



**“Natco Pharma Limited Q1 FY16 Results  
Conference Call”**

**August 13, 2015**



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**Moderator:** Ladies and gentlemen, good day and welcome to the Natco Pharma Q1FY16 Results Conference Call hosted by IDFC Securities Limited. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference, please signal an operator by pressing '\*' and then '0' on your touchtone phone. Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Nitin Agarwal from IDFC Securities Limited. Thank you and over to you, sir.

**Nitin Agarwal:** Thanks, Vipin. Good morning everyone and a very warm welcome to Natco Pharma Limited's Q1FY16 Earnings Call hosted by IDFC Securities. On the call today representing Natco Pharma Limited Management Mr. Rajeev N. – Vice Chairman & CEO and Mr. Rajesh Chebiyam – Vice President, Business Development & Corporate Support. I hand over the call to the NATCO management team for some initial comments and then we will open it for Q&A. Go ahead sir.

**Rajesh Chebiyam:** Thank you Nitin, this is Rajesh Chebiyam. Good morning everyone and welcome to Natco's Conference Call discussing our Earnings Result for the First Quarter FY16 ending June 30th, 2015. Before we get started we would like to state that we may be making certain forward-looking statements during this 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 the participant questions is the property and Natco and cannot be recorded or rebroadcast without Natco's expressed written permission.

Now moving on to our earnings results, the company recorded an aggregate consolidated net revenues of Rs.225.54 crores for the quarter ended June 30th, 2015, this is against Rs.211.48 crores during the same quarter last year. Reflecting an increase in the top-line of roughly 6.6%. The net profit after tax on consolidated basis was Rs.28.23 crores as against Rs.33.46 crores for the same quarter last year. Although this is a decrease of about 15.6% compared to the same quarter last year, the company continues to expect strong sales growth with high margin products in the quarters of this fiscal years.

Coming down to the segmental breakdown, I will give you approximate numbers in terms of the different breakdown for the main segment. For the API sales roughly about 20% of the total net sales is clocked by API at 46 crores. Domestic comprised roughly about 7.5 crores and exports 39 crores. Formulations reflected about 63% of the total revenue sales, again roughly around 143 crores. Further breakdown into the Formulations, exports were 36 crores, oncology 62 crores, the non-oncology brand pharma 28 crores, third party and miscellaneous about 17 crores, this was the total domestic with onco non-onco brand and third party the figure is about 107 crores. US retail was approximately 23 crores, Brazil around 5 crores, other operating income about 8 crores. So that makes up for roughly the total net sales.



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On the domestic **(Inaudible-4:14)** front the company continues to do well based on our earlier estimates we had given a run rate of roughly about 10 crores per month, we are glad to say that we have exceeded that number. On the overall sales for the quarter for Sofosbuvir we are approximately at about 37 crores, two-thirds of that is clocked by our own brand Hepcinat. On the ANDN filings we have 36 filings today, so we have done one recently. The earlier numbers that we had given was 35.

And finally in terms of the guidance for this fiscal year we expect on the top-line between 1050 crores to 1100 crores net sales. On the PAT level our estimates are between 150 crores to 160 crores. We are making certain assumptions behind these numbers, the assumptions would predominantly include that of course we will continue to grow well including launches of the Sofosbuvir combinations, also with an assumption that we would win the standard in South America. This assumption also includes no new commercial launches for the fiscal year in the US.

So that is just the overall picture. Let me hand it over to Mr. Rajeev Nannapaneni. Thank you.

**Rajeev Nannapaneni:** So I think Rajesh has done a preface of where we think we are going to go I am happy to take questions so I think you can start.

**Moderator:** Thank you sir. Ladies and Gentlemen, we will now begin the question-and-answer session. Our first question is from the line of Anuj Momaya from Value Quest Research. Please go ahead.

**Anuj Momaya:** Sir any updates on Copaxone approval, have you received any further queries from US FDA?

**Rajeev Nannapaneni:** Yes, we have recently received some queries, we have turned around and we have answered them. So from what I understand all the queries have been answered, so there is nothing pending as of now.

**Anuj Momaya:** So when have we reverted back to the US FDA?

**Rajeev Nannapaneni:** Recently I was told, I think the last set of answers were given a couple of days ago I think, very recently, we got it probably about 10-15 days ago and I think we reverted back with less than 10 days.

**Anuj Momaya:** So we are not hopeful, because you said in your opening remarks that you are not hopeful of any US launches during this year?

**Rajeev Nannapaneni:** I never do, I never put Capaxone guidance ever, I think we always say that if it happens then this is what will happen but we never give guidance because of the complexity of the generic and let's be honest, we have been waiting for an approval for last few months and it has not happened. So if I keep guidance then it just becomes difficult. So what we prefer is because of



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delays with the FDA and because of the complexity, it is hard to judge a timeline. All I can tell you is there are no queries pending, so that is the best answer I can give. And we are positive that it will happen very soon but we are unable to judge the time line.

**Anuj Momaya:** So on a quarterly results this bulk chemicals during the quarter have seen a significant dip, so what is this regarding to?

**Rajeev Nannapaneni:** See what happened was June of last year we had a stocking quantity of a particular generic and so that is why the profits were higher and...

**Anuj Momaya:** Even sequentially 72 crores and this quarter it is 56 crores, so even sequentially the top-line has come down.

**Rajeev Nannapaneni:** Which one, top-line on what?

**Anuj Momaya:** Bulk chemicals.

**Rajeev Nannapaneni:** I think API is not doing... Let's start with comparing on Q-on-Q, it has definitely come down because of that one time shorting and sequentially I think probably it has not dropped that much, maybe what has happened, if we say 72 crores it probably includes even billing to what you call the formulation division as well., you are probably reading out of the segments sales I think. See basically what happens is when you report numbers we only show third party numbers, so we in net of 72 crores from the internal sale. The other reason why chemicals business is not growing so well is, one is that 50% to 60% of the capacity is being used for internal consumption. And second of all is the business has been little flattish, that's probably been one of the weaker businesses that we have had, so I think both factors are contributing to a more sluggish sale of the API division.

**Moderator:** Thank you. The next question is from the line of Gagan Borana from ICICI Securities. Please go ahead.

**Gagan Borana:** Sir I have a couple of questions, first is on Sovaldi pricing in India, so after our launch in late March 2015 and it has been almost about four, five months now, so how have you seen price movement happening in Sovaldi now?

**Rajeev Nannapaneni:** The way we predicted it, I mean has Rajesh said in the call last quarter our brand did about 24 crores, our Hecinat brand, so that I think this year realization of about Rs.9500 to Rs.10000 for a bottle which is more in line with what we have said in the guidance that we had given, that is what we had expected, more or less on that line. With a margin of as we predicted about 28% to 30% is the margin that we are having, it might improve a little bit in the next few months but that might be more or less same.



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- Gagan Borana:** 28% to 30% would be EBITDA margin?
- Rajeev Nannapaneni:** Not really EBITDA, it is sale minus expenses more or less.
- Gagan Borana:** Sir secondly on, we were planning registration for generic Sovaldi in some of the international market like Egypt, Indonesia, Vietnam, so where are we in terms of registration and...
- Rajeev Nannapaneni:** We are planning, so we have started filing, we have filed couple of the smaller South American countries and we have filed in one CIS country and I think we are going to file in Indonesia, I think Indonesia being one of the bigger market we are going to file I think this month is what my colleagues have told me. So we are pursuing the filings and as you know Gilead has given 100 countries where you can file, even Africa also we are proceeding. But the upside and all I do not see anything coming up, you will probably see some launches in 2017 financial year, this financial year we will not see anything. Typical registration takes 1 to 1.5 year in most of the countries so we should see something where I think in 2017 you will start seeing it and 2018 I think you will see most of it.
- Gagan Borana:** Sir more specifically on Egypt, what are our expectations in terms of time lines of launching Sovaldi in Egypt?
- Rajeev Nannapaneni:** Egypt, we cannot launch Sovaldi in Egypt my friend because you cannot import formulation into Egypt mostly for a local company.
- Gagan Borana:** So in terms of arrangement we will be having arrangement with a local party over there, so...
- Rajeev Nannapaneni:** We are working on those deals, we are working on those, we are doing technology transfer and we are working on it. Gut as of now I cannot give any visibility, I think I have not factored that in the earnings, Egypt is very complicated also because you also have API from China coming in at very low prices. So it is tough to break but we will get some business, I am not saying we will not get any business but we are not giving any guidance on Egypt. I think the biggest market, the way I look at the business right now I think of the HEPC portfolio I think 40% to 50% will come from India, rest of the 50% will come from the other countries like primarily Indonesia, CIS, Nigeria, Kenya, so these are the countries we are trying to look at, Vietnam, Burma, so these are the countries we are looking at.
- Gagan Borana:** And one last question sir, on the oncology business, we have seen a good growth in this quarter 62 crores versus about 43 crores at the same last year, so how do you see this business going forward in terms of what will drive growth in this segment?
- Rajeev Nannapaneni:** The brands have done well, we have not had any big launches but the base of it has done well, it is giving about 20 crores to 21 crores a month so it is doing well and in terms of new launches we do not have anything in the next few months, I would suspect the next set of oncology



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products we are having probably end of the year or early next year, really good ones. So the business is growing around 8% to 10% so that is exactly what is driving it. In terms of launches in domestic, I think what is going to drive is the Hecpinat brand will drive it and I think the combinations also are coming in. So with those licenses if everything goes well subjective to DCBI's approvals and everything goes well, maybe we can launch it in October quarter. So I would see right now as Rajesh has surfaced our domestic business is doing about 100 a quarter, so I see this business growing if the combinations and everything goes well by the end of the year we expect this business to go to 130 a quarter. So 125 to 130 I think that is what I am expecting, but all obviously we are getting the licenses on time and we launch on time, I think that is.....

- Gagan Borana:** Sir can you just repeat the name of the product which you mentioned?
- Rajeev Nannapaneni:** I am not giving the guidance on the combination, we thought it is of strategic importance but if you read what the healthy therapies are you can probably make a guess.
- Moderator:** Thank you. Our next question is from the line of Nimish Mehta from Research Delta Advisors . Please go ahead.
- Nimish Mehta:** If you can just repeat the guidance from the net profit for FY16, I just missed that.
- Rajeev Nannapaneni:** What we are assuming is, we made couple of assumptions in that Nimish that I expect that the HEPC portfolio will do well and the second assumption is that we are able to close Venezuela tender, we won the tender we have to close the tender in terms of payments and all. Assuming that these two events go all the way we are expecting our guidance is 1050 crores to 1100 crores of top-line and a profit after tax of between 150 crores to 160 crores. And the guidance also assumes that I have taken zero upsides from any of the US products.
- Nimish Mehta:** Sorry, you are not considering...?
- Rajeev Nannapaneni:** We have not factored in any US launches.
- Nimish Mehta:** The other thing I just wanted to know, we have been seeing a very flattish other expense in this quarter itself, other expense has been like 56 crores this quarter versus almost like 55 crores I last quarter.
- Rajeev Nannapaneni:** There is an increase you are saying or...?
- Nimish Mehta:** This is a flat, I mean there is hardly any increase. So now that we have been doing so well in Sovaldi brand itself and also I assume R&D expenses also would have gone up, so what is the reason...?



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- Rajeev Nannapaneni:** Sovaldi doing well will not increase R&D, I do not think that will happen.
- Nimish Mehta:** No, no R&D for the ANDAs and Sovaldi.
- Rajeev Nannapaneni:** I think it has been steady state but if you ask me pointedly I cannot answer that question, let me check with my guys and tell you where any reason right now I do not have the numbers that spread to answer on my hand right now.
- Nimish Mehta:** Are we capitalizing any R&D expenses?
- Rajeev Nannapaneni:** I do not do that, I have a policy Nimish I never capitalize R&D, you see our amortization column is always....whatever we spend we spend.
- Nimish Mehta:** And finally on Sovaldi, do we have plans to manufacture the API as well or it will be sourced and will be only manufacturing?
- Rajeev Nannapaneni:** I think we have a contract arrangement with Laurus for that. So Sovaldi is not to be made by Natco, it is made at Laurus. I think they gave us the competitive advantage to launch so that is why we are working with, but we are fairly competitive on the pricing thing, I am happy with the arrangement.
- Moderator:** Thank you. The next question is from the line of Hitesh Mahida from Antique Stock Broking. Please go ahead.
- Hitesh Mahida:** Sir first thing is, just wanted to know what is the situation in Venezuela and are we facing any repatriation issues there? And second thing is, sir with combination Sovaldi launches also coming in can we expect the margins in Sovaldi to pick up going ahead?
- Rajeev Nannapaneni:** Let's start with Venezuela first. In terms of our experience, whatever billing that we have done last year I think we have recovered about 80%, 85% of the money, so we did not have any issues. Having said that, there is a little risk, I am not going to comment that there is no risk at all but our experience so far has been different, it has not been so flat. It is tricky, I mean let's not take that away from the table but so far we have done okay. So the second question was combination, margins on Sovaldi combination, I do not expect we get better, it would be clearly competitive because it is such a large market, pricing is very aggressive but still I think we will do the same amount of margin that we are making right now in the brand and on the B2B it will be much lower.
- Hitesh Mahida:** And sir any update on rev limit, I mean where are we now in terms of where is the hearing going and last we had a Markman hearing in 2014 and post that there has not been anything, so what is the update there?



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**Rajeev Nannapaneni:** I think you will probably hear something on it in the next few months, that are obviously a very important event for the company so this will determine how the future is going to because this is a very high value item. The I think we will probably go to trial maybe early next year is what I was told, so maybe in the next six months I think we will get clarity where we are and what is going to happen. I do not see any visibility right now but probably there is something in the next five to six months.

**Hitesh Mahida:** And where are we in terms of getting approval for rev limit?

**Rajeev Nannapaneni:** There is very few things pending so we expect they tell it us sometime soon, very soon, hopefully in the next few months.

**Moderator:** Thank you. Our next question is from the line of Vrijesh Kasera from Edelweiss. Please go ahead. Please go ahead.

**Vrijesh Kasera:** Sir on the Ipi case that Mylan has filed for, there is expectation that verdict would come by the end of this month or early September, just wanted to know there has been press that the historical verdicts have been in favor of the generics and it has been 63:37 kind of a ratio. So if at all comes in our favor so how do you see the market shaping up, would we be able to launch it immediately or how does it work because this is something new for us? If you could just throw some light on this.

**Rajeev Nannapaneni:** As you said I think we are expecting a verdict by August end and early September and if it is positive, assuming it is positive and if that goes well then we need to probably look at the 40 milligram. If the 20 gets approves then I think I will feel very comfortable even to give you guidance on 40 as well. But as of now I cannot say anything honestly, I do not want to say anything because I do not know how it is going to play out. So let's wait for the verdict then I will speak to Mylan and then probably give you some guidance of how it plays out. As of now the honest answer is I do not know, so let me speak to them but it is all contingent on the verdict, if the verdict is positive then we will probably have to reassess where we are and I will speak to Mylan and give you a more color.

**Vrijesh Kasera:** That would still require a US FDA approval, right?

**Rajeev Nannapaneni:** Of course, it requires an approval but there are so many moving parts so I am not able to judge. So let's get the verdict in our favor and if that happens then I will speak to Mylan, I will give you some guidance on where we are.

**Vrijesh Kasera:** And one more question, post this new query that we have received, so earlier we were thinking that we would be getting an approval by September odd, probably we were hoping about that, now do we think that this calendar year it would be difficult to get an approval since Mylan has already not included the Copaxone in the guidance now?





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- Rajeev Nannapaneni:** I am not able to say honestly, because we have answered whatever queries are pending, so we have done our part. So when will FDA give an approval is tough to judge and so in terms of guidance and all I never give guidance firstly, so I mean Mylan you see guidance on the **Inaudible 23:09** so that is their prerogative, but I cannot speak for them but generally because of the complex generic it is very difficult to give time. So I am hoping it will happen sooner but I do not want to give a timeline because we have been waiting for long now, it is hard to now put the timelines.
- Vrijesh Kasera:** Sir we have a number of around 15%, 16% of market share that Momenta has right now in the generic Copaxone market, is this the right number or do you think there is some discrepancy in that and how do you see the market shaping up once you get an approval on this?
- Rajeev Nannapaneni:** I cannot judge what numbers Momenta is having but I think there is a lot of interest for the generic and a lot of people are really interested in buying the product and we see possibility of a very good conversion. Also, market will shape up is very speculative, I think let's get the approval and I think we can make and probably get some guidance form Mylan how to do this.
- Moderator:** Thank you. The next question is from the line of Rahul Bejal from Bharti AXA Life Insurance. Please go ahead.
- Rahul Bejal:** I understand there are some plans for capital raising, so if you could just throw some color on that, and if that is the case then what is the end use for that and what time lines are we looking at?
- Rajeev Nannapaneni:** As of now we have filed with FIBB so we are waiting for approvals, so we are still waiting for their response so we expect something soon. As you know the public can also file with FIBB so we have to see how that plays on. So once we get the approvals then I think we will assess which is the good time to go. And regarding the end use of the money, we want to use it for capital expansion, so what we want to do is we want to build a clone of our tableting line, we only have one tableting line with US FDA, so we want to have another US FDA approvable plant, that is one major CAPEX that we are planning. And the second CAPEX that we are planning is the expansion of our chemicals capabilities and general maintenance CAPEX, so that is what we are planning. So the timing of when we are going to do it and all, we have taken all the resolutions as you are aware, the part of the reason why we done is because the paperwork and all takes a lot of time as you see the FIBB clearances and the AGMs and all, we got that sorted out. So we will make a call, we have not decided when but we will make a call.
- Rahul Bejal:** Right. But given the fact that or the assumption that we have a lot of interesting products coming up in the pipeline over the next two three years which can generate a lot of cash flows, so why not go for a bridge loan, I mean why go for dilution of equity?



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**Rajeev Nannapaneni:** I will make that call my friend, I have not made that call but generally I located some amount of debt, I do not like to take a very large amount of debt so I have a number in my mind, so if it exceeds that number then as a sense of financial prudence I do equity, that has always been my mentality and I think if I see them exceeding that number then I will probably look at equity, as of now we are comfortable. But having said that if I believe there is we have to do CAPEX now and the cash flow is six or eight months later or one year later then generally I would prefer some portion of it be funded by equity. This comes from the overall mentality of the company that we go after such complex generics where the outcomes are so uncertain and part of the reason that we are able to do in terms of filings and complexity it is a fact that we never had high amount of debt isn't it. It is a philosophy thing, a lot of people have argued with me saying that look at your EBITDA, look at your debt equity ratio it is quite low so why you are too concerned, but it is a philosophy. But I will make the call, I have not made the call so I will make it but I am conservative, I am financially a bit conservative, strategy wise I would say I am very aggressive but financially I am conservative.

**Moderator:** Thank you. The next question is from the line of Monica Joshi from Bajaj Allianz Life Insurance. Please go ahead.

**Monica Joshi:** I just wanted to understand what were the set of questions that were raised by the FDA in their latest communication to you? Without going into details, whether they were an extension of an earlier communication you had with them or these were whole new set of data points or questions that they raised?

**Rajeev Nannapaneni:** I think if you have seen the table Teva's petition a lot of revolves around the chemical reaction scheme and the **(Inaudible-29:05)** chemical property, composition and the structural signatures for the polymerization and the de-polymerization and some biological assays, so these are the issues that lot of the questions are all about and sameness on that front. I cannot specifically tell you what the questions are but they revolve around these three, four topics.

**Monica Joshi:** And these were addressed by the FDA sometime earlier also, or is anything that has come which is new to you?

**Rajeev Nannapaneni:** No, no I was present in the call, these questions were answered in less than two weeks, so we had all the data, we just compiled and gave it back to them. So we got the questions, I do not remember the exact date but I think we got it about two weeks ago and then they have turned around within less than I think less than 10 days ago, 10 or 12 days of turnaround. So what I understand they have already answered.

**Monica Joshi:** That is good to know, but the question was that yes you did not have to run any additional data from your side, you probably had it with you, the question was, were any of these points which were raised in this latest data from the FDA, an extension was or what was earlier asked by the



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FDA over the last few months or has anything new come in terms of any additional requirement that they wanted from your side, you may have had the data but...

**Rajeev Nannapaneni:** See basically we had the data with us and it was the way it was presented, I think that is what I was told and I think we have the data, we compile it and give it back to them. So there were not major additional work that we needed do to answer the question. So the data was already available, it was not, I think they wanted more detail if you want you can go with that.

**Monica Joshi:** Would you have had a guess whether any of this relates to proving any sort of let's say substitution in the generic area because that has been a question that has been going around with Sandoz, Momenta that your generic has to be substitutable with Copaxone. So do you think any of this related in any format or any form to suggest that the FDA is trying to establish complete substitution?

**Rajeev Nannapaneni:** I think obviously they have laid out a general criteria for sameness of a generic, I think a lot of the questions are revolving around that.

**Monica Joshi:** And this was the case earlier too, so this is not something...?

**Rajeev Nannapaneni:** Absolutely.

**Moderator:** Thank you. Our next question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.

**Dheeresh Pathak:** I just want to know how much we did from Venezuela last year and Brazil last year?

**Rajeev Nannapaneni:** Last year, I am guessing okay, do not hold me to it, I think it is about 50 crores to 60 crores is what I remember.

**Dheeresh Pathak:** In Venezuela?

**Rajeev Nannapaneni:** Yes.

**Dheeresh Pathak:** Brazil was how much last year?

**Rajeev Nannapaneni:** Brazil, I do not remember, I do not remember, there is some API sales and some from the sub. It I think did about 14 crores, 15 crores, I am just working out a memory so I might be wrong a little bit but in that region. API sales I think were very good, API sales were may be 30 crores or so in that region, 30 crores to 35 crores.

**Dheeresh Pathak:** And when you give us the export numbers, that includes US and that includes Venezuela and Brazil you give separately, right?



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- Rajeev Nannapaneni:** When I give you export numbers I include products which are manufactured in India and directly exported from India. And when I include Brazil numbers it includes the subsidiary in Brazil which does a distribution business which is not included in the export numbers, those are in the consol.
- Dheeresh Pathak:** But lot of it is basically Venezuela and US, right, the export number?
- Rajeev Nannapaneni:** If you look at our export business, yes a lot of the business comes from US, Venezuela and Canada, these are the top three markets.
- Dheeresh Pathak:** And this year when you sit in the guidance you have included some tender which you won but not executed, so that is worth how much?
- Rajeev Nannapaneni:** Asking you to say that again my friend, you gone soft on some part.
- Dheeresh Pathak:** So when you said you included some tender in your guidance which you have won but you are yet to execute, what is the value of that tender?
- Rajeev Nannapaneni:** I do not want to give you the precise number, it is more or less in that same range of last year.
- Dheeresh Pathak:** And one last question, earlier you had talked about I think two or three products one was Bosentan and Budesonide, those we should expect next year?
- Rajeev Nannapaneni:** It is hard to tell, I will tell you in terms of the filings, I will deliberately speak about the filings, I mean things have been very slow with the FDA, so in terms of my confidence, I will tell you where we are made for another so that you understand that why and then I leave it to you how you want to expect. Of the things that we are planning out in the next 18 months, obviously depends on waiting approvals as you know, I am only talking about ANDAs which we are expecting in the next 18 months. Tamiflu, we already have a **(Unclear-34.36)** so that is good and three is Budesonide we have capsules, we got a CRL on that so which is good so we are replying to the CRL this month, so if CRL reply goes well then everything goes well and we should expect an approval by the end of the year subjected to FDA approvals. Bosentan, I only got an acceptance recently, took about a year to get an acceptance. So the patent expiry is in November so I do not know my friend, I do not know whether I will get approval on time, I am not able to judge Bosentan. Azacitidine also got filed a year ago, we are yet to get an acceptance. So that also I am not able to guide you on the revenue. So if you were to have it a guess, I think Tamiflu provided with face reading goes well and we are able to concert into full then that looks possible. Copaxone subjected to approval looks possible, Budesonide if the PRL is closed nicely and we are able to not get any other queries that looks possible in the US. And in Europe we are next year expecting Bendamustine and we are expecting Imatinib, it is a November expiry in Europe. These are the major ones...



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- Dheeresh Pathak:** Can you just seize the opportunity for Bendamustine and Glivec in Europe next year?
- Rajeev Nannapaneni:** Bendamustine I mean if I have to have, again we are guess so it is hard to guess. Bendamustine probably would be like we are selling some quantities this year itself, including this year and next year, I am only guessing, do not hold me to it, maybe about \$5 million, \$6 million opportunity. Imatinib, if everything goes well maybe Europe launch is about 8 million to 10 million.
- Moderator:** Thank you. The next question is from the line of Surjeet Pal from Prabhudas Lilladher. Please go ahead.
- Surjeet Pal:** I just missed your comments on that similarity of your filing on Copaxone vis-à-vis the patented one, because what Mylan said is that the query they have received which implies that they are on the same page where FDA are as far as sameness or similarity of your product be it polymerization or de-polymerization. Could you throw some light on that because I missed your statement on that?
- Rajeev Nannapaneni:** No, just let me reiterate what Mr. Malik said in his conference call, so a lady asked me what is the nature of the queries when they are looking at approving the product, I have laid out this three, four important points which was Natco chemical properties, our structural signature of polymerization, de- polymerization etc, etc. And what Mylan is saying that we are on the same page as the FDA in terms of sameness, I think that is what they are saying.
- Surjeet Pal:** So 505B2 kind of approval is now totally out of question?
- Rajeev Nannapaneni:** From what I understand it is a outright generic.
- Surjeet Pal:** Yes, so basically what makes you think that it will be too optimistic to accepting or to discount the possibilities of Copaxone launch in this year's guidance for you considering that the generic approval from FDA is a bit complex matter to guess, but why suddenly you came to the conclusion it is not to take into your guidance for this year?
- Rajeev Nannapaneni:** Do you want me, you are saying that I should take it to guidance or you are saying I should not take it guidance?
- Surjeet Pal:** You definitely have some thought when you have decided that not to include the Copaxone in your guidance, so I just want to have some color on that.
- Rajeev Nannapaneni:** I never included my friend, I never do, even last year I never did and this year I never, as a company I am very conservative. How can I say that, again I just reiterating because of the complexity of the generic I never did, it is only Mylan which took it out, I never put in to take out.



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**Surjeet Pal:** As far as Sovaldi is concerned and the kind of competition already brewing in domestic market including the big guys like Cipla, do you think the margin which currently you are getting as well as the market share, do you think it will be maintained or it will be spoiled with too many competition?

**Rajeev Nannapaneni:** I think we have been fortunate, I think we have done well with the brand, I think we are probably the biggest brand of Sovaldi in the market today, generic business of Sovaldi right now. I think from what I understand, the closest competitor would be probably doing 40% or 50% of our sale, so that way we have taken off well so we are trying to use the advantage that we have had by taking off well sort of extent that to the combinations as well. Do I expect the same sort of margins we made? I think the margins are pretty bad already, I think they cannot get worse than they already are. And also some of the drugs are also making it in-house, so that also gives us an advantage and we have a unique partnership model with the API company where we give profit share on the sales but we ask them at cost basis. So we have built in a very interesting model, so I am confident that I think we should do well. And another fortunate thing is that we are probably the first company who had got the license, so that also gives us an advantage. So we really play out the market, there are really two manufacturing licenses in the market Hetero and Natco and so that across are much better. And if anybody is selling a generic is either buying it from them or us, so that also gives us some advantage because we are controlling them. And even based on the comparative pending licenses in Delhi, I think it looks like it is only Hetero and Natco were aggressive for **(Unclear-40:52)**

**Surjeet Pal:** And the last question is on Venezuela, see you said that you had basically intended business in Venezuela, right?

**Rajeev Nannapaneni:** I am sorry, say that again my friend.

**Surjeet Pal:** So I can understand the other part, as far as tainted business is concerned is there any kind of surety of your money on dollar, in case given the kind of tentativeness of the country and if gets into default, do we have any surety of the tainted business money you will be getting in dollars as it is?

**Rajeev Nannapaneni:** Yes there is some surety, I think generally I do not want to get into details but broadly it is based on our experience, we have last three four years been consistently doing Venezuela business and we have recovered money all the time in spite when even barrel went to \$40 also we have recovered money. And there have been delays, sometimes we had one default we had which we carry in our balance sheet but is covered by ACDC, so that is why we have insured the default. But I will be lying to tell you that it is not risky but I think we are fairly confident that we will be able to do it, but we have done it every year in the last five years.

**Surjeet Pal:** So what are the current remittance which is pending in the country to come to your India?



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- Rajeev Nannapaneni:** See I have answered this question earlier, so last year we did about 50 crores to 60 crores of business, 80% of the money was recovered.
- Surjeet Pal:** And currently how much remittance is left?
- Rajeev Nannapaneni:** 13 crores we are carrying in our books, but we are also saying that it is covered the ACDC also.
- Moderator:** Thank you. The next question is from the line of Rahul Solanki from Edelweiss. Please go ahead.
- Rahul Solanki:** Rajeev, I wanted to check have you received target action date for rev limit?
- Rajeev Nannapaneni:** A target action date, I do not think there are many things pending, I think we anticipate, I do not remember we have a target action date on that but I think we are expecting approvals very soon, so a couple of minor things pending, more or less we are anticipating approvals by the end of the year. Target action date typically are bring given for products which are filed after October 2014 I think, we are not getting it for the older ones, like the new ones if you file they will give you a target action but the older ones, again I am subjected to correction, but form the older ones I do not think they are giving that sort of guidance, I have not seen that for older ones.
- Rahul Solanki:** Just one more question, regarding the assets that have been in-licensed by Dr. Reddy's from Amgen, would you be able to comment whether you were also in consideration?
- Rajeev Nannapaneni:** Reddy's have done a in-licensing deal with Amgen, and what is the question again?
- Rahul Solanki:** So there were a couple of oncology assets too in the deal...
- Rajeev Nannapaneni:** Yes, of course, what about it?
- Rahul Solanki:** So there were a couple of oncology assets that Reddy's has in-licensed, so I just wanted to check if you were also into consideration?
- Rajeev Nannapaneni:** We were in consideration with Amgen, is the question is were we under consideration when Amgen made deal with Dr. Reddy's, is that the question?
- Rahul Solanki:** Yes.
- Rajeev Nannapaneni:** No, I was not under consideration, I do not even know Amgen. I mean you look at Natco we pick fights with everyone, so I do not know any multinational would want to... sometimes I work when them, most times very aggressive on the patent supply. I don't think I have too many multinational friends, if you want to answer that question.
- Moderator:** Thank you. Our next question is from the line of Sangam Iyyer from Subhkam. Please go ahead.



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**Sangam Iyyer:** Sir just had one query, since in our top-line we are not taking any US products, are Fosrenol and Prevacid, when are we expecting approval for these products?

**Rajeev Nannapaneni:** Very good question. On Prevacid 15 mg nothing is pending, I mean waiting approval, so it simply sitting there for so many year. Fosrenol also, I will just check the regulatory side, it has been sitting on the FDA for so long. All these tablets have been sitting with the FDA for a nearly three to four years, so we know after four years and all it is so difficult to give guidance so I stopped giving guidance for these products. But things that I know for sure are going to happen, we are closer to approvals, we are giving guidance's but things which are like in review we are not giving guidance. I know it has been pending for long but personally as of now I do not have any clarity, maybe team has.

**Sangam Iyyer:** For HEPC treatment which the guidance that we have been giving of around 120-odd crores kind of run rate for the year, are we factoring in any combinations sales in this or is pure Sofosbuvir?

**Rajeev Nannapaneni:** Actually what will happen is it will be a little trick here, what will happen is one particular combination which is Harvoni is what everybody is expecting will be launched. 20% of the market will shift to the combination because that is Type 1, so 20% of the Indian market is Type 1. So when I am saying 120 crores I assuming only Sovaldi, I have not assumed the combination.

**Sangam Iyyer:** Based on our last interaction as well, we are in advance talks to supply for the combinations as well, right?

**Rajeev Nannapaneni:** Yes, we are seeing **DPDI 47.25** to get the license, yes. And I have given the guidance earlier, I have said what we are expecting is we are doing 100 crores a quarter and on the domestic we expect this to go to 125, 130, it is probably partly driven by the increase of sale of the standalone Sofosbuvir and also the addition of the combinations.

**Sangam Iyyer:** Basically the full year number that is now currently at around 1050 crores to 1100 crores factors in certain part of the combinations in this financial year?

**Rajeev Nannapaneni:** I am assuming certain portions of the combination will kick in and I am also assuming the tender also, yes and the business growing the way it is growing.

**Sangam Iyyer:** So just to understand on the run rate for the Sofosbuvir standalone and the combination put together. At 8000 odd so being the pricing or 9000 being the pricing assuming that is exit rate for this financial year, where do we see the contribution from HEPC as a therapy in FY17 assuming that is purely India?

**Rajeev Nannapaneni:** I think the key will be like this, first is we are doing, I mean it is all making assumptions, do not hold me to it but I will play out a very positive assumption, I will play out a medium assumption, I will play out a pessimist assumption so that you understand. So right now our run rate, I am





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talking about brand, I am not talking about B2B because the profitability is very low, so our brand right now having July we had sale of let's say 10 crores, so we see the brand doing about 10 crores to 12 crores every month of this quarter, so you are saying at 17 we see that business going to about 130 crores to 140 crores and the combinations will add another 60 crores, 70 crores if everything goes well. So we see the whole HEPC portfolio going to 180 crores to 200 crores. Plus, if the export business comes in and the realization starts coming in I do not expect anything like a year from now, so then maybe the run rate will increase. So what we are expecting is now it is 10, maybe in about 8 months or 12 months we should take it to 17 to 18 a month, and once the export business starts coming in maybe we should start doing about 25 crores to 26 crores a month.

**Sangam Iyyer:**

So sir exports will contribute around 8 crores to 10 crores per month?

**Rajeev Nannapaneni:**

Yes initially and I think eventually I expect the export business also to equal the India business. But all are very positive assumptions that I have made based on registration going on time and our ability to execute and getting the registrations and all. So I mean in my mind I think you can do 300 crores or 350 crores of revenues, I think that is what I feel but provided I am able to execute everything smoothly. If the bios go well, I file, I get all the inspections done and we get approvals on time and then we are able to get a good market share and also my friends who I am competing with are not, so far I have been the first off the block and they do not play catch up with me and then sort of make it less lucrative for me so then you can spread down the numbers based on what I have said. So these are all multiple factors that are there, but I mean to answer your question in an indirect sort of way, this business has a potential to go to 250 crores, 300 crores very easily, it is not difficult.

**Sangam Iyyer:**

So on a steady state assuming a normalized kind of a competitive scenario HEPC as a treatment can actually fetch us around 300 to 350-odd crores as a revenue?

**Rajeev Nannapaneni:**

I think so, over a period of two years yes, I think it is possible, I think if we are able to execute everything nicely yes. And the nice thing about this revenue is it is comparative, I am not going to take that away but the scale is very good and even if you make 25%, 30% margin you are talking about 75 crores to 100 crores of free cash which is generating, so it is nice, it pays for the bills and it is a steady state revenue. And again it is not dependent on US and Europe and unregulated market because business if you are getting from India and rest of the world. So it is a good offset to what we are doing in the other market, I think a lot of times people have asked me other than oncology you do not have any other portfolio, so now we have a portfolio which is a strong non-oncology portfolio and second, it also addresses the issue of having a revenue base outside the United States and the regulated market which is also fairly sizable, so all of that gets addressed through the HEPC portfolio.

**Sangam Iyyer:**

And in terms of Trianda that we guided earlier, that was for Europe or US?



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- Rajeev Nannapaneni:** The timings I am giving it for European launch, not for US.
- Sangam Iyyer:** And just a follow-up on the oncology product launches that we are looking at in towards the latter half of this year Q4 of early next year, just wanted to understand the kind of incremental revenue growth that the base business can see because if I just add the Sovaldi component here that itself gives us another incremental 10% to 12% kind of a growth for the base business for the next financial year. How does that oncology piece that would contribute, I just wanted to understand that?
- Rajeev Nannapaneni:** We are doing about 20 crores, 21 crores a month right now in oncology in India, so we expect our business to grow around 15% to 20% every year. But Sovaldi is a house lab, Sovaldi has taken our domestic business from 258 crores to 300 crores to 400 crores, 500 crores over night isn't it. So Sovaldi is something which is hard to replicate.
- Sangam Iyyer:** I know it is very hard to replicate but given that at a base of 1100 if you are seeing an incremental 100-odd crores coming in from Sovaldi and is the HEPC treatment itself and that is again growing to before the steady state comes through, that adds a flip to your base business and the cash flows, right, so to a large extent that is helpful in growing the business as well.
- Rajeev Nannapaneni:** Absolutely, I think but in terms of guidance I expect about 10%, 15% growth on the oncology to answer your question, but what is going to be outlier is going to be the HEPC portfolio because we see we have actually doubled our domestic numbers because of HEPC, isn't it. I mean we have not doubled it right now, we have increased it by 50% but I expect it should double in a matter of 12 months in the HEPC portfolio.
- Moderator:** Thank you. The next question is from the line of Prakash Agarwal from Axis Capital. Please go ahead.
- Prakash Agarwal:** Sir just wanted to understand this HEPC market better in terms of what would be the current penetration level specially in the India market since you are more entrenched in India today, so what would be the penetration level and would some price discounts, I believe India market is very price sensitive, would price discounts would help in higher penetration level because I believe the market is big. So if you could help us understanding this and secondly, is government part of purchasing plan which could help the market grow going forward?
- Rajeev Nannapaneni:** Let's look at their numbers, let's say we are doing about 10 crores to 11 crores a month and you are getting an average of about Rs.9500 a bottle, you are selling about 13,000 bottles a month. So what I have done is I have divided 12 by 10,000 for mathematically making simple, so it is about 13,000 patients a month you have. So the point I am trying to make is, if you can take this 13,000 patients who are treated per month to 26,000 patients a month we are doing 20 crores a month. So I am assuming a very modest 20%, 25% market share, I am leaving 75% to everyone else. So to exceed this number of 250 crores, 300 crores all you need to do is figure out 25,000 to



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30,000 people is what you need to treat every month, so each patient stays on your drug for about six months, we are treating about 50,000 people a year, just to put things in math. In terms of incidence and all people say India has about 12 million to 13 million patients of HEPC and the RW markets of where we have licenses the market is about 125 million in terms of diagnosis it takes a long time to diagnose, you could carry a HEPC virus for many years and we do not get diagnosed and most times, it is not fatal all the but when it is fatal it affects your liver. So if you diagnose with HEPC immediately you will get on the sedative and you can try to cure yourself up off HEPC. In terms of government purchasing and all, as of now this market is driven by private cash market, it is not driven by the government purchases. Do I see that happening? Maybe if the cost of therapy was to drop like maybe 4000, 5000, yes, from the state funded reimbursements would happen, but that will take maybe another 12 months to happen with better economies of scale and more competition and better therapies in place the cost also will drop dramatically. But the potential is enormous, as everybody realizes and we do not have to treat so many people to get the scale that I am talking about. And relatively we play it out, the competition is limited only amongst the five, six guys, who are the five six guys? You have Hetero, you have us then you have amongst the bigger Indian companies we have Cipla, you have Cadila, the you have Mylan and then you have the smaller licensees. But the major competition I see is from these guys and from the bigger companies it is Cipla, Cadila and Mylan and also companies like Hetero and Stride. So it is not 25, 30 guys, it is more like 6 or 7 guys. We are the first kid off the block and then we do, we play our strategy brightly, I think it makes sense, I think it will do quite well.

**Prakash Agarwal:** And secondly sir on this emerging market like markets like Egypt, Indonesia and all where we plan to file sooner, the strategy would be to enter in market with a partner or we might go ourselves in understanding the market?

**Rajeev Nannapaneni:** No, we are going with a partner in these countries.

**Prakash Agarwal:** So how does the math work there and also with Gilead, I mean the royalty I assume is early teens, is that right?

**Rajeev Nannapaneni:** No, 7%.

**Prakash Agarwal:** And how does the marketing arrangement work, I mean just a hypothetical arrangement, how does it work when we enter these markets?

**Rajeev Nannapaneni:** You Distribute the products no, you give it to the guy and then he distributes the product and we pay royalty on it. We sell \$100, I mean take out the expense you have to pay 7% to them.

**Prakash Agarwal:** Yes, that I got, I was trying to understand what happens with the partners in Indonesia, Egypt?

**Rajeev Nannapaneni:** No, no you pay the royalty.



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- Prakash Agarwal:** And then his marketing cost and then you share the profit or is it just you pay...?
- Rajeev Nannapaneni:** The time is up to get into details, we have different models for different levels if we do all or any.  
  
I think we conclude the call gentlemen, Nitin?
- Nitin Agarwal:** Yes. Any last comments Rajeev then we can probably go ahead and close it.
- Rajeev Nannapaneni:** Nothing I think, I have answered all the questions, I think everybody has covered all the questions or less.
- Nitin Agarwal:** Thanks everyone for participating in the call and thank you to the Natco Management Team for sparring their valuable time.
- Moderator:** Thank you. On behalf of IDFC Securities that concludes this conference. Thank you for joining us, you may now disconnect your lines.