



**PARTICIPANTS:**

MR. ANIL RAGHAVAN – CHIEF EXECUTIVE OFFICER

MR. NARENDRA LAKKAD – BUSINESS DEVELOPMENT

DR. SIU-LONG YAO – CLINICAL RESEARCH

DR. NITIN K. DAMLE – DISCOVERY BIOLOGY

DR. PATRICK BURNETT – CLINICAL RESEARCH

DR. HANY MICHAEL – CLINICAL RESEARCH

DR. YASHORAJ ZALA – FORMULATION DEVELOPMENT

MR. JAYDEEP ISSRANI – BUSINESS DEVELOPMENT



**Moderator:** Ladies and Gentlemen, Good Day and Welcome to the SPARC Annual Investor Update Conference Call. As a reminder, all participants' line 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 touch tone phone. Please note that this conference is being recorded. I would now like to hand the conference over to Mr. Jaydeep Issrani. Thank you and over to you, sir.

**Jaydeep Issrani:** Good Evening and a Warm Welcome on the SPARC Update on NDDS and NCE Projects. We hope you received the presentation we sent out sometime back. This is also available on our website and the transcripts will be also put up on the SPARC's website soon.

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

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

We have the entire SPARC management team with us on the call today and some of our team members are joining us from US. I would now hand over the call to our CEO – Mr. Anil Raghavan for his presentation. Over to you, sir.

**Anil Raghavan:** Thanks, Jaydeep for the introduction.

A very warm welcome again to all of you to SPARC's Annual Investor Presentation. This is our fifth in a row. These sessions have indeed helped us enormously to understand your concerns and priorities. Some of the threads from past interactions have grown into really enduring association we have come to respect. So I want to thank all of you for sharing our passion for creating a global innovation



business out of India and thank you for staying in touch and thank you for the participation today.

I want to take one moment to express our gratitude to all our investors for supporting our recent rights issue whole-heartedly. It is very important outcome for us given where we are in our journey. So, on behalf of everybody at SPARC, our board, our management team, I want to thank all of you for your participation.

We have most of SPARC's senior management here as Jaydeep mentioned. We are not planning to do a formal set of introductions at the start. We will do that when we come to do our slides. Our primary purpose for this call is to share with you the status of our late-stage products. But before we go there, I would like to take a few minutes to make some introductory comments and also speak very briefly about how our strategy is shaping up especially in terms of the direction of our preclinical programs and also how we are building up our operating model.

So let us start the presentation with Slide #3:

Let us begin with a brief bird's eye view of SPARC's overall portfolio: As you know, we have two NDA submissions under review by USFDA – Elepsia™ XR and Xelpros™ a BAK-free product in Glaucoma. We now have three late-stage clinical assets following that which we are trying to complete in the next 12-months or so. Baclofen once-a-day for spasticity in Multiple Sclerosis, Paclitaxel in our Nanotecton® platform and Sal-flu combination on our proprietary DPI device.

We have now five early stage clinical compounds, most of them initiated in FY'16 when we began our transition towards clinical development. One program in Oncology, that is our K706 program in refractory CML along with the first product on Abuse Deterrents platform and derma indication for our soft steroid S597. We have two more NDDS Programs in this early clinical list – one each in Ophthalmology and CNS.



I know it is very risky to make projections in this business. But we really see an opportunity to bring a significant share of these assets to market with compelling evidence to differentiate.

But the bigger story here is this: The nature of our business and the nature of our basket of products is changing. We started off with a predominant focus on novel formulations. How to make delivery better, was the question that we were trying to address to. Even as of 2014, only one-fifth of our projects involved New Chemical Entity. But in the last two years, the share has grown to almost 45% of our assets. Even in NDDS, we have now a pronounced preference for addressing really complex delivery challenges versus simpler reformulations. We are also narrowing our focus within the therapeutic area we are active.

So when we met last year, we spoke about our portfolio review process that led to the de-prioritization of some of our assets. We have now refined that process and institutionalized it. In this year's review we have decided to take out DICN from our active list. DICN as you know is Docetaxel on our Nanotecton® platform much like PICN. This was a low priority asset in the last couple of years because of the limited opportunity that we are seeing. Now, we have decided to park this program.

Slide #4 is a high level scorecard of FY16 in nutshell.

We have made important progress on all our late stage clinical programs. We have accelerated patient enrolment for both Baclofen studies, the efficacy program and the duration of action study. We have made significant progress in making the BE route viable for PICN and we have now initiated pivotal studies for Sal-flu in Europe.

Last year, we promised to take four compounds to clinical development. I am very happy to share with you today that we have done four INDs last year initiating early clinical trials. K706 is currently in Phase 1 in the US. We have started early studies for S597, our soft



steroid for dermatology, exploratory studies for the first product under Abuse Deterrents platform, we call it SDN-021 now have been completed post-IND. We have started clinical programs for both Tizanidine and Brimonidine.

Last year, also saw the commercialization of PICN in India under the brand name Bevetex®. Bevetex® generated substantial interest in the oncology community in India as safer, much more convenient option in a market which is still dominated by traditional Taxanes. We are very happy to see the initial momentum that we are seeing for Bevetex®.

We also had a fair share of disappointment in the commercial side. The regulatory compliance status of our manufacturing partner held up approvals for both Xelpros™ and Elepsia™ XR. In Elepsia™ XR's case we have seen a rescindment after we received a formal approval from FDA. In Xelpros™, we have received a complete response letter citing issues with the regulatory compliance status of the plant. We have now responded to the complete response letter for Xelpros™ and back in the regulatory process for approval.

We have addressed this manufacturing issue many times in the last year in conferences and other occasions we had met. But for additional clarity and transparency, I want to go through this issue one more time.

Our judgement is that Halol still offers our shortest path to approval for Xelpros™ and Elepsia™ XR. Our partner has taken an extensive remediation plan and we expect reaudit to happen for that facility anytime now. In the meantime, we have explored multiple alternatives both within the system and outside and studied the regulatory requirements for an alternate manufacturing site instance. Our understanding is we need additional stability data and bridging BE studies, making it a costly and time-consuming proposition. We have lined up several back-up options for both products as I said both internally in the system and externally. But we intend to trigger a Plan-



B only if we conclude that our Plan-A is certainly going to take longer than the Plan-B. That is where we are. We will hear from Narendra Lakkad later in the session. We have now out-licensed both these programs to Sun Pharma subsidiaries and we will go through the deal term in some details when we come for the Business Development Update.

Second point I want to make is a more longer-term strategic part. It is important that we learn from this experience. There is certainly an argument to be made for filing with the back-up option upfront. At the same time it also has implications in terms of cost, in terms of submission timeline.

We will now plan to file a back-up site with every upcoming submission whenever the economics of the product allows such freedom. We will carefully weigh the risk benefits of creating redundancy. I am sure some of you may have follow-up questions on this point and I am happy to take them when we open up this call later.

Now, let us move to Slide #5: Usually, in our interaction, we don't speak much about our early stage programs. Usually our focus is clinical development basket as it consumes much of our spending and represents more near-term commercial opportunity. I want to make a couple of points on a broader direction beyond the products which are in clinical development.

As I mentioned earlier, the orientation of our early R&D effort is certainly shifting, it is shifting towards more complex, higher value solutions involving NCEs, more complex formulations and it in some very early cases new therapeutic modalities. While our overall therapeutic coverage remains consistent that is Oncology, CNS, Dermatology and Ophthalmology, our focus is narrowed to more specific disease states and delivery problems within these areas, for example, in Oncology, we are focused on understanding different patterns of resistance in select cancers and developing smarter drugs



which can help overcome the resistance which is often driven by very specific mutations, or in the case of CNS, understanding molecular mechanisms involved in neuronal degeneration is emerging an area of active interest within SPARC.

On the delivery side, increasing retention and penetration of therapeutic agents would be the focus both in Dermatology and Ophthalmology. Being part of the global effort to raise deterrent levels in Prescription opioids abuse as we mentioned last year is increasingly becoming strategic priority for SPARC. As you can see, we are becoming a clearer and lot more selective player in identifying the problems we want to pursue.

On the operating model front, last year we spoke about strategic partnering and execution as two critical pillars of focus from a long-term perspective. We continue to work on both these aspects. We continue to make important inroads in connection in the academic community here in India as well as internationally particularly, in the United States. We have now three early stage Oncology programs involving significant working together with Tier-1 academic collaborators. Few more are in the works. We have substantially increased our engagement with academic research organization on multiple fronts for sourcing ideas, to get access to expertise in specific parts of the discovery cascade and certainly for gaining access to patients and clinical expertise.

In all this, we are learning that our proposition involving longer-term focus of much more firmer commitment to develop assets and lack of lot of bureaucracy resonates very well with academic investigators. So that is an area where SPARC is clearly seeing an opportunity and we are trying to step up. On the operations side, we continue to make investment to accelerate our process, especially in the time from conceiving an idea to filing an IND and we are looking to augment our capability to speed up the process, especially in areas such as Clinical, Data Analytics, In-Vitro Biology and Project Management.



So before I transition, I want to briefly touch upon our financials:

So let us move to Slide #6. So the first point I want to make is, in spite of the slower start that you have seen on Q1, you will see our revenues certainly growing this year and in the near-term. We have already licensed out Elepsia™ XR with the US\$ 10 million upfront payment in Q2, we will see additional payments in Xelpros™ as we go past the Halol situation, to commercialize in the US. We are also working to close another deal this year. So there is a reasonable confidence within SPARC that our revenues are going to grow this year.

But at the same time, with increasing number of clinical projects, our clinical spend is certainly going to increase substantially. We will also see our employee cost growing up as a result of targeted hiring in select areas like I mentioned in Clinical, Regulatory and some parts of Biology. We anticipate our spending to be more than our revenues at least till FY'18 when we expect to see royalty incomes of late stage program start kicking in.

We are happy to discuss this more when we come to the Q&A part of the call.

So now, moving to my final Slide #7, I would like to end with an outlook to set the expectations for FY'17. Very briefly, we are expecting to see approval for Elepsia™ XR and Xelpros™ coming this year where at least one of them moving to market later this year. On Baclofen we will conclude the patient recruitment for both studies setting the stage for a submission by mid next year. We plan to complete the BE and PIF studies for Sal-flu by Q1 of FY'18, targeting to file the product in Europe by next year. We are on a similar calendar for PICN planning to complete the pivotal BE study next year depending on our ongoing consultations with FDA and of course data. We are hoping to get a clinical proof-of-concept for K706 and



Brimonidine by end of FY'17. Additionally, we will initiate four more INDs this year bringing four more products to clinical testing.

So, as you can see, we are in a very important point in our young history. In the medium-term, we are looking to graduate our viable assets to market while rebuilding around more innovative higher value products at the earlier stage of our portfolio. So we are very excited to be where we are and I am looking forward to our discussion later in this call.

At this point, I will transition to Mr. Narendra Lakkad. Narendra heads our Business Development function globally. He will start the discussion with a brief update on Elepsia™ XR and Xelpros™.

Over to you, Narendra.

**Narendra Lakkad:** Thank you, Anil. Good Afternoon or Good Morning to all who are joining from different geographies in today's call. My name is Narendra Lakkad and I look after Business Development for SPARC.

We are on Slide #8 now. I would like to give a brief update on the current status of US commercialization plan for our lead products Elepsia™ XR and Xelpros™.

As Anil mentioned, both products are now awaiting marketing approval which is pending manufacturing site clearance. As you are aware, we recently announced that we have licensed Elepsia™ XR to a subsidiary of Sun Pharma for the US market. As per the agreed license terms, SPARC shall receive an up-front payment of US\$10 million. We would also be eligible for additional milestones and sales royalties on actual sales performance of the product.

Elepsia™ XR would be commercialized by a dedicated CNS sales team of Sun Pharma in the US which they are building now. Elepsia™ XR was evaluated by several potential partners over last couple of years. But when we compare all the terms that we received and the



relative strengths of the potential partners evaluating this product we believed Sun Pharma has several internal strengths and capabilities and ability to invest in commercializing Elepsia™ XR.

Xelpros™, as we disclosed last year, has been licensed to a subsidiary of Sun Pharma and will now be commercialized by Sun Ophthalmics, a new specialty division launched by Sun Pharma for branded ophthalmic products.

Moving to Slide #9, here we have attempted to give an overview of commercial opportunity for Elepsia™ XR in the US market. Elepsia™ XR is Levetiracetam Extended Release 1000 mg and 1500 mg once a day product, that has been developed with our proprietary Wrap Matrix™ technology platform. As you can see on the bar chart on slide, Oral Levetiracetam market has shown healthy prescription volume growth over years despite no promotion. As you all know this product has been genericized since long time. Total prescriptions have grown from 5.3 million in 2011 to 9.3 million in 2016 and it is still growing.

The daily dose for Levetiracetam is relatively high and more than 80% of epilepsy patients require dose in the range of 1 gm to 3 gms per day. There is no extended release Levetiracetam product above 750 mg and hence most patients need multiple Levetiracetam tablets in a day. As such, the pill burden in the Epilepsy patients remain high because most patients are on multiple drugs, and in fact more than 55% of patients take more than 6 pills a day for their Epilepsy treatment.

The Extended Release and the once- a -day profile were seen as major advantages of Elepsia™ XR by Neurologists in a primary market research that we conducted with the help of a third-party agency. Elepsia™ XR would provide a new therapeutic option to patients and physicians to reduce pill burden and help improve patient compliance.



We believe a peak sales potential of this product in the US is in the range of US\$50 million.

Moving to Slide #10, Xelpros™ is a novel BAK-free formulation, BAK is Benzalkonium Chloride, a preservative which is commonly used in Eye Drops. Xelpros™ is a BAK-free Latanoprost Ophthalmic Emulsion developed with SPARC's proprietary Swollen Micelle Microemulsion or SMM technology platform.

As you know, prostaglandin analogs are the mainstay of treatment of Glaucoma. The current market for prostaglandin analogs in the US is around US\$1.4 billion. Latanoprost is the most widely prescribed prostaglandin with around 67% market share in terms of prescription volume. As per the current market data over 12 million prescriptions were written for Latanoprost in the US in last 1-year.

Ocular surface side effects are common problems in BAK containing eye drops and it is an issue which occurs typically when patients need to take the treatment for chronic or a long administration. As per the market research data, 10% to 16% of patients on BAK containing products like Xalatan® or its generics developed Ocular Surface disease over a period of time. Xelpros™ provides a novel BAK-free option to such glaucoma patients. We believe Xelpros™ has a peak sales potential of US\$50 million in the US.

The approval & commercialization of both Elepsia™ XR and Xelpros™ are most important events which will provide much needed revenue which are critical for us to take forward our next stage of programs. We hope to accomplish the same very soon. I now request Dr. Yao to provide update on the next three most advanced clinical stage programs.

Over to you Dr. Yao.



**Dr. Siu-Long Yao:** Thank you, Narendra. If you are following along online you should be on Slide #11 now. A very warm Good Afternoon or Good Morning depending on where you are in the world. My name is Siu Yao and I help oversee Clinical Research for SPARC.

I am going to try to bring you up to speed on three products. Namely Extended Release Baclofen, PICN which is Paclitaxel Injection Concentrate for Nanodispersion, a specific formulation of Paclitaxel that has some key advantages and our Salmeterol Fluticasone Dry Powder Inhaler.

Slide #12 please: As many of you may know, Baclofen is generally available as a multiple 3 to 4x a day product. We are utilizing Gastro Retentive technology to convert the Baclofen into a once-a-day product. Basically, at a formulation level, this involves putting the Baclofen in a device like formulation that floats, expands and offers muco-adhesion once administered.

The effect of the formulation can be seen on the graph on the right side of the slide here. Here, you have drug concentration on the Y axis and time along the X axis. The orange line shows results with currently available immediate release Baclofen whereas the blue line represents results with the GRS Formulation. As you can see utilization of this technology smooth out delivery of the drug over the course of the day.

Slide #13 summarizes some of the market research that was done in support of our product. In surveys, the majority of doctors felt that consistent exposure with once-a-day administration is an important key benefit. Such characteristics will result in significant use of our product both for tier-II and tier-III formulary positions.

Some of this information is summarized in the graph on the right where you see that the market after introduction of the GRS formulation will consist of 40 to 60% of providers preferentially using the GRS formulation.



Finally, the Baclofen market is relatively large consisting of 630 million units growing at a 5% annual rate.

Slide #14 provides a summary of where we are clinically right now. Baclofen development has been agreed to with the FDA under the auspices of an SPA.

There are three key studies required for approval. More than 160 out of 214 patients are accrued in the pivotal phase-III efficacy study. The open label safety study has completed accrual and the duration of action study has accrued 84 out of a total 93 patients. Filing is targeted for 4<sup>th</sup> quarter of financial year 2018.

Slide #16 moves into PICN and summarizes some of the key advantages of PICN our Paclitaxel formulation which is under development. PICN utilizes our proprietary Nanotecton® technology which allows us to administer Paclitaxel without added Cremophor® or Albumin.

As you know Cremaphor is responsible for many of the infusion reactions associated with traditional Paclitaxel administration, so removal of the solubilizing agent from the formulation can decrease the incidence of infusion reactions and allow for faster administration. Removal of albumin further decreases the incidence of infusion reactions and also removes an ingredient that can be associated with a risk of infectious disease transmission. Removal of these components also allows for short administration times and administration of higher doses without pre-medication. As many of you know, PICN has already been launched in India as Bevetex®.

Slide #17 please: We had considered performing a Phase-III trial to get marketing approval but after more careful reviewing some of our pre-clinical data, we went on to do PK simulations and get additional clinical data to investigate a PK-based approach.



Some of those results are summarized in this slide. On the Y axis of the graph there is Paclitaxel concentration and on the X axis there is time in hours. You can see that whether you are looking at total or free drug concentration the curves for Paclitaxel or Abraxane® are very similar to the curves with PICN. This suggests that PICN may be bioequivalent to Abraxane®.

Because PK studies are generally quicker and less resource-intensive we have subsequently focused on this approach as a pathway to approval. Currently, based on some initial pilot clinical data, we are finalizing optimization efforts for study design and assay methodology and proceeding with the pivotal bioequivalence study in fourth quarter of financial year 2017 followed by filing approximately 1-year later.

Slide #18 summarizes some of the market opportunity with PICN. As you know Abraxane® sales, to which PICN would be bioequivalent are valued at almost US\$670 million in the US. Nonetheless, 70% of the market still consists of traditional Paclitaxel formulated with solvents such as Cremophor® with an estimated 150,000 patients being treated annually with solvent-based Paclitaxel formulation. For these patients, over 60% of doctors say that the incidence of hypersensitivity and ease of administration would be important factors in the choice of a formulation.

As a consequence, we believe that Taclantis™ or PICN has a significant opportunity to fulfill an important need for patients that would otherwise be treated with solvent based Paclitaxel.

Slide 20: which is my last slide set before I hand you off to Dr. Damle summarizes our progress with Salmeterol Fluticasone Dry Powder Inhaler.

Slide #20 and the next few slides go over our current activities with our Salmeterol--Fluticasone Dry Powder Inhaler. This inhaler utilizes technologies and more efficiently delivers drug to the target lung tissue such that only half the amount of each drug needs to be



administered in order to get the same amount of drug to the lung as an existing Seretide® Accuhaler®. The Inhaler also has the additional advantage of being able to deliver uniform doses despite differences in patient inhalational ability.

There are also some commercial advantages which are summarized in subsequent slides including favorable ratings on device characteristics as well as willingness to pay some premiums for the product.

Slide #21 provides a clinical update: For approval we basically have to demonstrate bioequivalence and characterize the performance characteristics of our device. The Peak Inspiratory Flow study will characterize performance and some PK studies will be used to demonstrate bioequivalent. The Inspiratory Flow study has started and is in progress and a low dose and high dose PK studies are about to begin soon. We are likely to file for marketing authorization in the fourth quarter of financial year 2018.

Slide #22 is a little complicated but has some important points. Each dot represents an anticipated characteristic of our inhaler. On the Y axis is the relative importance of that characteristics on a 0 to 5 point scale with 5 as the most important. On the X axis is how our product performs on that characteristic on a minus 3 to plus 3 scale, with plus 3 the most favorable.

As you can see in most of the study characteristics were viewed as important product considerations by the physician survey. In addition, the anticipated performance of our product with respect to these characteristics was uniformly favorable.

Slide #23: Some of the other marketing information I alluded to earlier is shown in Slide #23. Here you have potential prices for the product across the X axis and assessments of product value on the Y axis.



Physicians from a variety of countries were surveyed including France, Germany, Italy, Spain and the UK. Individual results are plotted as individual points and the line represents the aggregate result. As you can see a 10% premium was assessed as reasonable for our product with its particular characteristics suggesting that the innovative characteristics of the delivery device are valuable to physicians.

Slide #24 summarizes what I think many of you already know. The inhaled corticosteroid, long acting beta agonist dry powder inhaler products for Asthma and COPD are US \$2.6 billion market in Europe. Seretide® is one of the most widely prescribed combinations in Europe for asthma and COPD with sales of US\$ 1.1 billion. This product is seeing slow genericization with a few products already approved in some of the countries. We expect more generics may enter the market although adoption may not be as quick as we have seen for simple oral products. We believe this market may continue to offer opportunities with differentiated products like SPARC's Dry Powder Inhaler.

I know that was quite a bit of information but I hope I brought you up to speed on several of our more mature programs.

At this point I would like to hand things over to my colleague Dr. Damle, who will update you on our Chronic Myeloid Leukemia Program.

**Dr. Nitin K. Damle:** Thank you, Dr. Siu and Good Afternoon, Everyone. My name is Nitin Damle and I oversee Discovery Biology Function at SPARC and I will be discussing this afternoon our CML program with you.

We had discussed during our previous investors update our lead ABL kinase inhibitor K706, which is an orally active and potent ABL protein tyrosine kinase inhibitor capable of inhibiting BCR-ABL leukemic cells. K706 can inhibit not only native BCR-ABL but also various mutants of it including difficult to treat T315I mutant.



In addition to K706, we now have a backup or a follow on candidate in K954 as shown on Slide #26. While K706 is more selective ABL kinase inhibitor K954 is more potent in its ability to inhibit the T315I mutant of BCR-ABL.

What you see on the slide is the Kinome profile of these two molecules showing preferentially high potency inhibition of 8 to 13 different kinases including the ABL kinase. In contrast and although not shown here, Ponatinib, which is a benchmark TKI that is used in this setting with T315I activity shows high potency inhibition of 42 additional kinases and some of these are believed to contribute to Ponatinib's toxicity profile that limits its clinical use.

We have evaluated anti-tumor efficacy of both K706 and K954 in comparison with Ponatinib using imatinib refractory CML Xenograft. The results from this evaluation are shown on Slide #27.

In this study, we allowed the CML Xenograft to reach a sizeable volume of 1.5 cubic centimeters which is almost equivalent to the 5% of the body weight before the treatment was initiated. The treatment in this case was a daily oral treatment with any of the three TKIs that I mentioned earlier and the treatment period was for 21 days. Tumor growth was further monitored for additional 35 days or longer to observe regrowth on the CML Xenograft.

As shown in Slide #27 both K706 and K954 were able to cause regression of pre-existing large CML Xenograft. Treatment with either ABL inhibitor from SPARC further prevented regrowth of CML cells long after the discontinuation of the treatment indicative of long-term therapeutic benefits conferred by these two agents.

In this regard, anti-tumor activities of both ABL inhibitors from SPARC are similar to that observed with Ponatinib, the current benchmark for 3<sup>rd</sup> line treatment of CML.



The next Slide #28 shows the comparison where we exactly are with these two agents. We have completed the pre-clinical 90-day GLP safety assessment of K706 and opened an IND in the United States. Phase-I dose escalation study is presently ongoing and indicative efficacy data from this draft is expected to be available by fourth quarter of this year.

As for K954 we are currently conducting IND enabling toxicology studies with this compound and plan to file IND by fourth quarter of this financial year as indicated in Slide #28.

The next Slide #29 shows the results of a survey of key opinion leaders and practicing physicians for their impressions of the current treatment options that are available for CML in various settings.

There is a significant dissatisfaction with the existing treatment options in second and third line setting in CML as indicated on the slide. We believe that K706 offers an excellent therapeutic alternative in this niche setting due to superior combination of efficacy and safety which will be evident during the ongoing clinical trial.

On the next Slide #30, we have indicated commercial attractiveness of this niche opportunity. Approximately, 50,000 CML patients in the United States are treated annually with Tyrosine Kinase Inhibitors. Estimating target population in CML for the third line treatment is close to 6,000.

However there is clearly an opportunity for newer therapeutic such as K706 to showcase their therapeutic potential and acceptance in an earlier setting based on their superior efficacy and safety profile and we remain optimistic that K706 will be able to meet its therapeutic expectations for use in both these settings.

I shall now request Dr. Patrick Burnett to discuss our Dermatology program.



**Dr. Patrick Burnett:** Thank you Dr. Damle. My name is Patrick Burnett. I oversee the Dermatology Clinical Function for SPARC. I have the opportunity to speak to you on two programs from our Dermatology pipeline

Slide #32: The first project I will cover is SUN-597, novel steroid formulated for topical use which takes advantage of low systemic bio-availability to provide a favorable safety profile.

Both psoriasis and atopic dermatitis are being considered as potential indications for development of this topical formulation. Prolonged continuous use of topical steroid can result in both systemic and local cutaneous adverse effects. SUN-597 is designed and formulated to minimize systemic bio-availability and is anticipated to result in reduction in HPA axis suppression and skin atrophy. Two important side effects of topical steroids that commonly limit their use.

Preclinical animal model support improved efficacy and safety profile of SUN-597 compared to mid-potency steroids. On the next slide is presented an update on the development status.

Slide #33, this project is being developed under an open IND with the US FDA. The vasoconstrictor assay study has been recently completed. Phase-I healthy volunteer safety and tolerability study is planned for Q4 of fiscal year 2017.

In addition, the anti-inflammatory prodigy of SUN- 597 will be evaluated in the Phase-I study of psoriasis patients which is planned to start in Q1 of 2018. Further development for SUN-597 will guided by the outcome of these two studies.

Next slide please. Next, I would like to speak with you about our Minocycline Project. Topical Minocycline is a project in SPARC Dermatology pipeline targeted for patients with acne. Oral Minocycline is a commonly prescribed antibiotic for inflammatory lesions at moderate to severe acne with systemic treatment Minocycline can potentially result in undesirable systemic effects.



SPARC has developed the novel formulation for topical use that will avoid systemic exposure and is expected to be active in both inflammatory and non-inflammatory acne lesions.

On this slide pre-clinical data are shown to demonstrate proof-of-concept in a rodent model of Acne that uses the key Acne bacteria which is pathogenic in Acne. The inflammation on the Y axis is assessed by ear thickness and time in days along the X axis. Both the untreated and placebo show increasing inflammation over time; however, after treatment with either topical or Oral Minocycline, reduction in inflammation is observed.

As seen in the graph, magnitude of effect is similar between the oral and topical Minocycline. Based upon these favorable data and well accepted pre-clinical model of Acne, this project is being moved forward and is currently undergoing formulation optimization based on pre-clinical study results. Thank you for the opportunity to speak with you about our Dermatology pipeline.

Now I will hand the presentation over to Dr. Michail from our ophthalmology team. Hany.

**Dr. Hany Michael:** Thank you, Dr. Burnett. I am Hany Michail and I oversee Ophthalmology Clinical Programs.

If you look at Slide #37 what you see is a novel once-a-daily formulation of Brimonidine, a drug for Glaucoma that reduces the pressure in the eye. Typically, Brimonidine is given 3x a day. Once a day formulation technology consists of fine resin particles which bind the active drug. This technology is called TearAct™. This drug-resin complex spreads on the eye surface with each eyelid blink and then the tears activates the drug release from the nano-resin drug compound. This has the effect of delaying the immediate exposure of the drug and instead creates a slow consistent exposure to the eye surface.



As you see on the next slide #38, primary market research was done in the US to assess physician opinion regarding this once-a-day formulation compared to available Brimonidine which is 3x a day. The overall responses were favorable with the novel formulation preferred by ophthalmologists particularly for the impact on patient compliance as well as patient and physician satisfaction.

On the next slide #39 I provided a status update. We have completed IND enabling toxicology studies and have received clinical trial authorization. Currently, we are initiating the Phase-II proof-of-concept study which compares the SPARC once-a-day Brimonidine versus the standard competitor at 3x a day.

Thank you for your attention. For now I would like to introduce Dr. Yash for further update.

**Dr. Yashoraj Zala:** Thank you, Hany and Hello! Everyone on the call. My name is Yashoraj Zala and I am responsible for the Oral Formulation Development at SPARC. I will be updating on the progress of SPARC Abuse Deterrent Platform Technology.

Please refer to Slide #41. As most of you would be aware, prescription drug abuse especially opioids is a growing epidemic in the US and a cause of major concern for the law enforcement agencies and the US FDA. Thus the US FDA is encouraging pharmaceutical companies to develop Abuse Deterrent Formulations in both the Extended Release as well as the immediate release phase. Some staggering statistics reflecting the magnitude of the problem has been discussed on Slide #41. Notably 19,000 deaths reported due to prescription opioid overdose in 2014.

Moving on to Slide #42: This slide discusses the vulnerability of the immediate release or the IR Formulations to abuse. Sales data of some of the IR products in the US market have been shown in the right in the pie chart in the number of units.



Based on this diagram the highest selling IR opioid formulation is a combination formulation of Acetaminophen and Hydrocodone followed by Tramadol and the third highest selling product is again a combination of Acetaminophen and Oxycodone. The single component Oxycodone formulation ranks as the fourth highest selling IR product. Importantly, there are no approved IR opioid formulations with abuse deterrent labeling as of now in the US market. Immediate release formulations are most widely abused through the oral route by simply ingesting multiple units at a time.

So having shared with you this brief background on the abuse pattern of IR Formulations, I would like to describe that SPARC Abuse Deterrent platform technology as shown on Slide #43.

The SPARC technology consists of one phase made up of the Opioid API which is present in Intimate mixture with the pH responsive polymer. This phase is then mixed with a secondary component containing pH modifier. The technology works such that when multiple pills are ingested the pH modifier changes the environmental pH causing the pH responsive polymer to become insoluble and thereby restrict the release of the drug from multiple units. This technology is designed to deliver the therapeutic dose at prescribed number of units. Further the formulation would be modified to modulate the rate and/or extend of release. The number of pills beyond which release inhibition is desired can also be tailored using this technology.

It is expected that abuse through the intranasal as well as the injectable route will also be deterred just as resistance to tampering by common solvents mediated extraction.

Moving over to Slide #44, this slide shows a graphical representation of the Proof-of-Concept. The graph on the left hand side shows the Invitro release data of a single pill, that is a blue colored line, whereas the orange color curve representing the release rate when five tablets are evaluated shows a significant depression in the rate.



On the right hand side is a graphical representation of the Pharmacokinetic data and demonstrates successful in vivo proof-of-concept conforming the potential of this technology. The orange color curve shows the plasma concentration of SDN-O21 when multiple tablets, that is five tables were ingested by healthy human volunteers under Naltrexone block. The green colored curve represents the reference concentration, those normalized based on a single unit data. As it is strikingly obvious the SPARC formulation shows a significantly blunted C<sub>max</sub> of peak concentration with a reduction of about 50% and the delayed T<sub>max</sub> which is expected to influence the drug likability and possibly result in a less high being derived by the abuser.

Slide #45 discusses the updates under first program based on this technology. So SPARC opened an IND in the 3<sup>rd</sup> quarter of 2016 and conducted the proof-of-concept in vivo studies under this IND in the US. Based on the results of the studies, SPARC advanced the formulation development and optimization activity. The next planned step includes additional PK study in the FY-'17.

The next update is on our second program on Pain Management that is Tizanidine ER which is being evaluated for Musculoskeletal Pain. Please refer Slide #47. SPARC had formulated a controlled release once-a-day product based on the Wrap Matrix™ technology. The Tizanidine market in the US is estimated at 725 million tablets and growing at 11%. Since only an IR formulation is available in the market, the use has been somewhat limited due to the side effects such as orthostatic hypotension, somnolence and cognitive function impairment. The SPARC formulation is designed to address some of the side-effects which could possibly translate into better compliance and patient convenience. The schematic representation on the right hand side of Slide #47 shows a green colored curve of the plasma concentration expected from a good control release formulation as against the peak and valley red colored curve arising from an IR formulation.



Slide # 48 captures the Development Status Update for this program. A simulated driving study was initiated in the first quarter of 2017. This study is expected to demonstrate diminished side effect profile of the ER formulation as compared to the thrice-a-day IR formulation. The top line results are expected in the second quarter of 2017. The IND filing for this program has also been targeted in the same quarter. With this we have completed the update on the SPARC portfolio in the Pipeline Projects.

Slide #49 provides a quick summary of the status of our late stage program.

Thank you Ladies and Gentlemen for your patience. The update is now concluded and the SPARC core management team will attempt to answer any queries that you may have.

**Moderator:** Thank you. Ladies and Gentlemen, we will now begin the Question-and-Answer Session. We take the first question from the line of Ketan Gandhi from Gandhi Securities. Please go ahead.

**Ketan Gandhi:** Sir, it is regarding Baclofen. Are the patients recruited till date meeting the clinical endpoint as per the SPA with FDA?

**Anil Raghavan:** We would be able to know the clinical endpoints once the study is concluded and the data set is open. We have to reach 214 patients before we can open up the study. So we would not be able to say whether this meeting the clinical end points till the study is concluded.

**Ketan Gandhi:** What are the key factors that will drive the formulary position for Tier-1 or Tier-3?

**Narendra Lakkad:** The formulary position generally for branded products in the US when they are introduced for the first time, is Tier-3 and Payers generally are more vigilant and more careful in awarding lower tier status unless the product is providing a significant value over the currently available drugs.



**Ketan Gandhi:** On Slide #14, you have mentioned about 161 out of 214 and 84 out of 93. But in last presentation, this was supposed to be 240 and 135.

**Anil Raghavan:** There are slight difference between these data set. 240 patients you need to enroll into the study. So if you look at the last update, I think we had around 120 patients or something enrolled into the study. But you got to complete 214 out of this 240 enrolled to conclude the study. So if you look at the current enrolment number is around 190 plus in the study and completed number is 161. That is the difference.

**Moderator:** Thank you. The next question is from the line of Jayesh Gandhi from Harshad Gandhi Securities. Please go ahead.

**Jayesh Gandhi:** My question is regarding Slide #24. The amount which is given 2.6 billion, is what, it is dollars or it is...?

**Narendra Lakkad:** It is US dollars.

**Jayesh Gandhi:** On the same slide, Salmeterol brand and Salmeterol Generic can you just tell me why the difference is so much, 96% and 4%?

**Narendra Lakkad:** Generic products have just started getting approval in the Europe and they have not got approval in all the countries in the Europe. So that conversion from brand to generic has been slow.

**Anil Raghavan:** We may probably see adoption from newer patients as against patients who are stabilized on these drugs. So you may probably see some time before the generic actually catch on with significant market share.

**Jayesh Gandhi:** Sir, the time maybe two years or three years' timeframe or longer than that?

**Anil Raghavan:** I would not hazard a guess on how much time it will take, but in our products case, we are not a strict generic, we have marketable advantage on this program, in the sense, we are providing comparable PK profile at half the dose. So there is an advantage that



we bring to the table. So we are hopeful that we can have different behavior with our product.

**Moderator:** Thank you. The next question is from the line of Manish Jain from SageOne Investment Advisor. Please go ahead.

**Manish Jain:** My question is on PICN and that is Taclantis<sup>TM</sup>. just wanted to know if Taclantis<sup>TM</sup> approval in US is based on bioequivalence rather than indication-based clinical trial data, what commercial and clinical factors will drive a US doctor to prescribe Taclantis<sup>TM</sup> over Abraxane<sup>®</sup> especially critical applications like pancreatic cancer and others?

**Anil Raghavan:** Before Narendra come in, this is Anil, I will probably start that, if you look at if we get a pathway in the US market with bioequivalence profile comparable to Abraxane<sup>®</sup>, then technically we are eligible for all the indications of Abraxane<sup>®</sup> unless there is some specific patent protection in any specific area. So on day one, we will be able to compete with most of the indications of Abraxane<sup>®</sup> and then there are additional clinical programs that we can do. So even though our regulatory path into the market is driven by BE route, that does not prevent us from building up additional clinical data, building up a differentiation in select areas. So that is something which we definitely plan to do especially try to understand the safety advantage that we have seen this in the earlier studies and creating data to maximize that advantage. But at this point, our intent is to be in the market as soon as possible and BE route allows that option to be in the market as soon as possible and then we will try to see how best we can differentiate.

**Dr. Siu-Long Yao:** This is Siu Yao here. I would also add that there are some immediate advantages that we would see. So, for example, compared to Abraxane<sup>®</sup>, the Albumin has been removed and there is a risk of infectious disease transmission as well as risk of anaphylaxis with the albumin that is in Abraxane<sup>®</sup>. In addition, because of the way our drug is formulated compared to Abraxane<sup>®</sup>, the preparation time is much



shorter. Abraxane®, when you formulate it and when you mix it, can cause foaming and the solution has to be put aside and they have to let the foaming resolve before they can administer the product. Our product does not have that issue, so you can prepare and administer much faster.

**Manish Jain:** My second question was on K706. What really is the target clinical endpoint that we are trying to achieve from the Phase-1 study on 105 patients?

**Dr. Siu-Long Yao:** There are two purposes to the patient study – one purpose of the patient part of the study is to dose escalate in a multiple dose fashion so we can determine what the maximally tolerated and recommended dose would be going forward into a pivotal efficacy study. The second purpose of course is to determine if there is any response. We will assess response in the disease in a variety of ways including hematologic response, cytogenetic response and molecular response.

**Manish Jain:** Have we completed the Tox studies for 706 as per FDA needs or are there any additional Tox studies required?

**Anil Raghavan:** I think we have completed the Tox program and we also did an IND last year. So we have already started the Phase-1 program. There are two components in this Phase-1 program – the first component was on healthy volunteers and we are currently on that healthy volunteer program.

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

**Girish Bakhru:** First question on Elepsia. Given your guidance has not changed of \$50 million, how do you see additional approval in the market of Brivaracetam and a related product?

**Narendra Lakkad:** Brivaracetam got approval and it may reach market soon but molecule like Levetiracetam is a highly effective and it has continued to remain



front line treatment in the management of Epilepsy. So yes, there may be a conversion from Levetiracetam to Brivaracetam to some extent, but Brivaracetam need to prove the mettle in the market that it is really able to make a difference before we can really predict how much conversion may happen from Levetiracetam to Brivaracetam.

**Girish Bakhru:** Is the dosing profile very different between the two? I am not sure about this new drug actually.

**Narendra Lakkad:** What I understand is that dose is a lower, it is around 100 to 200 mg a day. So do not need high dose. That is from dosing point of view, Brivaracetam certainly has an advantage, but that alone does not make a much difference, the product needs to prove in a clinical setting that it works better than available treatment options for the physicians.

**Girish Bakhru:** Second question on again PICN. Last call you did mention that Cynviloq® was probably the closest other competing molecule. Any update on other products like Nanotax® or Abraxane® whether they are also Cremaphor and albumin free and where they are in the pipeline?

**Narendra Lakkad:** We do not have any specific update and we also rely on the information which comes into public domain and we try to gather all the information from available sources, but we do not have information or update about the products which you mentioned or at what stage of development they are now.

**Girish Bakhru:** On the overall relative benefit versus cost side, if you could give some color on like which are the assets which are actually taking up higher cost in terms of trials where if you could rank them the top leading late stage molecules in pipeline, where you see relative benefit versus cost highest?

**Anil Raghavan:** One good way to look at is there the products come with stage development. Late phase clinical program, Phase-III programs tend to



be a lot more expensive than other programs. So if you look at Baclofen, we have multiple patient study going on at the moment. It is probably the highest in terms of actual outflow in operating expenses followed by both PICN and Sal-flu. But the programs that will fast catch up are K706, K954 programs because we hope to kind of transition from early clinical which is PK study that we are doing now in the US to patient study, which Dr. Yao alluded to earlier. So if you take FY'17 and going into FY'18 our sense is that CML program will see more intensive actions there. We have been given a market outlook in terms of the revenue potential for these programs. The practice that we are trying to stick is we would probably come to a definitive market guidance when the product is closer to the market. So at this point, I am unable to give you a specific guidance in terms of what the revenue potential in terms of dollar terms of these specific programs, but in terms of ranking of cost, this is where it is.

**Moderator:** Thank you. The next question is from the line of Anubhav Agarwal from Credit Suisse. Please go ahead.

**Anubhav Agarwal:** Just one question on Elepsia. When we received \$10 million upfront on Elepsia, the upfront income would this have largely covered our development cost in the product?

**Anil Raghavan:** Yes, certainly.

**Anubhav Agarwal:** Just one clarity on the proposed service agreement with Taro and Sun Pharma. The new economics of 30% mark up, would this economics be any different from what we may get when we deal with Sun Pharma or Tara currently or this is anything different?

**Anil Raghavan:** Ever since we actually started having brought this provision to comply with transfer pricing obligation, we use 30% as the margin for all our services and that is expectation in India. So that is not very different for all the services that we source from group companies and also for services that is getting sourced from within SPARC, there are some



instances of services that are getting sourced from within SPARC. So we managed a consistent amount of 30% plus cost.

**Anubhav Agarwal:** So basically net-net no change in what the economics were currently and what is proposed now?

**Anil Raghavan:** Not at all.

**Anubhav Agarwal:** On this quarter revenue, you mentioned clearly that FY17 revenues it is a slow start, but will certainly pick up. But what happened in this quarter? This quarter run rate was just half of what we have been reporting so far. I understand we have two sets of revenues – one is milestone related, second is reimbursement for the trials that we do. Can you specify what exactly happened in this quarter where revenues were so low?

**Anil Raghavan:** Actually, if you look at the composition of the revenue there are three components – one is the royalty that you get from some of the programs that we outsource and then there is some cross provision of services there is reimbursement around those cross provision of services and finally milestones. What happened is if you look at last several quarters, there is some form of milestone payments that the products we have recently out licensed so we do not see any milestone revenue this quarter which is addressing the overall number. But when I have an outlook for the year, we have several options, in fact, if you look at Xelpros 10 million comes in the second quarter, so if you take half a year view, it will be more than above the normal that you see with 10 million.

**Moderator:** Thank you. The next question is from the line of Harit Ahmed from Spark Capital. Please go ahead.

**Harit Ahmed:** On Starhaler your Salflu DPI product you mentioned previously that the PK profile is comparable at 50% dose and I understand this product has been launched in India. So can you talk a bit about how the traction has been after your India launch and can their response in



India be seen as an indicator of how the traction will be once you launch in Europe and other regulated markets.

**Narendra Lakkad:** It is difficult to correlate what happens in India versus what may happen in a regulated market like Europe or other regulated markets. In India, there are several “me too” products using kind of a similar or a different kind of devices but claiming the same advantages. You do not see a significant price advantage and you will not be able to claim a price advantage although you may have some kind of differentiation because the payer is actually a patient.

So it is highly fragmented market in India and highly competitive with a very small price differentiation. So what may happen in India cannot correlate to what may happen in a regulated market. We would not say that we are happy with the current sales of Starhaler® product in India. It would have certainly done better but it is a moderately successful product I would say.

**Harit Ahmed** On SUN K706, the way I understand it is going to be a third line product TKI inhibitor and it is going to directly compete with Ponatinib which is the only comparable product in the market, but when I look at the sales data that you have shown Ponatinib sales have not seen much traction despite being in the market for around three years. So, can you comment a little on what are your differentiators versus Ponatinib for both the assets that you have?

**Anil Raghavan:** A couple of points: If you look at Ponatinib, has to go out of the market and come back with fairly significant black box warning of severe cardiac toxicity. So, the extent of toxicity that is demonstrated at the initial resonance so made it an unviable option for most of the people who are carrying T315I mutation. So, our sense is that we are an equally potent compound, developed activity that we expect to see which is comparable to Ponatinib but a much safer safety profile. So we have a significant option for third line patients to the CML. But what we are also seeing in the long-term in the second line setting, there is



a significant tolerability issues for compounds like Nilotinib or Dasatinib particularly Nilotinib carrying risk of QT prolongation. So if you look at profile of our compound, it is not just targeting T315I mutation, it is also targeting wild type BCR-ABL. So, with activity in the wild type and with activity in the mutation we really have an opportunity to scale up to the second line setting. So it can be at least for a significant segment of the patients who have safety and tolerance issue with current second generation TKIs.

**Moderator:** Thank you. The next question is from the line of Manushi Shah from Research Delta Advisor. Please go ahead.

**Manushi Shah:** I had a question on Octreotide LAR. Actually, it is shown as it is in pre-clinical stage. I just wanted to know that since it is just a generic of a brand, so you will have to conduct all the phases of clinical trials or just one or two and then it can be ready for approval because in the innovator limit is mentioned that they expect generic in Jan 2017. So I was wondering if SPARC be able to launch by Jan 2017?

**Narendra Lakkad:** As far as the preclinical requirement, preclinical studies for these kinds of complex products are done just to characterize the product formulation and see that we have a PK which is matching the innovator product. So that is the reason it is mentioned as a preclinical program. We need to do that preclinical proof-of-concept study before we do of human PK study. As far as the timeline which you mentioned, we do not believe we will be able to meet the timeline.

**Manushi Shah:** But then you are not to do the entire Phase-I, Phase-II, Phase-III, it is just preclinical and then some PK studies, right?

**Management:** Yes, that is right.

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



**Sameer Baisiwala:** I have got a few questions, but to begin with, from a layman's perspective, is it possible for you to explain the difference between pivotal Phase-III clinical trials that you are doing for say Baclofen GRS and versus pivotal BE studies that you plan to do for PICN and DPI?

**Dr. Siu-Long Yao:** The term pivotal just means that it is the primary evidence presented to a regulatory agency for approval of the product. Of course, we usually have to do many things to get a product approved, including preclinical studies and other clinical studies, but the key piece of evidence that we are going to use to get approval is usually termed the pivotal study. Now, depending on the type of project that you are doing, for example, for a purely generic product, you could do a pivotal Phase-I bioequivalence study to get approved while for other products where you are changing things or you have a totally new chemical entity for example you would have to do a Phase-III study to get approved and that we would call a pivotal Phase-III study. So hopefully that answers your question.

**Sameer Baisiwala:** Yes, it does. The pivotal BE would fall somewhere between the two, the generic one extreme and the Phase-III?

**Dr. Siu-Long Yao:** Of course, it depends on the situation but yes.

**Sameer Baisiwala:** So the question here is that do you have FDA's blessings when you have chosen to go the route that you are taking for PICN and DPI which is a simpler PK data?

**Anil Raghavan:** If you look at these two products, we are pursuing that for different markets, DPI is not being pursued for the US market. So we have an ongoing conversation with FDA on DPI for the US market, but that is not this update is about, this was mostly for European market. So answer to your question on PICN is there, so we had multiple consultations with FDA and we have signed off the protocol with FDA and we are also now in active consultation with FDA in tweaking some aspects of that protocol. So we have signed off protocol with FDA which is currently going through some amendment. In terms of



regulatory situation for DPI, we had consultations with three different agencies in Europe – Sweden, Germany and UK – and we have completed our high dose PK study for Sal-flu DPI. So we took the results and had a consultation with these agencies, and we have a guidance on what could pass as the regulatory pathway for these products in these markets. So that is guiding our program now.

**Sameer Baisiwala:** I get a little confused, Anil, when I look at Teva's filing that they had done for their DPI and that too has a lower dosing but they elected to take the Phase-III clinical path. So why is it that they are taking this more expensive, more cumbersome path and with the blessings of the regulators are taking a much shorter path?

**Anil Raghavan:** Correct, so if you look at the Teva's submission, that was for US, that is what you are referring to, right, so we are not pursuing as I said the US market with this program specifically for this reason. We had consultations with FDA and FDA's expectation for its DPI in the US is fairly elaborated clinical program. So long as we had to spend on a large clinical program on this program for US submission we do not believe the economics of this program, will work out with impending launch of generic. So what we plan to do is, once we have results from the low dosage PK and PIF studies for our European dossier, we will take those pieces of data to FDA again and see if we can use them in terms of what is required for US submission.

**Sameer Baisiwala:** Just on DPI again, I am looking at Slide #22 where you have detailed the characteristics and based on the physicians feedback, if I look at all these attributes that you are citing and where you are ranked the highest, none of them look to me to be medical reason, you are using half the steroid what so Glaxo had and I thought that is a main proposition but here it looks like things like ease of use and dose frequency and device shape and size, they all look pretty cosmetic if I may in nature and I think Narendra Lakkad also in the context of India launch said there is a minor differentiation. So I just wanted to



understand Is your proposition really scientific medically important or it is not?

**Anil Raghavan:** I think Narendra Lakkad is going to answer that question, but one point that I want to bring to your attention, these characteristics are device characteristics and most of the medical benefits come from Sal-flu combination. We specifically ask what is interesting from the device standpoint and that is why some of these factors are related to convenience or use and things like, but I will give it to Narendra Lakkad for further details

**Narendra Lakkad:** So when we did this research, these physicians were given the device in their hand and they were asked specific questions on different device characteristics. So this research brings about how physician perceives different characteristics of a device and how they rank compared to what are their expectations from a such device. About clinical advantage of half the dose, that is something we did not had data in hand to show them that this is the data and give us a kind of feedback that how you look at. We had a target product profile showing that we will have our advantage based on PK study where we will prove that we have a similar pharmacokinetics at half the dose. So, that needs subsequently to be backed by some level of clinical data post approval to really become a meaningful player in a market.

**Sameer Baisiwala:** Narendra, when you talked about \$50 million peak revenue potential from the two lead compounds, what sort of a volume share do you have in mind?

**Narendra Lakkad:** We have given the current volume market and what is the target sub-segment of market for our product. So which product you are specifically talking about -- Elepsia<sup>TM</sup> XR or Xelpros<sup>TM</sup>?

**Sameer Baisiwala:** Actually both. So what is your prescription share assumptions underlying this?



**Narendra Lakkad:** We generally do not share full market model or a forecast model but I would say that what our model is based on historically in a similar situation what other brands have achieved, so for example, if you are looking at an Extended Release formulation for a molecule which is already genericized and if somebody has launched an Extended Release product, what level of market share that could achieve and at what price level. We make our market share assumption based on what historically similar brands have done.

**Moderator:** Thank you. The next question is from the line of Abhishek Sharma from IIFL. Please go ahead.

**Abhishek Sharma:** I just wanted to understand what are your plans on the Biologics side? There is just a passing mention in the presentation. So, are you guys planning to build a pipeline, how far ahead of you and what kind of research spends are you looking at?

**Anil Raghavan:** Outside of that mention in terms of strategic direction that we want to take is to navigate outside out of the complete focus on small molecule; we do not have specific guidance on the programs that we are pursuing. But yes, we have started taking I would say baby steps to consider modalities, not just antibodies but things other than small molecules. So that will be part of SPARC future, but at this point, unfortunately we do not have a specific guidance on what kind of modalities or what programs are we may play in the next couple of years, we will have a lot more to talk about them.

**Abhishek Sharma:** Second thing is around infrastructure. You guys are now putting together CAD in vivo as well as on the call you mentioned in vitro. At some point in time, in order to add a revenue stream, do you intend to sort of lease out these as services to third-parties?

**Anil Raghavan:** No, not at all. That is the key differentiator that we have maintained right through the SPARC journey. We want to build SPARC up as a large globally competitive pharmaceutical company. So in spite of several opportunities to be a service player, because of the natural



advantages that we bring to play given our capacity in India. We resisted that temptation. That is not going to be our strategy at least as far as we can see at the moment.

**Abhishek Sharma:** One last question on Baclofen. You guys are still in the middle of trial, but has there been some interim data analysis, anything that you could report there?

**Anil Raghavan:** Nothing we can report at this point, we have not had data analysis on this program.

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

**Ketan Gandhi:** Apart from USA, are you planning to file Baclofen in other markets like EU, Japan or emerging markets? If it is yes, then timeline approval, number of patients required and the market opportunity?

**Anil Raghavan:** We do not have like a definitive plan to file this in other markets, but we are trying to understand the bridging requirements for other markets. So as we have more granular understanding on what is required and if such requirement makes sense from a commercial cost benefit standpoint we will pursue in these markets, but from an operational focus standpoint, our singular focus on Baclofen now is we update the programs required for submission in the US market and this is sufficient probably by second half of next year.

**Ketan Gandhi:** In last presentation, you stated that Breast Cancer program being collaborated with scientists in EU. Any status on this sir?

**Anil Raghavan:** So what you are referring to is an early stage program. So we have a collaboration going on and there is any definitive progress in that program. The way we structure this interaction is, this is mainly intended to provide an update on clinical stage or near clinical stage asset. So these programs where we are collaborating with academic innovators in for breast cancer and as I mentioned earlier in the



presentation there are a few other programs also. They are early stage discovery programs and we do not have specific guidance on these early stage programs in this update

**Moderator:** Thank you. The next question is from the line of Manish Jain from SageOne Investment Advisors. Please go ahead.

**Manish Jain:** My question was on abuse deterrence that can this platform technology be applied to other molecules within the abuse deterrents category and are you focusing on Hydrocodone first or naltrexone using this technology?

**Anil Raghavan:** So two questions: On the first question, certainly yes, we have applicability of these platforms for several products which are abused recreationally and also there is potential application in overdose prevention in other therapeutic category. So we look at the broadest class of applications possible. Yes, there is certainly legs beyond the current opioid program we are pursuing. Manish, we are not disclosing the actual asset as part of the introductory product for this platform. So we will probably look to do that in the near future.

**Manish Jain:** My second question was on Brimonodine that besides Phase-II proof-of-concept study, what can be the requirement for Phase-III study and to get the product approved?

**Anil Raghavan:** I will pass on this question; (Dr. Hany Michail who is on the call, he heads Ophthalmology Development.

**Dr. Hany Michail:** The requirement for the Phase-III for the FDA is equivalence study to the currently marketed Brimonidine formulation. So that is a one Phase III study to go forward.

**Manish Jain:** My last question was on 597. That besides the proof-of-efficacy study that we are doing, what are the other clinical trials or tox studies required for approval by FDA?



**Anil Raghavan:** I will invite Patrick who can talk with you in more detail answer to that question.

**Dr. Patrick Bernard:** The approach that we are going to take is to demonstrate proof-of-concept in patients and then move through Phase-IIb study to determine precisely the correct dose and we believe two phase-III studies would be required for approval.

**Moderator:** Thank you. The next question is from the line of Sameer Chheda from Wama International. Please go ahead.

**Sameer Chheda:** I would like to know usually these programs, what is the cost of the research which is there to develop from the start till the end and how do we price it when we license it to the pharma companies?

**Anil Raghavan:** That is very difficult to answer question. Depending on the therapeutic area, depending on clinical expectations of the agency, depending on other regulatory work that we do toxicology and pharmacology, the program cost can vary substantially. There are indications like in some cases ophthalmology or some of the bioequivalence products where it can be relatively low, but late stage large clinical program can run into millions of dollars. So it is very difficult to kind of put your finger on a specific number as an indicative average for development of the product. So, in terms of the licensing deal price determination, we use multiple price determination mechanism. Most effective way we have used is we actually invite and get bids from multiple players. So we engage several potential partners and attract term sheets from interested parties which give us a sense of what is the perceived value of the products. That is one part of the price determination. The second part of the price determination is we do a ground-up market model. We have a sense of the intrinsic value of the product based on our sense of the addressable market and price that we can attract from the marketplace on the strength of the IP and also the attractiveness of the benefit package that product provides. So we have an internal sense of where we need to have the licensing deal to



make this attractive and also it gets validated by multiple players who participate in the process. In some rare cases, we also engaged independent valuers. But in most cases, that is not required if there are multiple players.

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

**Sameer Baisiwala:** Narendra, just a question on the two upcoming launches as and when they get approved – Xelpros and Elepsia. After the approval, how much time will it take for you to get in the market, a) and b) how will you decide on the pricing... what is the mechanism that you need to go through?

**Narendra Lakkad:** After the approval, the timeline for getting into the market is not likely to be very long because our partner is already parallely preparing for the launch. We just need to make our commercial batches ready for the launch purpose. So the manufacturing lead time is an important lead time and during that period commercial team may be ready for the launch. So we do not expect a long time gap between the approval and the launch. As far as the reimbursement of the product is concerned, that will be actually led by our commercialization partner and there is payer access, or managed care access, is kind of a big process and you need to go with your documented evidence about the data which you have and negotiate prices based on the value which your product offers. So, it is a kind of mutual negotiation and agreement on the price at which you may get a kind of tier access. What preferred reimbursement tier you would like to put your program in and if you want to put that program into that tier, at what price payer is willing to pay. So it is a kind of marketing tactics and which we will get to know once products are approved. So first thing important is that we need to have approved product to go to the managed care to go for a pricing negotiation.



**Sameer Baisiwala:** Any first guess that you may want to take, it would be what tiering that you prefer and where do you think you finally end up the tier-2 that you are aiming for?

**Narendra Lakkad:** Finally, it is going to be a decision of a commercial team and SPARC may not have kind of voting say, we would have opinion, but may not be a kind of final decision of SPARC because commercial team need to achieve that success, but typically these kind of programs are put in a Tier-III. Any branded products comes in the market in the US, they are first put in a Tier-III. What you would like to ensure is that you do not get a Tier-III with additional restrictions, so like a prior authorization or a kind of step edit, that is something you would want, but that is all a matter of negotiation and the price at which you would like to market whether payers are willing to pay.

**Sameer Baisiwala:** This Tier-III would have what percentage co-pay over here? I would imagine this is the highest.

**Narendra Lakkad:** Yes, Tier-III is having a copay in the range of \$50 to 60 in a monthly treatment.

**Sameer Baisiwala:** When you say your peak sales expectation is \$50 million, which year do you think you will be achieving that after the launch?

**Narendra Lakkad:** It would be fourth year or fifth year, because you need to drive prescriptions, you need to get managed care access and you need to have your products in all the formulary so that the prescriptions you generate get reimbursed. So it is a process. For branded products, typically takes two years just to get your product into all the formularies.

**Sameer Baisiwala:** When do you think you break even for the product at EBITDA level?

**Anil Raghavan:** That is more of Sun question because the operational expenses in terms of sales, infrastructure is going to be with our partner, not with SPARC.



**Sameer Baisiwala:** Let us say you kind of had discussion with many other players and the terms that you are offered by Sun was probably the most favorable one. What exactly did you have in mind -- royalty percentages better with Sun or the upfront 10 million, others were not even willing to pay you that much?

**Anil Raghavan:** So if you look at both these options, the upfront payment is not just the 10 million that you get you want to sign, we are also eligible for some other upfront payment depending on the approval and commercialization. So, it is not just the \$10 million that we are getting both in the case of Xelpros and Elepsia. But on both counts in terms of actual cash down on signing the deal and also milestone payments and royalties, all these three components, we could get a better deal from Sun.

**Sameer Baisiwala:** Versus that what you get is a partner which has probably no experience of doing this work, we do say especially on the therapies that you are going ahead ways. I assume that your other evaluators must have more ready infrastructure. So that not also play on your mind? Second, jus cynical mind, is this also a sort of statement on the medical appeal of the product?

**Anil Raghavan:** We do not believe it is a statement on medical appeal of the product. I think the issue that both Levetiracetam and Latanoprost are trying to address and it is borne out by the research that we have conducted internally and also conducted by multiple partners who try to be the commercialization partner for this product. We do not have any anxiety about attractiveness given the spend and given the overall P&L of the product. Coming back, certainly it was a consideration. Our consideration needs to basically understand and identify the best partner for the asset. So we had extensive conversations with not just Sun, but also with other players in terms of the infrastructure that they are willing to create and also actual people who are going to be part of those things. So experience is not just institutional experience, it is also the experience of the teams that they are bringing together. So, in



due consideration, we have fair confidence in the kind of team that Sun is putting together in both these areas and also the scale of the team that they are putting together. So our conclusion was it is in SPARC's best interest to go with Sun, not because of the shared roots, but because of the strength of the proposition that they bring to the table.

**Moderator:** Thank you. The next question is from the line of Manoj Garg from Bank of America. Please go ahead.

**Manoj Garg:** I think in your opening remarks, you have indicated that both the products – Elepsia XR and Xelpros – you see the final approval in this fiscal year. Does it mean that you expect your partner will be able to resolve the manufacturing issues in this fiscal year itself?

**Anil Raghavan:** On this issue, I would stick with the guidance that they have already provided to the market and my understanding is that the guidance is they have made significant progress with the remediation and an audit is expected anytime. So we are reasonably confident that an approval this year is realistic possibility.

**Manoj Garg:** Because I think you have also alluded at least one launch in this fiscal year itself?

**Anil Raghavan:** That is our expectation.

**Manoj Garg:** Another thing which I would like to understand is when you look for a project to go or no go, what kind of hurdle rate of IRR you look for each of the projects and how does that qualify in your overall development scheme?

**Anil Raghavan:** This is a narrowing set of consideration. When you actually look at early on, when you are coming to a product, you actually look at more macro numbers in terms of the overall market size and also the money that you need to spend. But as we get closer to a more sort of a product concept, which has some evidence in the drug's in vitro and in



vivo animal study, then we look to sharpen the market model for that product. But the specific target in terms of the IRR or you can duly place for the product varies again significantly from the asset-to-asset because if you look at an opportunity in regular reformulations versus the complex reformulations versus NCE, these are very different value profile and the expectations of IRRs are different.

**Moderator:** Thank you. The next question is from the line of Manish Jain from SageOne Investment Advisor. Please go ahead.

**Manish Jain:** This was on PICN that based on US approval which other markets can you get into and when do you plan to start discussions for those markets?

**Narendra Lakkad:** We are right now pursuing BE approach in the US after extensive consultation with FDA. We have not had any consultation with European agency or any other regulatory agencies to get this product into the market. So our first call is to see that we have a product which is filed in the US and we have a data which we can go and talk to other regulators. So that understanding we will evolve once we have a data which is ready to be shared with other regulatory agencies.

**Manish Jain:** To the pivotal BE study that you all are planning to do, what is really the sample sizes, the patient sample size likely to be large enough?

**Anil Raghavan:** It is not going to be a very large study, but as I mentioned, Manish, we are still have some protocol tweets with and then discussions with FDA. So we are not in a position to commit to a final number in this call.

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

**Saion Mukherjee:** My question is on Elepsia™. So the market share that you would be getting would be largely from the Extended Release formulation of Levetiracetam?



**Narendra Lakkad:** The market share this product will take will be largely from 500 mg IR tablet which is actually 50% of use of all Levetiracetam tablets if you consider 500 mg immediate release product.

**Saion Mukherjee:** You mentioned Extended Release to be one of the advantages, but if you look at the market today large volume is still limited with IR formulation?

**Narendra Lakkad:** That is right, so large volume is still with IR.

**Saion Mukherjee:** I was wondering like why the market has not shifted to Extended Release because it is more beneficial. So what is the reason there?

**Narendra Lakkad:** So even with a small fraction of the total volume, I think Extended Release branded product is more than \$300 million. Conversion into the Extended Release has not happened because in the case of Extended Release innovator product that maximum dose which they could offer was only up to 750 mg and the dose which patient needs is in the range of 1 to 3g a day. So even if you have Extended Release formulation actually you still need to take multiple pills to get your desired dose. So actually there was no clear advantage of that Extended Release product.

**Saion Mukherjee:** For a product like this, what kind of sales and marketing effort your partner need in terms of sales force, how extensive is that?

**Narendra Lakkad:** They need to create a kind of field force in the range of say 50 to 75 reps initially and then depending on the volume or the value business is built up it can be expanded. Because it is a specialty prescription, so the large amount of prescription still come from the neurologists so which is a smaller segment of the doctors. So you do not need a very large field force to cover them.

**Saion Mukherjee:** On PICN, you mentioned that the consultation on study design is still ongoing with the USFDA and you have given some timeline in terms of pivotal study and filing. I am just wondering is there a risk to those



timelines, based on your discussions so far, do you think that we are very much to the end of finalizing the design?

**Anil Raghavan:** As I said, we have protocol which we have to finalize with FDA. We are looking to do some minor amendments that we do not expect to see significant delay kind of.

**Moderator:** Thank you. As there are no further questions, I would now like to hand the conference over to Mr. Jaydeep Issrani for his closing comments.

**Jaydeep Issrani:** Thank you, everybody for joining us this evening. If you have any of the questions that probably come later to your mind, you can send it to us through an e-mail and we will try to give an answer to that. With this, I thank you for the participation for the Annual Investors Update Presentation that we had today. Thank you so much.

**Anil Raghavan:** Thank you so much.

**Moderator:** Thank you members of the management team. Ladies and Gentlemen, on behalf of SPARC that concludes this conference. Thank you for joining us and you may now disconnect your lines.