



"Progress on R&D Pipeline"

September 19, 2019

MANAGEMENT: MR. ANIL RAGHAVAN – CEO

DR. SIULONG YAO – SR. V.P., CLINICAL DEVELOPMENT & OPERATIONS

DR. NITIN DAMLE – SR. V.P., INNOVATION

DR. VIKRAM RAMANATHAN – V.P., TRANSLATIONAL DEVELOPMENT

MR. CHETAN RAJPARA – CFO

MR. JAYDEEP ISSRANI – G.M., BUSINESS DEVELOPMENT



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September 19, 2019*

Moderator: Good day ladies and gentlemen and a very warm welcome to the Progress 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 phone. Please note that this conference is being recorded. Please note to resize the presentation, kindly click on resize slide icon appearing at the bottom right hand of the presentation. I now hand the conference over to Mr. Jaydeep Issrani. Thank you and over to you Sir!

Jaydeep Issrani: Thank you Zaid. Good Evening ladies and gentlemen, thank you for joining today for SPARC's annual update on R&D Pipeline. On the call today we have our CEO, Mr. Anil Raghavan and members of SPARC's senior management team.

The slides that will be using for the call today were sent out earlier during the day, 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.

The format of the discussion will be similar to what we have followed in the past i.e. we will go through the presentation and then open the call for questions.

Before we start, I would like to remind you that our discussion today include forward-looking statements that are subject to risks and uncertainties associated with our business that could cause actual results to differ from those projected in the presentation.

I'll now hand it over to our CEO, Mr. Anil Raghavan for his presentation.



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September 19, 2019*

Anil Raghavan: Thank you very much Jaydeep for the introduction Hello everyone. Welcome to SPARC's 9th annual investor update. Thank you all so much for taking the time to be with us today. This is one of the most important events on our annual calendar for many years now as we are always encouraged by the active engagement of our investor community. We look forward to a productive conversation as usual. Let me start with a few house-keeping points before we get going. Earlier today, we have uploaded the presentation deck we plan to use for this session at the SPARC website. I hope you had an opportunity to review the slides.

We plan to provide an overview of our key clinical programs plus an introduction to a new NCE we are transitioning to clinical trials this year. That is SCO-120, our oral Selective Estrogen Receptor Degradar. In terms of the Agenda, I will start off with brief introductory comments on our commercial and late stage pipeline. I will also touch upon some key elements of our strategy and go over major outcomes expected in the next twelve months or so. My colleague Dr Siu-Long Yao will cover our important clinical assets, i.e. SCO-088 in CML, SCC-138 in Parkinson's disease.

We have also opened up another front for SCC-138 in Lewy Body Dementia with an investigator initiated trial. He will also cover our plans for SCD-044 in moderate to severe Psoriasis and give an update on our other P3 clinical trials, PDP-716 in Glaucoma and SDN-037 in Ocular pain and inflammation. Both these studies are nearing completion this year.

Dr Vikram Ramanathan, Head of our Translational Development group will introduce the SCO-120 program. We are all set to open an IND with the USFDA for this compound. He will go over the pre-clinical rationale for this translation.

Dr Nitin Damle will discuss our pre-clinical pipeline development, particularly our focus on external strategic partnering. Nitin will talk about a few of recent relationships to illustrate how we intend to



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September 19, 2019*

use these partnerships to build up our early portfolio. Chetan will go over the numbers briefly, particularly the cash burn and projected requirements for the short/medium term. So that is our plan for the day. As usual, I have here with me the SPARC management team for the Q&A and discussion post presentation.

Let me also take a brief moment to introduce Mr. Michael Choi, latest addition to the SPARC team. Michael joined us recently from Pfizer as our global head of Business Development. Michael was the Business Alliances lead for Emerging Markets for Pfizer Essential Health. We are delighted to have him join our team at a time when we are looking to step up our strategic partnering both on the product out-licensing front as well as in early stage product sourcing.

As I said, I will start the presentation with few overview comments on some late stage programs before transitioning the call for a deeper dive on our Clinical pipeline. So let's get started with slide 6.

I am sure most of you are familiar with Elepsia[®] XR and Xelpros[®]. When we spoke last time, we discussed the turn around on the regulatory status of our manufacturing partner's Halol plant. As we hoped for at that time, we now have the FDA approvals for both Xelpros[®] and Elepsia[®] XR. We received the go ahead for Xelpros[®] in Q3, FY19 and Elepsia[®] XR in Q4, FY19. These are very important milestones for us, given the difficult trajectory we had to navigate. More importantly, these are our first set of US FDA approvals, certainly a proud moment for a young company like ours.

As you may be aware, both these assets were licensed to Sun for US commercialization. Sun launched Xelpros[®] in the US in Q1 of this calendar year. So still very early days. But we are encouraged by the partner commitment and initial response. We look forward to reviewing the full year response later in the financial year. The Elepsia[®] XR license was returned to SPARC earlier this year as a result of a broader prioritization of therapeutic focus of Sun



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September 19, 2019*

commercial strategy in the US. We are told that they have decided to deprioritize CNS as an area of focus for US commercial operations. We are currently in talks with multiple potential partners to finalize the commercial arrangements for Elepsia[®] XR. We hope to finalize a partnership in the second half of the current financial.

Taclantis[®], our Albumin free nano paclitaxel formulation progressed to a successful NDA submission earlier this year, after meeting the bio-equivalence endpoints in its pivotal trial. US FDA accepted our NDA application in Q1 and set the PDUFA date for Feb 2020. We hope to receive a market authorization and be the first non-infringing nano formulation of Paclitaxel in the US market to compete with the market leader Abraxane. At this point, it is worth mentioning that we are aware of a complaint filed by Abraxis Bioscience against us with the US District Court for the District of New Jersey, alleging that SPARC Taclantis[®] commercialization will infringe some of the Abraxane OB patents. As we have indicated in our exchange disclosure, we believe this lawsuit is without merit and we are committed to defending our NDA vigorously to help improve the choice for patients and physicians in this important class.

Let me take a moment to give you an update on Baclofen GRS, even though we have not included that in the presentation deck. We have now agreement with FDA for a revised protocol with Subject's Global Impression of Severity and Ashworth Scale of spasticity as a continuous variable as our primary end points. You may recall that we have met these end points in our earlier trial which missed its original primary end point which was a composite we have agreed under an SPA with FDA. As indicated earlier, we have no current plans to internally resource another clinical study to bring Baclofen to the market. We are currently exploring partnership opportunities to further develop this product. Conclusion of these programs offers a 'page turning' opportunity for SPARC. It is a validation for our operating model and our ability to conceive and execute differentiated products.



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September 19, 2019*

These experiences also offer valuable lessons on product selection and our translational processes in general. We have touched upon some of the necessary changes in our past interactions and we have captured those lessons to make appropriate changes to our operating model. But it is also important to note that the external environment these products graduated to was very different from the one in which they were originally conceived. That has ramifications for the SPARC proposition at a much more broader level and is worth spending a few mins to discuss.

Let's take a look at slide 7. The external environment we operate in has changed in very significant ways in the last few years. Both positively and negatively. Reimbursement environment across the globe and particularly in the US has become extremely value conscious and restrictive. Getting attractive pricing for innovations which move the standards of care incrementally has become increasingly challenging, even when such progress is meaningful from a patient's perspective. This is not only true for formulation led 505(b)-2 applications, but also for follow on NCEs in a validated biological pathway. The returns from follow on programs lagged significantly behind first in class players who reset standard of care. At the same time, significant scientific innovation and progressive regulatory environment is making absolute breakthrough therapies increasingly possible.

A host of new technology tools such as gene editing and computational discovery solutions are also helping to rewrite the script in fundamental ways. Much of this disruption is happening outside of the traditional mid-to-large Pharma discovery engines. They are coming out of academic innovation ecosystems and small, start-up biotech clusters. These groups take significant risks on attractive scientific hypothesis using smart, virtual models which are not capital intensive. While lack of portfolio breadth to hedge the risk make such efforts 'high risk' do or die enterprises, they offer important pointers for companies like SPARC. What are the key



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September 19, 2019*

lessons? Low risk, low hanging opportunities are mostly taken and gone. And the commercial attractiveness of such low risk, incremental plays have become very debatable in a fast changing payor environment. If we don't innovate to find ways to move the needle significantly for patients, it is difficult to build successful businesses. Creating value in times of such disruption also requires sharp focus on execution and continuous streamlining of the operating model to ensure both cost leadership and investment in core differentiating competencies.

SPARC is in the middle of such a transition. Our portfolio has moved substantially away from incremental innovation. That is beginning to show in our clinical pipeline as we will discuss later in this presentation. But much more so in our pre-clinical pipeline. 75% of our pre-clinical pipeline today are NCEs or New Biological entities. 30-40% of pre-clinical programs involve novel biological hypothesis which are not clinically validated, giving us several first in class opportunities. At the same time, that also raises the risk profile of our portfolio. But as I said, our business doesn't offer easy, low risk opportunities any more. We realize that and we are revising our strategy in significant ways to stay relevant in a rapidly evolving environment.

Let's go slide eight now. Execution remains our number one priority. We have several high value opportunities in our clinical pipeline. Pursuing them efficiently and ensuring that important milestones are tracking to plan are absolutely critical for us to execute the broader strategy. These four programs on the first bullet along with two ophthalmic P3 assets PDP-716 and SDN-037 complete our clinical portfolio. These NCEs have significant platform potential, especially SCC-138 and SCD-044 with many possible indications and settings across Neuro-degeneration and Autoimmune diseases. We have now near term visibility to substantial value inflections points. We have completed the clinical PoC studies for SCO-088 and have a clear understanding of FDA's registrational expectations for our



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September 19, 2019*

agent in last line CML setting. Our clinical POC study for SCC-138 is already recruiting. We have put in a significant level of effort to ensure it is supported by a high quality pre-clinical data set and a clinical design which is robust enough to provide a credible, reproducible proof of concept in a neuro-protective setting.

Our early clinical studies for SCD-044 offer substantial biomarker validation for our hypothesis, giving us confidence to go into a larger proof of concept study in moderate to severe psoriasis. In addition we are transitioning SCO-120 to early clinical studies later this year. As I mentioned earlier, SCO-120 is an orally available, Selective Estrogen Receptor Degrader for metastatic breast cancer. This field has been active in recent years and have seen some significant setbacks, especially in terms of tolerability. We believe we have an asset with desirable structural characteristics to overcome the challenges faced by early movers to this field. We have seen substantial evidence for its efficacy in both wild type and mutant ER setting and potential for meaningful synergies with key components of current standard of care in metastatic ER+. HER2- breast cancer, such as the CDK 4/6 inhibitors. We are particularly excited about the prospect of this program as we go into early clinical. We hope to gain early validation for its safety hypothesis in Phase I health volunteer studies soon. Increasing the depth and diversity of our pipeline is an important priority for us.

When we started out, we were primarily a small molecule formulation company, mostly leveraging highly validated biology. Our diversity in terms of novelty of biological hypothesis and modalities outside of small-molecules has increased substantially in our pre-clinical pipeline. Our external collaborations are a key component of this transition and we intend to continue this deliberate pivot.

Our low cost of failure is one of our key differentiating factors and will continue to be a significant advantage. This is more so in pre-clinical setting than in clinical development. The clinical programs,



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September 19, 2019*

especially our late stage clinical pipeline will pose significant demands on our resources. As our clinical commitment grows, it is imperative we review our exit strategy. We intend to move away from an aspiration to own all our viable assets, all the way to major market authorizations to a mix of hold and exit. Especially once we reach early clinical proof of concept. We believe, that can release substantial resources to rebuild our pre-clinical portfolio meaningfully.

We will also review our operating model closely to define what is core to creating value in our model. Also with an objective to externalize wherever we have an opportunity to improve the productivity of deployed resources. That will also give us an opportunity to step up investments in core differentiating competencies to improve scale and to modernize them. So let me summarize this slide. We are making some significant changes to our strategy in terms of our portfolio mix, exit strategy and operating model. But while we do that, we will continue to be super focused on achieving near term value inflection points for key projects in our current portfolio.

Slide 9 please Here is an update from our annual portfolio review. We have deprioritized three assets after reaching significant proof of concept data points. Opioid Abuse Deterrence has been an important part of our portfolio in the recent past. We have achieved our target yield suppression levels from a PK perspective and established preliminary proof concept in a human abuse liability study. The next step for the program is a pivotal abuse liability study. But we do not intend to go forward alone as the legal and commercial risk profile of this class has increased significantly in the last year or so. Further progress in this important pursuit requires collaboration with a commercial player with continued commitment to the opioid market. We have decided to park the project till we find an appropriate partner. In the meantime, we are repurposing the platform to develop proof of principle for overdose prevention,



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September 19, 2019*

especially in indications where suicidal ideation is an important feature of the disease.

We have also decided to deprioritize the Liraglutide Long Acting Depot and Minocycline Micronized formulation after obtaining pre-clinical proof of concept. Both these de-prioritizations are based on our read on the changes in market opportunity and reimbursability of these propositions. In the case of Liraglutide Long Acting Depot, we believe oral GLP-1 analogues reset the standard of care, potentially advancing the application of GLP-1 oral therapies to earlier in the cascade. That raises questions about the role of long acting depots in the medium to long term.

We have also seen similar changes in the topical Minocycline market with multiple more nearer term products making progress, even though we may have a superior technology. We believe the required resources can be better utilized in programs with better projections. We are also happy we are taking these calls early on based on a continuously evolving and data driven view on the opportunity. That is a process we want to continue to improve as we move forward.

That's brings me to my last slide. Slide 10 Here are a set of expectations for the short to medium term. Commercial launch for Elepsia[®] XR and Taclantis[®] is an important priority for us. There are market and legal challenges here. But we are hopeful that we will be able to launch Elepsia[®] XR soon in the US. We will aggressively defend Taclantis[®] IP and work to put ourselves in a position to launch the product if we get a US FDA nod as we expect to get. As I said, we are initiating the pivotal trial for SCO-088. We expect to reach an NDA submission by FY23. We are currently recruiting for SCC-138 Parkinson's and Lewy Body Dementia trials.

We expect to have proof of concepts for these projects by FY22. We will also have P2 PoC read outs on SCD-044 in that time frame. We will be testing the safety hypothesis of SCO-120 in healthy human volunteers and will have initial read outs in the coming year, setting



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September 19, 2019*

the stage for its clinical PoC studies. We intend to transition at least one more asset into an IND next year. May be too early to talk about it, but most likely will be another Oncology NCE. And finally we will continue to focus on building out our pre-clinical portfolio.

Expanding novel biology and Biologics are priorities for us. We hope to talk about these projects more explicitly next time we meet. We will also stay open to doing transactions on some of our clinical stage assets. That not an active process as we speak. But we intend to be more definitive about our intent to exit programs after success in proof of mechanism studies. With that I am now going to transition to my colleague Dr Siu-Long Yao, Our Global Head of Clinical Development for a more detailed overview of the clinical pipeline. He will also touch upon the pre-clinical basis of some of newer compounds as appropriate. But before we go there, I want to thank you all again for your time today. I look forward to the rest of the presentation and the Q&A at the end. Over to you, Siu.

Siu-Long Yao:

Thank you, Anil. Good afternoon, evening or morning depending on where you are in the world. My name is Siu Yao and I help oversee Clinical Development at SPARC. It's really a pleasure to be with you and share some of our progress since our last meeting.

I'm on slide 12 which begins our brimonidine ophthalmic eye drops discussion. On slide 13, is a summary of our current progress. As noted on the slide, our Phase 2 study was completed with results demonstrating that once a day administration of our formulation is equivalent to three times a day administration of Alphagan® P, the current standard of care. This gave us confidence to move into a Phase 3 study with a design that essentially replicates the Phase 2 study. IOP is obtained at 3 time points and 20 sites are actively recruiting. We are getting close to half way done with recruitment. The last subject out is planned for 1Q FY21 but there will be a futility analysis prior to that in 3Q FY20. We have received a pediatric waiver for the program and hope to file the NDA in 4Q FY21.



Slide 14 begins the discussion on SDN-037 with details starting on slide 15. The pivotal study compares SDN-037 to vehicle control. 15 sites are recruiting and the majority of accrual has been completed as you can see in the figure on the right. Similar to the previous study with brimonidine, an interim futility analysis will be performed prior to completion of accrual in 4Q FY21. An NDA is planned for 2Q FY22.

The transition to the SCO-088 BCR-Abl program begins on slide 16 with details provided in slide 17. The goal of this program is to develop an inhibitor for patients with chronic myelogenous leukemia with disease refractory to existing inhibitors. Over the past year, we were fortunate to receive orphan designation status which will give us 7 years of US market exclusivity and which will waive the FDA submission fee. Our plans are progressing along and we are now in the transition from Part B in the current study to Part C, the pivotal registration phase of our study.

Slide 18 summarizes some of the encouraging results that we've observed to date. First of all, we've treated a very challenging population. 80% of the subjects have failed ≥ 3 TKIs which means that they've exhausted current standards of care. About a third of the subjects have at least 1 baseline mutation, which often is the basis of resistance to other TKIs and over half had disease that was progressing through the therapies that they were on. In spite of this, the hematological response rate, which refers to normalizing of the blood cell parameters, has been seen in nearly 80% of the subjects and over half have seen genetic evidence of abnormal cells disappear. 13/37 subjects have been on treatment for more than 12 months with continued benefit.

Additional information on the durability of responses in this challenging population is provided in slide 19. Here, you have the number of patients on the y axis and the duration of response on the x axis. As of this week, approximately 70% of enrolled subjects are continuing on treatment. It's important to note that the duration



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September 19, 2019*

of treatment will depend on when the subject was entered into the study so, for example, subjects entered more recently will not have been on treatment as long as those entered earlier in the study. What's especially encouraging is the observation that subjects entered early on actually started on lower doses and despite that they have been able to maintain their responses for quite an extended period of time.

Side 20 provides some insight into what we hope to see in Part C, the pivotal part, of our study. The population we are studying in this part of the study consists of subjects who have exhausted existing standard of care. The table in this slide shows the various dose levels we've studied going across the top with the first row showing the number of subjects at each dose that satisfy this criterion. The last row summarizes the number of cytogenetic responses that we've observed. As you can see, about half of the subjects in this very tough population that has exhausted existing approved therapies have responded. This response rate is consistent with FDA expectations for accelerated approval based on our end of Phase 1 meeting.

Slide 21 gives you a brief summary of safety. In short, SCO-088 has been tolerated very well. We've seen 2 serious adverse events, one of which was really related to disease progression and the other involved some back pain that required hospitalization for pain management. Other than that there have been occasional instances of some inconsistent GI and musculoskeletal disturbances.

Slide 22 is a summary. As I mentioned, we completed an end of Phase 1 meeting with the FDA and obtained guidance on what would be required for an accelerated approval with Part C of our current study. We are currently in the process of startup for that part of our study with FPI planned for 4Q FY20.

An overview of SCC-138, which is the same drug, for the treatment of Parkinson's Disease begins on slide 23. Slide 24 briefly



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September 19, 2019*

summarizes the program. As noted in the sub-title, the purpose here is to actually change the course of Parkinson's Disease which has been a pretty elusive goal with conventional therapies. Biologically, treatment of neurons derived from subjects with Parkinson's Disease with SCC-138 is able to result in a host of beneficial outcomes including preservation of Parkin activity, modulation of autophagic flux and alteration of alpha synuclein inclusions. There have been several models providing preclinical POC including a PFF or pre-formed fibril model and an AAV or adeno associated viral model.

Clinically, we have been able to complete studies demonstrating supportive PK, evaluating the effect of food (which was modest) and demonstrating safety and exposure in subjects with Parkinson's Disease. A Phase 2 proof of concept study is in progress and I will provide details on all these aspects of the program in the subsequent slides. To date, there's been no evidence of tolerability issues or QT prolongation which has been associated with agents such as nilotinib.

Before I start with slide 25, I want to provide some background for you. In disorders such as Parkinson's Disease there is an accumulation of misfolded proteins. The accumulation of these misfolded proteins burden cells and can result in their death. Autophagy is a process by which cells can remove these misfolded proteins. Slide 25 describes an in vitro study in which inhibition of c-Abl by SCC-138 augments the autophagic flux system in a system in which neurons derived from human stem cells were subjected to oxidative stress. LC3-I is part of an autophagosome that is formed when misfolded proteins or organelles are targeted for autophagy. When autophagy is initiated, LC3-I is cleaved to form LC3-II which is used as a marker of autophagy. This is seen in the upper panel on the right. In other experiments, SCC-138 not only increased the levels of LC3-II but also sustained their levels 2-3 fold higher than vehicle-treated controls over a 2-week period. P62 is another protein that complexes with LC3-II in an autophagosome and its



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September 19, 2019*

levels are also similarly increased indicative of augmented autophagy in response to SCC-138 as shown in the lower panel.

This neuroprotective effect of SCC-138 was further evident in a mouse model of Parkinson's Disease in which preformed fibrils (PFF) of alpha synuclein were injected into the brain to simulate Parkinson's Disease in the mice. Slide 26 shows the results of oral treatment with SCC-138. There is dose-dependent restoration of motor capabilities such as turning time on the left panel and grip strength on the right panel. On the left panel you have the time it takes a mouse to go up a pole, turn around and come down on the y axis. The bars going across the x axis represent the effects of controls in the first 2 bars and different doses of SCC-138 in the subsequent 3 bars, consisting of placebo, 15 mg/kg and 45 mg/kg. PFF injections cause the Parkinson's Disease like symptoms in mice. As you can see, doses of 15-45 mg/kg of SCC-138 make the mice perform as if they had not received injections of the disease causing PFF.

Similar results were observed with grip strength shown on the right. Force is shown on the y axis. Going across the x axis are columns that represent normal controls in the first 2 columns followed by PFF injected mice treated with various doses of SCC-138. As you can see, treatment with doses of 15-45 mg/kg resulted in grip strengths similar to normal control mice shown in the first 2 columns.

Slide 27 provides microscopic evidence to support the results of the behavioral studies. On the y axis you have the number of tyrosine hydroxylase neurons, which is a measure of the number of cells that are able to function relatively normally. The columns again represent normal controls in the first 2 cases and progressively increasing doses of SCC-138 in the last 3 columns. As you can see, a dose of 45 mg/kg was able to result in mice with a number of normal cells very similar to that observed in the normal control mice in the first 2 columns.



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September 19, 2019*

Slide 28 shows the results from a rat model in which an abnormal form of synuclein is introduced through viral infection by adeno associated virus. The number of tyrosine hydroxylase, or relatively normal, neurons is shown on the y axis. A normal control is shown in the first column on the x axis. You can see that a dose of 45 mg/kg in this model resulted in mice with nearly the same amount of relatively normal cells as the control group represented by the first column on the left.

Slide 29 summarizes clinical progress. A traditional 2 week exposure, escalating dose, study has been completed in subjects with Parkinson's Disease involving doses up to 384 mg. The drug has been well tolerated without any serious adverse events. A study evaluating CSF concentrations in the central nervous system after 7 days of treatment was also completed and confirmed that adequate exposures were being obtained in the central nervous system.

The design of the ongoing Phase 2 proof of concept study is summarized in slide 30. The ProSeek study is a 3 arm study consisting of 2 doses of SCC-138 and placebo in subjects with early stage Parkinson's Disease. The primary endpoint is that commonly utilized in the field, namely the Movement Disorders Society Unified Parkinson's Disease Rating Scale Parts 2 and 3. The study was started in February and we are hoping to finish acquiring the necessary information by 4Q FY22.

Finally, slide 31 just introduces you to one of our emerging efforts with this compound in another neurological condition. Dementia with Lewy Bodies is a disease very similar to Parkinson's Disease with what's believed to be a large amount of overlapping pathology working through a similar mechanism of action. It is also characterized by cognitive decline but there is a more prominent role for hallucinations. It affects approximately 1.4 million US people annually and is the 2nd most common cause of dementia in the elderly. We have partnered with investigators at Georgetown



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September 19, 2019*

University in the US to conduct a safety and tolerability study that is expected to complete by early 2021.

Slide 32 begins the transition to SCD-044 for the treatment of autoimmune disorders such as psoriasis. This is a project that is being done through a collaboration with a company named BioProject in France. Various preclinical animal models have identified psoriasis as a potential target and a Phase 1 healthy volunteer study was recently completed.

The design of this trial is summarized in slide 34. The study consisted of 3 parts. Part 1 consisted of a single ascending dose study. In that part of the study, it was shown that doses of 1 mg were able to reduce the lymphocyte count by 55%. Part 2 of the study demonstrated the absence of a food effect while Part 3 showed that a gradual escalation scheme from 0.3 to 0.6 to 1 mg was able to achieve target lymphocyte reductions of 50-60% without causing symptomatic decreases in heart rate.

Some more detail of the information we learned from this study is summarized in slide 35 which compares the relationship between heart rate and lymphocyte counts. On the left y axis you have the percent decrease in lymphocyte count which is represented by the solid line and results of 57%, 79%, 70% and 59%, while on y axis on the right side of the graph you have heart rate decrease from baseline with the numerical results of 10.4, 13.0, 17 and 8.33 shown embedded in the columns. The various columns represent different dose regimens. The first column is 1 mg daily, the 2nd column is 2 mg daily, the 3rd column is a gradual escalation scheme consisting of 2 mg followed by 4 mg followed by 6 mg whereas the last column consists of a regimen of 0.3, then 0.6 mg followed by 1 mg dosing. As you can see, the 0.3 followed by the 0.6 followed by the 1 mg gradual escalation scheme resulted in a 59% decrease in lymphocyte count, which is within our target range of 50-60% reduction with the least effect on heart rate. Based on results with other agents such as ponesimod in this class, we believe that this



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September 19, 2019*

amount of lymphocyte count reduction will be sufficient to demonstrate success in psoriasis.

Slide 36 is a brief update on the program. We are planning to file an IND in 3Q FY20 since the initial study was done outside the US, and we will start the Phase 2 psoriasis study in 2H FY20.

I'm on slide 37 now. SDN-021 is a program utilizing a technology which we hope will be useful in deterring opioid abuse. Going to slide 38, in the case of an opioid, the technology blunts the maximum drug concentration which is often associated with the euphoria that abusers seek. The technology is also able to deter abuse by other routes, including injection and snorting. Furthermore, an aversive agent that is part of the technology further prevents tampering. Some of the results are shown in the graph on the right. On the y axis you have drug concentrations and going across the x axis you have time in hours. The top orange line represents results obtained with the current marketed formulation of the opioid whereas the lines below in green and blue are the results obtained with SDN-021. As you can see the maximum exposure to drug is blunted.

This is further highlighted in a pilot study, on slide 39, that was conducted looking at drug preference in drug abusers. These results are shown in the graph on the right which depicts the difference between SDN-021 and the existing marketed drug in drug liking. As you can see, SDN-021 was favored less than the marketed drug by abusers suggesting that the technology is working.

We've applied this technology to the problem of anti-depressant overdoses and this is reviewed on slide 41. Here, the technology restricts the amount of drug released when multiple pills are ingested at the same time. The results of a single dose PK study are shown on the right. The purpose of this study was to demonstrate similar bioavailability between the formulation which prevents multiple drug overdose and the existing marketed form of the drug.



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September 19, 2019*

Drug concentration is shown on the y axis and time is shown on the x axis. You can see that the PK curves are very similar suggesting that we've accomplished our first goal of making sure that the technology releases drug properly when the drug is used appropriately. A multiple dose proof of concept study to demonstrate inhibition of absorption in the setting of multiple pill ingestion is underway.

That's my last slide. At this point I'd like to turn things over to my colleague Vikram Ramanathan who will walk you through an exciting upcoming program that we have coming forward.

Vikram Ramanathan: Thank you Siu and good morning, good afternoon or good evening to you all. I will be giving you an update on the preclinical studies of our Estrogen receptor degrader SCO-120 which is getting ready for IND filing with the USFDA. This is the first time we are talking about this program. We are happy to share that we have completed a range of studies in vitro and in vivo in xenograft studies. We have also undertaken the full range of preclinical safety studies for IND filing.

Slide 44 gives a background on the target estrogen receptor and its application to the therapeutic area of BrCa.

The compound that will discuss SCO-120 is an orally bioavailable selective estrogen receptor degrader also referred to as SERD.

As you know anti-estrogen therapies are the mainstay of treatment for about 70% of women with breast cancer whose tumors express the estrogen receptor- α . These therapies act by countering the growth promoting effects of estrogen.

Compounds that lead to degradation of the ER α receptor are deemed to offer a superior therapeutic approach in the treatment of ER α +ve breast cancer.

A large proportion of ER α receptor +ve patients who have metastatic breast cancer develop resistance to anti-estrogen therapies because they develop drug resistant mutations in the ER α receptor.

The figure on the right is a diagram that represents the linearized primary structure of the ER α receptor. Towards the right of the figure in the light blue region is shown the mutations in ER α that confer drug resistance to it. These are largely in the ligand binding domain of the receptor i.e. the region in the receptor where both the endogenous ligand estrogen, as well as ER α inhibitors and modulators bind.

The only currently approved Estrogen degrader is Fulvestrant. Fulvestrant however has limitations because it is a painful intramuscular injection and the drug level that can be achieved with the injection is limiting.

SCO-120 is a novel orally-active selective estrogen receptor (ER) degrader-or SERD-that acts by degrading both the wild type and drug resistant mutant forms of ER. Through this mechanism of action, SCO-120 works to inhibit the growth of breast cancer which are ER alpha positive.

I now refer to slide 45.

In data that I am not presenting here, we have found that SCO-120 shows potent in vitro activity in the low nM to sub-nM range in MCF7 breast cancer cells that carry either the WT ER α or its Y537S and D538G mutant forms. We have studied SCO-120 driven degradation of the ER α receptor, growth inhibition of the breast cancer cells, and the corresponding effects of the drug on ER α driven gene transcription.

Consistent with this, in vivo we see significant tumor growth inhibition with SCO-120 in xenograft models. This is shown in the plot.

This plot exemplifies data in subcutaneous xenograft model of MCF 7 breast cancer cells expressing the ER α Y537S. In red are the vehicle treated control animals; as expected with increasing number of days, the mean tumor volume increases. In purple are the data with Fulvestrant treatment; it shows some reduction in tumour growth but it is not complete. By comparison, in green are the data with SCO-120. With increasing doses there is a dose dependent reduction in tumor volume.

These data are with standalone SCO-120. However this class of SERD molecules offer an ideal combination partner for synergy with the CDK4/6 inhibitor class of drugs such as palbociclib. We have studied this in vitro and found evidence for synergy with CDK4/6 inhibitors, and in the next slide is data from in vivo xenograft studies.

Slide 46 shows preclinical in vivo xenograft data with SCO-120 either alone or in combination with CDK4/6 inhibitors.

In the graph on the left is data with WT ER α xenografts. In red are vehicle-treated control animals; as expected with increasing number of days, the mean tumor volume increases. The purple closed squares is data for parenteral Fulvestrant treatment; it shows little to no effect in the model. In green is oral SCO-120 alone – it shows good effect. At the bottom of the graph in pink squares is a combination with SCO-120 plus palbociclib; remission is seen. In comparison the yellow line for Fulvestrant plus palbociclib shows improvement over either agent alone, but not as good as the open pink squares. Finally the dark blue line is the effect of the CDK-4/6 inhibitor palbociclib alone. These data indicate the potential for combination of SCO-120 with CDK 4/6 inhibitor class of drugs.



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September 19, 2019*

Most importantly data with the resistant ERa Y537S mutant on the right show the same potential for synergy. Again the open pink squares showing combination of SCO-120 plus palbociclib shows superior effect with remission of the mutant drug-resistant xenograft compared to the combination of fulvestrant plus palbociclib.

These data indicate that SCO-120 is a compound with potential for ERa+ breast cancer both on a stand-alone basis, as well as in combination with CDK4/6 inhibitors.

Slide 47 describes our preclinical toxicity studies.

SCO-120 has been studied in a full battery of safety studies. Subchronic repeat dose studies have been completed in mice, rats, dogs and monkeys and the NOAEL values have been established. The compound shows an encouraging tox profile.

We have also completed the battery of in vivo safety pharmacology studies where effects in the central nervous system, the cardiovascular system, and the respiratory system have been studied and no adverse effects were seen.

Also a panel of 87 receptors and kinases have been studied for off-target interaction with SCO-120 and the compound is generally clean. Also the compound does not show off-target effect of increasing uterine weight.

With this background, I now refer to my last slide 48

SCO-120 is now getting ready for IND filing and this will be done in Q4 FY20. This is an exciting time for the project and we look forward to taking the compound forward to the clinic as a potential meaningful treatment for ERa+ breast cancer patients who have developed drug resistant mutations to the classical agents like tamoxifen and are likely to have developed metastatic breast cancer.



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September 19, 2019*

We look forward to sharing an update on the clinical studies in the coming time. I now hand over the baton to my colleague Dr Nitin Damle who will give you an update on our partnerships and collaborations.

Nitin Damle:

Thank you Vikram, and good afternoon everyone. My name is Nitin Damle and I will be focusing on our initiatives in building SPARC's product pipeline for the future. SPARC has established expertise and core competencies in medicinal and process chemistry, and formulation sciences, and our current pipeline is a testament to these core competencies. Until recently, SPARC had emphasized development of reformulated products based on the 505B(2) strategy and hence our current late stage pipeline has a sizable representation of products based on formulation innovation and novelty in drug delivery systems. However, in light of the changing pharma business environment and commercial challenges with 505B(2) products that Anil earlier alluded to, SPARC has reset its priorities to now emphasize novel chemical and biologic therapeutic entities. While moving forward and with the inclusion of an added dimension of biologic therapeutics, we emphasize NCEs and NBEs as the future contributors to the growth of SPARC. That said, we will nevertheless continue to leverage our strengths in formulation sciences wherever applicable towards creating novel drug delivery systems.

Therapeutic focus for SPARC is consistent with our emphasis on creating novel first-in-class or best-in-class therapeutics with significant intellectual property protection and commercial potential as shown on Slide 51. We have emphasized four therapeutic niche areas; Oncology, Immunoinflammatory Diseases and neurodegeneration. In addition, our expertise in novel but complex drug delivery systems can and will be leveraged in creating differentiated products for the Ophthalmology therapeutic niche.

While we continue to ideate internally for novel molecular targets and product development opportunities, we have placed a



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September 19, 2019*

significant emphasis on academic outreach by globally engaging, via collaborations and partnerships, external academic centers of excellence and strategic research service providers. While our current efforts in this direction are primarily in the United States at present, we will be expanding our outreach to other global academic centers of excellence including those in India.

SPARC offers focused research grant support to academic innovators in order to, not only source novel ideas but also leverage their domain expertise and experience in a given therapeutic niche. While academic innovators contribute immensely to the origination of ideas, they often need the preclinical and clinical drug development infrastructure in order to translate and advance their ideas into viable therapeutics for the benefit patients. SPARC is able to provide such an infrastructure support, and thus, SPARC offers an attractive alternative to the more traditional venture capital route wherein SPARC contributes not only in funding the project advancement but, also contributes by providing in-kind services and internalizing such R&D programs as SPARC programs.

I would like to note here three specific examples in this endeavor. First is the collaboration between SPARC and Washington University in St. Louis, MO as shown on Slide 52. This collaboration was established in 2018 and we are in a process of evaluating a number of potential novel drug discovery and development opportunities identified for use in cancer therapy. SPARC will be an active contributor to advance these opportunities further.

The second collaboration, I would like to mention here, is a drug discovery collaboration between SPARC and Hitgen, as shown on Slide 53. Hitgen, based in Chengdu in China, has developed a technology platform in which a very large chemical library has been built. A unique feature of this library is that each compound in this library has a unique DNA tag that can be used to make the structural identification of compounds that bind to molecular targets of interest. This is a unique and intellectually sophisticated



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September 19, 2019*

alternative to the brute force of robotic high throughput screening in order to identify "hits" during drug discovery. Hitgen has already started screening their DNA-coded compound library for hits against a SPARC-chosen molecular target of interest in the Oncology space.

The third collaboration is the recently established collaboration between SPARC and University of Arizona, Tucson, AZ as shown on Slide 54. It is based on a novel semisynthetic entity, discovered at the University of Arizona, for a potential therapeutic use in the treatment of treatment-refractory metastatic carcinomas. Even if I have noted here only two academic collaborations, we have, under consideration, a number of additional collaborations with other high profile academic centers in the US.

I would like to conclude my part of this presentation by stating that the fruits of these collaborations will be apparent as contributors to the SPARC pipeline of NCEs, NBEs and novel delivery systems in the future Investor presentations. Thank you very much. I shall now request my colleague, Chetan Rajpara, CFO at SPARC, to continue this discussion further. Chetan.....

Chetan Rajpara: Thanks, Dr. Damle, for a detailed overview of SPARC's collaborations and partnerships. Hello everybody. I plan to go over the SPARC financials and cash position, at a high level. I will keep this really brief. Slide No. 57 please...

During FY19, Total income was at INR 1,964 Mn (USD 28.1 Mn) [up 136% from INR 832 Mn], while Total expenses (incl. interest & depreciation) were at INR 3,418 Mn (USD 48.9 Mn) [up 4% from INR 3,292 Mn], resulting in to a Net Loss of INR 1,454 Mn (USD 20.8 Mn) [down 26% from INR 1,970 Mn] for the year.

As Anil mentioned earlier, we received USFDA approvals for Xelpros[®] and Elepsia[®] XR, generating a cash inflow of USD 13 Mn, in FY19. Let me update you on our latest quarterly financial results,



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

which is not part of this presentation, but published on our website. For Q1-FY20, Total income was at INR 210 Mn (USD 3.0 Mn) [up 16% from INR 180 Mn], while Total expenses (incl. interest & depreciation) were at INR 1,152 Mn (USD 16.6 Mn) [up 40% from INR 825 Mn], resulting in to a Net Loss of INR 942 Mn (USD 13.5 Mn) [up 46% from INR 645 Mn] for the quarter.

As you may be aware, the company has raised an aggregate sum of INR 5,000 Mn (USD 71.4 Mn) over last 2 years, by way of preferential issue of warrants. We received the last tranche of INR 1,500 Mn (USD 21.4 Mn) in Jan-2019.

As far as liquidity status is concerned, Cash on hand as at 31st August 2019 was INR 788 Mn (USD 11.0 Mn). For FY20, approx. 60% of the expenses are budgeted for the clinical programmes. However, we are aggressively managing our costs and working to control our non-clinical expenses tightly. The gap between the income and expenditure for FY20 would reduce, if we are able to monetize certain assets by end of this year, as we plan.

That's all from me today, on the financial update. A big thanks to all of you, for joining the call. We look forward to the Q&A.

I will now hand over the call to Jaydeep for facilitating the Q&A.

Jaydeep Issrani: Thank you Chetan, I will briefly talk about our pipeline before we transition to Q&A session.

As you can see on slide 59, our initial set of programs have been approved or nearing registration and as Anil mentioned, majority of our current programs under development are NCEs depicting the deliberate strategic shift we have taken over the last couple of years. Going forward, we will continue to focus on NCEs and biologics in the identified therapeutic areas and will update you as we make progress on those programs. With this, I would like to open the call for questions.



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

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

Ketan Gandhi: Sir one suggestion can you present this updates on a quarterly basis because publicly listed innovative companies in the US, they provide quarterly updates?

Anil Raghavan: Thank you for the suggestions Ketan. When we move forward to a more fuller clinical stage portfolio I think there may be a change but at the moment the progress on the portfolio is substantial on an yearly basis and this is modeled around R&D days. Thank you for the suggestions, but if you have questions on any program on our portfolio, please reach out to us and we are happy to kind of address them on a regular basis.

Ketan Gandhi: Sure and my first question, is it possible for you to share the peak sales potential for the following products Xelpros[®], Taclantis[®], PDP-716, SDN-037 and SCO-088 and when do you plan to out-license each of these products and do you have any alternate manufacturing as far as each of these products?

Anil Raghavan: So I think we have not included very finite peak sales projection for these programs in this presentation but Jaydeep can actually talk about the market environment and the opportunity space for each of these program and that would probably help in a contextualized potential of these program.

Jaydeep Issrani: Thank you for the question, as Anil mentioned we do not provide specific number or guidance with regards to peak sale potential but what I will do is, I will quickly give you some sense of how the market is for each of these programs today. Currently Based on IQVIA database Xelpros[®] or the Latanoprost market is around \$200 million when we put together all the Latanoprost formulations that are currently available. The important point to note here is the unit growth that we see in this market even though Latanoprost has



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September 19, 2019*

genericized several years ago, you still see unit growth rate of about 10% to 11% for the last couple of years. So that still presents an opportunity in this area and we all know that Latanoprost is the most important drug, which is used for treatment of Glaucoma even today in US. So that is briefly about Xelpros®.

On Taclantis®, the current market is valued around \$750 million that is all formulations of paclitaxel. If you specifically talk about Abraxane that is valued around \$700 million in US. Here again you will see that the unit have been consistent for the last several years. There was an increase in unit or the prescriptions for Abraxane when the approval for the pancreatic cancer indication was granted to Abraxane. So this still continues to be an attractive market. Brimonidine is around \$450 million market half of that is still with the brand product 0.1% Alphagan® P. So that also talks about the opportunity when you have branded product, that presents with an opportunity to command certain level of revenue share in the total market.

Ketan Gandhi: PDP-716?

Jaydeep Issrani: PDP-716 is the Brimonidine opportunity I just mentioned about that.

Ketan Gandhi: SDN-037 and SCO-088?

Jaydeep Issrani: SDN-037 is a program for which we have not disclosed the molecule, but it is steroid eye drop. Since we have not disclosed the molecule as of now, we can talk about the overall market of steroids, which is about \$750 million in the US. The reference products unit sales have been stable, for the last five years. I would restrict myself giving specific numbers on this as we have not disclosed the molecule yet.

Ketan Gandhi: Sure, SCO-088?



Jaydeep Issrani: For SCO-088 when you look at the market we currently have five tyrosine kinase inhibitors, which are already approved. The peak sales of Imatinib went up to about \$3 billion in US alone and post genericization the value has come down, but I would like to point out the atypical phenomena, which we have observed in this market, post expiry of Glivec patent, the volume and prescription both have declined for Imatinib, which is very unusual of what we have been used to seeing. At the same time, the other agents which were second and third line agents for example Dasatinib or Bosutinib and even Ponatinib. The market share both in terms of units and prescriptions have increased for the last three or four years or post genericization of Imatinib. So if the trend, stays or remains the way it is where you see the uptake of newer TKIs better than the older ones even after being available at a lower price, then we see a significant opportunity for a newer TKI something like SCO-088 where we have an advantage in terms of providing efficacy at the same time being relatively safe compared to available TKIs

Ketan Gandhi: Sure. Sir when do you plan to out-license each of these products, any timeline Sir?

Anil Raghavan: Currently the scenario that we are pursuing is taking SCO-088 to market authorization and looking at clinical proof of concept or other NCE programs that we are talking about and at the same time as Chetan indicated, we are opportunistic and there is also interest in the market, so we do not close the door on opportunity to do a transaction, but at the moment internal operating plan is to take SCO-088 all the way to market authorization and so all the other NCEs at least up to phase 2 clinical proof of concept.

Ketan Gandhi: Sir why I am asking this is because we have only Rs.80 Crores of cash lying with us. So how do you plan to fund these clinical trials?

Anil Raghavan: I think that is a question that obviously we are internally thinking a lot about and there are in our opinion multiple options for us. Clearly there are potential exits for us, both in terms of some the



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September 19, 2019*

late stage, 505(b)(2) opportunities like Taclantis[®] or some of the opportunity that Jaydeep spoke about and there is also an opportunity to exit early stage assets. Alternatively we can also look at asset-specific funding, which is non-diluted funding on a particular asset and that is a path which was taken by a lot of early stage company without raising fund on the company and there is definitely interest in many of these NCE assets as we go into phase 3 and more definitive clinical trials and then the third option is always on the table that is if we need to bridge with an additional round then we will have to come back to the market.

Ketan Gandhi: Sure Sir any indication for Xelpros[®] early income for FY2020-21?

Anil Raghavan: Xelpros[®] is at an early stage, it is very early days for commercialization. The internal targets are low single digit million dollars but we do not have definitive guidance in terms of how this will go and this is just the Q2, Q3 after we commercialized this, we plan to review with our partner by end of the first full year.

Ketan Gandhi: Sir Do you have any alternative manufacturing site for each of these products?

Anil Raghavan: As we mentioned in last several calls, we go by the economics of these programs. So if you have programs which are relatively modest revenue potential then we do not have the space to entertain another secondary manufacturing site, but as we go to larger programs especially NCE programs and some of the larger 505 (b)(2) opportunities, we intend to have second manufacturing site.

Ketan Gandhi: My last question is on Taclantis[®], can FDA approval be received in February 2020 even if Celgene litigation is not resolved until February 2020?

Anil Raghavan: That is an interesting question, yes, I think at that point it becomes tentative or conditional approval, but commercialization would



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

require resolution to the legal process, so we are working diligently to resolve this, so that we can launch the program as soon as we have marketing authorization.

Ketan Gandhi: Sir one assumption that what are the key attributes that SPARC will look for its marketing partner including an ability to launch the product at risk if FDA approval is received with Celgene litigation pending.

Anil Raghavan: Ability to really launch the product at risk would be interesting, but our hope is that we will be able to resolve this in a shorter timeframe, but what is really important for us is partner's ability to maximize the yield in the key therapeutic segments of Abraxane and nano Paclitaxel which is pancreatic cancer, breast cancer and also lung cancer, so presence in these areas and ability to build up the product and these classes is really important as a partner and this will also require investment because even after Abraxane generics shift the market, Taclantis[®] would have an opportunity to be the only promoted product in the market until these patents run out, so as we promote, this product can grow and we would require the financial muscle to sustain that effort over the longer period of time.

Ketan Gandhi: Thank you Sir. I have some more question I will join back in the queue Sir.

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

Manish Jain: I was wanting to start on SCO-088 where we have stated that the first patient in is being targeted for Q4 current year, when will the last patient be enrolled?

Anil Raghavan: Good evening Manish as we said for SCO-088, we just had our end of stage 1 interaction with FDA, we have clear sense of what is required from a clinical setting standpoint. The guidance that we have from FDA is that we need to look for patients with three lines



of failure including Ponatinib. So our original hypothesis when we spoke about this program last year was total accrual time of 12 months and we are now extending that to at least 18 months on an aggressive basis and on a conservative basis two years to complete the accrual and then we need to have data maturity time of one year, so the FY23 projection that we have given in this presentation is based on that assumption of two years of accrual and one year for follow up, these are the underlying assumption in terms of when the programs will be able to go to FDA for an approval.

Manish Jain: And is it o.d. or b.i.d. in dosing?

Anil Raghavan: o.d.

Manish Jain: Okay, because when I am looking at Asciminib Novartis ABL 001, it is b.i.d., beside that do we have any other advantages over Asciminib?

Anil Raghavan: They are in two different settings, if you look at ABL001 program which is the Novartis program. They are essentially looking at second line or third line approval going up against Bosutinib. Our approval in clinical setting that we are testing is in last line where there is no standard of care at the moment, so we will come with two different dataset and from two different brackets. We will be the last line option to begin with and in parallel we would also do a comparative trial with Imatinib to progress this product to earlier line. So our market registration strategy is different and we expect to have a safety advantage but that is at this point a speculation. We would like to see the data from both these programs, since ABL001 has a comparative trial, it is going to take significantly large number of patient, our trial would be shorter, single-arm. Open-label study with 150 patients while the Novartis program would be a 250 plus patients trial comparing with Bosutinib. So to summarize we believe these products will operate at two different settings and we believe that we can have a safety advantage because of its extreme, selective kinase inhibition profile, but those are the things which



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

need to be established with data once we have the read out from this trial.

Manish Jain: Great and we also were having 954 which was a backup molecule to 706 or SCO-088 now, so are we still developing 954 and if yes for what indications?

Anil Raghavan: We do not feel the need to further the 954 proposition at the moment. It was a backup for SCO-088 and now that we have proof of concept for SCO-088 in the CML setting. We do not intend to take over K954.

Manish Jain: Great, moving onto SCC-138, I am just trying to understand given the kind of exciting opportunity that we have like we are developing it for DLB simultaneously, why cannot we develop in a product for other indication such as Huntington's, ALS?

Anil Raghavan: We have a broad set of preclinical studies going on for SCC-138. We have studies going on in Alzheimer's disease which is a big front for us and we are also testing it in Huntington's disease and in this presentation, we have only disclosed the clinical trials, which are currently open both for Lewy body dementia and Parkinson's disease. We hope to transition this program to additional indication particularly Alzheimer's if the preclinical data is supportive, so there is background work going on which is not discussed in this presentation.

Manish Jain: And just add-on this one on DLB study that we have spoken in the presentation, just wanted to be clear that does the study enable an NDA filing or it will need to be further studies?

Anil Raghavan: This is a very early stage, pilot study with two investigators at Georgetown University, our intent is to basically get an early feel since we are investing in a much larger and robust proof of concept in Parkinson's disease, we wanted to get a feel in another setting where the theater is different, it is the front part of the brain. So this



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September 19, 2019*

will be much smaller number of patients and we are targeting around 50 patients in this trial. That will only give us a sense of early activity and that needs to be backed up by a development program if that is positive.

Manish Jain: Excellent, I actually had two questions each on SCD-044 and SDN-21, but I will join the queue.

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

Jayesh Gandhi: While we are in discussion with potential partners for licensing of Elepsia[®] XR, can you share ballpark amount what we are looking for?

Anil Raghavan: It is very early for us to give indication on what the expectation is. Earlier we have licensed this to Sun and we have even shared some of the. At the moment we do not have a firm guidance in terms of milestone expectation or royalty expectation, but we would like to see a similar kind of royalty structure which was in the lower teens last time around that is the ballpark, but this also needs to be taken in the context of the comments that I have made about the challenges in the formulation market space. So the value proposition around incrementally innovative propositions have weakened quite a bit, so this projection that I make should be also taken in the context of that overall environment.

Jayesh Gandhi: Okay, that is all from my side Sir. Best of luck for future.

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

Sameer Baisiwala: Thank you. I am in a flight so pardon me for the background noise, very quickly Anil, for Taclantis[®], has 30 months NDA suspension periods gets triggered or it does not get triggered for your filings?



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

Anil Raghavan: Our understanding is that the 30-month suspension was triggered when Abraxis BioScience filed complaint against us at New Jersey Court but we are still waiting to be served, we intend to cooperate with Abraxis which would help them understand the non-infringing nature of our products. To answer your question this 30-month stay is triggered.

Sameer Baisiwala: Okay and just one final one from my side and that is for the return of molecule Elepsia[®] XR from your arm's length partner Sun Pharma, are you getting compensated in any which way?

Anil Raghavan: Originally the deal had upfront commitment from Sun, and that was substantial for a product of this nature and that is a non-returnable upfront for the program so in that sense we do not have an obligation to give that back. There is no additional compensation that we will receive.

Sameer Baisiwala: Okay great. Thank you so much.

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

Manish Jain: For SCD-044 besides psoriasis, will you explore trials for atopic dermatitis, multiple scleroses or bowel syndrome.

Anil Raghavan: Again we have a significant set of preclinical possibilities Manish for SCD-044, our first intent is to be in the clinic for moderate-to-severe psoriasis and several dermatology indications are possibilities for this program and we will make a disclosure as soon as we are ready to extend this IND, but in terms of your specific question on multiple sclerosis we are less likely to go for multiple sclerosis, because you already have a couple of agents from this class I mean one is already approved and one is almost nearing approval, so right from the beginning multiple sclerosis is not one of our focus areas for this program.



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

Manish Jain: Okay and when we look at Ozanimod of Celgene or Fingolimod, what is your understanding today the edge that SCD-044 has over that?

Anil Raghavan: Fingolimod is the early generation program and that is a broad S1P activity because of S1P broad activity it has cardiovascular issues and GI toxicities and significant set of liver issues. So the second generation products came as a response to some of the toxicities of products like Fingolimod, our product is a very selective S1P1 receptor agonist which is highly potent and we would fancy our chances to be a best in class inhibitor of S1P1 compared to other products in this class and we also saw clinically meaningful level of lymphopenia as Dr Siu-Long Yao mentioned earlier , very safe from a cardiovascular setting, very safe dose regimen of up titration, so that gives us a range of opportunities particularly in an unexplored area like dermatology. There are preclinical data both standalone and comparison with some of the competitive agents, so we are looking forward to that.

Manish Jain: And my next question was on SDN-021 and SDN-118, do they both address different markets if you want to so would you want to license them to two separate companies?

Anil Raghavan: Yes, the underlying technology platform is the same in its construct, they address two different problems. In SDN-021, we are trying to create a platform, which deters opioid abusers while in programs like SDN-118 we are trying to keep the yield from the multiple pill abuse or overdose below the toxic threshold. So that in disease like depression where the suicidal ideation is the key tenet of the disease, we are trying to keep the overall yield and the bioavailability under the toxic threshold. So they address two different issues and the reason why we thought we should partner for SDN-021 before initiating additional clinical programs is we need a partner with strong commitment to opioid market. Opioid market has its challenge as you might have seen from the experience of Purdue and other players, so we need someone with a strong long-



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

term commitment to the opioid market to further develop and so we will not make additional investment we will not commit to additional study till we have an arrangement with an appropriate player. The depression, potential to address suicidal ideation risk is an attractive proposition, so we are doing a proof of concept study, we have an early proof of concept set of data which was discussed earlier but we are doing additional proof of concept to see effect at higher level of overdose can we keep the overall bioavailability under the toxic threshold and if we achieve that then it can be an interesting opportunity for many of these issues.

Manish Jain: Great and my last question before I join back the queue was on we mentioned about focus on NCEs and biologics, but we have not mentioned about the capability set that we have created in biologics. I would appreciate if you can give some insights on the biologic capabilities that we have developed?

Anil Raghavan: So in the last couple of years as the high level touched upon, you are familiar with our internal competencies having seen that in close quarters over the last several years, it is mostly built around small molecule discovery and development and also delivery system development and commercialization, but in the last couple of years, we have made a deliberate divert to other modalities particularly antibodies and bi-specific antibodies is an opportunity for us. We will talk specifically about a platform that we have created that is one avenue that we have internally created and there is a core team that has come together to design and develop a platform internally. Also outside of that platform, we have biologic intent in some of the partnerships that Dr. Damle spoke about so we are working on both internally developing assets and also sourcing assets. This can go through the same preclinical engine that was helping us with small molecule development. So we are seeing a potential of portfolio coming together and we hope to talk more about this proposition and potential in the coming years.



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

Manish Jain: Thank you so much. I had one question on SCO-120, but I will join back the queue.

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

Manish Jain: Just on SCO-120 quite exciting data that you all have shared in combination with Palbociclib, so here the development pathway given that you have already had a meeting with FDA, what really will be the development pathway here?

Anil Raghavan: Let me get in Siu at this point he will be able to answer that data.

Siu-Long Yao: So in our initial meeting with FDA I think it was a relatively routine meeting and we agreed that we would start with healthy volunteer study followed by a study in cancer patients as the last line of therapy I think subsequent to that it will depend on what we see. If we see good activity I would imagine that we would even have the chance to get approval in a single arm study in refractory patients at that point. We have also considered the combination with Palbociclib and other CDK 4/6 inhibitors as well as with other agents, right now we are hoping to see great activity in the setting where the subjects have mutations that are not effectively treated by any existing therapy that would warrant accelerating the approval.

Manish Jain: Outstanding, very, very exciting. Thank you so much.

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

Jaydeep Issrani: Thank you everybody for being on call. As we do not have any more questions, we will now close this call. In case you may have any follow-on questions or you would like to have additional details on what we discussed today, we will be happy to meet and address those questions and provide you with answers. We will put up the



*Sun Pharma Advanced Research Company Limited
September 19, 2019*

transcript of this call shortly on our website along with a recording of today's discussion. Thank you so much for being on call today.

Moderator: Thank you. Ladies and gentlemen on behalf of Sun Pharma Advanced Research Company Limited that concludes this conference. Thank you for joining us. You may now disconnect your lines.

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