Sun Pharma Advanced Research Company Ltd.
Transcript of Management Presentation
4.00 PM, August 24, 2017

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Moderator: Ladies and gentlemen, good day and welcome to SPARC's Conference Call for Update on R&D Pipeline. As a reminder, all participant lines will be in the listen-only mode. There will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the conference call, please signal for an operator by pressing '*' then '0' on your touchtone phone. Please note that this conference is being recorded. I now hand the conference over to Mr. Jaydeep Issrani from SPARC. Thank you and over to you sir.

Jaydeep Issrani: Thank you, Stanford. Good evening and a warm welcome for the SPARC Update on R&D Pipeline.

We hope you have received the 'Presentation' we sent out sometime back. The 'Presentation' is also available on our website, that is www.sparc.life. The call transcript will also be put up on SPARC's website soon.

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

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

We have the entire SPARC management team with us on the call today – Dr. SiuLong Yao has joined the call from USA.

I now hand over the call to our CEO – Mr. Anil Raghavan for his presentation.

Anil Raghavan: Thanks Jaydeep. Good afternoon everybody.

A very warm welcome to our sixth annual investor update. As I have mentioned in the past, this annual investor day is certainly a big deal for all of us here at SPARC both in terms of the encouragement and passion we derive from this and also as an opportunity to reflect on our strategy and execution. So thank you for being here. And for a lot of you, who have been tracking SPARC for some time, thank you for coming back. This means a lot to us.

The structure of this call is not very different from our past updates. Our primary purpose for this session, as always, is to provide an update on our clinical stage programs and review our overall strategy briefly. We have consistently maintained a set of disclosure standards to bring programs into public view and a major one is the need for higher discretionary spending. We plan to talk about a couple of our late stage discovery programs today for the first time, in this call.

SPARC's senior management team is here with me for this session. We do not plan to make individual introductions in the interest of time. We will start with an overview of the progress we have made in the last twelve months or so before moving on to program level updates. We have also included a review of the market potential of our late stage assets and a brief commentary on our financials before opening up the call for the Q&A.

So let's go to slide 5 to get started.

I want to go over some key aspects of our overall strategy and our short to medium term priorities in the next couple of slides before reviewing our progress since we last met. I think it provides an appropriate backdrop to contextualise what we are doing.

All purposeful journeys are built on certain beliefs about what you can bring to bear and what you can reasonably aim to achieve. Foundational assumptions. So when SPARC started

charting its own course, we were guided by three important beliefs which formed the foundation of everything we have done ever since.

The first one is this. Core competencies we carried from our generic history such as our strength in process chemistry or formulation sciences are capable of delivering far higher value if we can smartly go after different opportunity sets. So low hanging fruits in the 505(b) (2) pathway is a substantial part of what we started out with and it will continue to be an important part of our intent. But gradually we built up our medicinal chemistry and enabling biology infrastructure to transition our portfolio to a better balance now, between delivery system products and NCEs. Now our portfolio is becoming a lot more evenly matched.

Secondly – It is very important for us to navigate this journey in a sensible, risk-mitigated manner. With so much excitement around break through science and significant unresolved burden of disease, it is easy to get side tracked. But we like to keep big part of our focus on validated biology. Where the mechanism is clear. We want to stay away from target related risks at this stage of our evolution. Equally important is the need for a narrower therapeutic focus. When we have a significant interest in delivery system innovation, it is tougher to limit the theatre, than in the case of a pure play discovery start-up. But we have deliberately chosen a narrower playing field to certain problems in Oncology, some CNS conditions, Ophthalmology, Dermatology and Pain, particularly Pain from an Abuse deterrence standpoint.

And third and final point is our commitment to a longer game. We believe this eco-system we are in, is maturing to a point where we can see a wave of Indian companies competing with affordable, innovative solutions for unmet needs of patients globally. In this process, our industry will build Important institutions, create significant amount of value and eventually am sure, will go beyond its comfort zone – that is small molecule chemistry and formulations. SPARC's true mission is to be a leading player in this exciting next chapter of Indian pharma

story. A lot of our investments, relationship building, competencies and infrastructure development are all driven by this vision. That is why we also maintain an exploratory interest in novel targets and other modalities. But we realize it can increase our risk profile to an unacceptable level if we are not careful. So we give very high priority for building partnerships to bridge our gaps when pursuing opportunities outside the domain of our core expertise.

So for us, the second point is the important one. Drug development is an inherently high risk business. We all know that. We want to navigate this, in a measured, deliberate manner. One step at a time. We have to keep a very sharp focus on the short term execution. That will give us the right to think big and hopefully, be more adventurous in the future.

With that overview, let's move to the next slide to talk a bit more about our current priorities.

Slide 6 please.

We have five late stage clinical programs which can help us generate short term cash flows. Elepsia XR, Xelpros BAK free, Baclofen GRS, Taclantis or PICN and Salmeterol Fluticasone DPI. Concluding these programs is our number one short term priority for reasons which are fairly obvious.

Equally important for us is our early stage clinical portfolio. Our early clinical assets demonstrate the evolution of SPARC. The first five programs are all relatively simple, delivery system innovations. At the next stage, we have a mix of new chemical entities and more complex formulation assets. There are eight programs, evenly split between NCEs and NDDS projects. These eight programs together represent our medium term opportunity space. We want to drive this really hard towards POCs in the next 12 - 18 months and proceed to registrational clinical programs if the data supports further development. So this basket will remain a huge part of our execution focus in the short to medium term.

At the same time, we will continue to build out our operating model with a view to add important competencies for the future and augment our early stage portfolio with progressively increasing value per asset. I will touch upon both in a bit. But before I go there, I want to review our progress on our near term priorities first. Later on in this update, we will get into a lot more detail on each of these programs. But here are the headlines.

So let's get to slide 7.

Let's start with Elepsia and Xelpros – these are two of our most near term opportunities. Our primary manufacturing partner is continuing with their planned remediation to reverse their FDA compliance status. We do not have a concrete timeline at this point for this effort. We have initiated alternative manufacturing plans for both products now. We are planning the resubmission of Elepsia and Xelpros from other plants. So our plan B is now on in full swing. Its early days for both these transfers. We intend to consult the agency to figure out the shortest possible route to get back in the queue while we make progress with manufacturing from these locations. On this, we will come back with a more concrete set of timelines, as soon as we are in a position to do so.

We have made really good progress with the three programs, immediately following Xelpros and Elepsia. They are, as you know Baclofen, Taclantis and Sal-Flu DPI. We have completed the studies we have agreed with the European regulatory agencies for the DPI program. We will go over the results and next steps when Siu comes in for his segment. We have completed the patient accrual for the registrational studies for Baclofen. This is a significant milestone for SPARC. We expect to complete the program in late September with top line data expected by October. We will plan to do a dedicated call on Baclofen later in October. Taclantis is currently recruiting for its pivotal BE program. We expect to complete this study in the first quarter of next financial year. We are really excited about the progress we made here and these programs can give us important short-term cash flows if, off course data comes in line with our expectations.

We had a flurry of activity in our early clinical portfolio in the last 12 months. We have completed the K-706 Phase 1 healthy volunteer studies, initiated the Multiple Ascending Dose study in CML patients. We are currently actively recruiting for this program globally.

We have completed the PoC for our Once-a-Day Brimonidine program for Glaucoma. We will go over that data shortly. On another major area of our focus, we obtained important validation for certain key elements of our Abuse Deterrence platform through pilot PK studies for SDN-021. Both these programs will now move to the next phase of its development plan.

We have also initiated early clinical studies for two of our NCE programs: SCD-044 and S-597.

SCD044 is a collaborative effort with a French biotech company, Bioprojet. This is a, S1P receptor agonist which uses lymphocyte trafficking to treat auto-immune disorders. We are enthusiastic about the promise of this high selective compound, going into early clinical studies.

We are also very excited to explore our ABL kinase inhibitors in Parkinson's Disease. This is certainly an attractive opportunity with no substantial standard of care to arrest or slow down the progression of the disease. We are dealing with new, really interesting biology here with disease modification potential. But we also want to be upfront with the risks. The mechanism is not sufficiently validated in a clinical setting yet. We will review our hypothesis for both these programs in more detail later in this session. We have initiated a dose range finding study for K-706 in Parkinson's patients after filing an IND earlier this year.

This, as you can see is a significant increase in the overall clinical development load for SPARC. Now SPARC is a fair balance between clinical stage assets and pre-clinical discovery and development programs. This off course is going to increase our cash burn substantially. We will maintain a high translational bar

in terms of data quality in go/no-go decision making to increase the probability of success and reduce risk levels for our late stage clinical trials.

But foreseeing a significant increase in our clinical spend, we have raised an additional Rs. 500 crores through an allotment of preferential warrants. We have also deprioritized two of our programs, Octreotide depot and Tizanidine based on our review of available data, strength of our IP and the overall economics. We will discuss additional details of our projected cash burn when Chetan reviews the financials later during the presentation.

Now let's move to slide 8, here is an update on our progress on some key elements of our operating model. As those of you, who have been on these calls earlier, knows our focus on capability development has some specific objectives. A really important one is our need for building out a competitive discovery biology and clinical sciences capability. We continued to infuse external talent, we continued to invest in infrastructure and systems to enhance the quality our competencies in this area. That will go on, especially focused around specific therapeutic areas we would like to pursue.

Another major development is our planned move to a new R&D facility in the outskirts of Baroda. We are in the process of building out a state of the art facility at Savli GIDC campus for transitioning our team from the current SPARC campus at Tandalja. We are aiming to accomplish this before the turn of the financial year 18.

Building high quality computational chemistry and pharmacology capabilities is an important priority for us. We have developed reasonable expertise in the application of computational systems in drug discovery. This has been one our investment priorities for the last few years. We aim to continue to build on this area, we believe there are opportunities to find efficiencies, reduce timelines and improve outcomes through the application of a whole host of tools - modelling and simulation

systems, deep learning, high performance computing and image processing. We are very excited about these foundational capabilities we managed to build in the last few years. It provides us a platform to build a key differentiation for the future.

Another critical area of differentiation for us, is our openness to engage academic community in a creative manner. We built on our past work in this area last year, to begin building longer term strategic relationships with leading academic eco-systems. Our belief is that, our ability to collaborate with positive intent using a basket of resources with very little bureaucracy gives us a competitive advantage in these settings which, we intend to fully leverage.

Lastly, we have significantly enhanced our corporate and scientific governance layer by augmenting our SABs and corporate boards. I am sure most of you have taken note of the induction of Mr. Mark Simon and Dr. Ferzaan Engineer as independent directors on the SPARC board. These very accomplished life science professionals and entrepreneurs, adding to the overall quality of thinking and scrutiny from our corporate board. We have also added several high quality scientific leaders such as Dr. Rakesh Jain from Harvard Medical School, Prof. Philip Needleman from Washington University, St Louis to our Scientific Advisory Board. This is a key objective for us. We will continue to build out the advisory support we have to improve the quality of scientific input going into our discovery and translational decision making.

These four themes, functional capability development, building out a robust computational pillar, strategic partnering and scientific governance will continue to drive the evolution of our operating model as we pursue our vision for leadership in innovation globally. I want to make a couple of more points on our long term portfolio strategy before I transition.

Over to slide 9 and I will keep this really brief.

We will further narrow our focus within our core therapeutic areas to develop deeper expertise and more productive eco-systems. In Oncology where we have a major commitment, we will focus on resistance pathways with clear molecular bases in select tumour types. CNS and ophthalmic neurodegenerative conditions are another problem set, we would like to focus on. Inflammation and Auto-immune disorders will continue to be a target area as it touches many therapeutic areas of our interest, such as dermatology and ophthalmology. Pain, and particularly helping to solve this tragic problem of prescription drug abuse and address the long term need for safer, un-abusable pain management products will stay on as a significant focus for our group.

I would like to reiterate couple of points from my earlier comments before we move on. Formulation led programs to address delivery challenges will continue to be an important part of our R&D effort. Especially when we have an opportunity to build leverageable platforms. In that sense, Abuse Deterrence platform is an excellent example of the kind of platform development opportunity we will look to have more of. And on the innovation side, we will slowly move beyond validated biology into newer targets, especially when we can repurpose our existing assets in other disease contexts. Like we are doing in the case of Parkinson's. We hope our academic collaborations will give us cover, and play a major role in helping us find attractive new targets with reasonable risk profile.

As we have mentioned many times in the past, our interest is in fully prosecuting an asset to the point of market eligibility, particularly in developed markets. But let me also add this. At the same time, our clinical commitments are going up at a significant clip, given the number of programs reaching late stage development. So we are going to be a little bit flexible here. We will evaluate our portfolio on a regular basis to validate our priorities and the need for exiting programs early, especially if we face difficult resource allocation challenges. But for higher

value, higher probability assets, we would like stay in the hunt as long as possible.

Now let me give you my last slide – over to 10

Here is a snap shot of what to expect in the next twelve months or so. I have spoken about most of these in my earlier comments. So let me not repeat. We are going to do a slightly deeper dive, into some of these programs now in the next segments. But before we get going with that, I want to thank everyone on the call for taking the time to be with us today. This really means a lot for us. I look forward to our Q&A later on in the session.

Now please welcome my colleague SiuLong to talk about certain clinical stage programs. Over to you Siu.

SiuLang Yao: Thank you, Anil. As Anil mentioned, my name is Siu Yao and I oversee Clinical Development for SPARC. I'm going to spend the next few minutes trying to get you up to speed on the progress we've made in some of our key programs in clinical development.

Slide 12 summarizes our progress with the baclofen program. As you may recall from last year, this program is under a special protocol assessment with the FDA. The program consists of three phase 3 studies, of which the efficacy study represents the pivotal study. Two of the phase 3 studies, namely the duration of action study and the safety study, have been completed since last year. Complete data are available for these studies, and these data are currently being analysed. The efficacy study has completed accrual and the last patient out is expected shortly. Results for this pivotal study should be available in October of this year, with a planned NDA filing by the first quarter of fiscal year 19.

The next two slides, slides 13 and 14, summarize the status of the salmeterol fluticasone inhaler program. This program consists of three key studies as well. There is a peak inspiratory flow study, a high-dose PK study, and a low-dose PK study. All three of these studies have been completed.

The PIF study showed that the results obtained with the SPARC inhaler were well within the required range, and all types of patients were able to successfully actuate and use the device. The high dose PK study demonstrated that the pharmacokinetics of fluticasone and salmeterol with the SPARC inhaler were comparable to those of the Seretide® inhaler. The low dose PK study also showed that fluticasone PK was comparable between the two inhalers, but the peak concentration of salmeterol was somewhat higher with the SPARC inhaler and, therefore, BE criteria were not strictly satisfied. Safety was similar to Seretide® in all these studies.

Slide 14, please. Based on the results of these studies, SPARC is in the process of confirming the path forward with EU regulatory agencies.

Slide 15 summarizes some of the data that we've accumulated over the past year with Taclantis, SPARC's paclitaxel formulation. This is a non-Cremophor®, non-albumin based formulation which is anticipated to be devoid of the safety and preparation issues associated with existing formulations.

Over the past year, pilot PK studies were completed that suggested that the pharmacokinetics of Taclantis are similar to those of Abraxane® and that a BE route to approval may be viable. Some of these results are summarized in the graph on the right side of this slide. Drug concentration is on the y axis and time in hours is on the x axis. Total paclitaxel concentrations are in red and free paclitaxel concentrations are in blue. As you can see, the curves for Taclantis and Abraxane® overlap, suggesting that the formulations result in very similar exposures of the active pharmaceutical ingredient.

There have not been any unanticipated safety findings with the SPARC formulation and 4 subjects have already been randomized in to the pivotal PK study. The US NDA filing for this compound is expected to occur in 3rd quarter of fiscal year 19.

Progress with K706, our potent, highly selective, orally bioavailable BCR-ABL inhibitor is summarized in slide 16. This inhibitor is active against common mutants, as well as the difficult to treat T315I mutation. A single ascending dose study in healthy volunteers has been completed and some of the PK results are shown in the graph on the right.

In this graph, drug concentration is on the y axis and time is on the x axis. The results with doses of 6, 12 and 24 mg are plotted. The pharmacokinetics demonstrated that the drug was orally bioavailable and that the pharmacokinetics supported once-a-day administration. Exposures were dose proportional, there was no food effect and the compound was safe and well tolerated. A multiple ascending dose study in CML patients is in progress and 2 dose levels have been completed.

As summarized on slide 17, we are planning to complete the multiple ascending dose study by 4th quarter of fiscal year 18 with initiation of a pivotal efficacy study by 2nd quarter of fiscal year 19.

Slide 18 provides information on our program with brimonidine. As you may know, brimonidine is a commonly used 2nd line medication for glaucoma. However, currently available brimonidine is dosed 3 times a day and this can lead to compliance issues. SPARC is developing a novel once-a-day formulation that utilizes our proprietary TearAct technology.

Some clinical results with the SPARC formulation are summarized in slide 19. These results are from a randomized proof of concept study in 140 glaucoma patients. The graph shows intraocular pressure on the y axis, and time in days on the x axis. The squares represent results with the SPARC formulation, while

the triangles represent results with currently available Alphagan. As you can see, the results with the SPARC once a day formulation are very similar to the Alphagan 3 times a day formulation, and the prespecified equivalence endpoint was met in this proof of concept study.

So, based on these results, we are planning an end of Phase 2 meeting in the 3rd quarter of fiscal year 18, as summarized in slide 20, and initiation of a Phase 3 study in 4th quarter of fiscal year 18.

Slide 19 is my final slide. This summarizes the status of SUN-597, a novel topical steroid formulated to spare normal skin and minimize systemic side effects. Over the past year, we opened an IND with a Phase 1 study. We are now planning to initiate a pilot psoriasis study and get top line data in the 3rd quarter of fiscal year 18. This will be followed by a safety study in the 4th quarter of the same year. The necessary preclinical minipig toxicity study has been completed, and the results of all these studies will be used to guide subsequent development.

At this point, I would like to introduce my colleague, Dr. Nitin Damle, to take you through some of the promising preclinical programs. Nitin.

Nitin Damle: Good afternoon, My name is Nitin Damle and I head the Biology function at SPARC. I will be discussing two new programs that we are disclosing for the first time with the investor community.

You have already learnt, from Anil and Siu, about SUN-K706, SPARC's proprietary ABL TKI, that we are developing for therapeutic use in CML. I am going to discuss the use of K706 as a potential therapeutic option in the treatment of Parkinson's Disease. PD is a neurodegenerative condition, in which dopamine producing neurons are killed and lost. Dopamine is a critical neurotransmitter that controls the organized movement of the body. There are more than 10 million people worldwide

suffering from Parkinson's Disease. The available therapies are largely symptomatic and there are no truly disease modifying treatment options available as yet that can protect the loss of dopamine producing neurons.

So what causes such a loss of dopamine producing neurons? A dominant mechanism responsible for such a loss is the inability of these neurons to eliminate misfolded proteins and damaged organelles like mitochondria, cellular garbage, using a process known as autophagy. In case of Parkinson's Disease, it is alpha synuclein that is overexpressed and aggregates to form Lewy bodies, which are the hallmark of Parkinson's Disease. In normal cells, such aggregated misfolded proteins are cleared by the cellular garbage disposal system. However in PD, various components of this garbage disposal system are inactivated in dopamine-producing neurons.

So where does cABL fit in all these events? cABL is a pleiotropic tyrosine kinase and is present in all nucleated cells. Oxidative stress often activates cABL. Once activated, ABL phosphorylates various protein substrates, many of these are involved in clearing cellular garbage, to render them inactive. This allows misfolded proteins to accumulate and eventually compromise the viability of the dopamine-producing neurons. In addition, cABL also activates proteins that facilitate programmed cell death in these neurons. So the net effect is the loss of dopamine-producing neurons over the years and the emergence of various symptoms of Parkinson's Disease.

In K706, we have an excellent cABL inhibitor. It is potent, orally active, and exhibits superior safety / tolerability profile for which we think that K706 is the best in class ABL TKI. We evaluated the ability of K706 to protect dopaminergic neurons from degeneration in an acute model of PD in mice. As shown in slide 24, K706 is able to protect the loss the dopamine-producing neurons in a mouse model in which a neurotoxin, MPTP, causes oxidative stress that leads to the loss of dopamine producing neurons. The top left panel shows the normal mid brain region

showing the presence of neurons expressing tyrosine hydroxylase (TH), a key enzyme in the synthesis of dopamine. In the middle panel, one sees almost total loss of TH expressing neurons whereas majority of them can be protected by K706 treatment as shown in the panel on the top right. The two bar graphs show that the protective effect of K706 is dose dependent.

With this background, we have initiated a double blind, randomized, placebo controlled, multiple dose, phase 1 study of K706 in patients with PD and are in a process to plan for a phase 2 POC study pending completion of the above safety/tolerability assessment in PD patients. We remain optimistic about this evaluation that allows us to leverage our own asset in this highly unmet disease.

I am going to shift gears and talk about our yet another NCE program which we refer to as SCD-044. This program is a collaboration between SPARC and Bioprojet, a biotechnology company in France. This program is in the autoimmune inflammatory diseases therapeutic arena.

SCD-044 is an agonist or activator of Sphingosine-1-P (S1P) receptor. S1P is an important lipid mediator that is generated by multiple cell types and acts on multiple cell types including cells of the immune system. Lymphocytes are constantly transitioning between various lymphoid organs such as lymph nodes, thymus and spleen, and the peripheral tissues including the diseased tissues. Often the disease causing lymphocytes reside in lymph nodes where the antigen priming occurs and once primed, these cells leave the lymphoid environment and enter peripheral blood to seek the diseased areas where their contributions are needed. S1P simulation increases affinity of various cell surface adhesion molecules for their ligands and the result is that the cells are retained / glued to the lymph node microenvironment. Hence the thought was that if we introduce an agonist of S1PR, it would bind to S1PR1 expressed on various lymphoid cells and make the disease-causing lymphocytes cells to be retained in the lymph

nodes. The consequence of an effective S1PR1 agonism is the state of lymphocytopenia; the lack of presence of lymphocytes in the blood. This does not mean that the drug is killing lymphocytes, just that they are redistributed and sequestered in lymphoid organs and not represented in the blood in the appropriate proportions.

The first POC of this strategy comes from fingolimod from Novartis. Fingolimod is indicated for use in the treatment of multiple sclerosis. However, in addition to its ability to cause lymphopenia and therapeutic efficacy in MS, fingolimod also has appreciable cardiovascular toxicity that limits its chronic use as a therapeutic. This cardiotoxic effect of fingolimod is believed to be mediated by S1PR3 which is highly expressed in cardiomyocytes. The S1PR agonist that we have developed in this program is selective by 10,000 fold for S1PR1 over S1PR3. SCD-044 is orally bioavailable with acceptable pharmacokinetic properties in various species. SCD-044 is as effective as fingolimod in causing lymphopenia in multiple species. In the safety pharmacology assessment, unlike fingolimod, SCD-044 is devoid of cardiovascular side effects as expected based on its poor binding to S1PR3.

As for its preclinical development, we have completed preclinical efficacy studies in various autoimmune disease models. In addition, we have also completed cardiovascular, respiratory and CNS safety pharmacology studies, and 13-week GLP toxicological assessment in rodents and primates to enable regulatory submission for FIH application. We intend to develop this molecule in Europe and have filed IMPD with the European Regulatory Agency. We anticipate that the phase I FIH PK /safety / tolerability study of SCD-044 will be initiated in Q3FY18. We have not yet finalized the autoimmune disease indication or indications for which this molecule can be developed further as a treatment option.

I will stop here and request my colleague, Yash, to discuss delivery systems innovation. Thank you.

Yashoraj Zala: Thank you Nitin.
I will be sharing updates on 2 of the delivery system innovations.

The first update is on SPARC's Abuse Deterrent program – SDN-021. So Slide No 30, captures some statistics for prescription opioid abuse pertaining to the United States. You would note that in 2015, more than 20,000 deaths have been reported due to prescription opioid overdose.

Between the immediate and extended release opioid formulations, about 66% of Abusers prefer Immediate Release formulations, because they are easier to manipulate by different routes like snorting, Injection or simply consuming multiple number of pills orally. As you can understand the last one is the simplest and there is no solution as on yet to deter that form of abuse.

As depicted in the graph on the right hand side, hydrocodone and oxycodone are the most preferred opioid drugs for abuse via the oral route.

Notably, from the 10 Abuse Deterrent formulations or ADFs as they are termed, which have been approved till date by the US FDA, there is no Immediate Release formulation which targets abuse deterrence for oral multiple pill consumption.

Moving over to Slide No. 31.
This slide describes the technology on which SPARC's SDN-021 is based.

As shown in the schematic representation, the technology involves the use of a pH responsive polymer along with a pH modulating agent.

The pH modulating agent is present in such a concentration in a single pill, that it does not change behaviour of the pH responsive polymer and therefore allows therapeutic dose to be

released for the patient use. On the other hand when multiple pills would be consumed by an abuser, the pH modulating agent concentration from a number of pills would change the stomach pH and thus influence change in pH responsive polymer, which in turn would cause blunting of release of the opioid drug. Thus a lower plasma concentration of drug will be delivered depriving the abuser from the desired "high".

Importantly, additional features of the SPARC technology also include deterrence via the injectable and the intra-nasal routes.

The next Slide, Slide No. 32 describes the pharmacokinetic characteristics of the lead formulation of SDN-021.

The plasma profile on left hand side is of a single unit of SDN-021 and the reference product. The orange and the dark blue lines represent the fasting and fed profiles of SPARC formulation.

While SDN-021 single unit administration demonstrates potential to be bioequivalent in the fed state, in the fasted condition the Cmax was observed to be lower, though AUC was complete. We believe the observed PK pattern will support efficacy of SDN-021.

The plasma profile curves on the right hand side of Slide 32 depict the multiple pill pharmacokinetic behaviour of lead formulation under the fasted and fed states. The blue line represents the reference product in fasting condition.
As is obvious from the graph, SDN-021 in the fasted condition, i.e., the green line shows that Cmax is blunted by about ~ 50% as compared to the reference product.

The red line represents SDN-021 in the fed condition and indicates reduction of Cmax by about 30% coupled with a delay in Tmax which could possibly lead to less liking of SDN-021 in the Human Abuse Likeability Studies.

Slide 33 summarizes the development status of SDN-021.

In-vitro Category 1 and pilot Human Abuse Liability Studies have been planned in Q3FY18.

A consultation with USFDA has also been planned to discuss registration pathway and Abuse Deterrence Label for oral multiple pill abuse & other routes like snorting and injection.

I will also be sharing the progress on SPARC's lead topical program, i.e., Minocycline topical as described on Slide No. 34.

Minocycline is a broad spectrum antibiotic and SPARC has developed a topical formulation for use in treatment of Acne vulgaris.

As shown in the Pre-clinical Proof of Concept study in the Acne model, i.e. the graph on the right, the topical formulation demonstrated similar activity to marketed Clindamycin topical gel.

SPARC has completed toxicity study in rabbits while toxicity study in mini-pigs is ongoing.

A pre-IND meeting is planned with USFDA by fourth quarter of FY18 and the IND submission is targeted in first quarter FY19.

I now hand over to my colleague Ajay to continue updates on delivery systems progress.

Ajay Khopade: Thank you Yash.

Today, I am presenting a new program from our ophthalmic early pipeline that is ready to go in to a full development phase. Aligned to the pain and inflammation, strategic area of interest, SPARC has developed a novel technology for the delivery for an ophthalmic steroid.

Ocular steroids are widely used for the treatment of pain and inflammation following cataract surgery and other inflammatory conditions. All together, they have approximately 750 million dollars sales in US. While clinical benefits of steroids and side effects are well documented, the knowledge on formulation and its correlation to the ocular steroid exposure is not well understood. Consequently, variety of eye drops in the form of suspension, gels and emulsions are available in market. These formulations may cause blurring of vision and unease to the patient. Moreover, they are also administered 3-4 times a day.

To address these issues, SPARC has developed a clear colourless solution instead of white hazy eye drops, as shown in the image on this slide. User can easily appreciate the significance of experience they may have on putting a clear eye drop in the eye over milky drops. These eye drops are formulated at a lower strength and to be used twice a day instead of 4 times a day.

Slide 36
The technology we developed for ocular delivery of steroids has three key features: 1. Solubilisation 2. Retention, and 3. Permeability enhancement. Steroids are water insoluble compounds. Our technology uses non-ionic, cationic and anionic solubilizers to provide a unique nanometre sized micelle with neutral surface property. Steroid is entrapped inside the tiny micelle structure as illustrated in the figure that looks transparent to the eye. The polymeric components further stabilises the micellar system and also provides bio adhesion and retention. In synergy with the above said solubilizers, it also increases the permeation of steroids across cornea. SPARC has filed IP on this technology which once granted will provide long term patent protection.

Slide 37
The formulation has been tested in multiple clinically relevant models of inflammation and evaluated for different inflammation markers. Data from two such studies is presented on this slide. The first graph on left hand side shows the data on acute uveitis

model. Uveitis is characterised by migration of inflammatory cells in anterior segment of the eye. These can be quantified and measured using slit lamp. Decrease of inflammation is assessed based on reduction in cell count in the anterior chamber. Steroid treatment reduces inflammation thereby reducing the cell counts. As shown in figure, the SDP-037 treatment twice a day has significantly reduced cell count in anterior chamber compared to the control and similar to the reference formulation administered four times a day. The graph on right hand side shows data from another model which involves pricking rabbit's cornea which simulates cataract surgery process. When corneal integrity is compromised by this procedure, there is an increase in inflammatory marker called PGE2 in aqueous humor. When inflammation resolves there is a decrease in PEG2 concentration. This figure also clearly shows significant reduction in inflammatory marker compared to control and comparable to reference. These models establish that the technology is able to retain efficacy even if steroid strength is reduced and is delivered two times a day.

Slide 38
With this initial proof of concept data we have reached out to USFDA for guidance on the requirement towards filing and approval. FDA has accepted our proposed approach and agreed for a single phase III pivotal trial for registration. We plan to open an IND by the end of this financial year followed by the initiation of clinical trial early next year.

With this update, I handover to Narendra for business updates on SPARC programs.

Narendra Lakkad: Thank you Ajay.

I will be sharing some details about the market opportunities for our late stage programs.

We are on slide 40 now. Baclofen GRS is SPARC's one of the most advanced and promising program. Immediate release Baclofen is required to be administered at 3 to 4 times a day which is inconvenient for most patients.

Majority of physicians that we have interviewed in our primary research believed that steady state blood levels and once a day dosing are key benefits of Baclofen GRS.

Immediate release Baclofen continues to remain the standard of care in US for spasticity associated with multiple sclerosis. It is a very old molecule and highly genericized; however the volume continues to grow at double digit and has now reached close to 800 million unit doses per year.

An estimated 10 million prescriptions were dispensed in US in last year. Prescriptions are written by a wide spectrum of specialties but we believe 25% - 35% of the total prescription market is potentially an addressable market.
We believe with the clear differentiation of once a dosing backed by a large clinical study, Baclofen GRS will get reimbursed at a premium price. We estimate a peak sales potential of this product at $100 mn.

Moving to Slide no 41.
Taclantis, or PICN, is a Cremophor® and albumin free formulation of Paclitaxel.

Cremophor® based paclitaxel formulations are associated with severe hypersensitivity reactions or in simple language we know them as allergic side effects.

Cremophor® based paclitaxel formulations require patients to be premedicated with high dose corticosteroids and antihistamines and infusion is administered very slowly over a 3 hour period. In spite of the premedication and slow infusion rate, several patients do experience serious hypersensitivity reactions.

In the primary research that we conducted in US with a sample size of 75 oncologists, oncologists confirmed that in their own practice on an average 12% of patients have documented hypersensitivity reactions.

Taclantis, being Cremophor® free eliminates the need of premedication with corticosteroids and anti-histamines. Also it can be given in a short 30 minute infusion at a significantly higher dose compared to generic paclitaxel.

No significant hypersensitivity reactions were observed in multiple clinical studies that we have conducted with Taclantis. So we believe this a clear differentiation that Taclantis offer over Cremophor® based paclitaxel formulations.

Moving to slide 42
In US, Overall Paclitaxel volume sales are stagnated over last 2 years. The treatment landscape is rapidly evolving for several cancers due to introduction of newer and more effective drugs. Both in metastatic breast cancer and in advanced lung cancer newer drugs are becoming the standard of care which may limit the use of Paclitaxel in future in these indications.

Albumin bound paclitaxel is currently approved in metastatic breast cancer, lung cancer and the pancreatic cancers. 65% of patients with these cancers still use generic Cremophor® based paclitaxel largely because of Albumin bound paclitaxel is expensive has reimbursement challenges.

We believe at an appropriate pricing there is a significant opportunity for conversion to the novel formulations like Taclantis.

Next Slide no 43
Let's look at the current market dynamics of Salmeterol-Fluticasone DPI market in the Europe.

Total inhaled corticosteroid and long acting beta agonists dry powder inhaler market in Europe is estimated at $2.5 Billion. Seretide® Accuhaler® has a current market share of 34% in the total market. This has been gradually declining on account of significant acceptance of the newer once-a- day ELLIPTA® device based products and price reductions of Seretide® Accuhaler®. So far generics have seen lower adoption in the market. Market may see additional competition; however, it is still large enough to offer meaningful opportunities for differentiated products like SPARC DPI.

Slide no 44
Coming to Brimonidine market opportunity. Over 2.7 million Glaucoma patients are living in US which is expected to reach 4.3 million patients by 2030. Glaucoma is a disease of an old age. The prevalence is projected to increase primarily because of the ageing population in the US.

As per IMS, current glaucoma market in US is estimated at $2.7 Billion and 35 million prescriptions were dispensed in last year. Prescription volume is growing at a healthy CAGR of 4.1% over last 5 years.

Brimonidine is the highest prescribed anti-glaucoma drug after prostaglandins with current sales estimated at $430 million.

Slide no 45
Brimonidine market has seen acceptance of improved brimonidine formulations and such formulations are being reimbursed at premium price.

Brimonidine was initially approved as Brimonidine 0.2% eye drops. Tolerability issues led to development of lower strengths of 0.15% and later at 0.1% .

Brimonidine 0.1% and 0.15% continues to dominate the market in both value and volume terms in spite of availability of the generic versions of Brimonidine 0.2% eye drops.

We believe a differentiated once a day formulation of Brimonidine would take a meaningful market share from this very compelling market.

Slide no 46
Let's talk about the market opportunity for K0706 in Chronic Myeloid Leukaemia.
With advent of Imatinib and subsequent next second generation BCR ABL tyrosine kinase inhibitors, CML as a disease has become a chronic manageable disease and many patients are living for several years.

However, some patients do fail to the initial and second line treatments and there are very limited treatment options for such patients. We therefore believe there is high unmet need for the treatment resistant CML.

As per our estimates, there are about 50000 patients living in US with CML, globally this number could be much larger.
In the last investor presentation, we have shared some data from our primary research that suggested that, there is a very low physician satisfaction scores with the available third line and beyond treatment options.
Additionally about 15% of patients discontinue treatment with second line drugs due to tolerability issues.

As you have seen, K0706 is highly selective kinase inhibitor and has consistently demonstrated its efficacy and in several preclinical and toxicological studies. We have now established PK and safety in single does in healthy volunteers and are rapidly recruiting patients for testing safety and efficacy at multiple doses.

We believe that the safety and efficacy advantage in third line setting may give us a significant market opportunity.
Thank you for listening. Will be happy to take questions if any later during Q&A

Over to Chetan Rajpara, our CFO for the financial update.

Chetan Rajpara: Thanks, Naren, for the detailed update in business.

This is Chetan Rajpara. I am the CFO of the company and joined SPARC in Feb this year. I look forward to staying in touch with you all.

Let me give you a high level financial summary. I will keep this really brief.

Slide 48 please
During FY17, Total income was at Rs. 1,946 Mn ($30Mn) [+18.5% from Rs. 1,642Mn], while Total expenses (incl. interest & depreciation) were at Rs. 3,149 Mn ($48.5Mn) [+34.5% from Rs. 2,342Mn], resulting in to a Net Loss Rs. 1,203 Mn ($18.5Mn) [+71.9% from Rs. 700Mn).

For Q1_FY18, Total income was at Rs. 246 Mn ($3.8Mn) [+0.5% from Rs. 245Mn], while Total expenses (incl. interest & depreciation) were at Rs. 1,036 Mn ($15.9Mn) [+70.4% from Rs. 608Mn], resulting in to a Net Loss Rs. 790 Mn ($12.1Mn) [+118% from Rs. 363Mn].

As far as Liquidity Status is concerned, Cash on hand as at 30th June 2017 was Rs. 282 Mn ($4.3Mn). Approval delays on Xelpros and Elepsia have certainly impacted our cash flows. As we mentioned earlier, we are working aggressively to get to approvals for these programs. Further, some cash is also locked in due to implementation of GST and pending service tax refunds.

Now, let me move to the next slide no. 49 for a few additional points on our cash situation.
For FY18, approx. 55 to 60% of the expenses are budgeted for the clinical programmes. However, we are aggressively managing our costs and are working to control our non-clinical expenses

very tightly. The gap between the income and expenditure for FY18 would be reduced, if we get the favourable data for Baclofen GRS and able to encash it in this year as we hope.

We raised Rs. 5,000 Mn ($77Mn) by way of preferential issue of warrants. Of this, we received 25% amount i.e. Rs. 1,250 Mn ($19Mn) in mid Jul-17. We shall receive the balance 75% ($58Mn) upon the conversion of warrants by investors, which will take place latest by mid Jan-2019.

We are in process of acquiring the R&D facility at Savli, near Baroda, and plan to invest a sizable amount including for the cost of improvement. This will be funded from the proceeds of our exit from our current facility. We will share more details on these transactions soon.

So, that brings us to the end of our presentation today. Thank you all for your valuable time. We will now open up the call for the Q&A. Looking forward to a lively interaction.

Over to the moderator for Q&A session!

Moderator: Thank you very much, Sir. Ladies and gentlemen, we will now begin with the question and answer session. We will take the first question from the line of Ketan Gandhi from Gandhi Securities. Please go ahead.

Ketan Gandhi: Sir, do you plan to target additional indications by doing clinical trials after the approval of Baclofen which can enhance the scope of this molecule?

Anil Raghavan: Hi, Ketan. This is Anil Raghavan. At this point we don't have intent to pursue Baclofen in additional indications. There may be opportunities for other compounds, like we spoke about K706 as a compound where we may probably pursue multiple indications. For the programs which are formulated for a specific purpose, we would like to stay with what it has been formulated

for and in case of Baclofen it is spasticity in multiple sclerosis patients.

Ketan Gandhi: Sure. Sir using abuse deterrence technology, are you simultaneously developing any other molecules for abuse deterrence?

Anil Raghavan: I spoke about the platform potential of the abuse deterrence technology. The intent with SDN-021 is in a way a proof of concept for the platform and once we have reasonable confidence on the platforms ability to deliver what it is intended to deliver, certainly we have plans to go beyond just that one compound and eventually our sense is that it may become attractive in broader swath of opportunity.

Ketan Gandhi: Sir, can you provide the status of using this platform to prevent overdose in other non-abuse deterrent products? I think you have given that in previous annual update.

Anil Raghavan: We do not speak about specific compounds. But we definitely have intent and early preclinical work going on in that area. Suicidality is a big issue and overdose is probably as tragic as abuse and related issues. We clearly have intent to go into suicidality and there are classes that we are targeting.

Moderator: Thank you. We take the next question from the line of Anubhav Aggarwal from Credit Suisse. Please go ahead.

Anubhav Aggarwal: One question on Baclofen GRS. We have estimated peak sales potential of $100 million from this drug. When I see this in IMS existing market is roughly about $100 million and we say that we can potentially address about 25%-35% of the market. So does simple maths imply that you expecting pricing to be 3x of current generics available in the market?

Narendra Lakkad: The current product, the immediate release Baclofen is highly genericized and once we have data supporting once-a-day dosing label, we believe that we will be able to price it differently, at premium price and which may not be 3x of a

generic price. It may be similar to branded products sold in the US.

Anubhav Aggarwal: But is this number correct at the IMS level of the generic product right now is $100 million?

Narendra Lakkad: That is right.

Anubhav Aggarwal: Then Narendra, why it will not be 3x. When you are targeting market share of about one third on a $100 million base and expect your sales to be $100 million.

Narendra Lakkad: Generics and the brand price in the US are very different. Generics are typically sold at 80% to 90% discount of the brand price. Sometimes even more. Baclofen is highly genericised and as I said earlier that provided we have data support, we will be able to price it differently, at a branded price and at that price the value of the current market that we are saying $100 million is substantially different.

Anubhav Aggarwal: And Narendra, when you have done a primary research on this that you basically showed it to physicians, did you take any view from there on pricing as well?

Narendra Lakkad: We do, yes.

Anubhav Aggarwal: Did you do it over here?

Narendra Lakkad: It was done in USA.

Anubhav Aggarwal: Correct. But in this study, basically this peak sales potential is already pricing in the potential you got as a view from the physicians.

Narendra Lakkad: We have done a qualitative market research with physicians and we have also done a qualitative market research with the payers and based on that we have a confidence about these numbers.

Anubhav Aggarwal: Okay. Thank you. The second question is on Brimonidine. When do you think, you have mentioned this phase III trials you have

started in fourth quarter of this fiscal. So roughly when this phase III trials will finish and we can file the NDA for the drug?

Anil Raghavan: So our timeline at this point is going to be a function of our consultation with FDA. We will be taking these results to FDA in the next quarter and our objective is to start a trial, probably in the first quarter of the calendar year 2019, that is the last quarter of current financial year and probably a little over a year would be an appropriate timeframe for the completion of this clinical program. So we are talking about completion by end of next financial year and the submission thereafter if the data supports.

Anubhav Aggarwal: Thanks, Anil. The reason I was asking that because the patent expiry on Alphagan is January 22, so that is what I was asking that we may end up getting approval of our product very close to the patent expiry of Alphagan and the large part of the market size of Brimonidine today is Alphagan. So do you think that may impact the potential because we are so close to the patent expiry?

Narendra Lakkad: The current Alphagan P product is having a label of 3 times a day dosing and product which we are developing is once-a-day. So that is a clear differentiation and that will be backed by a clinical study. And if that study is meeting the end point, then we have a differentiated product. Of course there will be potential generics to Alphagan P, but we believe that we will have an opportunity for a differentiated product. As I explained about scenario between 0.2% and 0.15% or 0.1% market today.

Moderator: Thank you. We take the next question from the line of Krish Shanbhag from Pride Capital. Please go ahead.

Krish Shanbhag: Sir, just to add to the question earlier on Brimonidine OD and if you could also tell about SDP-037? Can you provide me the time required to complete phase III as well as the likely number of patients for the clinical trials to get regulatory approval in the US?

Anil Raghavan: I think I have Dr. Hany Michael on the call. Hany, can you answer this question?

Hany Michael: The clinical trial would roughly last about a year and the number of patients will be about 300 per arm, so 600 patients in total is what is required for the study and we are expecting it to be completed with enrolments and everything in a year .

Krish Shanbhag: So what is the time when we expect it to be done?

Hany Michael: That is what I said, it will be completed in a years' time.

Krish Shanbhag: Okay, from now?

Anil Raghavan: Once the study starts which is in the fourth quarter of this financial year.

Krish Shanbhag: Yes. That I understand for Brimonidine OD, right?

Anil Raghavan: Yes. The phase III program for SDP-037 is expected to start in first quarter of FY19.

Krish Shanbhag: Okay. Thank you. My second question is on K706. How do you plan to overcome the patient availability for timely enrolment for CML as well as Parkinson's?

Anil Raghavan: These are two different questions. On the CML, we are already on a global program and we have significant number of sites active in this program and we also have significant engagement with the key opinion leaders in Parkinson's.

We have seen substantial support for proposition of K0706 in the CML study, we do not anticipate any challenges as we build momentum for the study based on the data from earlier legs of the program. We don't foresee a significant issue, but the timelines need to be factored in for the aspect that we are going for difficult patients in this setting. The phase III program plan that we have, essentially factors in patient setting which is coming after multiple lines of treatment.

On the Parkinson's trial we are probably too early to comment on. We are at this point, going through a dose range finding study. But we do not see recruiting Parkinson's patients for a disease modifying therapy to be a significant issue, because you have a large pool of patients who just don't have any meaningful option. So in that sense, we do not feel that we will hit a wall in terms of patient recruitment in Parkinson's trial.

Krish Shanbhag: Okay. I would like to squeeze in one before I join the queue again. At what stage, will you choose to take either the 706 or the 954 into final stage of the clinical trial?

Anil Raghavan: We have a timeline of sometime in the first part of next year to do that. We are currently in a dose escalation study in patients where we are assessing the safety of K0706. We will be IND ready for K954 probably by last quarter of this year and the latest by the initial part of the first quarter of next year. At that point we will take a call and there may be other opportunities for K954. We are also exploring in pre – clinical setting other opportunities for K954. So we will take a call on the relative positioning of 706 and 954 probably towards the end of this year or early part of next year.

Moderator: Thank you. We will take the next question from the line of Surya Patra from Phillip Capital. Please go ahead.

Surya Patra: Just wanted to have some sense on the Elepsia, as you said alternate plant that you are looking for manufacturing at this moment as a plan B. Say on that can you give some clarity, whether it is plant of somebody else then the partner which is already known or what is the commercial timeline that we are anticipating and what is the way forward basically for Elepsia and Xelpros at this moment that you are having?

Anil Raghavan: At this point, for both products we are in early stages of setting up the manufacturing runs in these plants that we have chosen. We have to take batches from both these plants for both these products. We need to have significant amount of stability data coming from exhibit batches. And also in Elepsia's case, we may

have to do bridging PK study. In both these cases, we will go back to the regulator to have a consult and get more accurate sense of how much stability data we need and there is a regulatory expectation and we would like to make a case once we have some early data coming in. So at this point, as I said in my earlier comments, I won't be able to set specific timeline in terms of when we can have a resubmission if we pursue this plan B.

Surya Patra: Sir on resubmission, what timeline that one should expect considering it is already when you evaluated earlier from site A and if you go to a site B, then what regulatory timeline one can be anticipating for this?

Anil Raghavan: 6 months for submission.

Surya Patra: Okay and the other question is, on the R&D effect, since the model has shifted from the delivery system based innovations to the new molecule and even biologics along with the delivery system based model. So what is the kind of R&D budget that we are now evaluating for let us say current year and in next 3 years, to be specific that would be a useful indication.

Anil Raghavan: It is difficult to kind of go into specifics, but what we are expecting is that, a lot of research to transition into Novel Chemistry. We are now beginning to see 4 programs, 5 indications coming into the clinical setting and they are at early clinical development at this point. As we move forward and if we are fortunate to have good data supporting moving forward, phase III or the registration leg of these studies is where the consumption or cash burn is going to substantially take up. And looking for that trend, we will see substantial double digital growth of our clinical expenditure if these programs proceed the way we expect it to proceed. Beyond that, I don't want to commit to a specific number at this point because there are too many moving parts. Data coming in on a certain way, aggressively prioritized updates on the quality of data and also the market movement in terms of therapeutic space shifting. So

we will be very selective in terms of compounds and indications to proceed.

Surya Patra: Okay. Just last one question sir. On the monetization of the pipeline, any change in the thought process if you can?

Anil Raghavan: I briefly touched on this. Our intent which is slightly different, we would like to stay in the game as long as possible. But at the same time, building on the response that I had on the earlier question, we may actually come to situation where there may be conflicts on resource allocation. So if we see substantial conflicts on resource allocation and if we have promising asset, then we would look at other models of engaging like partnership with others etc.

Moderator: Thank you. We will take the next question from the line of Ketan Gandhi from Gandhi Securities. Please go ahead.

Ketan Gandhi: Sir it is regarding Taclantis. If your BE study fails, would it make commercial sense to develop this drug further by completing phase III trials for bladder cancer? If yes, how much time will this take?

Anil Raghavan: Well, I don't want to be hypothetical on this, but at this point, we have done substantial exploratory PK study and there is a good rational basis for moving this product into a pivotal BE study and during this presentation and on earlier occasions we have shared what is striving our confidence going into this BE study. And at this point, I would offer the best see what happens in April.

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

Sameer Baisiwala: A question on DPI combination. Now with the results that you had with Salmeterol peak concentration higher in low dose studies, what is the path forward? Is the drug approvable and what would the regulator ask for you to approve it?

Anil Raghavan: I think we are seeing an interesting situation here and we think this product approvable, certainly approvable in the high dose

and the mid dose which is where much of the opportunity is and on the low dose, if you carefully look at the data what we are seeing is extreme variability on the reference compound side. So we think we have a reasonable argument to go back and see if we can bridge between the high dose and the low dose, but that is a matter of review and consult with the agency. I don't think we can conclusively say that all the 3 doses would be approved, but we have reasonable grounds to entertain all.

Sameer Baisiwala: And when do you expect this discussion with the regulator? I thought it would have already happened.

Anil Raghavan: No. It is being planned at this point. I think it is scheduled for this quarter.

Sameer Baisiwala: And one of the outcomes is possible that the two of the higher doses get approved and the lower dose doesn't get approved. Is that what you are saying?

Anil Raghavan: Absolutely. That is a possibility.

Sameer Baisiwala: Okay. Sir my second question is on Baclofen GRS. Now in your assumption of the peak sales of $100 million sales estimate, what is the tiering that you have assumed? Is it tier 2 or tier 3?

Narendra Lakkad: We have assumed tier 3.

Sameer Baisiwala: Which means very high copay and low reimbursement, right?

Narendra Lakkad: Once we have a label, we will have extensive discussions with payers, we will understand to what extent we will be able to price and what tier we get. But it would be closer to market kind of a possibility to get some clarity. However, in a market model, we typically assume that this kind of product will get placed by payers in tier 3 with a higher copay compared to generics.

Anil Raghavan: And Sameer, that is the reason why we have taken a very conservative position otherwise if you look at the base volumes, of all products, they are still growing at almost double digits. In that sense, there is a significant opportunity especially because

of the shift away from opioids. So we are taking a conservative position because of discussions we ought to have once we have approvable products with the payer.

Sameer Baisiwala: That is fair enough. So how do you strike the out-licensing deal assuming it is a $100 million conservative or it is a much higher number?

Anil Raghavan: So that is the conversation that we need to have with potential partners and we are actually having those conversations now and in those cases, typically it is not just conservative case. One will build out several cases depending on different assumption sets. And you factor in effects on the positive side in a structure.

Sameer Baisiwala: Okay, got it. And just very curious why did you think Narendra that only 25% to 35% of the total market can be addressed with this?

Narendra Lakkad: Baclofen is prescribed by wide number of specialties. It is a matter of field force deployment, what is the most optimal deployment at which you get an optimal coverage. Based on the data which we have looked at about the prescribers and high decile prescribers, we believe that with restriction on patient population similar to IR Baclofen we will be able to reach out to specialty doctors like Neurology and Osteopathic medicine doctors, those who are treating this particular indication.

Sameer Baisiwala: What is the label limitation that you have?

Narendra Lakkad: There is no limitation; the label is same as Baclofen IR that is approved for spasticity associated multiple sclerosis. But if you look at the use of Baclofen, it is being used for several acute or chronic musculoskeletal pain indications.

Sameer Baisiwala: Fair enough. So if it is being used for wider indications, then why can't your products also not be used for those?

Narendra Lakkad: We can't promote. We can't make projections.

Sameer Baisiwala: Okay, got it. And just one final question sir, with the permission on Taclantis, I mean, how do we read that you have had quite a bit of successful pilot BE study and should that not necessarily lead to a successful pivotal BE study?

Anil Raghavan: The pilot studies are definitely indicative but there is also an element of probability in that. Hence I don't think we can go ahead and say that based on the pilot study we have a 100% chance. There is an element of risk in any clinical endeavour and our statements are essentially building in that element of probability.

Sameer Baisiwala: Okay, I understand. And in your presentation slide 41 for Taclantis, you say that 12% have hypersensitivity in the actions if they are using Cremophor base paclitaxel. So Narendra, is this really the target market for you because this is the one which is facing hyposensitivity?

Narendra Lakkad: This is not the target market. What we are trying to say is what are the problems associated with Cremophor® based paclitaxel formulations? The physicians do know what can go wrong or what could be a potential side effect. And these are very serious and acute side effects and those who are in clinical practice; they all have experienced how difficult it is to manage such side effects. The perception is always there and that is the reason, when albumin bound paclitaxel was launched with less possibility of such hypersensitivity reactions and one can give higher dose with shorter infusion time, they could capture substantial market. So what we believe is that if you have a similar formulation, certainly you have opportunity to convert from the current Cremophor® formulations to non Cremophor® based formulations like Taclantis.

Sameer Baisiwala: Okay, got it. Sir, albumin base got 35% and 65% remain with Cremophor base, right?

Narendra Lakkad: Currently, yes.

Moderator: Thank you. We will take the next question from the line of Kuntal Shah from Sage One Investment Advisors. Please go ahead.

Kuntal Shah: Yes, I might have joined late, so question might have been addressed. But the question I had was regards to DPI, what kind of additional work is required for approval in EU market and likely time and cost for the same and what is the potential milestone income likely on Xelpros, Elepsia post getting FDA approval?

Anil Raghavan: We have covered the Sal – Flu question. We have completed the set of studies the European regulators have asked for and we have discussed, if you go back to the presentation you have the results of the study in the presentation and we are currently in the process of consulting the European regulators. And we hope to conclude these consultations in the current quarter and thereafter we will plan for filing. We do not think that we have to do additional studies at this point for Sal – Flu. Deal structure for Elepsia and Xelpros were publicized. We haven't specifically spoken about specific milestone amount. So that is something which we haven't disclosed so far.

Moderator: Thank you. We take the next question from the line of Manish Jain from Sage One Investment Advisors. Please go ahead.

Manish Jain: My question pertains to abuse deterrence that we stated on slide 32 that the Cmax was lower than the required for BE studies. Can you just highlight what is the significance of this to get to FDA approval?

Anil Raghavan: Manish, let me get Dr. Yash or Nitin to answer that question.

Nitin Dharmadhikari: What we see is that in fasted state we have lower Cmax compared to what the reference product has. But we believe that this product will be efficacious because it is not too low. Yash presented that, there is probability of product being efficacious but it doesn't lie in a bioequivalence range and we believe that it will be efficacious.

Anil Raghavan: The key challenge here in this product is essentially balancing the bio availability on a single pill or prescribed levels with multiple pills. At this point we are looking to have bioequivalence on both sides. What you are seeing is a single instance. But in multiple use on single pill beyond the second or third pill, we are seeing steady state PK comparable to the reference product. So we believe that there is reasonable ground to conclude bioequivalence, but that is again something which we are going back to the agency. Most critical part is the blunting that you are seeing on the multiple pill end of the study. So on a fasted basis at 5 to 6 pills you are almost seeing 50% blunting. And on Fed state between our Fed state and the most vulnerable part of reference product we are seeing a 30% odd difference which we believe is sufficient for making a likeability difference. So if we have a product which can give you bioequivalence and near bioequivalence on the prescribed levels and have around 30% blunting which will translate into a likeability difference. That is where you can actually make a dent on abusability of the product.

Manish Jain: And given that it is a huge issue at this point of time not only for FDA but even at the political level. What kind of support do you envision in terms of doing studies on lesser number of patients or fast track status not only helping you in the first molecule and could you based on the success of this first molecule, how quickly could the follow-on molecule come through?

Anil Raghavan: If you actually look at the clinical programs for these studies, it is not substantial clinical load and what we need to have is a statistically significant population where you can demonstrate what you need to demonstrate. So in terms of execution challenges of the clinical program, it is not substantial except that we are going to do this in a special population of abusers. In that sense, the support that you would appreciate is not in terms of accelerated timelines or concessions in terms of number of patients, but on the legislative side and on the political side, you are right and there is a lot of momentum now going for this problem and there is also at the same time

apprehension in the effectiveness of the early generation of abuse deterrence products because most of those products only address the tamperability of those formulations. The most common and the easiest form of abuse remained open which is taking a bunch of pills. So in that sense, if we manage to deliver what we are promising through this platform that is a huge step-up in terms of the proposition of this platform and at that point, we have additional opioids lined up which are going through exploratory formulation development at this point and we are also looking on other classes like anti-depressants and benzodiazepines. So in that sense, there are other avenues which will open as we spoke about in response to an earlier question once the platform gets validated.

Manish Jain: Thanks. And just an extension on clarification based on this, so given that 10 abuse deterrent products already there in the market based on what you all have presented so far. We will clearly have significant edge even compared to these 10 abuse deterrent products already approved in the market.

Anil Raghavan: All these 10 abuse deterrence products as I had mentioned Manish, none of them actually addresses the core issue of multiple pill oral abuse, they all address other routes of administration like nasal abuse or snorting, tampering and things like that. So you have a formulation which addresses multiple routes of abuse and shuts down the most common form of abuse which is oral abuse, you are not moving the needle.

Moderator: Thank you. We take the next question from the line of Krish Shanbhag from Pride Capital. Please go ahead.

Krish Shanbhag: This question is to Chetan. SPARC was spun - off about 10-year before, in 2007 and after about 10 years journey in the company, we still need external funding of capital to fulfil our programs, even recently we have gone for a capital infusion. So when do you think the monetization of existing programs could take care of future development because now we are also entering into biologics as you mentioned in the presentation.

Anil Raghavan: This is a fair question. And let me address this on behalf of Chetan. I think there are two ways to look at this. One is the sheer time this journey has taken and also the other way to look at is how much money has been sunk into this overall effort. I for one and most of us in our team and the promoter group would agree that we have been basically slow to ramp up in terms of building momentum for actual innovative development. So in that sense if we have to go back and redo this whole thing, we would be probably much faster than we did. But where we take a lot of encouragement from is the fact that the clinical portfolio that we managed to build in any setting pattern would have taken a substantially more money than what we have taken and in fact not even closed and it would have taken several multiples of what we have spent, what is in terms of infusion. So in that sense, you have a model here which has clearly demonstrated that it can bring both Novel Chemistry and complex formulations with great potential like the platforms that we were talking about at much lower cost than you can do with this in US or in any other market. And I will go back to the point that I earlier made. We have a long game. So what we wanted to do in the first leg of this journey was to ensure that we have a proof of concept for the model and clearly with almost 10 plus products in clinical development now at substantially lower cost of development per product for bringing an asset to market and bringing an asset to clinic. We have demonstrated that this model can work and the question is how effectively we can scale from here on. And to go back to the second leg of your question which is how soon we will see cash independence. There are cash events coming up in the company. Baclofen, if we are fortunate to have good data, would give us a near term opportunity. Taclantis would give us near-term opportunity and then we will also see Sal - Flu and products on our abuse deterrent platform coming up as we go into the second and third year of our outer year projections. We have a cash flow opportunities lined up as we move forward. But at the same time, we want to aggressively pursue the clinical opportunities that we have and some of the opportunities that we are talking about whether in oncology or neuro-degenerative conditions or

in abuse deterrence, as they have higher value proposition. So we are going to pursue this as hard as we can. So in that sense for the foreseeable future, we will continue to see a disconnect between how much we are spending and how much we are earning in terms of cash flow. And we will like to find ways to fund that and that is where we are and we feel very confident about the path that we are on.

Krish Shanbhag: Sir everything that you said on the call is well appreciated by investors, as mentioned in the presentation that we are yet to receive 75% of the preferential issue. Is that a fair estimate that thereafter more or less our products will take care of the incremental. That was my question, but because you still have to receive 75% of the preferential issue money?

Anil Raghavan: That is an interesting question, but I do not want to commit to a specific financial outcome lead this in a call like this. There are outcomes which can lead to that in terms of products maturing and deals struck at a certain rate and so that I do not rule out a possibility, but I also do not want to confirm that as the way forward for us. I am sorry I am not able to answer your question conclusive manner but that is where we are.

Moderator: Thank you. We take the next question from the line of Anubhav Aggarwal from Credit Suisse. Please go ahead.

Anubhav Aggarwal: One clarity on Taclantis. Just wanted to check that the commercial unit for Taclantis is gaining lot of markets for Cremophor® base paclitaxel or this is like we are expecting lot of market share gain from Abraxane® as well? Why I am asking that is because in prescriptions, Cremophor® base paclitaxels are in large portion, but in dollar value they are very small market.

Anil Raghavan: No, both. I think there is an opportunity to gain share from Abraxane®, the moment you have a differentiated product and a non-infringing product in the market, that is definitely going to split the market and in that sense, there is clearly an opportunity to gain share from Abraxane® and at the same time, with increase affordability and also intensive competition, there will

be higher transition from the generic end of this market. So we think that both these are drivers of demand for us.

Anubhav Aggarwal: Sure, that is helpful. And I have one more question. Let us say if all goes well, SPARC can potentially have 4-5 molecules in market in next 3 years let us say by fiscal 21 and you mentioned that you do not want to mention number, but I just wanted to check that top line of $100 million, is it big stretch for SPARC or that is adjusted for partner stake that is a remote possibility by fiscal 21, fiscal 22?

Anil Raghavan: This is something which we have consistently stayed away from, in the sense that actually projecting aspirational top-line or projected financial number. So I do not want to get into actually committing because this is a risky business. Clinical programs can go anyway. So it is not like other businesses where there is a direct proportionality between effort input and outcomes that you can get. So given the uncertainty of the whole setting I would stay away from making projections like that, but we have reasonable grounds in terms of the data quality that we have done and that is why we have made the translation decisions that made and so in that case, we are reasonably hopeful about some of these outcomes that we are alluding to. I am very uncomfortable making that as a commitment at this point.

Moderator: Thank you. We take the next question from the line of Manushi Shah from Research Delta Advisors. Please go ahead.

Manushi Shah: I have two questions actually. First one is on Xelpros. I just wanted to understand that for example there BAK free Travatan as well as BAK-free Moxeza and both of them have decent sales, though the molecules with BAK are completely genericized. So do we expect something like this for BAK-free Latanoprost as well?

Narendra Lakkad: In case of Travatan, they shifted their old product into a BAK-free product and there was no generic competition at that time. So whatever you see today was sales of Travatan, which got converted to Travatan Z. In our case, the situation is different

because Latanoprost is a generic since last few years and now we will be coming up with this differentiation and we will be selling this at a different price. So we will get a kind of share from the market, but you cannot expect that we will have a situation like Travatan Z.

Manushi Shah: One more question in Elepsia XR. How it is different from Keppra XR and what is the unmet need that Elepsia XR is meeting?

Narendra Lakkad: Elepsia XR is compact tablet of higher strength of 1000 mg and 1500 mg which can be given once a day. The innovator, Keppra XR is available only up to 750 mg. They have a 500 mg XR once a day and 750 mg XR, but if you look at the dose or the way the product is prescribed, more than 50% of patients require a dose above 2 gram a day which means even if patient is prescribed Keppra XR, patient needs to take 4 to 6 pills depending on the dose that patient is given. And so we have a technology which helps us to make a compact size tablet and because of that, we are able to develop higher strength products. So this is a differentiation against Keppra XR.

Manushi Shah: The number of times tablet has to be taken, in your case it will be 2 times versus.

Narendra Lakkad: It is once a day, but you need to take few more pills for epilepsy. So reducing pill burden, is the advantage.

Moderator: Thank you. We take the next question from the line of Prakash Agarwal from Axis Capital. Please go ahead.

Prakash Agarwal: Sir, just trying to understand the market opportunity for Taclantis. So it would be directly linked to the paclitaxel market and how big it is?

Narendra Lakkad: As we have stated, there is a market of Abraxane®. Abraxane® is approved for three indications and has reported sales close to $650 million in the US in last year. But only 35% of total number of patients who get paclitaxel, get Abraxane®, 65% of patients still get a generic version. We are assuming total market

opportunity for us and at appropriate price, we will be able to take share from both Abraxane® as well as a generic paclitaxel.

Prakash Agarwal: The question actually I am trying to understand like how you given some idea on Baclofen, just trying to understand that what could be the opportunity for us in terms of conversions from both these markets and the run rate that we can expect as peak sales?

Narendra Lakkad: We will give more clarity or at least our internal estimate closer to when we have data readout, we will be able to give more clarity about how we are thinking as a market. But right now, we just presented an idea about what is the kind of opportunity.

Prakash Agarwal: And secondly on the plant that you have, if you could give, is this acquisition in refurbishing cost. So what is the approximate cost and how long you would take it to make it fully functional?

Anil Raghavan: So this is not exactly plant cost. What we are doing is we are actually transitioning our R&D infrastructure in Baroda. Currently, we are in a co-located facility with Sun Pharma at Tandalja and we are exiting that facility and we are moving into own R&D centre in Savli GIDC campus. We have not made disclosures in terms of specific numbers, but we have given approximate numbers in the board resolution which sought approval talking about roughly around 30 plus crore investment in the acquisition of the property and also another 10 to 15 crore investment in the buildings. So we are talking about an investment which is about 40-45 crores.

Prakash Agarwal: And you would be shifting by what timeframe sir?

Anil Raghavan: Our intent is before the turn of the financial year.

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

Sameer Baisiwala: I was just looking at the DPI Slide #43. Of the total relevant market which I think is 977, how do you break it between two higher dose and one lower dose?

Narendra Lakkad: Actually, we understand more than 90% of Seretide® Accuhaler® sales are coming from the high and mid strength.

Sameer Baisiwala: This was very helpful. And the second question is for SCD-044. What is the arrangement that the company has with Bioprojet?

Anil Raghavan: We have not made disclosure on that and in terms of broad outline; we have a 50%-50% cost split and various splits on different markets. I do not want to actually make a full disclosure without consult from Bioprojet and we can probably make announcement at an appropriate time. What we are really looking to do is once this product clears Phase I where the discretionary spend will go up substantially; at that point we will make full disclosures in terms of our arrangement with the Bioprojet both in terms of split of cost and also revenues.

Sameer Baisiwala: I am just curious because most of the time companies would get into these arrangements after PoC data is out. Here you have entered into almost a pre-clinical stage. What gives you that confidence?

Anil Raghavan: No, Sameer. This is not an arrangement we have entered post pre-clinical. This asset is actually developed by SPARC. It was a co-development, joint development effort between Bioprojet and SPARC. The concept came from Bioprojet and chemistry and some of the pharmacology development came from SPARC. So in that sense, it is not something which we brought in after it reached a certain development maturity. It is something which we have conceived together and develop together.

Sameer Baisiwala: And just one final question. Since you need the capital now, why did you get into the preferential warrant scheme? I think you mentioned that the balance 75% will come in January 2019, if I am not wrong. So would you not have looked for other options to get the money upfront?

Chetan Rajpara: I think this was the quickest route we could take, any other option like rights issue or any other mode of funding would have taken a lot of time and need of fund was quite urgent. Also

in terms of issue expenses, this is most economical option. And Jan 19 is the latest date by which investors will have to exercise their right to convert the warrants into share, it could be earlier also.

Moderator: Thank you. We take the next question from the line of Manish Jain from Sage One Investment Advisors. Please go ahead.

Manish Jain: Just continuing on abuse deterrence. In terms of pricing power with payers and achievement of peak sales, should you get the approval the way you are looking at. Would you get significant pricing power with the payers?

Anil Raghavan: This is a very fluid situation at this point. This is a significant issue for this civil society, but payers typically have fairly aggressive view on this. But at the same time what is changing the environment is in several states, now there are state legislative led efforts to come up with regulation which mandate prescription of abuse deterrent products when abuse deterrent products are available. So we will see especially in states where opioid crisis is significant like in the case of say Florida or West Virginia and in places like that. In Florida, we already have a legislation, but the legislation is now confined to procurements where government funding is involved, but as a trend what we expect to see and this is what we gather from our conversations also is that the moment you have reasonable data on effectiveness of abuse deterrents you are going to see a significant societal pressure and legislative pressure on adoption of these technologies. So this is a conversation that we need to have. We are also doing a lot of work on health economics. The cost of abuse is not clearly understood and we have to make a case on the overall cost of abuse to the payers. So if you actually prevent somebody from becoming an abuser, there is a significant gain and we got to make a pricing argument based on the health economic benefit and that is something which we are doing a lot of pre-work on at the moment.

Manish Jain: So this is very helpful, Anil. And just a follow-on, does it also ensure that the time required to reach peak sales potential can also get curtailed in this product?

Anil Raghavan: That is a possibility, but we do not know that at this point. There is a possibility where if you see significant legislative action that can be a possibility, but we do not know that at this point.

Moderator: Thank you. We will take the next question from the line of Manushi Shah from Research Delta Advisors. Please go ahead.

Manushi Shah: I just had a follow up on my earlier question. What is the percentage market share SPARC expect from Elepsia and Xelpros like when compared with Latanoprost and Levetiracetam XR, Keppra XR and Xalatan?

Narendra Lakkad: We have not given a detailed market model, but we have given peak sales potential for Elepsia XR and Xelpros in the last update. For both products we have projected peak sales potential of $50 million.

Moderator: Thank you.

Jaydeep Issrani: Thank you very much for participating in today's call, we would like to close this call now and in case we have missed answering any of the questions, we would request you can send it to us or to our IR team and we get those questions answered for you. Thank you so much for joining the call again.

Moderator: Thank you very much, sir. Ladies and gentlemen, on behalf of SPARC that concludes this conference. Thank you for joining us.