Sun Pharma Advanced Research Company Ltd.
Transcript of Management Presentation
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Participants:

Mr. Dilip Shanghvi – Chairman & Managing Director

Dr. T. Rajamannar – Executive Director

Dr. Nitin Dharmadhikari – Solid oral innovative delivery systems

Dr. Ajay Khopade – Injectables and other liquid innovative delivery systems

Dr. C. T. Rao – New Chemical Entity Development

Dr. Shravanti Bhowmick – Clinical Research

Dr. Atul Raut – Clinical Research

Mr. Kirti Ganorkar – Business Development

Mr. Narendra Lakkad – Business Development

Moderator: Ladies and Gentlemen, Good Day and Welcome to the SPARC Investor Update. 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 the conference please signal an operator by pressing '*' then '0' on your touchtone telephone. Please note that this conference is being recorded. I now hand the conference over to Mr. Nimish Desai. Thank you. And over to you sir.

Nimish Desai: Good evening and a warm welcome on the SPARC Update on NDDS & NCE Projects. We hope you received the presentation we sent out sometime back. This is also available on our website for downloading. The call transcript will also be put up on SPARC's website soon.

It would be appropriate to mention that the discussion today may include certain forward-looking statements and this must be viewed in conjunction with the risks that SPARC business entails.

During today's call, we will make an effort to answer all your questions, but if time does not permit I request all of you to please send in your questions to the IR Team.

We have the entire SPARC team with us on the call today. Let me briefly introduce the team to you. We have Mr. Dilip Shanghvi – Chairman and Managing Director; Dr. Rajamannar – Executive Director; Dr. Nitin Dharmadhikari who handles the Solid Oral Innovative Delivery Systems; Dr. Ajay Khopade who handles Injectables and Other Liquid Innovative Delivery Systems; we also have Dr. C.T. Rao who handles the New Chemical Entity Development and we have Dr. Shravanti Bhowmik and Dr. Atul Raut who handle the Clinical Research. From the business development team, we have Mr. Kirti Ganorkar and Mr. Narendra Lakkad.

I now hand over the call to Dr. Rajamannar for his presentation. Over to you sir.

Dr. Rajamannar: Thank you, Nimish. Good evening to all who are on the call. I am happy to share some of the updates from the last call of March 2013. Three important developments have happened for Paclitaxel Injection Concentrate for Nanodispersion (PICN). We are delighted to have the Indian marketing approval for this product and we also had successful end of Phase-II program discussion with the US FDA and we shall be initiating the Phase-III program in US and other rest of the world markets. It is also important to mention here that we have secured the PICN patent grant which is valid up to 2028. And we are also working on developing other programs where the product could be used for many other indications than what we are currently studying.

The other important aspect is the NDA filing for the BAK-free ophthalmic Latanoprost solution in US based on the Phase-III clinical program. This is an important objective where we learned about a lot of aspects of filing the NDA of a product. It is also gratifying to inform here that we have received the marketing approval in India for the Latanoprost and Timolol Ophthalmic solution in Q2FY14. In the last call, we had also shared updates regarding our NCE programs. For SUN-597 we had the superior efficacy compared to placebo. We have progressed on SUN-597 to initiate the Phase-I first-in human study in UK for the Asthma and COPD indication using the DPI product. We also initiated the Nasal program for SUN-597 for Allergy in Canada based on the US IND acceptance.

Now, I will move on to Slide #4. We are consolidating on the therapeutic areas to focus in terms of the resource utilization. The important therapeutic programs are Ophthalmology, Oncology, CNS and Respiratory. In Ophthalmology we have two platforms: Swollen Micelle Microemulsion (SMM) as well as the Gel Free Reservoir Technology (GFR). And as I mentioned in Slide #3 we have products already in the markets based on these technologies and we have also filed an NDA for one of our products. In Oncology, we have PICN as and a product in the market with the Liposomal Drug Delivery platform. The third program in the Oncology space includes products like Octreotide based on Biodegradable Depot technology and other products which are in the development. In the NCE oncology programs, we have a selective and potent Tyrosine Kinase Inhibitor which we think will have a significant advantage compared with the products approved in the T315I mutant system.

Moving on to the CNS, all of you know that we are developing Baclofen using the GRID technology, and there are also products based on the Wrap Matrix technology. In Respiratory, we have the efficient Dry Powder Inhaler (DPI) system wherein with half the dose; we are able to achieve the therapeutic benefit in the patients. We also have the soft steroid program in the respiratory segment. We also have the LTD_4 program for which we are planning to complete the IND requirements by end of FY15. I now request Dr. Ajay Khopade to present the Ophthalmology programs.

Dr. Ajay Khopade: Thank you Dr. Rajamannar. Good evening to all of you. I am Ajay Khopade working with the Formulation development group at SPARC. Today, I will be updating you on two ophthalmic programs from our existing pipeline. One is the BAK-free Latanoprost Ophthalmic solution and the second one is a fixed dose combination product containing Latanoprost and Timolol. Both these products are targeted at Glaucoma patients who develop dry eyes upon chronic use of BAK containing Glaucoma drug. Keeping eye healthy is one of the important targets of this therapy as it increases comfort and increases the success rate of Glaucoma treatment.

Slide #6: The first product is the BAK-free Latanoprost Ophthalmic Solution based on our SMM platform technology for water insoluble drug. With this formulation we will have reduced risk of ocular damage and also stability at room temperature thus reducing the risk of temperature excursion that may occur at the distribution channel.

Slide #7: Let me elaborate on the opportunity in US for this product. Out of the 3 million estimated Glaucoma patients in the US, about 2.2 million patients will need treatment with some kind of Glaucoma medication. Out of these, about 50% would develop Ocular Surface Disease (OSD) of some kind and about 27% of them would have a severe form of this disease. While BAK remains the main cause of OSD, and the current standard of care is a lubricating eye drug, in both these patient population, our product characteristics will be beneficial.

Slide #8: This slide gives you some indication of the commercial opportunity envisaged with this product. Out of about US$2 billion Glaucoma market in the US, Prostaglandin market is about 50% of the sales, with the annual growth rate of about 6%.

Slide #9: Among all the Prostaglandin used in Glaucoma therapy, Latanoprost is the largest selling Prostaglandin with more than 60% of the volume market share. Out of this about 10-16% of the patients are likely to develop Ocular Surface Disease. So, out of these 22 million units of Prostaglandin market, Latanoprost brand and other generic will comprise about 63% and out of which our product sales are expected at about 2 million units.

Slide #10: This year we have filed this product NDA in US and four select emerging markets. We are also evaluating various options of commercialization in US market and we are planning to file this product into additional 5 emerging markets.

Slide #11: The second product in this therapy area which we had discussed in the past is a fixed dose combination of Prostaglandin and Beta Blocker, which is a combination of Latanoprost and Timolol. The benefits of this product are same as described earlier. After completing Phase-III trial in India, with successful achievement of a non-inferiority margin, this product was filed in India.

Slide #12: The product is now approved and launched in India. The product will be filed in select emerging markets this year. We have also obtained guidance from the European regulatory consultants for European filing, and also the commercial potential of this formulation is being evaluated.

With this update, I will transfer the call to my colleague, Dr. Shravanti.

Dr. Shravanti Bhowmik: Thank you, Ajay. Good evening. I am Shravanti Bhowmik from Clinical Research, and I am happy to share update on this advanced technology product in Oncology from SPARC – Paclitaxel Injection Concentrate for Nanodispersion (PICN). I am on Slide #14: We have, in the past, shared information on the Novel Paclitaxel Formulation developed by SPARC using the Nanotecton technology. As you are aware, this is a Cremophor and Albumin free formulation with the added advantage of a very simple infusion preparation method.

Slide #15: For our Breast Cancer program, we obtained guidance from USFDA at the end of Phase-II meeting held in December 2013. The Phase-III clinical design has now been finalized. We will submit the complete protocol to USFDA in Q2FY15. We plan to initiate a multi-country clinical trial in Q3FY15.

Slide #16: Paclitaxel is also effective in indications other than breast cancer. We conducted Phase-I trials in India and US and enrolled subjects with all solid tumors. Being Phase-I, the number of subjects enrolled was limited; however, we observed efficacy benefits in several tumor types which deserve further the investigation in Phase-II trials. New cancer indications under consideration for Phase-II are Cholangiocarcinoma, Ovarian, Cervical, Anal Canal, Bladder Cancer and Melanoma. We plan to select a couple of indications for initiating Phase-II trials in FY15. The information that I have just shared is when PICN was administered as monotherapy. Paclitaxel is also administered in combination with other chemotherapeutic agents. To expand the use of PICN as a component of combination chemotherapy, we had initiated Phase-I studies in combination with Carboplatin. We have now identified the maximum tolerated dose of PICN in this combination. Our next step will be to select an indication for Phase-II studies.

Slide #17: I move to commercial potential of PICN in breast cancer in the US market. Our market research confirms that Paclitaxel is a standard of care in treatment of early and metastatic breast cancer. Currently, both Paclitaxel and ABRAXANE are not approved in a weekly dosing schedule for breast cancer. However, major use, that is, around 85-90% is in a weekly dosing schedule in this indication. An estimated 30,000 breast cancer patients are treated with Paclitaxel in US every year, of which 12,000 patients are with metastatic breast cancer. Additionally, 9,000 metastatic breast cancer patients are treated with ABRAXANE. So, as you can see, we can target a population of approximately 20,000 patients for PICN. With safety and efficacy established in weekly dosing regimen with our Phase-III program and added advantages of short infusion time and no pre-medication, PICN could address this patient population.

Slide #18: I present an update on regulatory status for PICN. As I mentioned earlier, we have guidance from USFDA on the Phase-III trial for metastatic breast cancer in a weekly dosing with plans to initiate the trial in

Q3 FY15. In India, we received marketing approval for PICN early this year and are planning to launch the product in Q1 FY15. I would like to complete this update with a brief summary.

As you have seen, the development program for PICN is extensive. A considerable amount of clinical data has been generated through Phase-I clinical trials in India and US and Phase-II, III in India. More than 1,000 treatment cycles have been completed in 200 plus patients – majority with breast cancer and a few with other types of cancer. None of the patients were administered pre-medication and efficacy and safety was similar to Paclitaxel and ABRAXANE. This therefore is one of the most important projects for SPARC. With this I hand over to Dr. C.T. Rao.

Dr. C.T. Rao: Thank you, Dr. Shravanti, and a very good evening. I am Dr. C.T. Rao from the Medicinal Chemistry Division. I have the pleasure of updating you on the status of our ongoing NCE project for the Leukemia program, namely the Tyrosine Kinase Inhibitor SUN-K706.

Slide #19: In the previous Investor Update we had discussed our New Chemical Entity SUN-K706, a Bcr-Abl Tyrosine Kinase Inhibitor for the treatment of a form of blood cancer that is chronic myelogenous leukemia, especially targeting patients who are resistant to Imatinib or intolerant to Imatinib, and other currently available Tyrosine Kinase Inhibitor therapies. As we have earlier disclosed, SUN-K706 has an excellent pre-clinical profile. It is a highly selective inhibitor of the Abl Kinase and its important mutants including the key mutant namely, T315I. Although the patient population with this particular mutant is very small, there is still an unmet need. The only drug which has been approved for this mutation is Ponatinib, which was approved last year and was recently withdrawn from the US market due to side-effects. It was again was reinstated with a black box warning for patients having cardiovascular problems. So there is still an unmet need in this area. Our New Chemical Entity SUN-K706, unlike Ponatinib, is a very selective Kinase Inhibitor and it is not a pan kinase inhibitor like Ponatinib, so we expect that this would not have the off-target side-effects which were seen in Ponatinib. This we have also seen in our animal studies. We have now developed a very stable and bioavailable formulation for which we want to perform clinical studies in future.

Moving on to the next slide: Using this new formulation, we just tested the efficacy in mouse tumor xenograft model using CML cell lines and we find that there is a good dose dependent tumor inhibition in this model, indicating good bioavailability and also good efficacy.

Going on to the next slide: Besides the oral efficacy, in our safety studies using this molecule we have found that it has very low potential for cardiovascular side-effects which are seen in some of the Tyrosine Kinase Inhibitors in this class, and also other side-effects like thrombocytopenia which is seen in Dasatinib. So our

compound is devoid of these particular side-effects and we expect that in clinical studies also this molecule would be devoid of side-effects.

Next Slide: Using this new formulation, the Regulatory Safety Pharmacological Toxicity studies using K706 have been initiated and would be completed by Q3 FY15 and IND filing is expected in the subsequent quarter. With this I hand over to Dr. Dharmadhikari to discuss the CNS programs.

Dr. N. Dharmadhikari: Thanks you, Dr. Rao. Good evening. I am Dr. Nitin Dharmadhikari and I head Oral Development at SPARC. Currently, I am on Slide #23: I will update you on the status of two products based on Wrap Matrix and Baclofen ER based on the GRID system.

Slide #24: This slide gives the update for Levetiracetam ER 1000 mg and 1500 mg. As you are aware, SPARC has filed an NDA in early 2012-13. We received complete response letter from the USFDA. Post complete response letter, we had an interaction with FDA. To address FDA's concerns we propose to do one additional PK study, for which FDA response is positive. We plan to complete this study and submit the response by Q2 FY15.

It shall be noted that SPARC owns substantial intellectual property (IP) lasting till 2028 for this product. The IP covers composition and dose ranging from about 800 to 1600 mg of Levetiracetam for once-a-day product. We believe this IP can protect this product from early generic competition once the product is launched.

Slide #25: This slide gives the details of market access study and potential for this product in the US market. Our study showed that pill burden is a key issue for epilepsy patients and some of them are ready to pay higher co-pay to reduce this. As per US IMS, market growth for Levetiracetam is 11% and out of 600 mn tablets sold, 400 mn are for the dose more than 1000 mg. Thus we believe that this product has a good market potential. We also expect to commercialize this product at a significant premium to generics.

Slide #26: Venlafaxine 300 mg. This is the second product, which we have developed using Wrap Matrix technology. We have filed the NDA for this product in Q4 FY13. We have the received complete response letter in which USFDA has asked for clinical data to establish safety and efficacy of 300 mg dose. Post response, SPARC conducted a meeting with FDA in February and proposed to provide data from a published literature. It is also noted that the current labeling of Venlafaxine ER in US is up to 225 mg and FDA wants data to support safety and efficacy of the 300 mg dose.

Slide #27: This slide gives the details of Baclofen GRS. This is once-a-daily product for spasticity available in multiple strengths ranging from 10 mg to 60 mg. This product offers steady therapeutic level for once-a-day

dosing. This product is also protected by strong IP for formulation and method of treatment. These patents will offer protection to this product till 2027.

Slide #28: This slide gives details of market access studies and US market potential for which we have done the study. The US has nearly half a million patients suffering from spasticity. Baclofen is 'Gold Standard' for treating symptoms of spasticity. Key Opinion Leaders (KOL) and Payers have opined in this study that Baclofen GRS offers advantages in efficacy and patient convenience. We expect 5% to 10% switch from IR to GRS and Baclofen market is growing at average growth rate of 8% to 10%. We also expect to get significant premium for this product over generics.

Slide #29: It gives updated status on the clinical and regulatory front for Baclofen GRS. We are conducting Phase-III efficacy study in 300 patients. 28 sites are actively recruiting patients for this study and we are also increasing the number of sites to enhance the rate. Safety study in 200 patients is also progressing. Third study to prove ability of Baclofen GRS to provide once-a-day relief will start in next few months.

Slide #30: We are also evaluating Baclofen GRS in alcohol dependence. The Phase-II study conducted in 180 patients showed a numerical superiority but did not show statistical significance. SPARC is consulting experts in this area on a study design and also evaluating commercial opportunity in Europe to decide the path forward for this program. With this I hand over to my colleague, Dr. Atul to take the call further.

Dr. Atul Raut: Thank you, Dr. Dharmadhikari. Good evening, everyone. This is Dr. Atul Raut from Clinical Research. I will be updating you on the Respiratory programs of SPARC: There are three main programs: One is Salmeterol-Fluticasone Dry Powder Inhaler. Another is SUN-597 which is our Soft Steroid. And third one is SUN-L731 which is LTD_4 antagonist.

Slide #32: Let me brief you about our Dry Powder Inhaler of Salmeterol and Fluticasone. It is a uniform dose delivery system which is independent of inspiratory flow rate. It consistently delivers higher amount of drug to lungs. It eliminates double dosing and dose wastage. It provides all kinds of feedback, like audible, visual and tactile upon dose administration. There is a glow-in-the-dark feature for easy night-time use. And there is a feature for assisting visually impaired, as a reminder to refill the device when 8 doses are remaining. The device is small, convenient and easy-to-use and it is compliant with the stringent US FDA and European requirements. And as you are aware, this product is already approved and launched in Indian market. For US we are planning to file IND for this product in Q3FY15. For Europe, we already have submitted the clinical trial application to the Germany regulatory authority and this study is also submitted to Ethics Committee and

study is planned to be initiated very shortly. For emerging markets, we have identified one emerging market for which we plan to submit our filing in Q1FY15.

Our next product is SUN-597 which is a soft steroid. With this steroid, we have got good preclinical profile. It has optimal in-vitro potency for glucocorticoid receptors (GR) and in the high-throughput screening test the safety profile is very good and acceptable. It has in vivo potency and efficacy over a wide range of animal models of allergic inflammation of upper/lower respiratory tract. So preclinical data suggests that it is a safe corticosteroid and it will have a low systemic side effect and good efficacy in models of inflammation. For SUN-597, we are developing two products: One is Nasal Spray and second is a Dry Powder Inhaler which is for Asthma and COPD. So first let me update you on development of Nasal Spray. We have completed Phase-I program for this product in India and it was found safe. And last year we conducted a proof-of-concept Phase-II study in Germany, where we found that all three doses were superior to Placebo for efficacy, and safety profile was very similar to Placebo. The efficacy was comparable to marketed products like Mometasone and Fluticasone.

Slide #36: It gives the regulatory update for our SUN-597 Nasal Spray. We had a pre-IND meeting with USFDA for proposed Phase-II study for identification of optimum dosage and dosing regimen. We submitted the IND which was accepted by USFDA and we have initiated Phase-II study in this quarter and that study is expected to be completed in Q1FY16.

Slide #37: Let me just brief you about what are the commercial opportunities for this Nasal Spray in the US market. Allergic Rhinitis is a huge burden on allergy healthcare system in the US and approximately 25-30% patient population suffers from seasonal Allergic Rhinitis in the US. There are about 2 million missed school days and about 100 million missed work days annually and this will obviously cost indirect dollars to the health system. In the US Nasal Corticosteroid market, intranasal sprays are mainstay of moderate-to-severe on persistent Allergic Rhinitis, and as per US IMS data of 2013, this Nasal Steroid market is about US$2 billion. So, looking at the safety profile for this Nasal Spray and with about similar efficacy compared to the marketed product, we think that we will be able to penetrate this market of Nasal Sprays and we may have good opportunity.

The next product is SUN-597 Inhaler which is a Dry Powder Inhaler and we are developing this product for treatment of COPD and Asthma. We submitted a clinical trial application for this product with UK MHRA, and this was approved and the study has been initiated. This study consists of three parts; Part-I is a single dose study in healthy volunteers; Part-II is multiple dose in mild asthmatic patients and Part-III will give us indication about efficacy of our product. So that would be acting as a proof-of-concept study for this product.

The study is expected to be completed by Q2FY16, post which we plan to file the IND in the US and do a Phase-II program in the US in FY16.

Slide #40: Our third product is L731, which is a LTD_4 antagonist. This is highly selective and potent LTD_4 antagonist developed by SPARC. As you are aware, LTD_4 receptor plays an important role in Pathogenesis of asthma or nasal allergies also. The preclinical profile of our product shows that it is very potent and selective entity for antagonist; with a good oral bioavailability. It is a 10-times more potent if we compare its potency to Montelukast. And in preclinical models we have found that we have better efficacy and better duration of action when we compared our product with Montelukast. We have also seen that its onset of action is faster than Montelukast and obviously, there are no safety issues, that it has a very high therapeutic index. Currently, this product is in preclinical stage and we are preparing for IND filing by conducting safety pharmacology studies as well as toxicology studies and we plan to file a clinical trial application in UK in Q1FY16. With this update, I would now like to hand over the call to Kirti Ganorkar.

Kirti Ganorkar: Good evening. I am Kirti Ganorkar from Business Development Team. I am on Slide #42: As a part of the portfolio management and optimization, SPARC has done market assessment of some of the NCE programs shown in this slide, like SUN 1334H, B09 and G44. This assessment has shown that these programs are not viable and this will help SPARC to focus and prioritize on key programs and use the resources appropriately.

Slide #43: My colleagues have already presented to you the key clinical program which SPARC is conducting, I am just giving you a snapshot of these programs – and the first is Baclofen GRS for which we have already initiated two studies; one is a pivotal Phase-III studies in 300 patients and in addition to that we are doing a safety study. Parallel to these two studies we are also now initiating a 135 patient study which will establish once-a-day dosing of Baclofen GRS. Hence, for Baclofen GRS we are almost running three studies in parallel in US market.

The next program is PICN where we now have a data on 1,000 cycles and we have used this product in more than 200 patients. For PICN, we have successfully completed the end of Phase-II meeting with USFDA and this meeting gives us the guidance what we need to do in a Phase-III study. And for US market now we have clear path of doing a Phase-III study in metastatic breast cancer in a weekly schedule. So we will initiate this study in the next two quarters.

In addition to this, we are also doing a Phase-II studies for additional indications. As all of you know PICN has been used so far in a monotherapy but now we have completed a Phase-I study in combination with Carboplatin. And in future, we plan to initiate studies in combination with Gemcitabine.

Going forward to soft steroid, which is SUN-597, used for two indications; one is a nasal for Allergic Rhinitis; and second is a DPI for COPD and asthma. For SUN-597 nasal we have already completed Phase-I study. A Phase-II study in Germany showed that we are statistically superior to placebo and now we are conducting Phase-IIb study in Canada which will prove that this product is effective in Allergic Rhinitis. For SUN-597 DPI we have initiated the first Phase-I/Phase-IIa study. So this will establish the safety in the healthy volunteers as well as it will give us some proof-of-concept whether it works in Asthma patients or not.

Then the next program is DPI with Salmeterol and Fluticasone. This product has already been approved in India and we have relaunched the product in August 2013. We have initiated clinical equivalence study in Germany with the highest dose of DPI which is 250+25.

Slide #44: This slide gives the peak sales potential of some of the key SPARC programs. Before going into this peak potential I would like to put few caveats: These cash flows are estimated based on the market assessment done by SPARC and our interactions with industry experts. These cash flows can change substantially depending on with whom we partner, what is partner's ability to market this product and the doctor coverage of the partner. It also depends on what type of label we get for each product at the end of pivotal study. And most important is the cash flows will also depend on what kind of price reimbursement we will get from payors. So with this caveat, I would like to share with you that for first product, Latanoprost BAK-free we have estimated a peak sales potential between US$25 million to US$50 million. Again, just for the benefit for all of you, this sales potential will be in the hands of partner and SPARC will license this product to the partner.

For the second product, which is Levetieracetam ER 1000 mg and 1500 mg, the peak sales potential in the US is estimated to be in the range of about US$30 million to US$50 million. And in this program we have been granted a product and dose-specific patent which will protect Levetiracetam ER dosage form till 2028. So we hope that there would not be a generic competition. For Baclofen GRS there are three clinical studies, and this is a lengthy program. You need to appreciate that we need to do studies in patients with a difficult to treat indication. We target to file IND by 2018 and we estimate a sales potential with close of about US$100 million. As we said earlier we will expect the shift of about 5% to 10% of prescriptions from IR to GRS. On Baclofen GRS also we have good patent protection and we can protect this product from generic competition till 2027 with all patents granted.

Lastly, but most important is a key program of PICN, for which we have shown a sales potential of US$100 million to US$250 million only for one indication that is metastatic breast cancer. As I said earlier, we are developing this product as a monotherapy for two more indications and also in combination with Carboplatin for one or two indications. So PICN has the potential to become big. Currently, we have estimated the potential only for one indication but going forward we will share with you a potential for other indications also. Here also the patent has been granted in the US and which will expire in 2029.

In this Investor Update we are sharing with you the peak potential of some of our programs for the US market only. In the next Investor Update we will also share with you the peak potential of some of these programs in Europe, Japan and other emerging markets where we have plans to file these products.

Also, lastly, I would like to say that we are looking at licensing of these products to potential partners. By licensing SPARC will get upfront payments when we sign the agreement, we will get a milestone payment on approval or achieving certain sales, as well as we expect to get a royalty income on long-term basis. So this will be SPARC cash flow. My colleagues have presented to you all the programs, which require a large investment and we are trying to generate cash flows by licensing these products to various potential partners. If SPARC is not able to license out these programs to appropriate partners and not able to generate the required cash flow, then we may have to raise new funds so that these programs can progress to the next level. With this, we come to the close of this presentation and the floor is open for question-and-answers.

Moderator: Thank you very much sir. Ladies and gentlemen, we will now begin the question-and-answer session. The first question is from Riken Dalal of Finco Capital. Please go ahead.

Riken Dalal: For the product Exenatide, what is the technology differentiator, likely exclusivity in USA, what is the commercial opportunity in the US and other markets?

Kirti Ganorkar: You are talking about Exenatide which is a Sun Pharma program, so we would not be able to comment on this in the SPARC Investor Call.

Riken Dalal: Status on commercial assessment of 1334H for US market both for oral and ophthalmic dosages?

Kirti Ganorkar: The commercial assessment that SPARC has done for oral tablet product as well as the ophthalmic program. So we see that for the oral dosage there are a large number of products H1 antagonist which are already on the market and they have gone off-patent. Similarly, even for ophthalmology dosage,

there are H1 antagonist which are off-patents. And when we talk to some of the key opinion leaders and the peers, we feel that we would not get adequate reimbursement price which will justify developing this program further.

Riken Dalal: Regarding the royalty payments which you will be receiving in future, what is normally the percentage of royalty you would receive as a thumb rule?

Kirti Ganorkar: It is difficult to say because we have a various programs and indications like ophthalmology, oncology, etc. The royalty will depend on our negotiation with the partner what kind of label we get, what kind of price we will get as a reimbursement, what are cost of goods. So, there are a number of factors that will determine the royalty.

Moderator: Thank you. The next question is from Manoj Garg of DSP Merrill Lynch. Please go ahead.

Manoj Garg: Just wanted to understand as a thumb rule, after filing the NDA to USFDA, how much time it takes to get the approval or the response letter?

Kirti Ganorkar: After filing the NDA, the normal approval time is 10 to 12 months.

Manoj Garg: And the second thing, we have a tri-party kind of agreement between SPARC, Merck and Sun Pharma for few of emerging markets. Has any filing been done under that agreement so far?

Dilip Shanghvi: Merck and Sun agreement allows the use of SPARC technology. The primary agreement is between Sun and Merck. So any announcement related to filing or approval of the product will be made by the joint venture. So we cannot discuss this in this call. The SPARC technologies are included in the agreement in such a way that if Sun uses the SPARC technology for developing the product, then there are different royalty streams and a part of that royalty stream also goes to SPARC.

Manoj Garg: With a couple of NDDS, we are closer to launch in the US market, have we thought of about the route like whether it would be Sun Pharma who would be the partner or we will have a third-party to promote these products in the US market?

Dilip Shanghvi: I think ultimately it is all linked with the ability of the partner to market the product in the US. If Sun has an infrastructure to handle the product and is able to give terms which are more favorable than what SPARC gets from other manufacturers and it will be licensed to Sun. Sun has a right to market the product in emerging markets.

Manoj Garg: But not for the regulated market as a first right-of-refusal?

Dilip Shanghvi: There is no first right-of-refusal for the regulated market.

Moderator: Thank you. The next question is from Chirag Dagli of HDFC Mutual Fund. Please go ahead.

Chirag Dagli: When you say peak sales, over what period would these peak sales be achieved post launch? There must some thumb rule that you must have sort of factored in broadly see.

Kirti Ganorkar: Peak sales are sales which can be achieved in 3 to 5 years and you need to keep in mind that for a product like PICN which we are developing for different indications, the peak sales would come much later.

Chirag Dagli: So for PICN which is a relatively new market the peak sales would come much later?

Dilip Shanghvi: No, I think what we are saying is that PICN, we will start with one indication as a monotherapy, and as we continue to get additional indications at the subsequent point of time then peak sale for that indication will take additional time.

Chirag Dagli: And this US250 mn sales includes only one indication at the moment?

Dilip Shanghvi: US250 mn is for one indication.

Chirag Dagli: Of these four products that we have alluded to, how many will need a field force or promotion so to say to be sold in the United States?

Dilip Shanghvi: All of them will need field force.

Chirag Dagli: Then sir, given that this is relatively focused on few therapies, Sun could actually think of putting up a field force for these products?

Dilip Shanghvi: It can. It needs to be economically justifiable. You cannot support the field force in the US with one product with US$30-40 million.

Moderator: Thank you. The next question is from Parag Modi of Oaklane Capital. Please go ahead.

Parag Modi: My question was regarding the Wrap Matrix technology where we had some developmental problems with Venlafaxine and Levetiracetam. So would they affect the other products on the same technology platform? And also, what is the current peak sale potential for Venlafaxine, you have highlighted for Levetiracetam at US$30 million to US$50 million but you have not mentioned for Venlafaxine? Can you launch this in Japan because Japan has no generic yet? And what is the likely royalty and milestone for these particular products – Venlafaxine and Levetiracetam?

Nitin Dharmadhikari: The first part of the question I can answer, i.e., what will be the impact on the other products which are being developed on the Wrap Matrix technology. I think the issues which we have shared are specific to those products because there are expectations for that particular product, there is nothing to do per se with the technology. So these are specific issues for a specific product.

Parag Modi: The peak sales potential of Venlafaxine?

Kirti Ganorkar: We have not completed the market assessment but based on the product 225 mg which is on the market we estimated that peak potential would be anywhere between US$20 million to US$30 million for Venlafaxine 300 mg.

Parag Modi: and for Japan launch since there is no generic yet?

Kirti Ganorkar: Currently, our focus is to bring this product into US market, so we have not really studied Japan, because Japan requires additional clinical data or a bridging study.

Parag Modi: For these kind of products what are the thumb rules for royalty and milestone payments?

Management: It is difficult to give any thumb rule what we can get, because each product is unique and when we go to the partner the partner will also be unique and this is the first experience for SPARC to go and negotiate the licensing deals with other companies. So I cannot give a general guideline what will be the thumb rule.

Moderator: Thank you. The next question is from the line of Sameer Baisiwala of Morgan Stanley. Please go ahead.

Sameer Baisiwala: First question is on Baclofen GRS. If I am not wrong, I think it has already been one year since the Phase-III trials have been on and I think you are increasing the number of sites to further hasten it, whereas in the later slides you mentioned that the NDA filing would happen only 2018 which is 4-5

years from now. So how do you reconcile these two?

Dr. Shravanti Bhowmik: We have been adding the sites because our enrolment rate is currently below target and the target at which we need to reach we will need those many years to complete enrolment and that is why we have put December 2017 is probably the time when we complete the ongoing study and then we will be able to file in 2018.

Sameer Baisiwala: But just an observation, that another four years and one year has already been down at least, so five years, it is rather unusual for this length of Phase-III studies?

Dr. Shravanti Bhowmik: To clarify further, this is an indication of spasticity which is seen only in multiple sclerosis. As you are aware that there are a lot of disease modifying drugs which are already available to treat spasticity only are patients pool therefore becomes little smaller and to also comply with the stringent inclusion and exclusion criteria we need to screen a large number of subjects to get the right patient and that is the reason that we are going at this rate**.**

Sameer Baisiwala: My second question is for SUN-597, I think you mentioned it is quite comparable and efficacy to Fluticasone and Mometasone and this is for effectiveness in Allergic Rhinitis. A question here is if it is quite comparable then what would be the incentive for someone to go to SUN-597 versus the two available drugs?

Dr. Atul Raut: We have said that the efficacy is comparable to published data for Mometasone and Fluticasone. Having said that, what we are anticipating with our product is long-term safety, because these kind of products are approved for seasonal Allergic Rhinitis and perennial Allergic Rhinitis. Perennial Allergic Rhinitis needs long-term treatment with steroid. If we compare our product with Mometasone and Fluticasone we think that our safety profile will be better and that will be the advantage.

Sameer Baisiwala: Could you be more specific, which is a better safety profile…

Dr. Atul Raut: Hypothalamic pituitary excess suppression is basically the main concern on long term use of steroids.

Sameer Baisiwala: Sorry, what separation you said?

Dr. Atul Raut: It is hypothalamic pituitary excess suppression.

Dilip Shanghvi: All steroids have systemic side-effects, and that is the reason why oral steroids are not given long-term. And the other important thing is that for specially rhinitis and asthma, both these indications have a fairly large patient pool of children. And it is established in multiple studies that long-term use of steroids in children reduces the overall growth of the children in terms of height. So, if we can get efficacy in terms of comparability and we can get reduced systemic side-effects there is an interesting market opportunity here.

Sameer Baisiwala: If I look at your peak sales potential, it is for Latanaprost US$25 million to US$50 million and Levetiracetam is US$30 million to US$50 million, and that will be achieved in 3 to 5 years from the launch. Do you think these are profitable opportunity in considering the marketing expenses that one needs to incur on these two?

Dilip Shanghvi: I think all of these products can be additional products to a field force which is already visiting those doctors. They will not justify creating a separate field force with only one product. Now, when we talk of typically 3 to 5-year peak sales… and that is the industry standard. Now my own assessment is that for a drug which is fairly well-known and where we have a new improved dosage form we may be able to achieve this faster. But that is not something that we have experienced. So that is the reason why we will not be taking that as a position.

Moderator: Thank you. Our next question is from Ketan Gandhi of Gandhi Securities, please go ahead.

Ketan Gandhi: Are you developing an improvised version of Doxil for treating the hand and foot syndrome?

Dilip Shanghvi: The side-effect that you talk about is a side-effect because of the way the drug works, and the way it is distributed in tissues, because it is a liposome**.** So I think with this technology it is not possible to avoid the side-effects.

Ketan Gandhi: Are you developing more products using Liposomal technology?

Dilip Shanghvi: Nothing that we can share with you.

Moderator: Our next question is from Karthik Mehta of ICICI Securities, please go ahead.

Karthik Mehta: Hi, just wanted to understand that you mentioned in the event some of your molecules or some of your programs were not out-licensed, you may have to raise some money, we have some revenues of Doxil which have started for SPARC from the last three quarters? Would you also factor that and would

that also be a consideration to raise money? I am just trying to understand what is the expected increase in the expenses for SPARC over the next 3 to 5 years, understanding from that, actually most of our programs are in Phase-II or entering Phase-III.

Dilip Shanghvi: I think the idea would be to maybe minimize the dilution of shareholders, so we factor all the cash flow and revenue coming in to the company before we raise fresh money. I think we have not shared the potential cost going forward, but as I see some of the important products and especially PICN will go into fairly massive Phase-III study in a short time, unless and until we are able to outlicense one or two products we will need to raise money. Philosophically, I am not very keen to dilute the existing shareholders, but if there is a need for funding the project, then we will need to raise money.

Karthik Mehta: So assuming a scenario that some of the other products are out-licensed and you would always want to put that overall cash flows for PICN, is that a fair assumption or will it be that you would do it on a standalone basis for a molecule also?

Dilip Shanghvi: No, we may out-license PICN also, in which case subsequent cost of development can be either shared, but then the negative would be that somebody invests for Phase-III then he would pay much lower royalty.

Moderator: Thank you. Our next question is from Parin Gala of Gandhi Securities, please go ahead.

Parin Gala: My question is relating to Latanoprost and Timolol together. Sir, I believe the product has been launched in India in January 2014. Can you share the response by the Indian patients? And then what is the milestone income and royalty to SPARC for this product in India?

Dilip Shanghvi: We do not give out specific product-based milestones and royalty, but it has been launched in India and Kirti can brief you about how the product is doing.

Kirti Ganorkar: For the Latanoprost BAK-free which has been launched in India, and as per the current IMS, so Sun has about 50% market share followed by Pfizer at 27% and Cipla at 23%. Similar case I see with Latanoprost, Timolol which is a small market, but there also we have about 50% of the market share in India, then Pfizer is with 30%.

Parin Gala: And Sir, the other question regarding same Latanoprost and Timolol, you have indicated three to five years, but in India and EU what would be the peak sales potential?

Dilip Shanghvi: Timolol and Latanoprost is a relatively small product, and generally used only for patients who do not respond to single ingredient Latanoprost, and our objective would be to try and get a bigger share of that market. But what I see is that over a period of time, the share of prescription of the Prostaglandin in the glaucoma market has been increasing. So if it comes anywhere close to what it is in the US, then I think it can be a very interesting product.

Parin Gala: Sir, the last question, like in clinicaltrials.gov, is there any particular site for the European Union also to follow for data availability?

Dr. Atul Raut: Yes, actually clinical trials for Europe, you can follow on EudraCt, that is European clinical trials site, just as we have clinicaltrials.gov for US.

Moderator: Thank you. Our next question is a follow-up from Riken Dalal of Finco Capital**.**

Riken Dalal: Regarding the fund raising program which you mentioned, will it be via equity or debt financing, because equity financing will be ultimately very costly in the long run, and ultimately debt is always cheaper than equity. If we are quite confident of our projects going forward and if we are confident of our pipeline of projects, then obviously debt financing will always be cheaper than equity financing.

Dilip Shanghvi: I think we also have to keep in mind that there is no tangible asset with the company, there is no current predictable consistent cash flow. So for a company with that kind of asset background, it will be a challenge to raise debt at favorable terms, but we would look at both the options.

Riken Dalal: Normally if a corporate guarantee is given by other good company, your flagship company, then it becomes much easier to raise debt at a cheaper rate?

Dilip Shanghvi: Yes, but why would anybody give anything without any consideration?

Riken Dalal: It can get a cost; SPARC can pay some fees to the parent company Sun Pharma.

Dilip Shanghvi: First of all, I think let us understand SPARC and Sun, they are two separate independent companies, they are not parent and child companies anymore. So that is an important consideration for you to keep in mind, relationship between Sun and SPARC is at arm's length basis. So that is one thing. Second is that I think for everything which Sun will do for SPARC, they will expect a return on that because it is arm's length relationship. Sun can buy shares of SPARC, that is a separate issue, but then that will kill the purpose of separating both the companies.

Moderator: The next question is a follow-up from Chirag Dagli of HDFC Mutual Fund, please go ahead.

Chirag Dagli: Sir, on the DPI opportunity, given that now in the United States, there is substitution possible, does this in anyway reduce the opportunity for our Inhalers in the market?

Kirti Ganorkar: I think in US there is guidance for developing a generic DPI, and as we said in the presentation, we are developing a 505(b)(2) product, because we have a different strength and more efficient device.

Chirag Dagli: Sir, that is what my point was, that it will be so much more difficult to prove, or to commercialize a superior product vis-à-vis a generic substitutable product especially when it does go off-patent by the time we come to the market?

Kirti Ganorkar: The product that we are developing it is not generic, it has some advantage, so we have a similar PK profile, but there would be certain advantages in terms of safety, which we need to see in clinical studies.

Chirag Dagli: So, the fact that there would be an opportunity for a fully substitutable generic in the market would not hamper its ability to be out-licensed in any manner?

Kirti Ganorkar: Currently, we are focusing our program on Europe and your question relates to US.

Participant: And sir second question Mr. Shanghvi, we are talking about not-so-stable kind of cash flow and possible dilution for SPARC, I am just trying to think, is there merit in folding it back into the Sun Pharma, that way some of these programs actually may not face cash flow issues?

Dilip Shanghvi: I think there is a reason why both the companies were separated, and management believes that there is justification and continued validity of those reasons. So as of today there is no proposal and plan to merge both the companies.

Participant: So between two options of folding it back, we would rather dilute than to fold it back?

Dilip Shanghvi: Yes, that is correct.

Moderator: Thank you. Our next question is from Prakash Aggarwal of CIMB. Please go ahead.

Prakash Aggarwal: One question here on the out-licensing environment especially when we have seen

recently large generic giants like Actavis acquiring specialty companies – Forest, who spends more than 30% of their top line in R&D, so would these large companies apart from innovators look out for more aggressive out-licensing, what is your sense there?

Dilip Shanghvi: Mergers and acquisitions happen because of many considerations. We do not understand all these considerations. My own view is that Generic business and Branded business are very different, they need to be run very differently, and they have different cost structures. If you integrate both the businesses in a common organization, it then becomes a very big challenge in managing the work discipline in a way whereby both the businesses are run efficiently. The only company which has been able to do it very well is Novartis, which has a totally separated independent subsidiary for managing Generic business. So I do not know how going forward this will evolve.

Prakash Aggarwal: But if we keep this M&A aside, what would you comment on the out-licensing environment, as couple of our products as you said are in advanced stage and we may look for out-licensing them due to higher R&D, so are we already seeing some interest and we are talking to a few partners, how should we think about this?

Kirti Ganorkar: What we can say the current out-licensing environment looks good because there are not many assets which are in Phase-III or close to pre-registration or approval. So it is my personal thinking this is a good time for SPARC to out-license a program and there is a fair amount of interest from different parties.

Prakash Aggarwal: Lastly, so would SPARC look at only at late stage out-licensing where the cash flow is quite high?

Dilip Shanghvi: For all the programs that we have shared with you, I think the interest is to license beyond proof-of-concept not earlier than that. Preferably at pre-registration or close to market, but definitely not before establishing proof-of-concept.

Moderator: Thank you. Our next question is from Manish Jain of Axis Holdings. Please go ahead.

Manish Jain: My question was on PICN, just needed one clarification, that the 200 patients thousand cycles, this you were referring to the US alone, or are you including India data as well?

Kirti Ganorkar: Both India and US.

Manish Jain: Based on the discussion with the FDA what really is the size required for Phase-III of patients?

Narendra Lakkad: That is something which we are currently working on because we need to make a certain statistical assumptions, and the study size will depend on that.

Manish Jain: And the way we did it in Baclofen GRS, will it make sense to take an SPA with the FDA on this?

Narendra Lakkad: So that is also an option, but so we are being plus and minus for both whether we should go, what would be an optimal strategy, whether to go for any SPA or go for filing a protocol and then asking for a written feedback.

Manish Jain: Yeah because my question was related to SPA was that I was trying to figure out is there any way we can look forward to an accelerated approval?

Narendra Lakkad: SPA is a different than accelerated approval if I understand correctly, and SPA only gives an opportunity for SPARC to get a binding commitment from FDA on the Phase-III design, other than that SPA does not offer any additional advantage.

Manish Jain: Last thing on PICN is based on the product performance till date, would you expect a premium over ABRAXANE in the US?

Dilip Shanghvi: I think ultimately we have to do much more detailed market assessment and interaction with payors and others before we can decide on whether we can get premium over ABRAXANE or not. We believe that the product is clearly having a few technical advantages over ABRAXANE but that whether that benefit we should use for improving our market share or whether we should use for getting a better pricing is ultimately a decision which we have to take to optimize the value of the product.

Moderator: Thank you. Our next question is from Krishna Prasad of Kotak. Please go ahead.

Krishna Prasad: Relating to the Depot injection platform that you have I think you have mentioned Leuprolide in the course of the presentation, but we do not find that in the actual presentation, if you could give us a sense of the timeline on where we are on Leuprolide at this point?

Kirti Ganorkar: So what I think Dr. Rajamannar wanted to say was Octreotide Depot not Leuprolide, so we want to clarify this here.

Krishna Prasad: So Leuprolide is not part of SPARC?

Dilip Shanghvi: Yes, that is correct.

Krishna Prasad: So just on Octreotide then, has there been any progress since the last time we had this update?

Dilip Shanghvi: There is nothing which is meaningful; we continue to work on the product. It is not a product that we are considering to drop.

Krishna Prasad: Sir, just the other question I think for the first time we have actually put out a peak sales potential for some of these products. So let us say something like Latanoprost where we have been working for a while now, how has this peak sales potential actually moved over a period – when we started off on this project was this number significantly higher or lower and how is this number sort of evolved over this period, if you could just give us some sense on that?

Dilip Shanghvi: Our own view is that reimbursement environment in the US in last 5-years has become far more demanding than what it used to be. So it would have had a negative impact in terms of peak sale potential.

Krishna Prasad: And would that be sort of a broader trend that you are talking about not just Latanoprost, but you are saying it is…?

Dilip Shanghvi: Yes, that generally applies to all differentiated products.

Krishna Prasad: Just very specific to Latanoprost if I were to understand this correctly the last Prostaglandin which got approval did not have a preservative, any reason why you think that has not really had a significant impact on their market sales, I am talking about Tafluprost?

Dr. Atul Raut: I think efficacy of Tafluprost is inferior to Latanoprost because if you see their approval they could not prove non-inferiority with Latanoprost and they have got approval doing non-inferiority study with Timolol. So I think efficacy may be the issue.

Kirti Ganorkar: More to do with the Prostaglandin efficacy

Dilip Shanghvi: I mean more related to the product than related to it being BAK-free

Krishna Prasad: Because you are playing on a BAK-free platform, would we require let us say a head-to-head study versus Travatan Z which is another BAK free in the market, would that be something that we

would need to do or at this point you think whatever you have done should enable us to get through in the market?

Dilip Shanghvi: It is not a regulatory requirement.

Krishna Prasad: But from a commercial perspective that is something that we would consider?

Dilip Shanghvi: I do not see that has an immediate requirement. For clarity, I think Travatan Z is a much bigger product than US$25 million to US$50 million that we are projecting for Latanoprost BAK free.

Moderator: Thank you. Our next question is from Krunal Shah of Amideep. Please go ahead.

Krunal Shah: My question is relating to tax that we paid in the Q3 this quarter. We have a carry forward loss of Rs.140 crores on our balance sheet as of 31st March, then why did not we set off the loss against the profit?

Dilip Shanghvi: I think it is MAT or AMT.

Moderator: Thank you. Our next question is a follow up from Kartik Mehta of ICICI Securities. Please go ahead.

Kartik Mehta: If I look at the products which have been discontinued especially 1334 oral, in the last presentation that was indicated to be in Phase-II, other than that almost all of them were either just completing Phase-I or they were just at the end of the pre-clinical, I just wanted to understand that what would make you discontinue a product when it is in Phase-I itself and may be not just wait until Phase-IIA? Is it that there were more similar drugs that would have come after you would have initiated any of the clinical studies?

Dilip Shanghvi: Before you take up any product for development you have a product profile in mind. Now if you do not achieve that product profile after whichever stage then you have to re-question whether you want to continue the product or not. So that is on scientific basis. The other some say 1334H you would be more based on market access, pricing and access. So even though we may get a product with the profile that we were looking for, but that would possibly not justify what you call investment because reimbursement will be very difficult.

Moderator: Thank you. Our next question is from Manish Jain of Axis Holdings. Please go ahead.

Manish Jain: I just wanted to understand on Latanoprost given that we have already filed the NDA, is there any additional meeting required prior to formal approval?

Kirti Ganorkar: No.

Manish Jain: On the marketing side typically for this kind of product what kind of sales force would you envisage in the US which would be required?

Kirti Ganorkar: When we talk to some experts, we understand that that we will need a field force between say like 50 to 70 people to promote this kind of product on nationwide basis in the US.

Dilip Shanghvi: And typically you would not reach 100% of the potential customers, you would reach top 20 to 30 decile of the customers.

Kirti Ganorkar: And 20 to 30 top docile would require anywhere between 60 to 75 medical reps.

Manish Jain: Just on Latanoprost, Timolol for the European market, last time we had indicated we will be doing the clinical studies in around 250 patients. So given that we are exploring filing in EU, have we completed those clinical studies?

Kirti Ganorkar: No, as we said in the presentation, now we have expert opinion regarding the registration of the product in the EU. So that is the current stage of the product.

Manish Jain: No sir, the clinical trials have completed?

Dr. Atul Raut: That 240 patient trial was done in India not in Europe.

Manish Jain: And the last thing was pertaining to PICN. In addition to US can you just give insights on the non-US opportunity for PICN?

Dilip Shanghvi: I think the product profile is very interesting and should have an interesting opportunity. As Kirti says that in the next presentation we will give you global potential for our products, we have not got enough validated information to share with you for all the products that is the reason why we are not sharing it this time.

Moderator: Thank you. Our next question is from Sameer Baisiwala of Morgan Stanley. Please go ahead.

Sameer Baisiwala: On Latanoprost BAK-free, when was the NDA actually filed?

Kirti Ganorkar: January-2014.

Sameer Baisiwala: And the second question is for Levatiracetam you said that in sometime in Q2FY15 is when you would be responding to FDA. Would the approval clock start all over again for 12-months then or would it be just few months before you get the approval?

Nitin Dharmadhikari: No, the 12-month is from the starting, but depends on what data you are filing, and then they will be giving you the date for that. So once you submit the data based on the data they will give you the date.

Kirti Ganorkar: It is not 12-months but it will be less than that, and generally they will give us the PDUFA date again.

Sameer Baisiwala: And the third question I have looking at the peak sales that you have given for Latanoprost and Levetiracetam in particular these two, is there something more that you can share… something like a per month therapy cost that you have assumed here?

Dilip Shanghvi: No, I think it is at a premium to the generic market but it is not priced as a new product.

Sameer Baisiwala: This is reasonable assumption or little conservative assumption?

Dilip Shanghvi: I think this is the assumption; this is something which we can share with you. I am not changing personality, so we will remain what we are.

Sameer Baisiwala: Sir, just an observation that for US$30 million given the effort that the SPARC has taken all this while and this needs to be split between cost of manufacturing, research cost which is royalty payment to SPARC then the marketing effort and then whatever is left is goes as a profit to the partner. It does not look like an awful lot?

Dilip Shanghvi: What you say is correct. I think what we discussed is that in last 4-5-years the reimbursement environment has changed. Our original presumption was that we would be able to market the product at a premium like a new product and that would have dramatically changed the numbers. Say like at one point of time Xalatan was a billion dollar product, and if we could achieve even 10% penetration of

market at Xalatan price, then we were looking at US$100 million product so that would have justified the effort.

Moderator: Thank you. Our next question is from Krish Shanbhag of Pride Investments. Please go ahead.

Krish Shanbhag: My question is on the starhaler DPI. What is the likely cost and time to complete the 200 patient studies in Russia, and the two Phase-III studies of 500 patients in the EU?

Kirti Ganorkar: We have not discussed anything regarding specific study numbers of the country where we are doing clinical study.

Krish Shanbhag: How has been the performance of the Starhaler in India post-2013 launch?

Kirti Ganorkar: Starhaler we have re-launched in India in August 2013 and currently, the response from the doctor is good, we are able to resolve the problems which were encountered in earlier launch, and currently, we are estimating anywhere between 12,000 to 15,000 patients on Combitide Starhalers. The initial response looks promising.

Krish Shanbhag: And what is your plan for in the emerging market of say Russia as well as in EU and USA for the Starhaler, and will Sun play a role in marketing of this product?

Kirti Ganorkar: As we said, in emerging markets Sun can play a role in marketing the product, but not in the developed market for Starhaler.

Moderator: Thank you. Our next question is from Manoj Garg of DSP Merrill Lynch. Please go ahead.

Manoj Garg: While we may have different partners for the products in the US market but I presume the manufacturing rights will remain with Sun Pharma for these products?

Kirti Ganorkar: That is correct. Manufacturing will remain with Sun Pharma.

Moderator: Thank you. Our next question is from Krishna Prasad of Kotak. Please go ahead.

Krishna Prasad: Just a question I think we have talked about how the environment has actually got tougher in terms of incremental innovation for the last 5-years, but at the same time as we look at the actual deals which are happening in specialty pharma space which are so broadly let us say aimed at incremental innovation, it appears the valuations are still fairly rich and a significant premium to the market price, so do

you see a disconnect here, or do you think indeed a very broad reading and it's probably specific to these assets which are out there?

Kirti Ganorkar: Are you are talking of Actavis deal?

Krishna Prasad: No, I am not talking about just Actavis deal, but in general the deals which have happened in specialty pharma space, in the context of what you describe as a tough environment for getting reimbursements and…?

Dilip Shanghvi: No, I think there is a dichotomy here, on one side you have a problem in terms of reimbursement, on the other side I think you have disadvantage in terms of not too many products available for marketing. So there is a significant interest in licensing products which are close to market, and we can get much better terms today than what were possible may be 3-4-years back, but I think it is also specific to therapy area, and the kind of field force that people have created anticipating approval of products.

Krishna Prasad: Which of those specialty areas you think were things have may be improved over the last 4-5-years, is there something that you could highlight at this point?

Dilip Shanghvi: We see interest for licensing all the products that are in development, but I do not think that is an overall assessment of all therapy areas.

Moderator: Thank you. Our next question is from Manish Jain of Axis Holdings. Please go ahead.

Manish Jain: This was on Baclofen, just wanted to understand that on the 135 patients study for duration of action, in addition to these 3 studies, do we have to do any additional studies before we file the NDA?

Dr. Shravanti Bhowmik: No, these are the three studies that we have agreed to with the FDA, and these are the ones which we will require for registration.

Manish Jain: Because the reason for this question was that when I was looking at clinicaltrials.gov data, this 135 patient study is stated that it was a Phase-II study?

Dr. Shravanti Bhowmik: This is a part of the package of three trials that we need to do to get registration and the reason it is listed as a Phase-II is because it is evaluating duration of action of the drugs, and the end point is more of a Phase-II end point and that is the only reason it is listed as Phase-II.

Manish Jain: On the alcohol dependence indication, frankly I could not understand the statistical data which

you have mentioned about, so what really is the roadmap for alcohol dependence now?

Dr. Shravanti Bhowmik: We said is that on the end points which we had in the alcohol study which was conducted in 180 patients in India, we were able to numerically see some benefit with Baclofen GRS; however, there was no statistically significant difference between Baclofen and Placebo. So that was the outcome of the India study. But what we also found in consultation with all our experts both in Europe and US is that the type of patients that are seen and the way they are treated for alcohol dependence is very different from that in India, and therefore we will have to do the trial outside of India to really see the outcome of Baclofen GRS and efficacy.

Moderator: Thank you. Our next question is from Jyoti Datta of Hindu Business Line. Please go ahead.

Jyoti Datta: Just for clarity, so has SPARC already started talking to foreign partners for licensing deals to bring in funds for further development? And secondly, just wanted a comment on how you see the clinical trial environment in India since you have so many products and trials underway and we have heard many companies saying that there are difficulties what has been of SPARC'S own experience?

Kirti Ganorkar: For the first question, SPARC has started discussion with the potential partner.

Dilip Shanghvi: In connection with this clinical trial environment in India if you see through the presentation most of our Phase-I and Phase-II studies that we are talking about even for other products we are talking about doing this study outside of India, that is because doing studies in India, obtaining permissions as well as getting all the requisite approval is taking far too long, and it is not justified in terms of delay. So that is the reason why even though we can do equally good studies in India, we are doing all of these studies now either in US, Europe or Canada.

Jyoti Datta: And that would be pushing up your costs quite a bit?

Dilip Shanghvi: It does. Also positive advantage is that these products ultimately will have a large sales potential in these markets. So we get market specific assessment in understanding much before we do an extensive case study.

Moderator: Thank you. Our next question is a follow up from Ketan Gandhi of Gandhi Securities. Please go ahead.

Ketan Gandhi: Can you please provide the PDUFA date for Latanoprost?

Kirti Ganorkar: Once we have the date from FDA we will let you know.

Moderator: Thank you. Ladies and gentlemen that was our last question. I now hand the floor back to Mr. Nimish Desai for closing comments.

Nimish Desai: Thank you everybody for joining us this evening and if any of your questions have remained unanswered I request them to please send them over to us and we will have them answered. Thank you.

Moderator: Thank you. Ladies and Gentlemen, on behalf of Sun Pharma that concludes this conference. Thank you for joining us and you may now disconnect your lines.