



“Natco Pharma Limited Q2 FY-16 Earnings Conference Call”

November 16, 2015



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MODERATOR: **MR. PRAFUL BOHRA – RELIGARE CAPITAL MARKETS**



*Natco Pharma Limited
November 16, 2015*

Moderator: Good day ladies and gentlemen and welcome to the Natco Pharma Limited Q2 FY16 Earnings Conference Call hosted by Religare Capital Markets Limited. As a reminder, all participant lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during this conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I will now hand the conference over to Mr. Praful Bohra from Religare Capital Markets. Thank you and over to you sir.

Mr. Praful Bohra: Yes, thanks Malika. So on behalf of Religare Capital Markets, I welcome everyone to Natco Pharma's Earnings Call to discuss the Q2 FY16 results. Today, we have with us the senior management of the company represented by Mr. Rajeev Nannapaneni who is a Vice Chairman and CEO and Mr. Rajesh Chebiam who is the VP of Business Development and Customer Support. I now turn over the call to Rajesh for the opening remarks. Over to you sir.

Mr. Rajesh Chebiam: Yes. Thank you Praful. Good morning everyone. Welcome to Natco's Conference Call discussing our Earnings Results for the second quarter of FY16 which ended September 30th, 2015. Joining me in today's call as Praful just mentioned is our Vice Chairman and CEO Mr. Rajeev Nannapaneni. So before we get started, I just want to clarify few things. I would like to state that we may be making 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 question is the property of Natco and cannot be recorded or rebroadcast without Natco's expressed written permission. Okay.

So now moving on to the earnings and business performance, hopefully you had a chance to go over our published results by now. Broadly, the company recorded a top-line net revenue of 237 crores reflecting roughly about 6.6% increase over the same quarter last year. On the PAT front, the number was 29.6 crores and a decrease over the last year's quarter by about 8.6%. The growth was constraint due to delay in certain sales to – when it is in the market. However, the domestic formulation business continues to do well both in the oncology and Hepatitis C related products. The company expects stronger sales growth and profitability during the second half of FY16. Getting down further into the breakdown of the revenue based on segments, of the 237 crores broadly, 39 crores is associated with the API, formulations 159 crores. US retail and subs 32 crores. Other operating income 12 crores. API specifically the domestic was 7 crores and exports 32 crores. Split on the formulation, oncology did 61 crores Pharma segment did 45 crores. Third party 28 crores, exports 25 crores. So the domestic formulation together with onco, pharma and the third party is equal 134 crores.

Specifically on the Sofosbuvir, our HEP C.nat brand did 40 crores during the quarter. The third party related SOF did 23 crores, so 63 crores in total. As of October 30th, the HEP C.nat brand



*Natco Pharma Limited
November 16, 2015*

clocked roughly on 90 crores in the revenue since they have launched. The leading brands of oncology segment continue to do well. Finally, on the guidance numbers for FY16, the company remains at the previously stated figures of top-line revenue of 1050 crores and on the PAT level, roughly on 150 crores. So again, I have stated earlier, this guidance is contingent upon two key aspects, one is realization of our revenues in an order. Second, launch of the Sofosbuvir combination drugs in India at the earliest and the realization in the increased sales driven by it. Okay. So I will wrap it up. Now we will open up for questions and come on to Mr. Rajeev.

- Rajeev Nannapaneni:** So good morning all. So I am ready to take questions. You may start.
- Moderator:** Thank you very much sir.
- Rajeev Nannapaneni:** Yes.
- Moderator:** Ladies and gentlemen, we will now begin the question and answer session. We have the first question from the line of Sameer Shah from Valuequest. Please go ahead.
- Sameer Shah:** Sir just wanted to know in terms of filings now what the plan is for this year and next year how many are we planning to file?
- Rajeev Nannapaneni:** You are talking about ANDA.
- Sameer Shah:** USA.
- Rajeev Nannapaneni:** So far I think this financial year we have filed three ANDAs and we think we should be able to file about five to six ANDAs this year. Going forward next year, we target to take it up to seven to eight.
- Sameer Shah:** Seven to eight. All right and in terms of subsidiary losses now, you know, how is – what is happening in Brazil and...
- Rajeev Nannapaneni:** Brazil is struggling Sameer, because Reals has depreciated dramatically, because there has been lot of weakness in country which are heavily dependent on commodities as you aware. So South America is going through a very hard time and it is indirectly reflected on our earnings, because our Brazil revenue in API and our Tender business in the Venezuela have not come through which was there in the previous year the same quarter which we are not able to show this quarter because of weakness there. That is also reflecting in the subsidiary losses and we have just put things in prospective. Reals has dropped from \$2.5 Reals to \$4 Reals now. So things are very tough now, but I think we are still positive. I think as long as we get our approval, we do not have any big approvals in Brazil. Filed about 12 filings, about three filings are expecting approval in 2016. So as long as the approvals come through, I think we should break even and most of the sub losses that are showing in consol, I think nearly 40%, 50% of



*Natco Pharma Limited
November 16, 2015*

losses are coming from Brazil. Brazil losses stop and automatically we consol losses to reduced. Okay.

Sameer Shah: All right and the combination drug approval, we have filed Harvoni in India, right.

Rajeev Nannapaneni: We have filed two combinations Sameer know, your name.

Sameer Shah: Yes.

Rajeev Nannapaneni: We have filed two combinations. We have filed Sofosbuvir plus Ledipasvir and we have also filed for the standalone pill of Daclatasvir. We believe that both this product should do extremely well. I mean you have seen the importance of Hep C. portfolio. Of the 237 crores, the Hep C. portfolio at 63 crores in our balance sheet, nearly 30% of our balance sheet and as of – I mean anything else hasn't worked, but this probably did very well and that covered up pretty much that didn't happen. We believe this portfolio should continue to be really strong and importance of these two products are these.

Sofosbuvir by itself it does not work, so you need to use in combination with the Ribavirin and Interferon. So Daclatasvir and Sofosbuvir is the new product called Hepatitis C. now and so it removes the injection and reduces the term of therapy as well, so that is why it is very important to launch Daclatasvir. Second is SOF plus Ledipasvir is also important because it treats a particular type of genotype-1, very difficult one to treat and again when you are in a portfolio, we need to have all the drugs that are there. We are being optimist again and it is all subjected to DCGI clearances and approval. If everything goes well, we are ready with the file. We have filed all the documents. All queries have been answered. We are anticipating approval end of this month or early next month subjected to DCGI. So if that comes then it will further strengthen our domestic portfolios.

Moderator: Thank you. Next question is from the line of Girish Bakhru form HSBC. Please go ahead.

Girish Bakhru: First again on CAPEX on – just wanted to know your thoughts on how the market is looking like at this situation. I mean I think Momenta recently also mentioned that Teva holding strongly to the higher strength formulation, so when do you see your product approval and what is your calculation of what kind of numbers you can see from the product?

Rajeev Nannapaneni: I mean I cannot tell what Momenta has made because I do not know, but to be very honest with you, I think our focus now is on getting the approval. I think we have said it on last conference call, we – there were some queries from the FDI, we have answered them promptly. So there were no queries pending from the FDI as such on the product. We continue to be optimist that we will get it soon, but unable to judge well, but soon I think it seems reasonable. In terms of numbers and all, again I am just going with what Momenta has shown.



*Natco Pharma Limited
November 16, 2015*

It seems reasonable. I think Momenta is doing well. So we hope as long as we are able to launch it, I think we are in good shape here.

Girish Bakhru: Right and Rajeev just on the overall market, I mean I am just wondering if more interest is now moving to 40 mg, so do you think larger opportunity is now shifting to 40 mg given that I mean timelines are mostly moving there and also the whole entire market has moved there. So would that be a larger market to play with eventually?

Rajeev Nannapaneni: If we are saying if the 40 mg approval comes, is that what you are saying, the generic approval?

Girish Bakhru: Yes.

Rajeev Nannapaneni: We had lot of issues on the 40 mg right. At first, we need to get an approval. Second issue is as you are aware there is an IPO proceeding in 40 mg, plus there are litigations pending in 40 mg. So lot of things is going on, so if any favorable outcome comes in these proceedings, yes, I think 40 mg looks very interesting.

Girish Bakhru: Right and just on Gleevec if could share, what – have you settled with the innovator? Any of there – any timeline that you can share on the launch of that product in US particularly?

Rajeev Nannapaneni: Okay, so just to put things in Gleevec. Gleevec we have filed in Europe and United States. Okay, so Europe I think we are expecting launch around November 2016 I think, June to November, in that region. I think there somewhere next filing in Europe. In the US, as you know, we have the filed the ANDA, so as of now I have nothing to report on the settlement, but in terms of approval and all, I cannot say. So I think as of now, it is very premature to say anything. But I can tell you this much, I filed the ANDA in June 2015, so it is about a year and 4 months since we have filed the ANDA.

Moderator: Next question is from the line of Mitul Mehta from Lucky Investment Managers. Please go ahead.

Mitul Mehta: Sir just wanted to get some sense on the regulatory front as far as our plants are concerned. You know we had an inspection sometime 8, 10 months back where we got the certificate and that had gone through, so any further inspection left, if you could just give us the timeline or very difficult to kind of?

Rajeev Nannapaneni: We cannot say – I will tell you broadly what I know about, but they always surprise in life.

Mitul Mehta: In fact, also my other question is as we all are reading and as the things are getting more and more stricter from the FDA side, what are some of the steps that we are taking so that it does not really hit us like a stormier.



*Natco Pharma Limited
November 16, 2015*

Rajeev Nannapaneni: Yes, I understand. Let me – I will tell you the inspection updates. We have three plants that we have filed with the FDA of which the formulation plant, it is in Hyderabad that has got injectable and orals, so that was inspected in May 2014 so with which we have everything is cleared for. Our API plants are inspected in Hyderabad in – which is why we may call the major APIs including the Copaxone and that got inspected around October 2014, so which we got clearance – and we have our smaller API plant in Chennai which make cytotoxic API so which we – we do not have so many filings from there. We have got couple of filings from there. So that is yet to get inspected, but we have filed an ANDA on that maybe about a year, year and half ago. In terms of risk mitigation, see what we do is we employ foreign consultants who do mark audits all the time and in our work, we like to believe that we have a good system and we do things carefully. I mean that is the risk that all companies run. So in terms of risk mitigation, I think modular thinking is we need to have another oral dosage firm factory. I think that is probably major risk mitigation that we are implementing right now. We have taken a site in Vizag and the construction is ongoing, so we are expecting our plant should be ready in about a year's time in Vizag. So once that facility is ready, we will like to move some of our products there sort of do some risk mitigation.

Mitul Mehta: So sir, when you say the API plant had got inspected in October 2014 and the injectable – I mean the oral plant had got inspected in May, so when is the next inspection?

Rajeev Nannapaneni: Its typical every 2 years is the – 2 to 2.5 years is what my experience has been. So we expect the inspections end 2016 on both the plants, mid 2016.

Mitul Mehta: Sixteen, but are there any surprise visits?

Rajeev Nannapaneni: They are all surprised. Like there is no – we have the both – both plant, I am just saying you my experience, one we got an intimation on Friday of that particular week and inspection started on Monday for the formulation plant and for the API plant, I think we got a one day notice. I think they came on a mid-week. I think on Wednesday of the week they started the inspection. We got intimation on Tuesday lunch that they are going to come. So they are all surprised. There is no prior intimate.

Mitul Mehta: Sir as far as the Copaxone for the full product goes, we understand that we have going to source it from Glen Pharma where the entire filling and everything is going to happen there. So even from the regulatory front, there plant is also inspected or there is going to be some sort of inspection there also.

Rajeev Nannapaneni: That particular plant which is in Hyderabad had that inspection that mean they are fully compliant. They have no issues there.

Mitul Mehta: So there are no issues. Okay. Sir as far as the Tamiflu goes, can you help us to understand the litigator aspect because we do have the tentative approval, so when do we kind of...



*Natco Pharma Limited
November 16, 2015*

Rajeev Nannapaneni: I think we will probably hear something on it in the next few months. We are expecting – we have to go to trial on that particular issue. So we probably got to trial early next year on that and we have that’s our anticipation and based on the outcome, we get to launch a generic hopefully next year. This is probably one of the bigger products that we have in our portfolio for 2016.

Mitul Mehta: And sir my last question is, you know, we recently read about Synthon clinical data we accepted by the European regulatory. I do not know if that has got accepted by the US FDA, but is there a fair reason to believe that the FDA might give them the green signal before us or do you sense any sort of risk there at this point of time on Copaxone.

Rajeev Nannapaneni: I will not privy to when Synthon will get approval okay, so I cannot answer that question. We still believe, we are optimistic that we should get approval soon, I am hoping soon. Regarding clinical data and all, I think FDA is not asking for clinical, so I think that question may not be pertinent to it. Europe, yes, is asking for clinical data that I agree quite for what I understand. Again I am not preview to everybody’s regulatory process, but what I understand we know we do not need to do a clinical trial in that in the US and I think our friends Momenta got with our clinical trial, what I understand.

Mitul Mehta: And sir lastly on Revlimid if you can throw some light.

Rajeev Nannapaneni: I have nothing to report honestly. I think we are preparing for a trial early next year. I think that is what I have. That is the latest I have on – and we are reverting tentative approach for which we have not got this year. So major event for Revlimid would be a tentative approval soon and probably a trial late early next year.

Moderator: Next question is from the line of Manoj Garg from DSP Merrill Lynch. Please go ahead.

Manoj Garg: Rajeev talking about Gleevec, are you sharing the partner’s name along with whom you have filed the Gleevec in the US market.

Rajeev Nannapaneni: It is Lupin.

Manoj Garg: Lupin. Okay and have we being challenged by the innovators, because I think that litigation is not still there in the patent litigation track record and all.

Rajeev Nannapaneni: I think we got sued I think. I am not privy to the exact detail, but I think we got sued Manoj, but I do not expect product to be so large, so I think that is why we are not bothered to talk about it in the new facilities because we think it is a fairly competitive product and another thing we have been **(Inaudible) 19.58** generic as you know they are still few pilots ahead of us from what I understand.



*Natco Pharma Limited
November 16, 2015*

Manoj Garg: Okay. Fair enough. That is helpful and Rajeev in recent call of Actavis or now Allergan, they have indicated a potential settlement with Celgene for Revlimid any take on that because I think they have highlighted and they are going to have a 50-50 kind of upside with Teva, I think that may come with the potential settlement with Celgene, any view on that.

Rajeev Nannapaneni: I cannot comment about it for say Manoj, because it is, you know the nature of the discussion, so I cannot comment about it, I think I am okay with any deal which allow us early generic launch of Revlimid. So I think we were optimistic that something good will happen, but again it is too premature to say anything like that.

Manoj Garg: Okay and in terms of time line, is it like the next 12 month probably we will have a fair visibility on this, I think on this product.

Rajeev Nannapaneni: I think it should be. I think we will get something on it but again. We probably going about a trial early next year. As I said we are okay with any deal as long as it allows with early generic, but as I have said it is too premature to talk about it at this time.

Moderator: Next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.

Nitin Agarwal: Rajeev for the products you filed this year, can throw some light in terms of should there any more Para-IV first-to-files the one that you filed or which you are looking to file for this year.

Rajeev Nannapaneni: Of the three that I have filed, I am not supposed to disclose. Some of them we are bond with confidentiality, so the first one I can disclose. The first one we filed was Abiraterone. We filed on our partners name I think. It is not filed on our name. It is – our partner is Citron. And we have FTF on that I think. So that was filed I think April 2015 I am sorry. That was the entry minus one date. We have another two filing – I am bond by confidentially, not to disclose, but so far we have filed three. So of the three that we have filed, first is Para-IV, second is also Para-IV, but not the first-to-file. Third is again a complex scenario, so we have filed three products so far.

Nitin Agarwal: And have they been accepted?

Rajeev Nannapaneni: Of the three, two have been accepted. The third one has not been accepted.

Nitin Agarwal: In terms of the filing that have made during the course of the year qualitatively how are they looking?

Rajeev Nannapaneni: They look good. They are expecting about 4 to 5 products. So we have another complex generic filing may be in another month or so. So I think the target of doing 5, 6 filings, I think we are able to meet and of which at least half of them will be complex and half of it would be formulations, so it is going back to the same consistent strategy of doing difficult products.



*Natco Pharma Limited
November 16, 2015*

Nitin Agarwal: In terms of your visibility for the launches over FY16 to FY17, has there been any sort of communication or any updates from the FDA which gives you more comfort on some of those launches.

Rajeev Nannapaneni: I think of the once that I can speak about, I think one is of course for in the calendar year '16 we have three, four products majorly. I think one is Tamiflu subjected to the court outcome. Second is Budesonide, so Budesonide we got a target action date of March 2016, so if that goes well, because we have got CRL and we have answered the CRL recently. So we have a target action date of March 2016. So if all goes well, we should be able to launch into the next financial year which is a very smart product. And then obviously, Copaxone that I already spoken about, these are the major launches or approvals that we are expecting and then Lanthanum Carbonate also we are waiting approval. And Bosentan and Rupatadine but these are major ones, but my top two, three would be Budesonide, **(Inaudible) 24.18** and Tamiflu, these are major ones we are expecting.

Nitin Agarwal: And what the status in Bosentan and there has not been any generic approval, the product goes off patent sometime month right?

Rajeev Nannapaneni: Goes off end of this month. We just got an acceptance Nitin, so we have not received a CRL as of now so I am not very optimistic that we will be able to launch on Day-1. So we will see I think – I do not think it will be a day 1 launch, fairly not.

Nitin Agarwal: On the Venezuela business, you did talk about in the last quarter also and I guess what you have been hearing is most of other company essentially are facing serious repatriation issues incrementally, so they literally and they majorly scaling down those businesses. So what the take on this business in terms of how we look in the second half of the year?

Rajeev Nannapaneni: There is a difference between us and them Nitin. I am not privy to everybody's business models, but broadly from what I understand lot of them sell in the private market so they are having repatriation issues. Once they sell the product, they are not able to repatriate the money because they are not getting the clearance from the **(Inaudible) 25.34** which is equivalent of RBI in Venezuela. I think we primarily sell to the government. I think that is the difference between our business and their business. In spite of all the crisis that happened in the last 5, 6 years, do you think oil prices go up and down in the last few years? We always got our money except for a small receivable most of the money we have recovered from Venezuela. If you look at our earnings tool same quarter last year, we had about 40 crores odd in the tender there and we have a good profitability last quarter. This quarter, we did not had anything unfortunately. So we have tender pending so we are just waiting for certain commitment on payments from I mean the paper work, so until that we do not want to send it. We are still optimistic, we should be able to supply. But again unless if we are clear it is hard to do a shipment. We are still optimistic. I think we should be able to do it. The difference is that I



*Natco Pharma Limited
November 16, 2015*

think because we are supplying to the government, so it was more about sovereign supply as opposed to a private supply.

Nitin Agarwal: And lastly on Europe I mean, how is Europe looking in terms of the next year and half for you?

Rajeev Nannapaneni: Europe I think the two big launches Nitin, I think we have Gleevec generic launch in Europe and the Bendamustine generic launch, so both of these are around mid of next year. So both are looking good together.

Nitin Agarwal: And how big can these opportunities be and how big are the markets right now in Europe for these?

Rajeev Nannapaneni: At the top of my head, I cannot recognize – the Gleevec is roughly about one and half billion Nitin and Bendamustine is about 183 million, so about 2 billion together.

Nitin Agarwal: And how do you see Gleevec playing out in Europe as an opportunity?

Rajeev Nannapaneni: It should do well I think. We are hoping we will get about 15%, 20% market share. We are tied up with a lot of good accounts. We are doing dossier supply sale to leading generic companies there. So I think my anticipation is 15% to 20% market share we should get.

Nitin Agarwal: That is pretty large share market share for the size of the product?

Rajeev Nannapaneni: It is good. I mean only I hope that the erosion is not too bad that is the only catch.

Nitin Agarwal: And, so on the last, the Gleevec you mentioned you filed in June 14?

Rajeev Nannapaneni: Gleevec we filed in June 14 and I think it measly got an acceptance, I think of 2 months, 3 months ago and I think we also got **(Inaudible) 00:28:06** recently for what I understand.

Nitin Agarwal: After the acceptance.

Rajeev Nannapaneni: After the acceptance. Correct.

Nitin Agarwal: In terms of regulatory wise, after the acceptance, when you supposed to notify the innovator?

Rajeev Nannapaneni: Yes, we did all that stuff and we got **(Inaudible)** also I think on that subsequent.

Moderator: The next question is from the line of Akhtar Mohammad from Karvy Stock Broking. Please go ahead.



*Natco Pharma Limited
November 16, 2015*

Akhtar Mohammad: Sir, my first question is regarding generic Harvoni. Is generic Harvoni expected to cannibalize generic Sovaldi or will it add to the sales?

Rajeev Nannapaneni: I do not think there is cannibalize of sales, because for what I have seen nearly 20% of the market is Genotype-1. There are 6 genotypes in hepatitis C. Ledipasvir primarily treats Genotype-1. Recently, we got approved for Genotype 4, Genotype 5 and Genotype 6. You probably saw that in the FDA site. India is primarily a genotype 3 market. 60-70% of the patients in India are tend to be genotype 3. So in fact, it would not cannibalize, not more than 20%. Second is we are having Daclatasvir is used in combination with Sofosbuvir and Daclatasvir works in Genotype 3. So we probably expect may be about 20% cannibalization, but it shift to the combination also on a revenue sec you will not lose any money. You just move up the value chain, because you are getting the combination revenue. We will strengthen our Sofosbuvir portfolio because of what you call the Daclatasvir, so we will get incremental revenue from that also. But let us be honest, again Harvoni will also be very competitive. I think Daclatasvir should slightly less competitive, but Harvoni I expect should be very comparative, but we have had good take off with this SOF so I think I am very confident that we should do well with the combination also.

Akhtar Mohammad: The doctors generally do they differentiate between genotypes, I mean is there testing available in India for genotypes?

Rajeev Nannapaneni: Of course I think what happens is first you get diagnoses for Hepatitis C, the later that determine which genotype you have, depending on what genotype we have, we will get certain treatment regime is given. In all treatment regime, Sofosbuvir is standard, so like what is the genotype will be SOF plus Ribavirin, SOF plus Interferon, so it all depends on the genotypes. It is all genotype driven. What is happening now is the treatment is moving away from Ribavirin and Interferon and moving to the combination pills, the newer generation combination pills.

Akhtar Mohammed: So you mean the generic Harvoni?

Rajeev Nannapaneni: No generic Harvoni, generic Daclatasvir, Sofosbuvir. See what is happening is earlier before these drugs came in it used to be injection therapy with about 30% cure. So what I am saying now with SOF becoming standard SOF plus the combinations will take over the whole therapy. Interferon and Ribavirin will not be used anymore.

Akhtar Mohammad: And the premium pricing for generic Harvoni is about like 25% compared to generic Sovaldi, Rs. 25,000 as oppose to 20,000, sir is that?

Rajeev Nannapaneni: That is 19,900. That is 25,000 is what we are anticipating would be the MRP, but MRP has no relevance. It will be all discounting. But net realization will be much lower, but MRP will be 25,000, correct.



*Natco Pharma Limited
November 16, 2015*

- Akhtar Mohammad:** What is the margin like in Harvoni?
- Rajeev Nannapaneni:** Similar margin I mean if we look at SOF portfolio, we are making about – I think after expense it is about 25% is what we are making.
- Akhtar Mohammad:** 25%. And how much sales are you expected to make on a monthly basis?
- Rajeev Nannapaneni:** 63 crores for total and our brand was about 40. 40 and 23 so 40 crores is our own brand.
- Akhtar Mohammad:** The 23 remaining is from?
- Rajeev Nannapaneni:** P2P business. We are giving it to Mylan and Cadila the raw material plus costing sales. This is our own brand, so the brand obviously makes more money than your transfer prices.
- Akhtar Mohammad:** Do you expect to make any similar agreements that you have for HCV for HIV franchise of Gilead given that they are champion of this field of antiviral therapy?
- Rajeev Nannapaneni:** I am not a big fan of HIV. I think all other friends are already being much ahead of us, that does not sound so interesting. Hep C. something that we have a good head start over the others and we have all the approvals we are getting and we are head start over the others. I am still not much convinced I mean I will never say no to something but if something unique opportunity comes we will have look at it but personally I am not very keen.
- Akhtar Mohammad:** How would Hepatitis B sir because they have a significant filling which is...
- Rajeev Nannapaneni:** Yes, B is interesting.
- Akhtar Mohammad:** So that agreement, will that extend to Hep B as well?
- Rajeev Nannapaneni:** I do not have any anything report that it is substantial to tell you right now. But in a broad sense, I will tell you Hepatitis B is interesting. If you are able to get the generic early, it is very interesting..
- Akhtar Mohammad:** Sir regarding Tamiflu, assuming that no outcome has been made until 2016 in the lower district court would do you launch, would that be at-risk launch?
- Rajeev Nannapaneni:** I think we will make that call in conjunction with our partner I think at that time. I think as of now I think it is premature to say. I think there is a still time so let us see how it plays out.
- Akhtar Mohammad:** That will be a full-blown trial right.
- Rajeev Nannapaneni:** I think with the question of that particular patent, I think the Federal District Court has said that this patent is invalid, that will go into the merits of that, correct.



*Natco Pharma Limited
November 16, 2015*

- Akhtar Mohammad:** The court has not made a ruling until August 2016, would that be at-risk launch for Natco or...
- Rajeev Nannapaneni:** As I said we will make that call then yes, so I think once we it is closer we will make that call. We are hoping that we will get a resolution by then. But if we do not, then I think we will make that call in conjunction with our partners.
- Akhtar Mohammad:** One last question sir regarding Copaxone, assuming you get an approval, how soon can you launch Copaxone?
- Rajeev Nannapaneni:** We are ready to go.
- Moderator:** The next question is from the line of Brijesh Kasera from Edelweiss. Please go ahead.
- Brijesh Kasera:** My question is on Treanda. There was a press article which said that Teva has settled for Treanda, have we settled for it in the US market?
- Rajeev Nannapaneni:** Yes, we have been, but I have not reported it because it was not a material event. As you know there are like 12 or 14 filings on Day-1 I think I remember that. Honestly, I am not overly optimistic about it. It is one of those.
- Brijesh Kasera:** We have finalized the date also on this?
- Rajeev Nannapaneni:** I think we are agreed to some date, I do not recollect some date. And an earlier date, they have given earlier date to someone else. I think that is arrangement because we are FTF. We agreed for a particular date launch. I think confidentiality prohibits us from telling us what that date is and we can launch it earlier if they give better terms to others. I do not think we are going to trial on it. I think others are going to trial on it, we are not going to trial on it.
- Brijesh Kasera:** And the day was con-call coming back to Copaxone I had query because I think they were mentioned in the call that 40 mg does not have any copay and that is what helping them to get the market share. Is my understanding correct or did I read the transcript correctly?
- Rajeev Nannapaneni:** I would not know. I am sorry Brijesh. I do not know. I would not know what that means. I will just check and I will let you know.
- Brijesh Kasera:** But that would actually...
- Rajeev Nannapaneni:** They are discounting in further without giving the discount of copay I would not know Brijesh, I will just check and let you know.
- Brijesh Kasera:** That is not a problem. And Strides in the con-calls said that they have launched the Sovaldi, Sofosbuvir basically in the few emerging market, have we launched Sofosbuvir in other emerging markets recently?



*Natco Pharma Limited
November 16, 2015*

- Rajeev Nannapaneni:** We are in the process of launching. We have launched. Of the country, we have filed about 8-9 countries so far. I think we have launched Nepal. It is a very small country. And then we have got South East Asia and now we are waiting approvals. I think in the next few months, we are expecting approvals. I think we have launched in Africa and couple of countries. If I remember right we launched it in Burundi or **(Inaudible) 38.05** one of the smaller countries we have launched. We have also launched in some of the small emerging markets, but the bigger ones are as I said last time in my call, the bigger ones are Nigeria, Indonesia, Vietnam I think and Myanmar, these are the bigger ones.
- Brijesh Kasera:** One final question you mentioned the drug that you have filed in April 2015, if you could repeat that?
- Rajeev Nannapaneni:** What products are these, I mean talking about the India domestic you are saying?
- Brijesh Kasera:** No the US filing that you did the three filing of that one...
- Rajeev Nannapaneni:** I said of the three, I am only allowed – I have only disclosed one, I am not disclosing others.
- Brijesh Kasera:** So that one product I missed the name, so if you could repeat it once?
- Rajeev Nannapaneni:** Zytiga is the brand name, and generic name is Abiraterone.
- Moderator:** The next question is from the line of Nitin Agarwal from IDFC Securities. Please go ahead.
- Nitin Agarwal:** In Sovaldi in the domestic market, have there been any more approvals since they have come in after the couple of approvals came in for yourself and Hetero early in the year.
- Rajeev Nannapaneni:** I think Mylan has got an approval think. I do not remember exactly, but so far I think Mylan also got an approval.
- Nitin Agarwal:** Does you expect everyone to really for Harvoni also the way they went for Sovaldi or...
- Rajeev Nannapaneni:** I think what is happened with Harvoni my instinct is based on again I stand to be corrected Nitin keep that as a precaution note all the filers that are there for Harvoni I think Natco and Hetero are advance filers in these products also and Daclatasvir we are the only filer as of now. May be in about three months' time I think other guys will catch up but as of now that's what it looks like. So on Harvoni what I think would happen is both of us will probably get approval around similar times few days to spare that way and both of us will launch our own brands plus we will give it to some P2P partners like Cadilas, Sun, or the Ciplas of the world. So you will see about six front-end brands and two manufacturing companies. It play out like this. Daclatasvir relatively should be less competitive for few months I think but we have to see how it plays out.



*Natco Pharma Limited
November 16, 2015*

- Nitin Agarwal:** On Sovaldi, I mean what is your own strength in terms of how the market share really splits between yourself and Hetero including the P2P partners as well as their own products?
- Rajeev Nannapaneni:** I think we are doing okay, I think between P2P and our own manufacturing of about 65% market share I think we have.
- Nitin Agarwal:** It is about a 100 crore sorts of a market right now there about.
- Rajeev Nannapaneni:** I am only guessing because IMS is terribly bad in covering this. But Daclatasvir and all **(Inaudible) 40.30** when we are going to launch and all, but we are hoping. Let us get the approval and I think we will see how it plays.
- Nitin Agarwal:** How is this product done globally Daclatasvir?
- Rajeev Nannapaneni:** It has done quite well. It is BMS product, so it has done well, but it has not done great because it used in combination with Gilead. Gilead has not worked with BMS on this product. They are trying to push their own combinations. So that is why we have challenged there but Daclatasvir as a drug is a good product.
- Moderator:** The next question is from the line of Gagan Borana from ICICI securities. Please go ahead.
- Gagan Borana:** Yes the combination of Sovaldi, we are saying Daclatasvir and Harvoni, the market size are we saying is it 20% of the Sovaldi market size?
- Rajeev Nannapaneni:** Sovaldi has a certain market share. Ledipasvir and Sofosbuvir is a combination tablet so if you have Genotype-I let us say Sofosbuvir is giving you Rs. 100 per prescription. Sofosbuvir plus Ledipasvir will give you Rs. 150 per prescription because Ledipasvir and Sofosbuvir are in a single film that is one. Daclatasvir is used in combination with Sofosbuvir so you get a separate prescription for Sofosbuvir plus Daclatasvir. But for every prescription of Sofosbuvir you need to take Daclatasvir. So it is not going to be 20% you understand if we are 100 films being sold 100 films of either Ledi and SOF will be sold. So both have to be used in conjunction so the market is much bigger. But all these depends on the price erosion of these molecule if the price erosion is greater than obviously it will be harder. But it is one to one if you take SOF you have to take other pill also.
- Moderator:** As there are no further questions from the participants, I now hand the conference over to the management for their closing comments.
- Rajeev Nannapaneni:** No thanks everyone here, so it has been great.
- Moderator:** Thank you very much members of the management. Ladies and gentlemen on behalf of Religare Capital Market, that concludes this conference call. Thank you for joining us and you may now disconnect your line.