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Transcript of the Investor Update

4 PM , June 10, 2015

Participants

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Moderator: Ladies and Gentlemen, Good Day and Welcome to the SPARC Investor Presentation Update on NCE and NDDS. As a reminder, all participant lines will be in the listen-only mode and there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I would now like to hand the conference over to Mira Desai. Thank you, and over to you Ma'am.

Mira Desai: Good evening, everyone and welcome to the SPARC update on NCE and NDDS. We hope you must have received the presentation that we sent out sometime back. This presentation is also available on our website for downloading. The call transcript will be put on SPARC's website soon. It would be appropriate to mention that the discussion today might include certain forward-looking statements and this must be viewed in conjunction with the risks that the SPARC business entails. As usual, we will first complete the presentation and then take questions. During today's call, we will make an effort to answer all your questions, but if time does not permit, I request you to please send in your questions to me.

I now hand over the call to Anil Raghavan for his presentation. Over to you, sir.

Anil Raghavan: Good Morning, Good Afternoon, Good Evening, depending on wherever you are joining the call from. A very warm welcome to SPARC Annual Investor Briefing Call. This is the fourth edition of this call. We want to thank everybody on the call on behalf of the entire management team of SPARC and also on behalf of our board. We are absolutely delighted to host you today. As usual, we are looking forward to a very comprehensive and meaningful conversation.

I want to make a couple of house-keeping comments before we get going with the call. First, about the Structure of this Presentation: Our format today is very similar to past presentation format; we are taking through the tried investor format, we will be starting with some context setting comments and then summarize the year has gone by, sharing some thoughts on the forthcoming year. We will also be talking at some length about some of our late stage assets in our portfolio; 10 of them which are mostly in the clinic or near clinic. We have taken this call from Mumbai, I have most of my senior management team with me in the room, but in the interests of time, we will introduce individual speakers when

they come in for their segments or when they step into answer questions. We hope to present for one hour which will give us enough time for a standard question-and-answer session.

I want to make one more important point before we get going. As many of you know, we are in the process of seriously considering going to financial markets with the rights issue. We have a go-ahead for a process from our board where the process imposes some restrictions on the kind of disclosures we can make especially about our future plan. We will be sharing some thinking on developments plans of our key assets, but as I am sure most of you know this is a very dynamic phase where plans can change depending on new evidence that comes in.

So, on that point of caution, I will now move on to Slide #3: We are going to start with a broad overview of the year that has gone by. 2014-15 financial year has been a year of significant milestones, and also some significant reflection on our strategy, I will come to the reflection part in the next slide. We have put some significant wins on the board this year. Probably most importantly, SPARC had its first marketing authorization from USFDA in March of this year for Elepsia 1000 mg and 1500 mg tab. We are very excited about this. We hope this is a significant improvement for millions of epilepsy patients who need to struggle with pill load on a daily basis. We are in the process of finalizing an appropriate commercial arrangement for taking this product to market in the US this year.

Our next most advanced program is XelprosTM which is Latanoprost BAK-free formulation for glaucoma. We have a marketing partnership now with Sun Pharma, many of you have seen the announcement yesterday. We plan to discuss some of the details of this arrangement later in this presentation. On the regulatory side for Xelpros, as most of you know, we had Complete Response Letter from FDA on our ANDA. The most important part of that Complete Response Letter was there was no additional demand for any clinical data or preclinical data on safety or efficacy. We have now responded to the CRL and we are back in the regulatory process.

We have also completed the PK program for our Salmeterol Fluticasone, DPI and we have some encouraging results. We have discussed these results with several major European regulators and we now have visibility to regulatory pathway for this product in Europe.

On PICN, which is our nano-technology-based reformulation of Paclitaxel, we have achieved several milestones this year. We have had some promising results from our pilot bioequivalence study comparing PICN with Albumin-bound Paclitaxel. We also had at the end of Phase-II consultation with the FDA and sign off on our Phase-III protocol for metastatic breast cancer. We also had promising data on Cholangiocarcinoma in the second line setting for this product. So, all these sets up a very important year for our PICN program. More on this in terms of specific next steps as we go into the details later in the presentation.

Moving on, Abuse Deterrent Technologies have been a significant area of focus for SPARC right through this year. Abuse of prescription pain medication has been a substantial societal problem, now assuming almost catastrophic proportions for some time now, especially in the US where abuse-related deaths and emergency room admission are really shooting through the roof. Today, we are happy to announce the SPARC has developed a platform technology. This can take deterrents and prevention in prescription opioid abuse to the next level. We will be sharing more detail on this program as we go into the business end of this presentation.

Finally, we had several meetings with the FDA and other regulatory agencies last year to discuss the development and registration pathways for many of our products entering the clinical stage now. We have at least four programs entering in the IND stage this year. We will discuss this further when we discuss the respective programs. And on the intellectual property side, we had 27 new grants this year, 19 new filings since the last update.

Now, we will move on to Slide #4: We have taken some important steps on the strategy side. Sharpened our execution, partnered more effectively and more often and rationalized our portfolio. We have some really important new additions to your leadership team... I have given a brief profile of some of the newer members of SPARC family in the next slide. We are also investing significantly in important capabilities like Computer-Aided Drug Design, Discovery Biology and Program Management. We have several new additions to our scientific and therapeutic advisory panel in the last 12-months. Many of them leading names there in the respective fields, giving us access to some really world-class expertise and relationship.

Speaking of relationships, strategic partnerships have always been a key driver of our agenda. We have recently concluded a co-development effort in the breast cancer area with a set of very renowned and successful innovators from Europe. We are also pursuing several other similar partnership opportunities across different engagement models and therapeutic areas.

Finally, as promised in the last call, we have taken a very hard look at our portfolio based on some really significant work we have done on the clinical and regulatory planning and also some original market research and payer research that we have conducted last year. Taking into account all these new inputs, we have decided to prioritize up-some programs, and also prioritize down-some programs. We see this as part of an ongoing effort to keep our portfolio relevant and short.

Next Slide lists three senior management hires we have concluded last year. I have joined as a CEO last April; Dr. Siu Yao who is on this call joined us in our New Jersey offices, heading up a Global Clinical Development function; Siu brings around 20-years of world-class clinical development and product development experience, and finally, we have good fortune of finding Dr. Nitin Damle to head up our Discovery Biology function; Nitin is a veteran biopharma development asset leader with almost 30-years of experience in firms like BMS and Wyeth. We will continue as a matter of guidance, selectively hire people with substantial been-there done- that experience to augment capability set we have.

Slide #6: Expands on the portfolio rationalization points I made earlier: We have taken a decision to deprioritize or narrow the scope of our development effort in the five programs we have mentioned in this slide. We have taken into consideration additional data that we have seen and information on clinical and regulatory pathway and marketing data that we have seen from some of the market research and payer research work we conducted this year in reaching this conclusion. We are now considering developing our LTD4 antagonist L731 for the Indian and emerging markets initially, and we will consider possibility of global development for this LTD4 program depending on how the early development goes in India. We have also taken a decision to deprioritize Venlafaxine Extended Release product and Latanoprost + Timolol fixed dose combination as we have now more clarity on the extentive work we need to negotiate the regulatory pathway for these programs in the US. Finally, we will be deprioritizing our S-597 and allergy and DPI program and Baclofen GRS for alcohol dependence. The reasons are on the S-597, we would like to focus on therapeutic areas of

our choice going forward and the chosen therapeutic areas for us are Oncology, Dermatology, Ophthalmology and CNS in the case of formulation innovation, and the decision on Baclofen alcohol dependence is driven by our understanding of market opportunity especially in European market and the cost of conducting trials for the regulatory pathway.

On the Next Slide #7, we lay out the important objectives that we have on our agenda for the next year. We expect to complete the discussions on finalizing a commercialization partner for Elepsia and we expect to launch the product in US market in the forthcoming year. As we said, we are happy to be back in the regulatory process for Xelpros with FDA and we are looking forward to process market authorization in the near-term. We have ambitious plans for PICN including launching the product in India and initiating pivotal trials for US approcal. We are also targeting transition four more products into the clinical development pipeline, clearly, marking the transition of our firm from a preclinical company to a clinical company. We are targeting INDs for K706, S597 topical and Brimonidine and one more product which we are finalizing as we speak.

On that note, I will now transition and forward to my friend and colleague, Narendra Lakkad who heads up business development for SPARC. On Slide #8 you can see a list of programs we plan to discuss, not necessarily in the order in which we are going to discuss. Narendra will begin this discussion on Xelpros. Over to you, Naren.

Narendra Lakkad: Thank you, Anil. This is Narendra Lakkad. I manage Business Development for SPARC. I would like to give update on Xelpros, so lets move to Slide #10: Xelpros, as we know, is a novel BAK-free Latanoprost Ophthalmic Emulsion developed with SPARC's proprietary SMM technology platform. This product was filed with FDA after doing the Phase-III clinical program in the US and it was under review with FDA and we received Complete Response Letter towards the end of last year. FDA did not seek any additional clinical or preclinical information; however, they asked for certain clarifications and information on labeling change of the products. One such change was changing the nomenclature of the product from the original proposed ophthalmic solution to ophthalmic emulsion; however, for this change, there was no requirement of doing any additional clinical work. We have addressed these requirements and have submitted our response to the FDA.

We go to the Next Slide: Here, there is an interesting development, earlier during the day we have given a press release which I hope most of you would have taken a note of, that we are very happy to inform that we have concluded our licensing deal with a Sun Pharma subsidiary for US market for Xelpros. Under this deal, SPARC will receive $3 million as an up-front and certain other milestone payments both totaling up to $16 million. Additionally, SPARC is also eligible for certain defined royalties and milestone payments both linked to the actual sales performance. So, this sets the stage for SPARC in terms of generating additional source of revenue in the near future.

Coming to the Next Slide #13: I will give an update on Elepsia XR. As all of us know SPARC received USFDA approval for Elepsia XR in March 2015 and this was the first NDA approval for SPARC. Elepsia XR is a novel formulation of Levetiracetam Extended Release tablets in strength of 1000 mg and 1500 mg, and these formulations are protected by several composition patents, which are granted in US and now listed also in the orange book. The last patent expiry for Elepsia XR is in the year 2027 which provides us a significant opportunity for value creation. Elepsia XR if you see was developed with SPARC's proprietary Wrap Matrix delivery technology platform and approval of Elepsia XR also gives validation to our technology platform competence.

We go to the Next Slide: This slide gives some flavor about the commercial opportunity for Levetiracetam. The pill burden for epilepsy patients continues to remain high and you maybe knowing majority of the epilepsy patients receive multiple types of drugs for managing their epilepsy, and as far as statistics, more than 55% of patients have to take more than 6-tablets a day. Levetiracetam is a very popular and very effective anti-epileptic drug, it is typically taken in conjunction with the other anti-epilepsy drug. The requirement for Levetiracetam is a very high dose, so patients who are on Levetiracetam, they need to take 1000 to 3000 mg dose per day which makes them take multiple pills for Levetiracetam in addition to their existing treatment for epilepsy. Elepsia XR being available as 1000 mg and 1500 mg once-a-day tablet provides an opportunity for reducing the pill burden to both physicians and patients and improve patient compliance. As far as market potential is concerned, Levetiracetam as a molecule continue to grow and in terms of volume. There were some 720 million tablets sold as per IMS during the last year in the US and market is still growing at 10-11% in the current financial year. We believe there is a significant opportunity to market Elepsia XR at a significant premium to the currently priced generic products.

Next Slide: I think this is the most awaited moment for SPARC and I am sure most of you are also awaiting some kind of announcement on this front. So we are working aggressively on licensing and commercialization of Elepsia XR. We have been discussing with several potential partners and we have had some advanced licensing discussions with some partners. We are working very aggressively to see that these discussions come to kind of a very productive deal conclusion for SPARC and we target to commercialize Elepsia XR in the US market by the second half of 2015-16.

With this I hand over to my colleague, Dr. Siu Yao who will take you through both PICN and DPI program.

Dr. Siu Yao: Thank you, Narendra, and I also want to extend a warm welcome to all our participants and depending on where you are in the world, good afternoon, good morning or good evening. As Narendra mentioned, my name is Siu Yao and I help oversee Clinical Research for SPARC. In the next few slides, I am going to go over both PICN and the SPARC Dry Powder Inhaler. So if you can proceed to Slide #17, this slide provides some background on PICN. As some of you may know, it is a Cremophor and Albumin free formulation of Paclitaxel, and as you may know the Cremophor has been largely responsible for most of the hypersensitivity reactions associated with Paclitaxel and use of albumin to deliver Paclitaxel by nab-Paclitaxel or Abraxane, for example, has been associated with the potential to transmit infectious agents, including prion-based diseases. So removal of these two components from the formulation might represent an important advantage. In addition, the infusion time that is required for PICN is 30-minutes and this compares very favorably to the 1-3-hours required for Paclitaxel. Because of the removal of Cremophor, there is no requirement for pre-medications for hypersensitivity, and the lack of the side-effects may allow for higher dosing compared to Paclitaxel.

The Next Slide, #18, gives you some information on the PK of PICN in comparison to nab - Paclitaxel. In the graph on the Y-axis is Paclitaxel concentration, and on the X-axis is time in hours. There are four curves there actually, a little bit small; the top two curves represent the nearly overlapping concentrations of total Paclitaxel following administration of 260 mg each of nab-Paclitaxel and PICN. You can see that there is a good overlap there. The lower curves show similarly good overlap between the concentration of free Paclitaxel for both PICN and nab-Paclitaxel. This suggests that demonstrating bioequivalence between nab-Paclitaxel and PICN and could be a reasonable path to approval, and we are in the midst of

confirming these initial PK filings and plan to perform a pivotal bioequivalence study towards the end of this financial year.

Slide #19 summarizes some of the results we are seeing with PICN in Cholangiocarcinoma. Briefly, we performed a study of PICN in patients who had been previously treated with greater than or equal to one line of chemotherapy. And as you can see, a response rate of nearly 20% was observed. To give you a little bit of context, it has been uncommon to see much of any activity for single agents in this setting and most single agent studies have been performed in chemotherapy naïve patients in order to demonstrate any activity and significant activity has really only generally been seen with combination regimens. The results we have observed here are very encouraging and we are in the process of discussing paths to approval for this indication with US and other regulatory authorities.

Slide #20 provides an update of our PICN Breast Cancer Program. We have completed end of Phase-2 CMC discussions with the FDA and have received concurrence on the Phase-3 protocol. Current plans are to initiate the study towards the end of this financial year.

The next few slides starting with Slide #21 reveal some of the commercial potential for PICN. As you all know, Paclitaxel remains a standard of care for many diseases including breast cancer. In the graph in the upper right hand corner, you can see that Paclitaxel sales have been increasing over time and in the graph on the lower right hand side of the slide, you can see that the number of doses administered have also correspondingly increased. Together, this suggests that the availability of PICN could address an important need for many many patients.

Slide #22 summarizes the results of some market research that was performed. In this study, physicians were asked about the appeal of PICN under a couple of conditions. The upper bar represents the appeal of PICN if it is as efficacious as Paclitaxel but safer than Paclitaxel. And you can see, 83% of physicians considered such a profile very appealing. A more conservative scenario is illustrated in the second bar, which asks physicians about the appeal of PICN if it is only similar both in efficacy and safety. As you can see, PICN remains appealing for about 60% of the physicians which is still very encouraging.

That was the last Slide I had in the PICN portion of the presentation and I would like to move on to an overview of the SPARC Dry Powder Inhaler now. Moving to Slide #24, this

slide lists some of the characteristics of the Inhaler that we developed. There are a lot of things here, so I will not go over every one, but it is basically a very nice device. Delivered dose is largely independent of the patient's inspiratory flow rate, and in addition, notably, it is able to deliver more drug to the target lung tissue so that lower amounts of drug need to be used to deliver equivalent amounts to the target tissue. There are also a host of features that make it patient-friendly, such as helping to track the doses that have been consumed and when a new refill will be needed.

The next slide, #25, gives you some early PK data that we obtained on the performance of the device. It is important to note that in this data we are administering half the dose of the compound compared to the dose required by the Seretide Accuhaler. So in the last graph, drug concentration is on the Y-axis and time is on the X-axis. The two lines represent the Fluticasone Plasma concentration following administration by either inhaler. You can see that the Fluticasone plasma concentrations are very similar even though only half of the dose is used with the SPARC inhaler. The graph on the right similarly demonstrates the results with Salmeterol. Again, the concentrations are very similar despite the administration of just half the amount used with the Seretide Accuhaler.

Our current plans for the program are summarized in Slide #26. We have had meetings with three EU regulatory agencies and have received similar advice from each agency. We are targeting completion of the clinical program in the 2017-2018 timeframe.

In Slide #27, we conducted primary market research to determine how the SPARC DPI device would be viewed when compared to the Seritide Accuhaler in the five major EU markets. As you can see, across many characteristics, respondents consistently viewed the characteristics of the SPARC DPI device favorably compared with the Seritide Accuhaler.

Finally, Slide #28 shows the results of some pricing research. In this study, physicians and payors were asked about the value of the product according to various prices that could be charged. The overall value is shown on the Y-axis and ranges from a very poor value for a certain price to a very good value for that price. The price compared to the Accuhaler price is shown on the X-axis and ranges from a price 20% lower than the Accuhaler price, to a price 20% higher than the Accuhaler price. Payors and physicians differed somewhat in their assessments; payors felt that a slight discount to Accuhaler would be warranted, whereas physicians felt that a slight premium to Accuhaler would be reasonable. Overall, however, it

does seem likely that a middle ground of parity to the Accuhaler price, may be reasonable. I hope that brings you up to speed on our SPARC DPI Program and our PICN Program.

I am going to turn you over to my colleague, Dr. Yash, to go over the next series of slides about Baclofen.

Dr. Yashoraj Zala: Thank you, Dr. Yao. A Very Good Evening to all. I am Dr. Yashoraj Zala and I lead the Solid Oral Formulation team at Mumbai. I will be sharing an update on Baclofen GRS program beginning on Slide #30. As many of you may be aware, extended release Baclofen formulation is based on the proprietary Gastro Retentive technology which is also referred to as a GRID technology. The GRID system is useful for drugs with absorption window within the gastrointenstinal tract. Baclofen GRS is a once daily formulation recommended to be administered with meals for optimal bioavailability and reduced side-effect of sedation. It will be available in six strengths ranging from 10 mg to 60 mg. This product as well as the technology is protected by a portfolio of patents with the last patent set to expire in 2027.

Moving over to Slide #31, this slide provides a snapshot of the prescriber's opinion about the position of Baclofen in spasticity therapy. This was obtained through market research which was conducted by SPARC. Further, the KOLs and neurologists who participated in this agree that Baclofen is still the standard of care to treat spasticity. When physicians and KOLs were asked about the prescription to last 20 patients for spasticity, they confirmed that more than 50% of multiple sclerosis and stroke patients were prescribed Baclofen as an anti-spasticity treatment.

Going over to Slide #32, this slide indicates that Baclofen is still a fast growing drug in the US and in the last 5-years Baclofen prescriptions have doubled. Of the 700 million units sold, 34% are originating from spasticity related neurological indications. The market research further also gave a confidence that Baclofen GRS may be priced at a significant premium over generics.

The next Slide #33 gives an update on the ongoing Phase III clinical trials in the US. Till date 128 patients of the targeted 240 have been enrolled in the study. To accelerate the recruitment in the Phase III efficacy study, SPARC has planned to add additional 25 sites.

The other two studies are progressing as per schedule. SPARC is targeting to file the NDA in the fourth quarter of the year 2017**.**

With this update, I hand over to Dr. Nitin Damle to take it forward from here.

Dr. Nitin Damle: Thank you, Dr. Yash. Good Afternoon. My name is Nitin Damle and I head Discovery Biology function within SPARC. I will be discussing Sun K706, a highly selective Bcr-Abl kinase targeted therapy that we are developing for use in the treatment of Chronic Myeloid Leukemia, also known as CML.

Slide #35: Imatinib is an inhibitor of the native or wild type Bcr-Abl oncogene and represents the first line therapy in the treatment of CML. In spite of its efficacy against newly diagnosed CML, resistance to imatinib treatment develops gradually and is often attributed to various mutations in the kinase domain of Bcr-Abl Oncogene that renders Imatinib ineffective as the TKI. There have been three additional TKIs – nilotinib, dasatinib and bosutinib that have been registered for clinical use with different degrees of success against various mutant forms of Bcr-Abl. However, none of these TKIs is effective against the T315I mutant of Bcr-Abl. In contrast, ponatinib, a multi-kinase inhibitor that has shown efficacy against Bcr-Abl and all of its mutant forms including T315I, has also been registered as a third line treatment option in the treatment of CML. However, its clinical use has been limited largely because of the off-target toxicities such as arterial thrombosis that can be fatal if not treated in a timely manner.

Next Slide: Our Compound K706 is a potent single digit nanomolar inhibitor of Bcr-Abl and its mutant forms, including the T315I mutant. What differentiates K706 from ponatinib, is the lack of ability of K706 to inhibit VEGFR2 to which is thought to be responsible in a large part for the arterial thrombosis associated with Ponatinib. Hence K706 may not exhibit safety concerns often associated with ponatinib treatment. K706, as I said, is a potent inhibitor of in-vitro growth of not only human leukemic cells expressing Bcr-Abl such as K562, but also their imatinib-resistant form. This growth inhibition by K706 is not observed with myeloid and other cell lines that do not express Bcr-Abl Oncogene.

Next Slide: K706 is an orally bio-available molecule and when administered orally has shown consistent systemic exposure in different species. We have conducted extensive in-view analysis of anti-tumor efficacy of K706 against human CML xenografts established in

immunocompromised mice. This molecule has exhibited potent inhibition of growth of xenografts human leukemic cell lines expressing not only wild type or native Bcr-Abl, but also those expressing T315I mutant against which most of the current first line TKIs are ineffective.

As shown in this particular slide, an example of the antitumor efficacy of K706 can be seen. Treatment for 14-days with K706 caused significant regression of otherwise imatinib-resistant K562 tumors. And we believe this data provides the necessary preclinical proof-of-concept for supporting clinical evaluation of K706 as potentially, a second line treatment option for imatinib-refractory CML.

Next Slide: We have developed an optimized formulation of K706 for clinical studies. We have conducted Safety Pharmacology and Toxicology assessment of K706 in rats and dogs. There is no evidence of any adverse effect at multiples of efficacious doses of K706. IND-enabling efficacy, safety and toxicology studies of K706 have been completed and we hope to file IND for this compound with the US FDA by the third quarter of this financial year.

Next Slide: We believe Sun K706 is an effective but safe pan Bcr-Abl targeted therapy and represents a significant clinical and commercial opportunity not only in the US, but also in the rest of the world. As indicated in this slide, even if imatinib still represents the dominant first line treatment option, the second line TKI such as nilotinib and dasatinib are also increasingly being used in the first line setting. The incidence of Bcr-Abl T315I mutant can be as high as 40% of CML patients that have failed second line TKI therapies. While Ponatinib is a third line treatment option, safety concerns surrounding its use have limited its wider use. A new effective and safe pan Bcr-Abl TKI like K706 can rapidly fill this significant niche.

In summary, K706 represents an effective and safe, orally-active pan Bcr-Abl Tyrosine Kinase Inhibitor and a potential treatment option for use in CML.

I shall now hand over to Dr. Ajay Khopade.

Dr. Ajay Khopade: Thank you, Dr. Damle. Good evening to all of you. I am Ajay Khopade and responsible for Non Oral Formulation Development at SPARC. I would like you to refer to the Slide #14, the title slide…please be on this slide, I will give some background on this slide. As you are all aware that one of the focus therapeutic areas of SPARC is

ophthalmology and glaucoma is a disease on which SPARC is actively working. This is because glaucoma is one of the leading causes of preventable blindness in US, affecting an estimated 2-3 million people, and my colleague, Narendra has given you an update on prostaglandin glaucoma product Xelpros earlier. Xelpros was based on SPARC's proprietary SMM technology which was developed to address unmet need of glaucoma patients who suffer from ocular surface diseases such as dry eye, also this was a product for the first line treatment of glaucoma. Today, I am updating on a new product under development for the second line treatment of glaucoma. There is substantial space exist for the second line therapy because there are tolerance, intolerance and non-respondent issues with the use of first line drug. And most of the second line drugs are to be administered 3x a day and have compliance issues.

Next Slide: Brimonidine is one of the most commonly used drugs in the second line treatment of glaucoma. It acts via decreasing synthesis of aqueous humor and increasing the amount that drains from the eye. It has to be administered 3x a time and currently, IMS data estimates market size of Brimonidine Ophthalmic Solution to be ~ US$500 million and about 3.5 million prescriptions are filled annually. It is a highly successful drug with an issue of patient compliance. To support this, I want to mention about two previous investigations from the literature; both these studies investigated the level of inconvenience to the glaucoma patients on BID and TID regimen of anti-glaucoma drug. The studies concluded that multiple dose regimens are inconvenient and lead to poor compliance, resulting in suboptimal pharmacological effect in about two-third of the patients. This stressed the medical need for once a day formulation of Brimonidine.

Next Slide: SPARC has developed a NanoTemplated Cluster Technology, i.e., NTC Technology to enhance topical delivery into Ocular tissues. We all know that tears protect eye. The eyes are also protected from the fine suspended air particulate extraneous matter and cell debris by a layer of mucous on the eye surface. Both of these are natural defensive eye cleaning mechanisms that present a barrier for drug delivery, which this technology uses to its benefit. SPARC's NTC Technology uses Nano Particulate Templates onto which water soluble drugs are adsorbed and then formulated as micro clusters in a bio-adhesive vehicle. As the eye blinks, the blink shear breaks these soft clusters and smears them on to the ocular surface pushing drug-loaded nano particles inside the mucous. Like dust and unwanted debris, drug-loaded nano particles are effectively trapped by sticky mucous constituents of the eye, thereby retaining them in a peri ocular region before clearing them

from the eye. At the same time, tear salt trigger drug release in the vicinity of ocular surface thereby improving absorption and providing an optimal benefit of the drug to the patients.

Next Slide: The NTC technology enabled Brimonidine Eye Drops have shown ability to translate into enhanced efficacy and pharmacokinetics in animal model and this slide gives an overview of animal experiments. The table on the slide shows the data from study conducted on Rabbit model of glaucoma. It is clear from the data that IOP reducing effect from Brimonidine once-a -day eye drop was improved compared to Alphagan administered 3x a day. Significant IOP reduction was obtained over 24-hours ensuring once-a-day efficacy from NTC-enabled Brimonidine. The graph on the slide shows ocular tissue exposure of Brimonidine. The data shows that the ocular exposures in both anterior as well as posterior chambers of the eye were improved. The high exposure in the anterior chamber is responsible for providing IOP reduction while improved exposure in posterior chamber is responsible to provide neuroprotection. Both these effects are important for providing an optimal therapeutic benefit to the glaucoma patients.

Next Slide: We believe that NTC technology has potential to be tailored for multiple ophthalmic drug classes. A patent has been filed covering this aspect of the technology. We have met FDA last year to understand the path forward on CMC preclinical and clinical requirements of Brimonidine once-a-day program. And taking this forward, SPARC plans to file IND in Q4 of this year.

This was an update about this new technology. Now, I hand over to Dr. Rao to update on Topical Soft Steroid Program.

Dr. C.T. Rao: Thank you, Dr. Ajay, and a very good evening to all of you. Myself Dr. C.T. Rao, heading the Medicinal Chemistry division at SPARC. I have the pleasure of updating you on our NCE, the anti-inflammatory topical soft corticosteroid SUN-597. Currently, we are developing this NCE for the treatment of dermal inflammations and I would be presently discussing on this.

Let us go to Slide #46: It is well-established that inflammatory skin disorders are treated effectively by topical corticosteroids and generate over 40 million prescriptions every year in the US. However, in several chronic dermal inflammatory conditions where long-term use of topical steroids is implicated, local side-effects such as skin atrophy occur invariably. We

have now developed a topical formulation of our novel soft corticosteroid SUN-S597 and tested for its efficacy and safety in animal models for dermal inflammation and we find it to be quite promising. We are delighted to inform that in terms of efficacy we find SUN-S597 topical to be comparable to the currently marketed potent steroid such as Fluticasone and Clobetasol but superior to marketed mild potent and low potent steroids, like Triamcinolone and Hydrocortisone respectively. Interestingly, in terms of local side-effects, SUN-597 topical differentiated from other potent steroids in that it demonstrated low potential for skin atrophy which is a very desirable aspect for topical steroids. Hence we feel that our product is superior by virtue of its efficacy to safety profile.

Going to Slide #47: This slide highlights the performance of SUN-597 in animal models for psoriasis, a severe and chronic dermal inflammatory disorder. In this model, mice are treated on skin with the chemical called Imiquimod whereby they develop symptoms like psoriasis, namely thickening of the skin, scaling and redness. The marketed formulation of steroids and SUN-597 are applied topically on these mice and the psoriatic symptoms are scored. It is evident from the figure which is on the slide that while SUN-597 (shown in red), scored similar to the marketed potent steroids, Fluticasone (shown in green) and Clobetasol (shown in blue), it scored significantly better than the low potent and mid potent steroid Hydrocortisone (shown in yellow) and Triamcinolone (shown in brown) respectively.

Going to Slide #48 which Shows studies further reinforcing efficacy of SUN-597 in the psoriasis model. In the same animal model for psoriasis we assessed the performance of SUN-597 topical versus the marketed topical steroid for quantifying the level of gene expression in skin for the key inflammatory mediators which are responsible for psoriasis, namely the Interleukin-17 and Interleukin-23. If you look at the figure, it is quite evident that the gene expressions for Interleukin-17 and 23 shoot up on induction of skin with Imiquimod. You can see the first bar in yellow and the second which is a placebo, indicating that the level of Interleukin expression has tremendously gone up on treatment with Imiquimod. These interleukins are inhibited by application of topical steroids. So here once again it can be seen that SUN-597 inhibits the expression of both these mediators at a level similar to the potent marketed steroids Fluticasone and Clobetasol while the inhibition is much superior to the less potent Hydrocortisone and Triamcinolone.

Next Slide summarizes the current status of SUN-597 topical. We have performed the required regulatory toxicological and safety studies on SUN-597. Our safety studies indicate

minimal skin atrophy with SUN-597. We have completed a pre-IND meeting with the USFDA and the response has been that our studies are quite adequate for IND. We plan to file IND in the next quarter and subsequently initiate the Phase-I human studies in Q3 of 2015-16. All in all, we find SUN-597 topical will be quite promising and expect our product to be a superior option in terms of efficacy and safety profile for dermal inflammation.

With this, I now hand over to Dr. Nitin Dharmadhikari to brief you on Minocycline Topical and some very interesting developments on oral delivery technologies.

Dr. Nitin Dharmadhikari: Thank you, Dr. Rao, and good evening, everybody. I am Nitin Dharmadhikari and I head Formulation Development function within SPARC. To start with, I will give an update on Novel Minocycline Topical Formulation and please refer to Slide #51. As you may be aware, Minocycline is the largest selling oral antibiotic in US for inflammatory acne. However, Oral Minocycline has various side-effects like gastrointestinal disturbance, candidiasis and dizziness. Being a drug of choice for the treatment of acne, SPARC has formulated a novel topical Minocycline. This formulation is expected to provide better bioavailability at the site of action and a reduced systemic exposure. This will possibly lead to a better safety profile and it will be efficacious.

Over to Slide #52: SPARC has conducted a proof-of-concept preclinical study in which this topical formulation demonstrated efficacy. The formulation has shown statistical significance when compared to both untreated control and a placebo.

I would like to go to Slide #53: SPARC has also filed patents covering this novel composition and we plan to file an IND in US by Q1 of 2016-17 to advance this program further.

From here, I will go to another update which is for the Tizanidine Extended Release tablets; Slide #55 please. Tizanidine is a drug, used orally in the management of spasticity and pain. Although approved for spasticity, use of Tizanidine in muscoloskeletal pain is quite common, and a large number of prescriptions are written in US for this indication. Tizanidine immediate release tablets and capsules which are commercially available today have a short half life and hence it is required to be taken multiple times in a day. Tizanidine IR is also associated with side-effects particularly somnolence. Somnolence interferes in the day-to-day function like driving and operation of heavy machines. This limits the use of Tizanidine IR during the day time. SPARC has formulated an extended release dosage form which will

improve patient compliance and is also expected to show improved side-effect profile. Slide #56 gives the status of this program. We have completed pilot PK studies and a pre-IND meeting with USFDA for this product, and we continue to conduct further Phase-II studies in year 2015-16 to take this program further.

With this I come to the last program which is Abuse Deterrent Formulations, please go to the Slide #58. As you know, Opioids such as Morphine, Oxycodone, Hydrocodone are drugs of choice for management of pain in United States. They are available as both immediate and extended release dosage form. Although Opiods are potent analgesic, they also cause euphoria and a feeling of high. For this they may be misused in excessive dose by patients as well as general population leading to social concerns. When consumed in larger dosage, Opioids also cause life-threatening side-effects like respiratory depression which may lead to the death. Opioid dosage forms are abused by several routes including oral, nasal and injection. Abusers try to manipulate the formulation by crushing and extraction to obtain the drug in a concentrated form for abuse. The serious problem of Opioid abuse resulted in about 348,000 emergency department visits in 2011 in the US and also several deaths. The Abuse Deterrent Formulations are those which resist the abuser's attempts to manipulate them and therefore USFDA considers the development of Abuse Deterrent Formulation a high public health priority.

As shown on the Slide #58, substantial commercial opportunity exists for Abuse Deterrent Formulations. Please go to the Slide #59. SPARC has identified an important area in the Abuse Deterrent space and initiated a development of technology platform and filed patent applications. Being an important area, SPARC has also completed a pre-IND meeting with USFDA to understand further pathway for development of these products. SPARC will use this technology platform for developing multiple opioid products. With this I close the detailed presentation on the product and hand it over to Anil for the concluding remarks.

Anil Raghavan: Thank you, Nitin. Slide #60 is the concluding slide we have, that is a recap of everything that we have presented so far in this hall. I want to thank everybody on the call for patient listening, conclusion of our presentation part of today's session and we will open up the call for questions now. Over to you.

Moderator: Thank you. Participants, we will now begin with the question-and-answer session. The first question is from the line of Dheeresh Pathak from Goldman Sachs. Please go ahead.

Dheeresh Pathak: Thank you for taking the time out and a detailed presentation. I am referring to Slide #6, I do not have the technical expertise to understand a lot of the information that was given on this call, but on Slide #6, where you have listed some of the programs which have been deprioritized, can you just walk us through one or two of them and give the reasons of why they were deprioritized because I am assuming in some of the earlier presentations you would have given data similar to the other molecules which would have sounded very promising, but what are the reasons of deprioritizing three or four of these molecules?

Anil Raghavan: Thank you. I think we have alluded to some of the reasons for deprioritization or in some cases narrowing our focus on these programs. It falls in different categories. When I look at Venlafaxine ER 300 mg and probably Latanoprost Timolol combination, the requirements from a regulatory standpoint is a need for clinical evidence reach a significant factor weighing on our decision. So we have taken a hard look based on our interactions with FDA and regulatory agencies in EU and our consultants, we have good sense of what is required to take these products to the finish line and we also have a sense of the market potential of these opportunities. So we have taken a hard look at that economics both from a cost of clinical development and the overall attractiveness of the market which does not support development of these products for advanced markets where there is a new regulatory law. So that explains probably Venlafaxine and Latanoprost. And a couple of other indications there S-597 nasal and inflammation, and Baclofen GRS for alcohol dependence. Primary driver there is our desire to narrow our focus in terms of therapeutic area. As you can see in one of the drivers for everything that we are doing on the strategy side, capability building side, we used to kind of start focusing on three or four major therapeutic areas and we have some depth of expertise in those areas of focus; Oncology is going to be a significant focus, Dermatology and Ophthalmology and if you look at the pipeline, we have several exciting opportunities coming up and we will have a continued focus on CNS because a lot of our formulation effort on solid oral is on the CNS side. So, we would like to kind of focus on areas where we can build more in-depth expertise and that explains why we want to kind of move on from Sun 597 nasal indications and Baclofen alcohol dependence which is primarily a one-off which we have in our

portfolio. And SUN-L731 is a little more complex opportunity there. We are doing this more deliberately, we want to see more clinical evidence before we can take a call on whether or not to develop this for external market. So, we would be doing proof-of-concept studies in India with a view to navigate the approval pathway in the Indian market and that would also give us a sense of the promise of this product and if the product is promising enough, and it lives up to the original hypothesis of superior efficacy to Montelukast then we will seriously consider taking this product to rest of the world.

Dheeresh Pathak: Ok, thank you for that. Second question is when you think about outlicensing and we have seen one now, can you just give us a broad framework of how you think about taking upfront payment versus taking a higher share of royalty?

Anil Raghavan: There are several points before I invite my colleague, Mr. Lakkad into this conversation, I just wanted to set some principles in terms of determining the structure and also price determination of these deals. In both these conversations that we had on Elepsia and Latanoprost which we just concluded, they had a variety of players on the table and feedback from them in terms of their interest levels would be a consideration, and we also have ground-up price model, market model in terms of market attractiveness of these opportunities and also a sense of the marketing expenditure and other expenditure which we try analyse for these products. So, we have a sense of the overall NPV of these programs and our final decision on how the structure, initial milestone payments vs later royalty payment is also driven by our immediate cash flow requirements, and our endeavor here is to manage the business as financially prudently as possible. So we would like to maximize our initial revenue stream so that we can fund a growing clinical pipeline and that is the key consideration in terms of deciding on eventual partners and you will see some of that as we go along with the decision on Elepsia.

Narendra Lakkad: Although many times we desire to have a deal which is more front-loaded but it also depends about potential partners how they view this as an opportunity in terms of market attractiveness, risk to commercialization, risk for generic entry, ability to get a premium price. Also the potential partner needs to put significant efforts and investment in terms of bringing the product to market. So there are upfront costs for them as well. So it is a question about what we expect from them, what potential partners consider as a value proposition and it is a question of negotiation and arriving at best value or a win-win situation for both parties.

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

Girish Bakhru: Hi. First question was on Xelpros. Actually, just wanted to know this formulation, is it a single dose or multi dose?

Management: It is a multi-dose vial.

Girish Bakhru: So would there not be a concern of say because of the preservative free formulation how do we ensure that there is less risk of contamination?

Narendra Lakkad: We are not using Benzalkonium Chloride as a preservative in these products but we use alternative preservative systems, maybe Ajay who is the formulation head for this program, can give a little more detail about this technicality.

Dr. Ajay Khopade: Xelpros is not a preservative-free product, but rather it is a BAK-free product, so we have removed BAK because of its ocular toxicity issues, but it does contain safer preservative which protects it from microbial contamination during its use.

Girish Bakhru: So if you have to kind of see it vis-à-vis the other prevalent formulations in the market, some of them which are BAK-free and have newer preservatives or say vis-à-vis even the generic Latanoprost, how do you position this product in…I know it will be difficult to probably give a market potential but in terms of pricing, do you think it will have a premium pricing to the generics and why would any consumer shift to this product?

Narendra Lakkad: Globally, there is a trend of removing Benzalkonium Chloride as a preservative in ophthalmology preparations. So I think in Europe, now we do not get a registration of any ophthalmology product which uses Benzalkonium Chloride, in US also, people have started shifting from a product containing Benzalkonium Chloride to a product avoiding Benzalkonium Chloride. So, I believe that is the value which physicians do understand and regulators do support that there is a value in an ophthalmology product which is not using BAK. So, we do believe that it provides an opportunity for us to price it differently than currently priced generic products.

Girish Bakhru: Would you be able to throw some light on what would be the potential sales opportunity here if the product gets approved?

Anil Raghavan: As I said earlier in the call, the current right issue process puts constraints on us in any specific discussing numbers, especially on some of these products which are near to market. So unfortunately, the process does not allow that we share that number in a straightforward manner.

Girish Bakhru: Second one was on the PICN. I understand there is a high unmet need when it comes to having safer oncology product with minimal side-effects. But where exactly say this product is in breast cancer treatment and if you could give some color on how much this pivotal study will take and when could NDA filing be for PICN in breast cancer?

Anil Raghavan: In terms of the NDA filing, we are in the process of determining the closest pathway for filing an NDA for this product, and as you can see from the detailing we have done on this product, we have multiple options, considering bioequivalence route is a possibility, we have pilot BE study with some encouraging results which Dr Rao discussed in this program. As we speak, we are doing confirmatory trials. We also are parallely gearing up for the Phase-III in mBC setting and we have given some guidance on when that study can get started. Cholangiocarcinoma is a whole new dimension and is a possibility that we can pursue. So, we are right in the middle of taking a decision, and also what we see from the confirmatory bioequivalence trial will have a lot of bearing on the time. If we feel we can pursue the bioequivalence route for marketing approval, we will see a more accelerated entry into the market and if we need to pursue mBC phase 3 trials, then we look forward to three to four **word missing** or even longer timeframe to market**.** Cholangiocarcinoma of course would give us an intermediate pathway but we cannot definitely comment on that because we are in the process of setting up a FDA consultation on at least two data **word missing** from Cholangiocarcinoma.

Girish Bakhru:Yes, this is of course a very new indication. In India, PICN is selling only for breast cancer or there are more indications?

Narendra Lakkad: It is approved for breast cancer indication.

Girish Bakhru: But you are not say targeting this indication in Indian market?

Narendra Lakkad: If we generate the data for this indication we will eventually market in India as well, but as of now we do not have data to support filing for additional indication.

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

Chirag Talati: Thanks for taking my question. My question is on PICN. How do you think your product compares with Cynviloq which will likely see a filing end of this year and if you do not end up using a bioequivalence pathway, do you think you will be competitive compared to Cynviloq, 4 years down the line?

Dr.Ajay Khopade: As far as comparison of PICN to Cynviloq is concerned these are two different technologies, one thing in common in both these products is that they are Cremophor free and albumin free…

Anil Raghavan: And specifically on your second question on whether we are going to be competitive three or four years down the line, the thing that we need to understand is the timing of this market is that with bioequivalence even though we may get a route to market this does not automatically allow substitution for Abraxane, so which means that whether it is a newer product or our product, we need to create clinical evidences and expand indications. So we are talking about a similar timeline for both products, if you look at their disclosures on the deal which they have recently done, the intent is to do additional clinical programs to create points of evidence in multiple indications, and also, more importantly, in combination with newer therapies that are emerging. So both these products are in a medium term journey of three to four years where you can feed multiple entry points into different indications, and there are some advantages which will be borne out by the clinical program, we do not want to prematurely claim those advantages without actually having the data to support those claims at this point.

Chirag Talati: If I understand it correctly, they have already completed their bioequivalence trials. So do you have some guidance from the FDA with regards to the bioequivalence trial design, number of patients odd? And secondly, if you do achieve bioequivalence, can you file for one particular indication and then go for clinical trials in other indications?

Anil Raghavan: There is a generic guidance on Paclitaxel generic which I think is going to be relevant for all these products and if we file through bioequivalence it is not going to be for a specific indication, so that will be a product which is bioequivalent…

Dr Dharmadhikari: ... Bioequivalence is a part of the program, because it is not the total program, because in addition to bioequivalence, you will have to also prove certain other things in a clinical program. So BE is one part of the whole program but it is also a major part of the program.

Moderator: The next question is from the line of Afzal Mohammed from Karvy Stock Broking, please go ahead.

Afzal Mohammed: Good evening. My first question is how many months has it been since SPARC responded to the Latanoprost CRL from FDA?

Narendra Lakkad: We have responded in the month of April.

Afzal Mohammed: Like, can you throw some light on the average timeline after you responded, FDA will take for approval?

Anil Raghavan: It resets the clock, I mean usually the clock is for 6 months, so if they have taken some time to consider the completeness of our response, and I think earlier this month we had confirmation that they are accepting our response as the complete response which they raised. So that resets the clock and hopefully we will have feedback on CRL on our submission in 6-months' time.

Afzal Mohammed: On Latanoprost generics in the US marketplace, how many BAK free Latanoprost generics are there?

Dr Ajay Khopade: To the best of our knowledge there are no BAK free Latanoprost generics in the US market as of now.

Afzal Mohammed: So Xelpros will be the first one to hit the market?

Anil Raghavan: Xelpros is not a generic.

Narendra Lakkad: If you have to make a generic you have to make an equivalent product to Xalatan, the moment you make a change in the formulation, it becomes a different product, you have to do a clinical study and prove that your product is not inferior to what is there in the market, which is exactly we did in a 500-patients phase-3 program and we proved that we are equivalent in terms of efficacy, we are not compromising on efficacy, but

we have a product which is not using BAK. So that makes it a differentiated product from a generic.

Afzal Mohammed:S ince it is highly differentiated product, will the patients be expected to prove a higher copay and you will be expected to do a higher premium to the generics?

Narendra Lakkad: That is our expectation and we have done some market research which also gave us the confidence that there will be possibility for us to price this product differently than the generic product in the market.

Afzal Mohammed: Any range of how much would be the premium?

Narendra Lakkad: We will not be able to give more specific information.

Anil Raghavan: Too early to comment on that.

Afzal Mohammed: Do you plan to file Latanoprost for approval in the other major markets, such as the EU and Japan?

Anil Raghavan: Not at this point, it is not one of our priorities for this year.

Afzal Mohammed: But you have it in the long term, sir?

Anil Raghavan: We will not rule out, but at this point, it is not one of our priorities.

Afzal Mohammed: For PICN, would you be conducting any head to head trials against Abraxane?

Narendra Lakkad: I think as of now there are no plans to do head-to-head comparison with Abraxane other than a BE program.

Moderator: The next question is from the line of Manish Jain from Sage One, please go ahead.

Manish Jain: My first question was on PICN, that if you can give insights on Cholangiocarcinoma, that are we looking at it as a mono therapy or as a combo with carboplatin?

Dr. Siu Yao: Right now, based on the preliminary data that we have, a nearly 20% response rate for a single agent seems very promising and so we do not feel that it would need to go into a combination study to get approved, so we would be looking at it as a single agent.

Manish Jain: What all indications are you targeting with the combination?

Dr. Siu Yao: We have studied some combinations with PICN, and we are exploring other possibilities, but we have not committed to any indication yet with combinations of PICN.

Manish Jain: My last question was that on PICN you all had indicated that you were working on ovarian, biliary, cervical melanoma as well as bladder cancer last year, if you can provide some more insights on that?

Narendra Lakkad: We did mention that because we have ongoing Phase-1 studies in the US and we have seen a kind of encouraging data from the Phase-1 program, so we gave an indication that these are some of the indications, probably we may be considering for development of PICN in different indications, but as Dr. Siu rightly said, that we have not really decided which indications other than Cholangio which we have disclosed this time, but other than Cholangio we have not decided which indication we would be taking up next.

Anil Raghavan: And also from a priority for the program standpoint, we would like to focus on obtaining shortest path to the market, so we have three clearly identified paths on this program, our focus is clear, and in the near future is to make sure that we conclude any one of those pathways to approval, but at the same time in the background we are doing additional studies and graduating these studies to a Phase-III program would be a significant step that we will take once we negotiate pathway to the market through anyone of these three identified ways.

Moderator: Thank you. Our next question is from the line of Preeti Arora from Enam Asset Management. Please go ahead.

Preeti Arora: Sorry, I joined the call a bit late, but if you could just explain Venlaflaxine ER has been pulled out, what is the reason, an NDA had been filed, you had got a CRL, so was it more the commercial opportunity or the additional work you would have had to do?

Anil Raghavan: No, the commercial opportunity is the considerations in any decision, but there is a little bit of evolution of FDA's expectation on this product, so our initial understanding based on our earlier consultation set of expectations about what we need to achieve on the clinical evidence side, and that expectation had changed, as the FDA's thinking on the product evolved. So the new thinking on what is required to approve these products puts additional burden of evidence, which is essentially shifting the costs benefit balance of this program. That was driving the decision to deprioritize Venlafaxine.

Preeti Arora: My second question is, there are BAK-free products in the US, so if you could just tell us how are they priced versus the generics and anything in terms of how they are doing in terms of sales, etc.?

Narendra Lakkad: Among the prostaglandins, I think Alcon had a initial formulation called Travatan which was containing probably BAK and then they reintroduced this product in the name of Travatan Z, using an alternative preservative system without BAK, but since Travatan was at that time a branded product, there was no essentially price difference, there was no generic to Travatan at that time, so there is no right comparator to really make any benchmarking.

Preeti Arora: What is the sales of Travatan Z as of now?

Narendra Lakkad: It is quite large in the range of say $500 million.

Moderator: The next question is from the line of Ketan Gandhi from Gandhi Securities. Please go ahead.

Ketan Gandhi: On Baclofen, how much time do you expect to complete the patient recruitment for efficacy study where you have recruited 128 patients till date?

Dr. Siu Yao: We are moving forward with recruitment, and we are adding additional sites. That was noted in the previous slide. Wee are hoping to get recruitment completed in the next year or two.

Ketan Gandhi: Can patients be common for all these three studies?

Dr. Siu Yao: There are slight differences or some differences in the population for the various studies. For example, in the open label safety study, the patient there is much more

general, because there are a very few requirements in order to be included, whereas in the other studies the requirements are a little bit more stringent since we are trying to focus on a certain type of patient to see the treatment effect.

Ketan Gandhi: How many Baclofen GRS clinical trial investigators are the key opinion leaders in US?

Anil Raghavan: Let me put it this way, we have several key opinion leaders on this program, I do not think there is a definitive way of saying, x many of them are leaders or if you find somebody else as the opinion leader, we have a significant number of opinion leaders, some of the most prominent names…. we are almost now expanding this to 70 or 75 sites, variably that will include the physicians with the largest patient population, but we may not be able to give you a percentage number in terms of the percentage of opinion leaders are in clinical trial.

Ketan Gandhi: Can we get $10 per day cost of therapy for Baclofen GRS in US?

Narendra Lakkad: It is very difficult to give any kind of number because there are several factors that will affect, and of course we make certain assumptions and make our business case, but right now we are not disclosing any kind of our assumptions or numbers, but eventually it will depend on the data which we generate and when we take it to the payers, they will determine what kind of premium we can get.

Dr Nitin Dharmadhikari: Overall, we are saying we will have a premium over generics

Narendra Lakkad: But we cannot give guidance about specific price for a product.

Ketan Gandhi: My last question is, beside USA, are you exploring to file this product in other markets such as EU, Japan, and a few emerging markets?

Narendra Lakkad: We continue to explore but you know that we cannot do too many things at a time, so we are right now focusing on completing our US program and registration in the US.

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

Chirag Dagli: I was on Slide #22, what we are effectively saying is that 60% of oncologists have found PICN appealing. So I was curious, a) why is there no payer feedback on PICN which is a much more later in the development stage and we have actually payer feedback for the DPI product, but if you can share some thoughts on payer feedback if we have done any survey?

Anil Raghavan: We do not have extensive payer feedback on this product given there is still some time for actual entry to the market, this was part of an effort to fine tune the target product profile of the product. So this is part of specific payer survey that we have done, but unfortunately we do not have substantial payer research at this point, which we will do as part of our market accesss closer to approval.

Chirag Dagli: But this survey that we have done, it is effectively on just 75 oncologists, is this how this is done in the industry as well?

Narendra Lakkad: That is right and this is a good number.

Chirag Dagli: Of a total of how many oncologists in the US Sir?

Narendra Lakkad: I think it is close to 6000.

Chirag Dagli: But you are suggesting that this is how it is done in the industry and this is …

Narendra Lakkad: Typically, market research take a sample size of around 1 to 2%, which gives you, because these are all qualitative market research, it gives you a feel about the market.

Chirag Dagli: My second question was on Octreotide. How do we take this product forward in terms of timelines or plans of what we are doing on this?

Narendra Lakkad: Octreotide continues to remain our priority program, so we are working on optimizing the formulation of Octreotide and once we believe that we have a reasonably good update we will be happy to share with you about Octreotide.

Dr Nitin Dharmadhikari: We continue to focus on the program. That is one of the plans put up by us.

Chirag Dagli But this is right now in Phase-1 and we will have to do Phase-2 and Phase-3, I am unclear on what pathway we will follow on this sir?

Narendra Lakkad: This is going to be a bioequivalence route, but as you know depot formulation, are all complex formulations and it is a very complex formulation technology to establish that we have reproduce the same kind of PK profile and we will be able to achieve bioequivalence to innovator.

Dr Nitin Dharmadhikari: In this program BE will be again a part of the program, which will be a major part of the program, but some other studies are also required to prove that your product is equivalent.

Chirag Dagli: Right now the Phase-1 is already on, on this, right, that is what the slide is suggesting?

Dr Nitin Dharmadhikari: Yes.

Chirag Dagli: On how many patients are we doing this Phase-1 Sir?

Dr Nitin Dharmadhikari and Anil Raghavan: Once we have conclusion on that, we will be able to share that information.

Chirag Dagli: But how does the formulation change between Phase-1 and Phase-3, if you started on Phase-1, then you should have worked on the formulation already is what I ….?

Dr Nitin Dharmadhikari: It is a question of achieving the results, which are satisfactory, and which tells you that you are ready to go ahead on the pivotal program, usually what you call is a pilot program as well as a pivotal program, usually these are the studies which you do as pilot studies, from these studies you conclude what do you want to do further. So we are there.

Chirag Dagli: And when does this pilot study conclude?

Dr Nitin Dharmadhikari: We will share that once we progress on it.

Moderator: The next question is from the line of Abhishek Sharma from IIFL, please go ahead.

Abhishek Sharma: Thanks for taking my question, a couple of them; one of your early slides talks about scientific advisory body, if you could just help us through, what is the exact role of this body, and what is the broad composition in terms of backgrounds of people?

Anil Raghavan: We talked earlier in the presentation about therapeutic areas of focus towards Oncology, Ophthalmology, Dermatology, and some CNS, indications, where program specific focus areas that appears, so we have for each of these therapeutic areas and also in some cases high priority programs, so more narrowly focused indications. We have created a panel of 3 or 4 leading experts in those areas. So we have several world renowned names there, but as a matter of policy to maintain our confidentiality we are not sharing the names of these people in public and this is also necessitated by the contractual commitment that we have with these individuals. So unfortunately we may not be able to disclose specific names as part of our policy on who man these individual therapeutic areas or give an indication of program specific advisory board, but objective and intent of these programs is to support the senior leadership in taking significant decisions both in terms of the evolution in pipeline as well as go-no go decisions on products.

Dr Nitin Dharmadhikari: Just to add to what Anil is saying, maybe they can be technology experts, they can be clinical experts, they can be regulatory experts, so those are the people you need in a program to support you and understand your further pathway, so they compose of various areas and then they contribute as per their expertise.

Abhishek Sharma: My second question is on Elepsia. I was going through the label, so the half life of Elepsia XR is 7 hours, which is equivalent to the existing Levetiracetam formulations available, so in a sense you are not reducing the pill frequency, but if somebody was taking 2 pills at a time, you are offering him that patient an alternative, is that right?

Dr Nitin Dharmadhikari: Yes, that is right, because Elepsia or Keppra both are given once a day, so it is a once-a-day pill, there is no further reduction possible in that, because it is taken once-a-day. What we are doing here, say for example , somebody is taking 2000 mg, today, option is take 4 tablets of 500 mg, we are giving them an option of taking 2 tablets of 1000 mg or so, so if somebody is taking 1000 mg, he is going to take two tablets of 500 mg, we will give 1 tablet of 1000 mg, in that way what we reduce is a pill burden, what it is

called because the way you would have seen it here, there are patients who are taking multiple pills and not only epilepsy pills but other pills as well. So the whole objective is to reduce the pill burden of the patient.

Abhishek Sharma: Around your drug design capabilities, the fact that you have acquired drug design capabilities, now do we see more emphasis going forward on new chemical entity development vis-à-vis the 505(b)(2) incremental innovation kind of projects that dominate your pipeline today?

Anil Raghavan: Directionally that is correct, so if you look at how far this pipeline has evolved, we actually started off as a pure play formulation improvement play and over the years our focus has been steadily shifting towards CADD? but at the same time we wont actually go away from the 505(b)(2) completely and we would like to ideally have a balanced hedged portfolio where there is still continuing focus on significant formulation improvement in complex formulation problems, while we focus on NCE development especially in therapeutic areas of our choice. So we agree with directionally what you are saying.

Moderator: The next question is from the line of Parin Gala an individual investor. Please go ahead.

Parin Gala: My questions are regarding PICN. First is, what is the number of patient sample size for Phase-3 trials in the US for MBC?

Anil Raghavan: We have a design which is being relooked at based on some of the early data that we have seen. Till we actually get started with the program we do not want to disclose the actual number of patients that we are targeting, but as a broad indication we are looking at something in between 500 to 1000 patients.

Moderator: Thank you. The next question that is from the line of Manish Jain from Sage One. Please go ahead.

Manish Jain: I just wanted to know for PICN, are we required to do any long term tox study?

Anil Raghavan: Pre clinical standpoint?

Manish Jain: Yes.

Narendra Lakkd: No, we do not need to do.

Manish Jain: And the pivotal-BE that you are looking to do, typically, what is the sample size required for that?

Anil Raghavan: It will be determined by what we see on the confirmatory B E program that is currently on.

Manish Jain: My last thing was besides US, any other market that we would like to get into PICN, ahead of US?

Anil Raghavan: We want to stay absolutely focused on the US market at this point.

Moderator: The next question is from the line of Hitesh Shah from Spark Capital. Please go ahead.

Hitesh Shah: Last year you had promised to share market potential of most of the SPARC products in non-USA market, can you provide some insight on that?

Narendra Lakkad: Unfortunately, as we said in the beginning of the call, because of the right issue compulsion, we are not able to share specific forecast on the numbers, of course we did say that but eventually we are remaining focused towards US, so we are putting our energies and focus to the US, and right now we have several programs which are closer to market or at a pivotal study, so we continue to remain dedicated to our US efforts, and once we have a visibility on the US pathway we will focus on the other markets.

Anil Raghavan: I just want to build on the points Narendra made and I think we have completed primary market research on most of these programs that we have discussed today, as promised in the last call. If you look at the decisions that we are taking in terms of prioritizing up some of the products and also prioritizing down some of the programs essentially it is driven by or a reflection of data that we have seen from these studies, so if you look at programs like K706, PICN or derma programs…

Narendra lakkad: We did a specific evaluation for say Sal Flu DPI and we have shared some information about EU opportunities, we evaluated Latanoprost and Timolol for Europe,

we evaluated Baclofen for alcohol dependence in Europe, so we did several primary research projects for evaluating Europeán market opportunity

Anil Raghavan: Those programs reflect in a positive readout from these market research surveys while some programs which Narendra just described shows in a not-so-positive readouts and it reflects in our decision to deprioritize on those.

Hitesh Shah: Besides Sun Pharma, are you developing any alternate source for manufacturing for SPARC products to insulate from a potential FDA problem and have you done that for Levetiracetam, Latanoprost, PICN and Baclofen?

Anil Raghavan: No, if you look at most of the programs on our portfolio today, we have pursued Sun as a manufacturing option, but in the long term, not because of any FDA problem, but we may probably look at appropriate manufacturing partners based on the technology involved or expertise that we need, but we do not see any compulsion to move away from Sun at this point.

Hitesh Shah: Can you provide the time to complete Phase-3 clinical trials in USA for Brimonidine OD?

Anil Raghavan: Brimonidine clinical program is going to be very similar to the clinical programs that we have done in the case of Latanoprost because with similar end points, we have taken around 3 to 4 years to complete Latanoprost program and that would be a good indication of what we may take from the market.

Hitesh Shah: Who will fight patent challenges for SPARC should such a situation arise when SPARC products are launched in USA?

Anil Raghavan: SPARC has a very well equipped IP cell and the strategic decision making around how we fight patent challenges will be driven by our own IP cell.

Hitesh Shah: What role will SPARC play in clinical development of MK3222 as well as Sun's…

Anil Raghavan: MK3222 is a program in-licensed by Sun Pharma, and Sun Pharma leads the development of the clinical program for MK3222.

Hitesh Shah: But Sir, when we go on clinical trial website, we see some representative of SPARC doing the work, so I was just confused in the terms of SPARC's involvement in the clinical development since especially we have now developed expertise in the same area?

Anil Raghavan: If we have a specific reference, we would probably look at that, but as a matter of ownership, MK3222 is a program clearly owned by Sun and I would not be able to comment on MK3222 in this call.

Hitesh Shah: What are the key constraints on SPARC's innovation program?

Anil Raghavan: That is a very broad question, I do not know how to interpret that question, but in terms of strategic focus, I have answered that question in pieces in earlier questions, we will continue to focus on creating a balance portfolio with focus on NCE and incremental innovation on novel drug delivery systems, also going to be our focus and we will try to balance those priorities in therapeutic areas that we have outlined earlier in this presentation, so we believe that we can actually move the needle of the standard of care in these therapeutic areas with our evolging capabilities in new Drug Discovery and Development and also innovation in novel drug delivery systems.

Moderator: The next question is from the line of Krish Shanbhag from Pride Investments. Please go ahead.

Krish Shanbhag: My questions pertain to the Dry Powder Inhaler. What is the likely cost and time to complete the clinical trial study in three EU countries stated in your presentation? In your presentation last year you had mentioned that two of these countries were Germany and UK. So if you could please tell us which country you have added? Also in your current presentation you have shown EU market opportunities for five countries. So will you use the clinical trial data of these three EU countries to get into five EU countries?

Dr. Siu Yao: Maybe, Narendra, maybe I can take some of the clinical question first. There were a lot of questions there; I am not sure I got all the clinical questions. I think one question you had was concerning the registration of the product in Europe. Although we did get opinions from three key EU regulators, I think our intent is to proceed with the centralized procedure which would mean that when we file, we would file simultaneously, basically in all 32 countries of the EU, and get simultaneous approval through the centralized procedure. So, when you refer to the two or three, we are just getting opinions from

individual regulatory agencies. Those regulatory agencies happen to be very prominent ones with respect to respiratory products and they also tend to have a lot of weight amongst the other 32 countries, and so that is why we proceeded with them but our intent is to file in all countries.

Krish Shanbhag: Can you just tell me the likely cost and time required to complete these studies in the three stringent EU countries?

Dr. Siu Yao: The cost, I may not be able to address perfectly and I do not know if I should address that. I think the process is that we have gotten feedback from the three EU regulatory agencies. The feedback has been relatively similar; we do need to proceed and perform several Phase-1 and 2 types of studies with sample size typical of those studies. I would say that the horizon to approval would be on a timeframe of years. I do not know how specific I can be, and I would have to defer to Anil and Narendra considering the rights issue that has been maturing.

Narendra Lakkad: I think we have given a guidance about our target filing date in Europe, which is in the Q4 2017-18, and we are in Q1 2015-16, so you may calculate how much additional time we need to complete our clinical program.

Krish Shanbhag: Do you have any plans of launching in the emerging markets before filing for approval in EU?

Narendra Lakkad: We continue to explore and evaluate, and if based on the data which we have already generated, if there is a possibility to register then we will be doing registration in those emerging markets, but if there are large country-specific requirements then probably we may not go ahead and do that.

Krish Shanbhag: What is commercial opportunity for say emerging markets as well as the three EU markets you discussed earlier?

Anil Raghavan: That is unfortunately the kind of question that we may not be able to address in this call given our constraints.

Narendra Lakkad: Also I think I just want to correct that we have not discussed that we will be specific to three EU markets, so we obtained the regulatory advice from three leading

regulatory agencies in Europe, but as Dr. Sui says, our intent is to register through a centralized pathway, so once we get approval, it will get approved in all the European markets. So the intent is to market in entire Europe, not just to three specific European markets.

Krish Shanbhag: Can you just indicate what is the size of the market there sir?

Narendra Lakkad: I think the market data, you can look at about how big is the Seritide in Europe and at what rate it is growing, based on, you can make an estimate, I may not be able to give specific projections and forecast as we have said before.

Krish Shanbhag: Are you developing any more products using the device being used for Starhaler?

Anil Raghavan: No, we do not have any more products in our portfolio at the moment.

Krish Shanbhag: What is relevance of your DPI in USA especially with many generic players gearing up for Advair in US?

Anil Raghavan: Like we did in the case of Europe, we are in the process ofpreparing for regulatory consultations in US, and we will take a call on the attractivess of the market based on regulatory consultations.

Moderator: The next question is from the line of Parin Gala, an individual investor, please go ahead.

Parin Gala: Would there be a toxicity study required to do PICN?

Anil Raghavan: No.

Parin Gala: And just to repeat the earlier question, if you could give the number of patient size for Phase-3 in the US for mBC?

Anil Raghavan: No, I have answered that question earlier also, at this point based on the data that we are working out the numbers for the study. I may not be able to give you an accurate number of patients for the study

Parin Gala: And when do you expect generic for Abraxane in the market, especially US?

Narendra Lakkad: We have no such information that when and whether there will be any generic drug.

Parin Gala: From what we understand Abraxane as approximate sales of around US$600 million, while in the last con call SPARC estimated it should be about $100-250 million. Just to understand, what is the reason for lower estimate when we feel our product could be significantly better than Abraxane?

Narendra Lakkad: I think those numbers which we have shared, we are neither confirming nor saying anything on that because of the restrictions we have. But broadly for developing this product we need to do several studies and get prescriptions for each of the indications. So we have to gradually build market for this product.

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

Dheeresh Pathak: Just to get a broader understanding of the generic competition to the product that you are developing through your proprietary technology, this would include Baclofen as an example, so for gastro retentive formulations, there might be various other platforms through which various other companies might be pursuing similar unmet needs. So when you have your product in the market, Baclofen GRS, is it possible for a generic company to do bioequivalence on your approved product but using a different sort of mechanism but able to achieve the same end goal, is that possible?

Anil Raghavan: Let me not address a specific hypothetical, as a matter of strategy what we are doing is, we are trying to strengthen the patent base and the IP cover that we have on all of these programs, we are very confident of protections that we carry for any of these programs and that is true for Baclofen, it is true for Levetiracetam and Latanoprost, and we should be able to take a call based on specific challenges that we may face in the future, but as a matter of strategy SPARC is a company driven by strength with IP, and as you can feel by the number of patents that we got granted in our young life and also the number of patent submissions that we have done last year, thats enormous focus for this team, so everything that we do and decide to pursue in the marketplace will carry some significant protection from such IP, that is the intent.

Dheeresh Pathak: No, I do not want to take any particular example. I just wanted to get a broader understanding that for a generic company using the different platform but trying to achieve the same endpoint, is it possible to file a generic product doing bioequivalence on your proprietary product?

Anil Raghavan: It will not be generic to our product, but if you actually are talking about solving the same problem with similar approaches, which may not infringe the protections that we may have, that is a possibility, I do not want to suggest that possibility that does not exist, it is certainly a possibility, but we have anticipated some of those approaches and try to create protections which cover not just what we are pursuing but also for some possible strategies to come around the approach that we have taken. So in that sense we feel very confident about the approaches that we have pursued not just for one product but for all products, that has been a major consideration for us in selecting products that we want to pursue and selecting products which we do not want to pursue.

Dheeresh Pathak: Would it be fair to assume that for products where you have done clinical trials you get at least three years exclusivity?

Anil Raghavan: That is right.

Dheeresh Pathak: Can you just highlight in which cases it can be more than three years?

Anil Raghavan: We are banking on the exclusivity driven by our intellectual property, in that sense, we are looking at a much longer protection for these products and just the regulatory protections that we get through …

Dheeresh Pathak: I understand the patent protection, I just want to focus on the regulatory protection.

Narendra Lakkad: Regulatory protection when it comes to the products which are done through the clinical trial and based on the Novel Drug Delivery System, regulatory exclusivity will be three years, that is what is the new product protection which you will get, in some cases there is a possibility of getting orphan drug indication, if that particular situation is there, so that is what, as far as regulatory goes, for the NCE program you can expect the NCE exclusivity which is for 5-years, **Dheeresh Pathak:** In any of the products that you discussed in your late stages, is there a possibility of an orphan drug indication?

Anil Raghavan: We do not want to comment on that at this point.

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

Chirag Dagli: Given that we are working on Octreotide, is it also safe to assume that we would be working on Leuprolide?

Anil Raghavan: We are not in a position to disclose additional information on that.

Chirag Dagli: Is it because it is early in development or you do not have it at all?

Anil Raghavan: We are not in a position to disclose additional information on the program.

Chirag Dagli: On Xelpros, so when we selected Sun Pharma as a partner, who else actually looked at this product sir?

Anil Raghavan: I will not be able to share the name of the player that we have considered but I can confirm that there is at least one player where we had substantial disclosure and we reviewed the possibility. We have gone through an agreement and significantly reviewed the possibility, and there were four or five players where we had term sheet in terms of expression of interest and after again having a framework. So before deciding on Sun Pharma we have actually looked at other possibilities and this decision was driven by what we see as critical capability, they are bringing to bear, or promising to bring to bear in taking this product to market and we feel very comfortable in the choice of the partner that we have made.

Chirag Dagli: So the decision was effectively based on the milestones that SPARC would have got, one versus the other deal?

Anil Raghavan: Not entirely, one is definitely financial considerations did play a part and explicit financial expectations did play a role, but we also made and did evaluate the potential of the partner to maximize the value of the product. So it is a combination of our need on the partner intensive effort and the ability that they can bring to the table in maximizing the value of the product, and also how that is translated into financial commitment.

Chirag Dagli: Sir, is it safe to assume that Sun's deal for SPARC was the highest NPV?

Anil Raghavan: That is correct.

Moderator: The next question is from the line of Saion Mukherjee from Nomura Securities. Please go ahead.

Saion Mukherjee: My first question is regarding Elepsia, we are looking for a partner. Firstly, why is there a delay there and what kind of partner would be ideal for this product, what kind of front end you would require to market this drug?

Narendra Lakkad: It is a question of getting a maximum value for a product and we are discussing with several potential partners, in fact, with very advanced stage of discussions with a couple of partners, so hopefully we will be able to conclude the deal sooner which is in the best interest of SPARC.

Saion Mukherjee: But what kind of front end you would require — is it required to be promoted by a large sales force, or what kind of front end capabilities you will need for this?

Narendra Lakkad: You will need 50 to 70 medical reps to promote this kind of a product.

Saion Mukherjee: This is something which Chirag asked earlier regarding the deal with Sun Pharma, so there is of course financial consideration, but if you look at the capabilities in the ophthalmology space, Sun Pharma is just starting out. In what way you think that, Sun Pharma would be doing a better job compared to some of the other companies who would have an established presence in ophthalmology?

Narendra Lakkad: I think there is a strong intent in Sun Pharma to create specialty marketing capabilities in the US space and ophthalmology is considered a core therapy area in Sun Pharma, I would not be able to speak much about Sun Pharma, but I think the kind of team which they are building in ophthalmology, we are quite impressed about their capabilities, and we believe they will be able to deliver best justice to a product like Xelpros**.**

Anil Raghavan: We will not be able to discuss Sun Pharma's plans in the Ophthalmology space in this call. Probably you should address that to Sun Pharma. But in terms of our choice of partner, we are very confident of the strength of the clients they have brought to us for maximizing value for our product.

Saion Mukherjee: On PICN, I understand there are some uncertainties around the timeline, but what is the earliest you think we can do a filing in the US for this product?

Anil Raghavan: As I said we are in the process of doing confirmatory trials at this point, we are looking for the outcome of that trial, we may be able to give guidance on when the product can go to the market, but at this point I do not want to speculate the outcome of scientific study.

Saion Mukherjee: This pivotal-B E study you are talking about right, which is expected at the end of this fiscal. What is the timeline for that study if you have any sense on that at this stage?

Anil Raghavan: We will be able to take a decision on this, this year and move on, we have listed our objectives for this program when we discussed this earlier in our presentation so our intent is to start a pivotal-B E program by Q4 of this year.

Moderator: Ladies and Gentlemen, due to time constraints that was the last question. I would now like to hand over the floor back to Mira Desai for closing comments. Over to you ma'am.

Mira Desai: Thank you so much for joining us for this investor call. It was a pleasure listening to your questions and responding to the same**.** However, if some of you may have other questions or we may not have been able to take your questions**,** we request you to please write in. Thank you. Good bye.

Anil Raghavan: Thank you.

Moderator: Thank you very much, ma'am. Ladies and Gentlemen, with this we conclude today’s conference call. Thank you for joining us and you may now disconnect your lines.