"8th Annual Investor Update on R&D Pipeline"

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Moderator: Good day, ladies and gentlemen, and a very warm welcome to the SPARC's 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 an operator by pressing '*' then '0' on your touchtone telephone. Please note that this conference is being recorded. I now hand the conference over to Mr. Jaydeep Issrani. Thank you and over to you, sir.

Jaydeep Issrani: Thank you Ali. Good Evening and good morning, I thank you for joining us today for update on SPARC's R&D Pipeline. I'm joined today by our CEO, Mr. Anil Raghavan and other members of our Leadership team.

The slides that will be presented on this call were sent out earlier today, we hope you have received the slides. The slides are also available on our website www.sparc.life . The call transcript will also be put up on SPARC's website soon.

Before we start, I would like to remind you that our discussion during this conference call will include forward-looking statements that are subject to risks and uncertainties that could cause actual results to differ from those projected in the forward-looking statements.

We will now begin the presentation and then move to a question and answer session. With that, I'll now turn the call over to our CEO, Mr. Anil Raghavan for his presentation.

Anil Raghavan: Thank you very much Jaydeep for the introduction. Good morning, Good afternoon or Good evening depending on where you are joining us from. We are happy to welcome you to our 8th annual investor update on our R&D pipeline. Thank you so much for taking the time to be with us today. I know many of you have been regulars on this call. Your consistent support and engagement over the years has been a great source of energy for all of us at SPARC. So welcome back.

We have a simple format for this call. We look to provide a detailed update on our clinical stage portfolio covering program strategy, immediate next steps and expectations for next 12 months. These are programs which consume the lion's share of our discretionary

spending. That has been our primary consideration for selecting programs for discussion during the annual investor day portfolio update. We have included a couple of new programs which are currently at an advanced translational research stage as we believe we are now ready to scale these programs to clinic in the short term. We also plan to cover key tenets of our overall pre-clinical strategy later in the presentation to give you a flavour of what is being pursued beyond the clinical stage assets and a commentary on the market environment of some of our key late stage programs. We have also included a brief overview of our financials during our presentation today.

I have my senior management team here with me on this call. In the interest of time, we don't plan to make introductions upfront. I will start with an overview of the progress we have made in the last twelve months before moving on to detailed program level updates. As always we look forward to a very lively discussion.

So let's get started. Please go to slide 5
People who attended this call in the last few years, that's most of you, are familiar with the regulatory challenges we faced on Elepsia™ XR and Xelpros™. They were primarily stemming from the inadequate compliance status of the facility of our manufacturing partner. We have better news to report this time. Our partner's manufacturing plant supporting Elepsia™ XR and Xelpros™ submissions has moved from 'Official Action Indicated' to 'Voluntary Action Indicated'. The shift in compliance status now allows us to pursue marketing approval from SUN Pharma's Halol plant.

SPARC has received Complete Response Letters for both these products citing manufacturing site compliance inadequacies. We have responded to US FDA indicating compliance readiness of the manufacturing site. That allows us to get back to the regulatory process with PDUFA dates for the review closure. We expect to hear from the agency by Nov 2018 in the case of Xelpros™ and Jan 2019 in the case of Elepsia™ XR.
As you know we have initiated activities related to a possible site transfer as a back-up manufacturing strategy for these products. We

will continue to maintain some of the preparatory activities, but on a low intensity mode.

The regulatory turn-around is certainly a positive for SPARC, allowing us access to additional milestone payments from our commercialization partner and a potential launch in early 2019. We have also made progress with three other late stage clinical programs.

Taclantis™, our nano-formulation of Paclitaxel has completed patient recruitment in the pivotal Bio-equivalence study last month. We are currently analysing the samples and we expect to have a read-out from this program in the October/November time frame. We have spoken about the PDP – 716 in Glaucoma and SDN – 037 in post Cataract surgery inflammation. We have completed the regulatory consultation on registration expectations and we are currently in Phase III study start up for both these programs. These are relatively short duration studies. We expect to have Phase III read-outs from both pivotal trials in the first half of next financial year.

We have started exploring potential partnership opportunities for all three of these programs.

Slide 6 please
These are certainly an important set of milestone moments for us. We had around 6 reformulation programs in our late stage development portfolio which represent the first wave of delivery system innovations from SPARC. We are now about to reach conclusions on all of these programs in the next 12 months of so. We have two NDAs coming from this basket. Two in Phase III clinical development and two programs which did not go the way we expected it to go. That's Baclofen GRS and Salmeterol – Fluticasone DPI. I want to take a moment to talk about the status of the Baclofen GRS and Salmeterol – Fluticasone DPI programs.

We had a detailed debrief on Baclofen last year when the study results came in. As you know, we did not meet the primary end point in our pivotal clinical program for Baclofen. The primary end point was a composite measure of treatment failure combining a one point drop in

Modified Ashworth Scale and Clinician's Global Impression of Change. While we did not meet our primary end point, Baclofen GRS met several important secondary end points which are clinically very significant. For example Spasm frequency, Night time awakenings or Subject's Global Impression of Change. We have consulted FDA recently to gauge the possibility of seeking a marketing approval with the current data set. While we could not get agency agreement to proceed to a submission, we have had important inputs into a possible rescue program. We are currently putting together a protocol for a supplementary study to further establish the safety and efficacy of Baclofen GRS as a treatment option for spasticity in MS patients.

In the Salmeterol – Fluticasone DPI program, we have concluded a multi-agency regulatory review for pursuing marketing approvals in EU. In some countries, we may require additional Bio-equivalence studies or Pharmacodynamic studies to make a strong case. However, our current read is that we may be able to pursue an application in select countries. We have partnership interest from potential partners for Salmeterol – Fluticasone DPI for some of the European countries. While SPARC currently does not plan to make additional resource allocation for clinical programs for either Baclofen GRS or Salmeterol – Fluticasone DPI, we intend to pursue partnership opportunities to license out these programs.

Let's move to the next slide please, Slide 7
We have several important learnings from the development experience of our first generation programs, as we pursue our early clinical basket where we have several important products in active dose range finding or proof of mechanism studies. Externally we have to recognise an increasingly challenging reimbursement environment where the viability of incremental innovation is diminishing significantly. So it is important to ensure the ability of our programs to move the standards of care meaningfully to stay relevant. We have also thought through our translational development and go/no-go decision making process quite a bit to make the filters more robust when we decide to move programs from pre-clinical development to costlier clinical setting. Another important consideration for us is the focus on platforms vs standalone development programs. Versatility of

a platform and its relevance across multiple indications is an important hedge in development. In early stage clinical development, we have five such platforms which we are exploring in multiple contexts.

We are pursuing our Abl Tyrosine Kinase Inhibitors SCO – 088 and SCO – 125 in both late stage Chronic Myeloid Leukaemia and a host of neurodegenerative conditions. Dr Yao later in the session will offer a more detailed presentation on the development status of SCO – 088 in CML and SCC – 138 in PD. Our S1P receptor agonist SCD – 044 similarly has opportunities to move the needle in moderate to severe Psoriasis, Atopic Dermatitis and IBD. Kristine will speak about our plans for SCD – 044 later in the presentation. We have three delivery system platforms in active development. Earlier I touched upon PDP – 716 and SDN – 037 on our Ocular Retention system. We have additional programs coming up on our nano-technology platforms SDE – 124 for Type 2 Diabetes and SDD – 098 for Acne. We have discussed Oral Abuse Deterrence/overdose prevention platform in the past. We are now advancing one more asset on this platform to clinical development. Dr Yashoraj Zala and Dr Ajay Khopade will cover these programs in more detail later in the presentation. But I would like to go over the extent of activity on these platforms and its potential opportunity/cost implications briefly before we go into additional detail.

Let's go to slide 8
We have substantial progress on SCO – 088 program with clear evidence for its efficacy in CML patients with multiple TKI failures and therapeutic window now emerging from the multiple ascending dose study currently in recruitment. We intend to go to a pivotal study targeting registration for CML patients with at least 3 TKI failures later this year. We will also parallely explore the potential of SCO – 088 in first line CML once we accrue a critical mass of patients in the first registrational study which we hope to complete in 2020.

SCC – 138 has also made progress with its safety evaluation in Parkinson's Disease, in addition to pursuing an exhaustive pre-clinical evaluation in multiple model systems and PK studies to establish its ability to cross the blood brain barrier. We are currently in early start-

up stage of an exploratory proof of concept study in Parkinson's patients which we plan to complete by H1 2020. We are also maintaining a backup asset in SCO – 125 which is currently ready to move to early stage trials if we require a back-up.

SCD – 044, our 3rd generation S1P receptor agonist is currently in a multiple ascending dose study. We have established therapeutically significant level of circulating lymphocyte reduction at the low end of the dose range, indicating significant therapeutic window. We are currently evaluating multiple auto-immune disorders to finalize a lead indication for its Phase IIa proof of mechanism study.

SDN – 021, first program on our Opioid Abuse Deterrence platform is currently completing the pilot Human Abuse Liability study which is an important proof point for the platform. We intend to go to a set of pivotal studies for SDN – 021 in the second half of this year with a plan to complete a submission in the first half of 2020. We are also introducing another program on this platform into early clinical studies with a similar calendar, subject to the product achieving proof of principle.

I spoke about the Ocular Retention platform with PDP – 716 and SDP – 037 earlier. Both are now in Phase III start-up, targeting read-outs in H1 FY20. On the nanoformulations and long acting depot products, we have two programs which are targeting to enter early clinical proof of concept studies in the medium term.

These programs together represent a significant part of SPARC's value and offer several development possibilities and challenges.

I want to touch upon this briefly in the next slide, Slide 9 please.
I want to leave you with a broad point on our strategy which is somewhat of a shift from our story in the last few times we met. We have significant value inflection points for our portfolio coming up in the short to medium term. In the short term we are targeting five outcomes which can generate incremental cash flows; Xelpros™ and Elepsia™ XR approvals, Taclantis™ pivotal readout, PDP – 716 and SDP – 037 Phase III completion. In the medium term we have several

important and very significant value inflection points coming up. SCO – 088 read out in refractory CML, SCC – 138 proof of concept in PD, proof of concept for SCD – 044 in Auto Immune disorders, Initial submissions on our Oral Multiple pill abuse deterrence or overdose prevention platform and additional proof of concept read-outs. At the same time, we expect to see significant scale up of our clinical expenditure in many of our programs in the medium term, especially on our NCE programs.

We will carefully review our cash flows, resource allocation choices and risk/reward profile of our programs to decide which programs we should continue to fund internally. We have some targets to release resources already as you can see towards the bottom of this chart. We are currently in active partnering negotiations on these programs. We will license out these programs to appropriate partners who can help us realize the commercial potential of these assets fully.

We can go over this in more detail during our Q&A.

Slide 10, kind of summarises our R&D priorities. We have a largish clinical portfolio for a company of our size and tenure. Executing them well, on time, on budget with excellent scientific rigour is our number one priority.

We will continue to shape our portfolio with an intent to balance our risks and maximize ROI. We will apply tough filters in translational decision making while we continue to build up our pre-clinical roaster. Dr. Nitin Damle will go over our pre-clinical strategy briefly later in the presentation.

We will leverage our internal focus on strategic use of data & computational capabilities and aggressive external innovation partnerships to grow our pre-clinical portfolio. Transitioning the focus of our discovery effort to the development of potentially higher value platforms is an important priority for us.

And finally we will continue to invest in the build-up of our operating model- Not just in augmenting our lab infrastructure; Investments in

data and computational capabilities is an important priority. Continuing investments in augmenting our clinical, regulatory and biology skillsets is also a key imperative. Given the increased demand on resources, our focus will be on improving the quality of our strategic assets as against increasing the scale of our operations. We will also continue to leverage our external commercial and academic partnerships to keep the internal capabilities to a core capability set.

And before we move on, on slide 11, we have a high level overview of our ongoing transition to our new lab at Savli near Vadodara, Gujarat.

Here is a photograph of the facility we are transitioning to. We purchased this facility from the proceeds of SPARC exiting its share of the current lab at Tandalja. We expect it to be a cash neutral transaction. The facility fit out is on track for a transition in the second half of current financial year. We plan to move everything except the GLP animal research facilities which includes our pharmacology and toxicology operations.

With that I am now going to transition to my colleague Chetan Rajpara, Our Chief Financial Officer for a brief review of our cash flow projections for FY19 and beyond. Before that I want to thank you all again for joining us today. I look forward to the rest of the presentation and the Q&A at the end.

Over to you Chetan.

Chetan Rajpara: Thanks, Anil for the detailed overview of SPARC's strategy and key growth catalysts.

This is Chetan Rajpara. I am CFO of SPARC, and have joined the Company in Feb last year. I look forward to stay in touch with all you.

Let me share a high level financial summary.

I will keep this really brief. Slide No. 13 please…
During FY18, Total income was at INR 832 Mn (USD 11.9 Mn) [down 57% from INR 1,947 Mn], while Total expenses (incl. interest & depreciation) were at INR 3,292 Mn (USD 47.0 Mn) [up 5% from INR

3,137 Mn], resulting in to a Net Loss of INR 1,970 Mn (USD 28.1 Mn) [up 66% from INR 1,190 Mn). There was an exceptional one-time income of INR 490 Mn (USD 7 mn) on account of profit on exit of our Tandalja premises.

For Q1 FY19, Total income was at INR 180 Mn (USD 2.6 Mn) [down 27% from INR 246 Mn], while Total expenses (incl. interest & depreciation) were at INR 825 Mn (USD 11.8 Mn) [down 20% from INR 1,035 Mn], resulting in to a Net Loss INR 645 Mn (USD 9.2 Mn) [down 18% from INR 788 Mn].

As far as liquidity status is concerned, Cash on hand as at 31st August 2018 was INR 1,764 Mn (USD 25.2 Mn). Approval delays on Xelpros™ and Elepsia™ XR have certainly impacted our cash flows. We expect to get the approvals for these programs sooner. The company has already received a sum of INR 275 Mn (USD 3.9 Mn) towards the service tax refund and interest thereon. Further, the unutilized input tax credit under GST is INR 189 Mn (USD 2.7 Mn) as at 31st August 2018.

Now, let me move to the next Slide No. 14 for a few additional points on our cash situation.
For FY19, approx. 55% of the expenses are budgeted for the clinical programs. 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 FY19 would be reduced, if we are able to monetize certain assets this year as we hope.

We raised INR 5,000 Mn (USD 71.4 Mn) by way of preferential issue of warrants. Of this, we have received 70% amount i.e. INR 3,500 Mn (USD 50 Mn) till mid Jul-18. We shall receive the balance 30% i.e. INR 1,500 Mn (USD 21.4 Mn) upon the conversion of warrants by investors, by Jan-2019.

We have acquired a new R&D facility at Savli, near Baroda, and plan to invest approx. INR 300 Mn (USD 4.3 Mn) towards the cost of improvement and new equipment.

That's all on financial update from my side. Thank you very much for your valuable time. Over to Dr. SiuLong, Head of Clinical Development & Operations.

Dr. SiuLong Yao: Thank you, Chetan and, again, a very warm welcome to our investors on the phone.

As Chetan mentioned, my name is Siu Yao and I help oversee clinical development for SPARC and I will walk you through some updates on our activities in Chronic Myelogenous Leukemia (CML) and Parkinson's Disease.

Slide 16 gives you an update on SCO – 088, our Abl kinase inhibitor for the treatment of CML, that is effective against BCR-Abl and many of its mutants, including the very difficult to treat T315I.

We are currently in the midst of a multiple ascending dose study and have completed 5 dose levels. Preliminary PK from this study is compatible with once a day administration and the first subject has had a notable response and has now been benefitting from the drug for over 17 months.

The graphic on the right provides you a little more information on the types of subjects that we have enrolled to date. As expected, most of the subjects are chronic phase subjects, but we do have a mix of other subjects, including those with accelerated phase, blast phase and Philadelphia chromosome positive acute lymphocytic leukemia.

Slide 18 provides some information on efficacy we have observed to date. This graph summarizes the effects of treatment on white blood count. As you know, it is the white blood cell count that is often too high in CML.

In this graph, on the y axis is white blood count, and going across the bottom on the x axis, are various groups of subjects. There are all subjects that have passed screening, subjects that have been eligible to reach Cycle 4 and subjects that have been eligible to reach Cycle 6. You can see that the number of subjects progressively decreases

across these groups because you can only be eligible to attain later timepoints when you come on study early. Those subjects coming into the trial later, are not eligible yet to reach the later timepoints.

The dotted horizontal lines represent the normal range.

Overall, approximately 80% of the subjects have attained a partial or complete hematological response and there have not been any cardiovascular events reported to date. There was some transient Grade 1-2 neutropenia, but this was reported in 1 subject only.

Slide 18 summarizes the current program status for SCO – 088. We plan to complete the multiple ascending dose study by Q4 FY19.

The pivotal study will be a single arm, open label, efficacy study in approximately 150 subjects who have failed 3 or more TKIs. We plan to submit the protocol to the US FDA in Q2 FY19, and start the study subsequently in Q3 FY19.

Slide 19 moves to our efforts in Parkinson's Disease. As you know, there are over 1 million people afflicted with the disease in the US alone. This number is expected to grow to 1.35 million by 2022 with about 60,000 new diagnoses each year.

Unfortunately, currently there is no disease modifying treatment and existing treatments can only manage the symptoms of the disease. This is summarized in the graphic on the left which gives you a breakdown of the existing classes of drugs used in the symptomatic treatment of Parkinson's Disease.

Slide 20 summarizes some of the preclinical studies that we've done with SCC – 138. As shown on the left side of the slide, there have been a series of preclinical studies that have been performed. There has been a pre-formed fibril model, an induced human pluripotent stem cell model, and a viral model among others like the MPTP model we reviewed with you last year.

Of the newer models, data from the stem cell model are most mature and show that treatment with SCC – 138 has beneficial effects on Parkin activity, autophagic flux and synuclein metabolism, and synuclein inclusions. Some more detail from the stem cell studies are shown in the graphic on the right, with autophagic flux on the y axis and time going across the bottom on the x axis.

The bottom black line represents results with placebo. As you can see over the long-term in this experiment, results with SCC – 138 were the most promising in this study, as represented by the top reddish-orange lines.

Slide 21 goes on to summarize some additional information about the drug and program. SCC – 138 is orally available and has potential neuroprotective activity as we discussed. In addition to inhibiting Abl kinase, there is activity against Fyn which may also be involved in the disease. We've completed 6 dose escalations and have not observed significant AEs in the Parkinson's Disease population. Finally, preliminary PK data indicate the presence of drug in the CSF suggesting that the drug is able to get to its site of intended action.

Slide 22 summarizes the current status of the program. We are in the midst of completing the ascending dose study in Parkinson's subjects and plan to initiate a proof of concept study in Q3 FY19.

At this point, I'd like to introduce Dr. Kristine Nograles who heads our dermatology and rheumatology programs. Kristine.

Dr. Kristine Nograles: Thank you Siu. This is Kristine Nograles, and I am happy to give you an update on the SCD – 044 Program.

We are now on Slide 24 of the presentation.

SCD – 044 is an oral, selective S1P1 receptor agonist that SPARC, in collaboration with Bioprojet, is developing for the treatment of autoimmune diseases.

S1P1 receptor agonists are promising for the treatment of autoimmune inflammatory diseases as they cause diminished migration of lymphocytes out of lymphatic tissue. This results in a decrease of circulating lymphocytes, thereby reducing inflammation.

We've conducted pre-clinical studies in animal models of autoimmune disease, including psoriasis, with very encouraging results.

Therefore a Phase I study in healthy volunteers was initiated in order to help establish the safety profile of SCD – 044.

As we can see on Slide 25, we have completed the first part of the Phase I study wherein single dose administration of 6 dose groups of SCD – 044 have been tested versus placebo.

Decreases in lymphocyte counts were observed at all dose levels evaluated, and a maximal tolerated dose has been established. The figure on the right displays the results on one of the doses tested, which demonstrates more than 50% decrease in lymphocytes from baseline at four to eight hours after single administration of SCD – 044. The terminal half-life is approximately 34 hours and this is independent of dose.

We are also happy to report that Part 2, which is the food effect study, has also been completed.

The results of Parts 1 and 2 have been encouraging, and we are now currently conducting the 3rd part of the study to evaluate the safety of multiple dose administration of SCD – 044.

Slide 26 summarizes the current status of the development program. We expect the Phase I study to be completed by Q1 FY20, and anticipate to initiate Phase II after that. The indications we are considering for development include psoriasis, inflammatory bowel disease and atopic dermatitis.

Thank you very much for your attention. Now I would like to turn the presentation over to Dr. Hany Michail, our Vice-President for Ophthalmology. Hany.

Dr. Hany Michail: Thank you, Kristine. I'm Dr Hany Michail, responsible for Ophthalmology clinical programs.

I would like to update you on PDP – 716 on slide 28.

This is an eye drop formulation of brimonidine, an alpha agonist, for once a day use in patients with glaucoma.

The currently available brimonidine is dosed 3x/day as a second line treatment in glaucoma. This formulation technology, called TearAct™, uses a drug-resin complex to enhance ocular retention for better delivery to the target tissue.
The reduction of dosing from 3x/day to 1x/day will be a relevant decrease in medication burden for these patients who typically have to dose eye drops indefinitely.

If you turn to slide 29, you can see we ran a human Phase II study vs. Alphagan® P which is dosed 3x/day. PDP – 716 met the pre-specified endpoints for clinical equivalence at all-time points. We also noted a comparable safety profile with no new adverse events.

On slide 30, we provide development update. With the Phase II data, we approached the FDA with a Phase III plan. We submitted the IND and gained alignment on a path forward that consists of one Phase III study with Alphagan® P as a comparator.

We will enroll roughly 666 subjects in 27 sites across US. We intend NDA submission by Q4 FY20.

Now, I'd like to tell you about SDP – 037 on slide 31.

This is a reformulation of a known steroid for reduced dosing frequency.
Most steroid eye drops today are dosed 4x/day, and are available as hazy/milky drops that blur the vision upon instillation.

SPARC has leveraged micellar technology to deliver a clear solution eye drop with 2x/day dosing.

On slide 32, we provide a brief status update.

We have shared our Phase III plan with the FDA and the IND was granted recently. We have alignment on a single Phase III study with vehicle control to support NDA submission.
We intend to enroll 386 patients across 15 US sites. We plan on NDA submission by Q2 FY20.

Thank you for your attention and I'd like to introduce Dr Ajay Khopade to continue.

Dr. Ajay Khopade: Thank you Hany and good evening to all those who have joined this call.
I am Ajay Khopade and I oversee Non-oral formulation development at SPARC.

We are on slide 34. This is an update on Tactlantis™.
Firstly, let me recapture the product in short. Taclantis™ is a new nanoparticle formulation of paclitaxel, free of Cremophor & human serum albumin prepared using SPARC's proprietary, IP protected Nanotecton™ platform technology. As you may already know, the product has been marked in India as Bevetex® for past couple of years.

Tactlantis™ is now in a US FDA registration trial versus Celegene's albumin bound paclitaxel, Abraxane®. Last year we had presented the data on phamacokinetics of Taclantis™ from our pilot PK studies. Comparison of pilot PK data and PK simulation exercises suggested that Taclantis™ may possess bioequivalent paclitaxel pharmacokinetic properties to albumin bound paclitaxel. Last year itself, SPARC launched approximately 100 patient pivotal bioequivalence cross-over trial. Study is conducted on patients with locally recurrent or metastatic breast cancer.

The pivotal trial stands fully enrolled. 142 patients were randomized out of which we have now a 99 evaluable patients. These will be

sufficient numbers that are required to meet the desired statistical power. The PK samples are currently under analysis and the data readout is expected by Q3 FY19 and NDA filing is planned in the Q4 FY19.

Slide 35
We are presenting SDE – 124 program for the first time to our valued stakeholders. It reflects our strategic commitment to leverage capabilities in complex drug delivery systems.

SDE – 124 is a formulation of GLP-1 receptor agonist. GLP-1 receptor agonists are the class of drugs used for the treatment of type II diabetes.

National diabetes statistics report 2017 released a data that estimated about 21 million people in U.S. had diagnosed type 2 diabetes inclusive of all ages. An estimated 1.5 million new cases of diabetes were diagnosed in 2015. It was a 7th leading cause of death in United States. The total direct and indirect cost of diagnosed diabetes in United States was $327 billion in 2017, a 26% increase over last 5 years and accounting to $237 billion of direct medical cost.

Now, talking about the market- GLP-1 receptor agonists have observed substantial gains in market share with sales exceeding $9 billion in 2017 which was attributed to the glycemic and non-glycemic benefits they offer, such as, low incidence of hypoglycemia, CV-benefits, weight and blood pressure reductions. There is 39% YoY growth and is expected to witness a CAGR of estimated 8.3% in next 5 years.

Problem with current treatment is that it has high injection burden per year. This leads to inadequate compliance and reduce patient outcomes.
To solve this issue, SPARC has developed a long acting subcutaneous injection for self-administration which reduces needle burden significantly ensuring patient acceptability. Head to head data in the literature suggest that the long acting GLP-1 receptor agonists

produce superior glycemic control when compared to their short acting counterparts.

The formulation is in the form of a gel that utilizes intrinsic gelling property of the active ingredient and excipients. Formulation is designed with primary focus on patients. We optimized our product for ease of injection and desired duration after determining that a significant patient population would accept and benefit from it. This patented technology allows for tuning of delivery rate and duration of treatment. The drug release occurs by slow erosion from the site of administration.

Slide 36
This slide presents data from preliminary proof of concept animal studies.

The graph on left hand side shows a comparative pharmacokinetic study in Sprague Dawley rats. The dark and light orange lines represent the highest & the lowest plasma concentration for the daily subcutaneously administered GLP-1 reference drug. The dark & light purple lines are respective peak and trough for the SPARC's weekly injection. You can see that the concentration lies between the peak & trough obtained from a reference injection suggesting that the target therapeutic concentration is maintained for the desired duration.

The figure on the right hand side shows the efficacy data in diabetic rats. The y axis in the graph represents the HbA1C levels. The HbA1C test tells you the average sugar levels in the blood over a period. The x-axis represents number of days. The different colored bars represent different GLP-1 formulations of Test and marketed reference controls. One can see that the HbA1c levels significantly decreased after treatment in all groups. The Test formulation is either comparable or better than the marketed reference formulations.

Slide 37
This slide shows the current developmental status of SDE – 124. Short term stability is ongoing on the prototype formulation. SPARC has received a positive FDA response to pre-IND submission. The written

response letter detailed the FDA's requirements for the CMC, non-clinical & clinical developmental plans and confirmed that the drug would be subject to the 505(b)(2) approval pathway. The FDA's response provides SPARC significant optimism for immediately pushing forward IND enabling activities towards Phase I early proof of concept studies in human.

I now handover to my colleague Yash to present further updates on other programs.

Yashoraj Zala: Thank you Ajay, Hello everyone, I am Yashoraj and I will take you through updates on SPARC's dermatology program first, followed by an update on the Abuse and Overdose Deterrence platform.

SDD – 098 on Slide No. 38 is indicated for the treatment of Acne. According to American Academy of Dermatology, more than 5 million people seek medical treatment for Acne and it is known that Acne can significantly impact productivity for affected individuals.

SPARC has developed a topical formulation of an oral anti-bacterial agent – Minocycline with an objective of providing a topical treatment option for Acne and at the same time reduce systemic side effects associated with oral dosing.

SPARC has completed the Pre-IND meeting with US FDA and we have received responses to queries and guidance on further planning of the program.

Currently, the Phase I enabling toxicity studies are ongoing.
The upcoming milestone for this program is the IND filing by Q4 FY19.

I will now move onto an update on SPARC's Abuse and Overdose Deterrent Platform.

SDN – 021, as discussed on Slide no. 40, is an abuse-deterrent formulation of an opioid in combination with another pain relieving agent designed for immediate release. SDN – 021 aims to address the unmet need of oral multiple pill abuse.

For the Immediate Release opioids or IR as they called for short, about 187 million Prescriptions are generated with an estimated value of about 2.23 billion USD.
Since IR formulations are easy to manipulate it has been reported that 66% of the abusers prefer IR formulations.

Though SDN – 021 primarily targets to curb abuse by oral route, it also has abuse deterrent properties for the nasal and intravenous routes as well.

SDN-021 has been evaluated in preliminary Category 1 studies.
Category 1 studies are in-vitro tamperability or manipulation studies which are conducted to determine the vulnerability of the formulation. Commonly employed methods include grinding or extraction for the purpose of ingesting, snorting or injecting, methods such as chemical and thermal stress studies which can separate opioid from other components and so on. The studies demonstrate SDN – 021's potential to resist commonly employed tampering techniques, which is a function of the chemistry based deterrence mechanism as well as the presence of an aversive agent in the formulation.

Slide No. 41 highlights the key findings from a primary market research which was conducted by SPARC in the US.

The slide depicts that 87% of the physicians view oral multiple pill abuse deterrence as a driver to utilize SDN – 021 whereas 75% of payers consider the deterrent property as a major benefit. These findings reinforce SPARC's original thoughts when this program was started.

Slide no. 42 captures the current status and plan of the program.

Currently, a pilot Human Abuse Liability study is underway, which will evaluate the drug liking Emax as the primary end point between SDN – 021 and an active comparator which is non-abuse deterrent.
The study was planned in two cohorts of which Cohort A recruitment is completed and Cohort B recruitment is ongoing.
The topline results are expected by Q3 FY19.

A Phase 3 clinical study to demonstrate efficacy has been planned in Q3 FY19, post FDA concurrence on the study design.
The pivotal Category 1 study is targeted to commence in Q1 FY20.

I now move over to Slide no. 43 which introduces SDN – 118 which is a new program targeted to deter overdose of prescription drugs.

Suicide from intentional overdose is one of the top 10 leading causes of death in the USA.
SPARC has developed a formulation of an anti-depressant based on its proprietary overdose prevention technology platform.
On ingestion of multiple pills - either intentionally or accidentally, the system works to reduce the release rate and extent of the drug.
Till date, SPARC has completed human PK studies on a single pill and now plans to progress further.

Before I communicate the future plan of the program, I would like to take you through the mechanism of the technology described as described on slide no. 44

The diagram on this slide shows that the formulation contains an API which could be either embedded or coated with a reverse enteric polymer. The reverse enteric polymer is soluble in acidic pH and insoluble at an alkaline pH.
The API plus polymer combination is further formulated into a dosage form, which contains a fixed quantity of a pH modulator apart from other excipients.
The step by step mechanism of release from a single pill is described below the diagram on the left hand side.
When a single pill is ingested, it disintegrates in the stomach and releases the pH modulator. The quantity from 1 pill is such that it does not affect the pH micro environment of the stomach.
Thus, the reverse-enteric polymer solubilizes and the therapeutic dose of drug is delivered.

On the right hand side below the diagram, mechanism of release from multiple pills has been explained.

When the multiple pills encounter stomach, they disintegrate and release the pH modulator.
The quantity of the pH modulator released from multiple pills is such that it changes the stomach pH micro environment.
The elevated pH restricts polymer solubility which in turn restricts the drug release.
Thus less drug is released at a slower rate in the stomach.
Since the reverse enteric polymer remains insoluble in the intestinal regions also, therefore drug release is retarded further.
Thus harm arising from overdose is likely to be reduced.

Going over to the status update on slide 45,

SPARC has completed the pre-IND meeting for this program with the US FDA and the IND filing is planned for Q3 FY19.
Further, Overdose Proof-of-Concept study has been planned in Q4 FY19. This study is designed to mimic the overdose condition in-vivo but without exposing the human subjects to toxic levels of the study drug.

With this update I request Dr. Nitin Damle to take it forward from here. Thank you.

Dr. Nitin Damle: Thank you Yash and good evening to you all.
My name is Nitin Damle and I will discuss strategies to develop early stage pipeline at SPARC.

Slide 47 please.
Consistent with our vision for developing novel innovative but differentiated therapeutics, our current efforts are focused on discovery of novel small molecule drugs. Earlier you heard from two of my colleagues about two of our novel chemical entity or NCE programs focusing on targeted therapies for BCR-ABL and S1PR1.
In light of our internal strengths and capabilities, we have been focusing on three major therapeutic areas; Oncology, Neurology and Immunology/Inflammation.

You already heard about our programs in Dermatology and Ophthalmology that reflect our current immunoinflammatory disease focus.
Our strategy in early stage drug discovery is based on the three prong approach: Internal ideation; External Innovation and Exploration of novel alternatives to NCE drug discovery.

As far as ideation for our internal programs is concerned, we have been pursuing the fast follower approach wherein we follow NCE discovery strategy in a clinically and commercially validated space. In this regard, we chase validated drug targets in the above selected therapeutic areas for NCE discovery and subsequent development.

While we focus on NCE discovery, we will continue to be engaged in a timely pursuit of commercially attractive 505(b)(2) opportunities leveraging our current strengths, capabilities and experience in formulation sciences in developing complex drug delivery systems.

In addition, we have also been exploring novel therapeutic approaches or modalities outside of traditional small molecule NCE discovery. However, I will not be speaking about these at this time.

Slide 48 please.
Our focus in the Oncology therapeutic area rests on attacking treatment resistance. There have been a number of exciting targeted small molecule therapeutics developed during the last couple of decades and the targeted therapy will continue to be a fertile area for drug discovery and development in the foreseeable future. While such targeted NCE therapeutics provide significant anti-cancer benefit, resistance often develops against many of such therapies. Resistance to these approved targeted therapies is often attributed to mutations in molecular targets that render the lead targeted therapy ineffective and thereby necessitating development of newer targeted therapies capable of attacking such resistant states. Our current lead program in CML with BCR-ABL inhibitors is consistent with this approach. In addition to mutations in the molecular targets, acquired resistance in tumors can also be due to the adaptation by tumor cells of alternative signaling pathway(s) not inhibitable by the lead targeted therapy.

SPARC is particularly interested in developing targeted therapies for hematological malignancies and endocrine tumors that are responsive to hormonal therapies. Some of the key examples of targeted hormonal therapies include Cyp17 inhibitor Abiraterone, Androgen Receptor-targeted enzalutamide, Estrogen Receptor alpha targeted Tamoxifen as a selective modulator or Fulvestrant as a selective degrader. Similar examples of targeted therapies in B lymphoid malignancies against which resistance develops are BTK-targeted Ibrutinib and Acalabrutinib.

Slide 49 please.
SPARC also has focused interest to develop disease modifying therapies for neurodegenerative diseases. Our current exploration of ABL inhibitor in Parkinson's Disease is consistent with this commitment. Currently, there are no approved disease-modifying therapies for any of neurodegenerative diseases and thus even an incrementally effective therapy capable of disease modification is very likely to be of high clinical and commercial impact. There are four main but unique neurodegenerative diseases that are often talked about, each characterized by unique misfolded protein inclusions that define the disease. For example, Parkinson's disease is characterized by inclusions of misfolded alpha synuclein that form Lewy bodies or Alzheimer's disease with inclusions of amyloid beta and tau. Two other neurodegenerative diseases, Huntington's disease and amyotrophic lateral sclerosis or ALS similarly show disease-specific protein inclusions. In spite of their uniqueness, each of these inclusions is believed to stimulate cellular responses that eventually culminate in the loss of viability of the involved neurons. In these examples, neuronal death is believed to be carried out by common mechanisms and also in a large part, due to the cell's inability to clear the inclusions by a process known as autophagy. So the drugs that accelerate autophagy are likely to be beneficial in controlling the disease advancement. We hope to focus, for drug discovery, on these central mechanisms that culminate in neuronal death.

Slide 50.
Now let me speak about our efforts in external innovation. To complement our internal ideation strategy, we have pursued external collaborations with global academic centers, research institutes and individual thought leaders in areas of our interest. In this regard, SPARC via collaborations, not only funds innovative research with select investigators but also provide in-kind contribution leveraging our internal R&D infrastructure and development capabilities. We have devised flexible partnering structures for such collaborations ranging from standard in-licensing of a mature but clinically untested assets to funding of individual projects with the exclusive option to in-license the assets in the event of successful outcomes.

As shown in Slide 51, an example of such an academic engagement, is our partnership with Skandalaris Center at Washington University School of Medicine in St. Louis, MO in which translational inventions are identified with the keen eye for commercialization.
In this collaboration, SPARC has joined the LEAP Program organized by the Skandalaris Center. LEAP stands for "Leadership in Entrepreneurial Acceleration Program". In this SPARC-LEAP program, we invite research proposals for funding in areas relevant to SPARC's interests. In this regard, SPARC will provide up to $250,000 in funding per program per year for up to three years to explore innovative science with a keen eye towards drug discovery. In addition, SPARC will also provide in kind support with unique capabilities from our internal infrastructure. SPARC holds the option to exclusively license any emerging intellectual property from this collaboration, on a worldwide basis.
We do look forward to the development of novel drug discovery programs from this key collaboration.

I think, I will stop here and hand over to Jaydeep Issrani to discuss the competitive landscape of our key programs. Jaydeep.

Jaydeep Issrani: Thank you Dr. Damle.
I will be sharing details about the market opportunities for our late stage assets.

We are on slide 53 now
Taclantis™, is a Cremophor and albumin free nano-formulation of Paclitaxel.
In the primary market research that we conducted in US, more than 45% physicians surveyed have documented hypersensitivity reactions in over 10% of their patients with Cremophor based paclitaxel formulations.
More than 60% of doctors say that the incidence of hypersensitivity and ease of administration would be important factors in the choice of a formulation.
Even though there are hypersensitivity reactions associated with Cremophor based paclitaxel formulations the market is still dominated by Cremophor containing formulations.
As depicted in the graph Cremophor based formulations account for ~70% of all units sales of paclitaxel in the US. We believe availability of novel formulations and pricing can be a major driver for shift from Cremophor based formulations to Cremophor free formulations like Taclantis™.

Moving to slide 54
PDP – 716 is a novel once a day formulation of Brimonidine. As per IQVIA, current US Glaucoma market is estimated to be at $3.0 billion and Brimonidine is highest prescribed anti-glaucoma drug after prostaglandins. Brimonidine commands ~14% of total Glaucoma value market with 3.7 Mn prescriptions dispensed annually.
Brimonidine 0.1% and 0.15% dominates the market in both value and volume terms in spite of availability of the generic versions of higher strength.
Branded product continues to garner significant share of prescription volume even though there is genericization.

Slide 55
Slide 55 depicts the preference of US ophthalmologists for use of novel once-a-day formulation of Brimonidine compared to currently available TID formulation.
Over 90% of the physicians surveyed said they would use once-a-day formulation of Brimonidine, suggesting large unmet need with respect to patient dosing and compliance.
We believe our novel once-a-day formulation can address compliance challenges associated with the currently available formulation and take meaningful share of the Brimonidine prescriptions.

Slide no 56
Moving on to market opportunity for SDN – 037.

SDN – 037 is novel BID formulation of an approved steroid for treatment of pain and inflammation post cataract surgery.
Cataract is the leading cause of blindness and affects more than 24 mn people in US over the age 40.
Topical steroids are standard of care for the treatment of pain & inflammation associated with Cataract surgery and the US topical ocular steroid market is currently valued at $ 750 mn with ~9 mn Rx dispensed annually.
Currently marketed formulation needs to be dosed four times-a-day and also caused blurring of vision. Our novel formulation is expected not to cause blurring of vision and with the advantage of BID dosing would provide significant compliance benefit to the patients treated with steroids post cataract surgery.

Slide no 57
Slide 57 provides update on market opportunity for SCO – 088 for the treatment of chronic myeloid leukemia.

As we know majority of patients stop responding to initial treatment with 1st and 2nd generation TKIs, there is a need for newer agents for treatment resistance disease.

SCO – 088 is developed to target treatment intolerance and resistance associated with the currently available tyrosine kinase inhibitors. Being highly selective kinase inhibitor it is expected to be free of cardiovascular side effects observed with other agents. As per IQVIA, there is increase in use of newer generation TKIs over last couple of years at the same time, as per primary market research conducted by SPARC there is a very low physician satisfaction score with the available third line and beyond treatment options.

We believe that the safety advantage observed with SCO – 088 may give us a significant market opportunity to position our compound versus available treatments.

That is all from my side and I Thank you all for your patient listening.

We now open the call for questions & discussion.

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

Ketan Gandhi: My first question is for SCO – 088, what is the timeline required for completing pivotal efficacy study and sample size of patients agreed with FDA and can this study becomes the basis for NDA filing?

Anil Raghavan: Thanks, Ketan for the question. Our current expectation is that the study that we are proposing to start towards the third quarter of this year is going to be the registrational study, we are in the process of mobilizing the startup of that program and we are also consulting with FDA as we speak, so we do not have signed off patient number yet for the registrational program, but based on the experience of similar

programs, we are assuming that this design that we are proposing would be the registrational study for this program. If we receive additional inputs from FDA which necessitate change in protocol we will treat that as an amendment to this program. Our intent is to complete this program in the first half of 2020.

Ketan Gandhi: Can this pivotal study become the basis for NDA filling?

Anil Raghavan: That is correct.

Ketan Gandhi: What is the key difference between SCO – 088 and SCO – 125 since both are focused in the CML?

Anil Raghavan: SCO – 125 is a backup compound. In NCE programs most firms actually would maintain a backup if something untoward happens to lead program. One would not want to go back to the drawing board and start all over again. So you typically have a follow-on/backup program which can step in if the lead program does not deliver as expected for example say safety issues or challenges in pharmacology property, hence one maintains a backup compound like we are taking for this program, but based on what doctor Siu presented and what we are seeing in this early program, we do not anticipate the need to move to a backup program at this point.

Ketan Gandhi: For SCC – 138, what is the likely size for Phase II and Phase III study before NDA filing?

Anil Raghavan: What we are now doing is the proof-of-concept study, the proof-of-concept study is a two dose versus placebo study and our current estimation is around 460 patients in this trial, and we do not have size estimation for additional Phase II study that we have to do or the registrational phase III. At this point we are focused on creating a proof of mechanism in this Phase IIa study that we are about to embark on.

Ketan Gandhi: My second question is on Taclantis™. In presentation you have not mentioned likely peak sales and time required to achieve peak sales. Any update on that?

Anil Raghavan: We have not projected out the commercials in this session, I mean, typically what we see is a four-year period to peak sales, but the

circumstances of this program is slightly different because we anticipate generics coming sometime in 2022, so we may probably look at this in two phases. We will have a phase where Abraxane® and non-infringing formulations of Abraxane® will have the field till sometime in 2022 and after that we will see introduction of limited number of generic products. There are a few things to be considered, 70% of the market is still on regular paclitaxel and not on nano paclitaxel, more wider availability of newer formulations will drive the significant conversion from regular paclitaxel to nano paclitaxel, so that phase probably will come from 2022 onwards when more generics come to market, we do not have a forecast that we can disclose to the market at this point.

Ketan Gandhi: What is de-risking strategy with regard to the manufacturing of this product, I mean, have you developed any alternate manufacturing site and our preparedness to fight the litigation from Celgene if FDA approval is received ahead of the resolution of litigation?

Anil Raghavan: Let me go ahead with the second part of the question. Our formulation is a non-infringing formulation which does not have albumin, so we do not anticipate genuine challenge coming in to our formulation, but we cannot rule out in this phase and we will see what we encounter. So at this point we do not see the grounds for an authentic challenge to the formulation because of the non-infringing nature. We are evaluating the need for alternative manufacturing site, this product will be filed from Halol at the moment and if we conclude that there is a need and if the economics support, then we will pursue an alternative site once the submission is made.

Ketan Gandhi: What is the likely size of Phase II trial for SCD – 044?

Anil Raghavan: As Kristine mentioned, we are still exploring multiple lead indications for the proof-of-concept study, we have psoriasis in mind where we have excellent pre-clinical result, we are also evaluating a couple of other options like colitis or IBD, atopic dermatitis can also be a possibility. So at this point we do not have closure on the lead indication. Until we have closure on the lead indication, we are not in a position to forecast out a size.

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

Manish Jain: I wanted to learn on the abuse-deterrent side, where Yash mentioned about the pilot studies right now. I just wanted to get a rough idea about the time required to complete the pivotal HAL studies and whether these pivotal HAL studies will suffice for NDA filing?

Anil Raghavan: Hello Manish, Good Afternoon. The time required for pivotal HAL study is not going to be a very longish, it is going to be less than a year to complete, but it is not going to be the only trial that we need to complete. As Yash mentioned in her slide, we will have Phase III pain study, which we are already initiating now and that will establish the efficacy in pain setting for this abuse-deterrent formulation. Then oral multiple pill abuse-deterrence need to be established in the human abuse liability study. We may probably also need to have additional PK studies and taste aversion study as part of the package and our expectation is that we will be able to complete all this by end of next year and we target closure of the development phase of this program towards the end of next financial year.

Manish Jain: On the marketing front, do you think one partner will suffice to mine the opportunity in US?

Anil Raghavan: At this point, our intent is to go with one major partner who can help us maximize the value of the program, but at the same time we understand the significant volumes involved and the significant challenges in ensuring continuity to the program, which in turn affects our ability to substitute unprotected formulations. We do not have fully etched commercial strategy in that sense, but also we need to factor in the challenges some of the other ADF products faced in terms of volume pickup. So one needs to balance out fairly smart commercial strategy and fairly smart pricing strategy to fully leverage the opportunity. We are in the process of concluding our market research, in fact we had read out from our market research recently, and as we move forward into later part of this year, we hope to formalize our commercial strategy based on what we are hearing from both prescribers and payers.

Manish Jain: On the FDA side, just want to understand a legal situation that once your product has established ability to supply the entire market, would generic Norco products and Norco be asked to withdraw?

Anil Raghavan: I do not want to speak for the agency, I mean, as things stand, current guidance does not allow that kind of withdrawal of generic Norco products, but we are seeing an increasing trend towards prescription preferences driven by statewide legislation. Several states including some largish ones like Florida, etc., now have statewide legislation which mandates inclusion of abuse deterrent products in formularies and preference of those products in state supported programs, which as a trend is clearly spreading on the back of increased awareness of opioid abuse problem and its magnitude. So we feel that it would be more policy driving that change as against regulatory mandate.

Manish Jain: One more question on abuse-deterrent itself. When I look at hydrocodone and oxycodone being the largest drugs and we are developing just one of them, is there a merit in developing both of them concurrently?

Anil Raghavan: If you look at the slides which Yash presented, there are two variance of the same platform and there is a little twist in the second product, so we are addressing two specific problems - one is the problem related to opioid abuse where we have to find a way to create less pleasurable experience and reduce the propensity to abuse. While in overdose prevention which is equally important problem in many classes like antidepressant or benzodiazepine, the challenge is to ensure the availability or yield of the drug under certain toxic threshold. So in that sense what we are doing at the moment is testing out two proof of principle programs, in the case of opioid abuse-deterrence the proof of principle is near in the sense as soon as we have a read out from the human abuse liability study, we have proof of principle for that platform and we would at that point expand it beyond the first product to at least a few more products on the platform.

Manish Jain: Moving on from abuse-deterrence, I had a question on the derma products have we deprioritized S597?

Anil Raghavan: We have conducted exploratory trial in psoriasis with S597 topical and we have seen reasonable activity for S597 topical in the psoriasis trial and we are looking at the options for that program. The topical steroids is a crowded market and we need to look at our ability to create a meaningful differentiation. We are in the process of analyzing that data before taking a call on further developments. As things stand, I do not have disclosure to make in terms of formal deprioritization of the program, but at the same time there are several considerations that we need to take seriously before we commit to Phase II program including competing program for resources.

Manish Jain: Just an associated question on derma side on Minocycline where we have decided to out-license it sooner rather than taking it through clinical development ourselves. Roughly wanted to understand what will be clinical trial cost involved in this?

Anil Raghavan: Again it is hard for me to give an exact number here, but we are clearly talking in terms of closer to $25 million to $30 million for development and also being a microsphere product manufacturing cost associated with this is also quite significant. As you can see in our portfolio, we have now several early clinical programs which are all scaling up to either largish proof-of-concept trial and/or in some cases late stage registration program and we want to manage this in a financially prudent manner. So there is only limited basket of resources that we can commit to some of these programs and that is the call that we have taken in terms of which programs we should own going forward and which program we are probably better off taking out from resource allocation standpoint.

In that sense Minocycline is one such program where we have definite partnership interest, there is only very limited number of players in this market, Minocycline is an important product in Acne. As we saw significant velocity for transition from oral product to topical product in Clindamycin, we believe there is enough strength in the value proposition and at the same time we need to look at what these programs are competing against in our internal portfolio and we see some of the other programs are better bet for resource allocation compared to Minocycline.

Moderator: The next question is from the line of Subroto Sarkar from Mount Infra Finance. Please go ahead.

Subroto Sarkar: Sorry, maybe I missed out like, can you just help me to understand the simple thing like what will be the market potential for like Elepsia™ XR and Xelpros™?

Anil Raghavan: In earlier editions of this call we have made guidance for Elepsia™ XR and Xelpros™, both were in the range of $50 to $75 million and we do not see a reason to revise that early estimate that we have shared with the market.

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

Ketan Gandhi: Regarding PDP – 716 and SDN – 037, for Phase III how many patients have been enrolled till date and have we experienced any challenges for patient enrollment?

Dr. Hany Michail: We have not started enrollment yet, we are in the process of activating the sites for both of those studies, so we have not had any problems.

Moderator: The next question is from the line of Manish Jain from Gormal One. Please go ahead.

Manish Jain: I just wanted to understand rationale to develop SDE – 124. Primarily are we trying to enter a new formulation such as a long-acting self-administered products or is it to get into diabetes or it is just an opportunistic plan since we had the technology available in-house?

Anil Raghavan: Let me first tell you what it is not, it is not a deliberate entry into the diabetes market and we do not have any strategic intent to get into the diabetes market given its complexity and also the need for more specialized clinical expertise to navigate such programs. We do have internally fairly robust long-acting depot technology on the back of the work that we have done on nanotechnology platforms and microsphere platforms. So this is an opportunistic leverage of in-house capability and we feel that the market opportunity is real and especially the product that we are talking about is a class leading GLP-1 product and we have seen from the experience of Exenatide, patients and prescribers would

like to stay on the agent that has worked for them, so in that sense this agent has been the market leading product for a long time and even with introduction of newer product, the franchise continue to sustain and grow. We feel that latent demand for a long-acting product for this specific active is a significant unaddressed opportunity and that is what we are opportunistically going after.

Manish Jain: My second question was on Xelpros™ and Elepsia™ XR during results call by Sun, Abhay Gandhi was stating that they have a huge bunching of branded products getting clubbed together, so there was a risk that he could delay the launch of Xelpros™ by 6 to 12-months. Now here you have partnered with a partner already. How do you ensure that for your future pipelines, you avoid this kind of situation happening to SPARC products?

Anil Raghavan: First of all I do not want to comment on Abhay's comments he might have made on the call. We do not have any formal communication from our partner that there is a possibility of delay in the launch of these products. You have specifically mentioned Xelpros™ has the potential delay. My understanding is that ophthalmic effort is very active.

Manish Jain: My apologies, it was Elepsia™ XR.

Anil Raghavan: Right, so my comment is true for both products that if you anticipate a delay in Elepsia™ XR we will actually look at that when we have more formal communication from Sun, our commercialization partner. At this point there are commitments on the launch of these products if we feel that our value of the platform cannot be leveraged with the current arrangement then we will at that point look for alternative partners, but we do not feel that that is going to be the case.

Manish Jain: My last question today was on SCO – 088. At what point of time do we start leveraging on additional indications that we can go after for these products in addition to CML?

Anil Raghavan: Even though it is quoted separately as you have been following this program for long, the program in Parkinson's disease is essentially leveraging the same compound. So we are very interested in the neuroprotective role of the Abl pathway and we are exploring our Abl

tyrosine kinase inhibitors in multiple neurodegenerative context. We see two tracks for our Abl program going forward and certainly the last line setting in CML that we are pursuing for registration is our immediate opportunity which can realize in 2020 timeframe and we are also seriously interested in the first line opportunity in CML and there may be interesting ways to make yourself relevant even if that initial lines are getting genericized. We feel that for safer and efficacious product, there may be important clinical strategies to still make yourself a viable operator in the initial setting in CML. We will be pursuing first line study in CML once we accrue a substantial number or critical mass of patients in the last line setting and parallelly we have significant interest in neurodegenerative conditions, Parkinson's was a primary theater so far in terms of pre-clinical evaluation and last year we have made a transition to clinical evaluation with the safety cohorts and also PK studies to establish its ability to cross the blood-brain barrier. Now we have increasing pool of evidence to establish this as attempt worth making in neuro-degeneration, we intend to go beyond Parkinson's while actively pursuing a proof of mechanism studies in Parkinson's disease.

Moderator: Thank you. We will take the next question from the line of Harit Ahmed from Spark Capital. Please go ahead.

Harit Ahmed: On the two ophthalmic assets, PDP – 716 and SDN – 037, given these have potential NDA submission for the next 18-months, can you share which manufacturing facility you will be filing these from? Your efforts on partnerships for these two assets. Can you share some more color what stage are you at now and any potential timelines for closing a partnership?

Anil Raghavan: So let me address the second part of your question first. We are in active conversations with multiple potential partners for these programs and we hope to conclude these discussions soon. I do not want to give you an exact timeline for closure of these programs because you know the nature of the kind of conversations are uncertain but at this point we are encouraged by the kind of response that we are getting and the stage that we are in, we are very much on plan for partnering out these programs. In terms of manufacturing, we have currently developed this product from a plant very near to Sun plant near to Halol… not Halol

itself and we will continue to explore the need for a backup site as we get closer to the submission.

Moderator: Thank you. We will take the next question from the line of Manish Jain from Gormal One. Please go ahead.

Manish Jain: On SDN – 037, just want to understand given the kind of profile that we have, is there a room for premium pricing over the current available opportune branded product that we will have SDN – 037 compete over?

Anil Raghavan: Yes, we believe so, if you look at that space of steroids particularly in cataract surgery and more broadly in that market, recently there was an approval for loteprednol which is a milder steroid. The product that we are developing has dedicated franchise and certain committed prescriber base. So we believe that product offers a certain niche in the overall steroid basket in ophthalmology and particularly in inflammation resulting from cataract surgery. So our sense on your question whether we can justify premium pricing, we believe that there are grounds to believe that we can.

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

Sameer Baisiwala: Just a quick one, Anil here, on Taclantis™, what sort of filing would this be 505(b)(1) filing that you would be doing?

Anil Raghavan: This is (b)(2) Sameer.

Sameer Baisiwala: That means that technically speaking the innovator can bring about a lawsuit which can suspend your approvals for 30-months?

Anil Raghavan: It depends on the patent supporting our program. We feel that the technology that we are bringing up is absolutely non-infringing in the sense that it does not have albumin and it is not Q1, Q2 same product, so we do not think that they have legitimate grounds to come up with the challenge and ask for 30-months stay but we will play as it comes and we do not want to comment on their strategy.

Sameer Baisiwala: No, it is just that it leaves a room to do that and no matter how strong your position is, it can delay the commercialization prospects, so that was a technical point.

Anil Raghavan: Our sense is that it is still a possibility, but we believe that given the non-infringing nature we may probably be able to navigate the litigation process in an expeditious manner compared to infringing product if at all it happens.

Sameer Baisiwala: It is that one year to do your submission and another year for maybe approval and then god forbid litigation that is another 24 to 30 months, you are already at 2022, so just checking on that?

Anil Raghavan: No, I have several hands going up in the room to answer that question, but before I let them in, let me make one point, we have actually completed the study and we do not actually see one year to submission, but on the finer points probably Vinita and Jaydeep can address.

Vinita Kulkarni: The first patent that expires I think is in December 2023, so being clearly a non-infringing formulation, we really do not see much chances and then we have some scope of settling.

Sameer Baisiwala: Can you repeat the second part?

Dr. Nitin Dharmadhikari: The first patent that is expiring in December 2023 where we believe we are clearly non-infringing.

Vinita Kulkarni: So the 18 months stay would anywhere cover up all that period.

Sameer Baisiwala: But courts will decide that and courts can take anywhere 20 to 30 months.

Anil Raghavan: We are not ruling that out, we feel that this is an important franchise for them and even though we have grounds to believe and have confidence that we can prove this is a non-infringing platform, we cannot basically say that we do not expect litigation challenge and that has to be part of the strategy.

Vinita Kulkarni: Yes, we could plead for a summary judgment of non-infringement that may clearly come before 30-months.

Sameer Baisiwala: Just moving on, couple of questions for partnerships. Would PDP – 716 and SDP – 037 be a typical innovation type partnership where you get upfront milestone and then royalties and that is what I want to focus more which is some mid-teens or something, just a broad structure, I do not want the numbers versus for say Taclantis™ which would be more of specialty or specialized generics of tie-up with 50:50 sort of profit share or even more, would that understanding be correct that these two would be very different type of partnerships?

Anil Raghavan: Let me first comment on possible partnerships on both ophthalmic platforms that we are seeking. In those programs we are trying to de-risk and also release resources by getting the partner to fund the Phase III program. So in that sense it is not going to be like post-approval or post-submission deal, we are looking to do a deal before the submission. It may involve reimbursement of clinical expenditure and also the partner assuming some risk of probability of success. I do not want to comment on specific numbers in terms of royalties, but that would be the nature of the transaction. We have not actively started negotiating PICN, we want to first complete the out-licensing of these two programs and wait for the outcome of PICN because that is the clinical risk that we have already taken and we have completed the study and we do not want to start exploring serious negotiations before we have the outcome of those programs.

Moderator: As there are no further questions, I now hand the conference over to Mr. Jaydeep Issrani for closing comments.

Jaydeep Issrani: Thank you, Ali and thank you, everybody for being on the call today. This was a very lively interaction that we had. Hope we provided answers to all the questions that you posed. Just in case you have follow on questions which you could not pose during this discussion, you can write to us and we will revert back to you with our responses. Thank you once again for being on the call. Good bye.

Moderator: Thank you very much. Ladies and gentlemen on behalf of SPARC that concludes this conference call for today. Thank you for joining us and you may now disconnect your lines.