responding to the query I am just wondering on the API side, has there been any major changes from the initial dossier that was filed or it is been just minor queries which were coming from the FDA?
- Rajeev Nannapaneni:** I think since the beginning we have done a lot of work which required us to do lot of things and all that work has been done and completed. When I say we have pending it means that we have addressed all the issues that FDA has raised and I think we are anticipating the approval and we have met all the guidance requirements that have been put on the side.
- Sayan Mukherjee:** No, I am just trying to understand the complexity of the issue here in the sense that if there were some major changes done, so when was it done and how long we have travelled on that path. I mean was it like a year back or two years back?
- Rajeev Nannapaneni:** See if you know this was filed in 2009 I think, so it has been almost 7 years now. So the travel path has been 7 years if you want think over that way.
- Sayan Mukherjee:** But I mean just is it like you started or made some major changes where in, though it looks 7 years but where there is some major changes which is taking this long time? So I am just wondering when was the last major response of change done?
- Rajeev Nannapaneni:** I think all the work has already been done. I think everything on the guidance requirements have been made and we expect that we should get an approval this year. I think that is the position where we are.
- Sayan Mukherjee:** Okay and that would be applicable for 40mg as well right, because the API would be....
- Rajeev Nannapaneni:** Yes, absolutely yes.
- Moderator:** Thank you very much Sir. We have a last question from the line of Tushar M from Anand Rathi. Please go ahead
- Tushar M:** Just what the Hep C portfolio would like to understand, though it is growing at the rapid pace, what would be the volume growth and the pricing growth?
- Rajeev Nannapaneni:** You said volume growth and pricing growth right? Volume is growing extremely well I think on quarter-on-quarter we are able to see 20%-25 % percentage growth in the volume. The pricing is dropping but again the raw materials cost is also dropped, so overall we have



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benefited on both sides. I think, things have not stabilized yet it on the Hep C portfolio. I think I just said when the early gentleman I think Nitin asked me about, where do I see this going. Maybe it will grow another 20%–25% before it stabilizes.

**Tushar M:** In terms of volume?

**Rajeev Nannapaneni:** In terms of value.

**Tushar M:** Okay but then you see this raw materials prices also still going down or will be in the line with the prices or prices falling much faster than the raw material crisis?

**Rajeev Nannapaneni:** I think both are moved as the same direction, so that way our profitability has improved slightly I think we have not loosed too much. Pricing has dropped dramatically so has the raw materials, so we are befitted on both sides and because also pricing drop the volume has done well. So I think we are okay as of today. I think we are doing alright. Going forward I think I see there is still another 20%–25% potential on where we are from now.

**Moderator:** Thank you very much Sir. Ladies and gentleman there was the last question. I would now like to hand the floor back to management for closing comments, over to the management.

**Management:** I think that's about it, thank you very much. I think we have done.

**Moderator:** Thank you very much Sir. Ladies and gentleman, on behalf of Edelweiss Securities, that concludes this conference. Thanks for joining us you may now disconnect your lines. Thank you.