"Sun Pharma Advanced Research Company Ltd. Annual Update on R&D Pipeline"

September 10, 2020

MANAGEMENT: **ANIL RAGHAVAN –** CHIEF EXECUTIVE OFFICER

SIULONG YAO – HEAD, CLINICAL DEVELOPMENT & OPERATIONS

NITIN DHARMADHIKARI – HEAD, DRUG DELIVERY SYSTEM

MICHAEL CHOI – HEAD, BUSINESS DEVELOPMENT

RAJESH RANGANATHAN – HEAD, PARTNERSHIPS & PORTFOLIO STRATEGY

VIKRAM RAMANATHAN – HEAD, TRANSLATIONAL DEVELOPMENT

NITIN DAMLE – CHIEF INVESTMENT OFFICER

CHETAN RAJPARA – CHIEF FINANCIAL OFFICER

JAYDEEP ISSRANI – GENERAL MANAGER, BUSINESS DEVELOPMENT

Moderator: Ladies and gentlemen, good day and welcome to SPARC's Annual Update on R&D Pipeline. As a reminder, all participant lines will be in the listen only mode. And there will be an opportunity for you to ask questions after the presentation concludes. Should you need assistance during the call, please signal the operator by pressing "*"then "0" on your touch tone phone. 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, Raymond. Good evening, everyone. Thank you for joining us today for SPARC's Annual Update on R&D pipeline. I hope you and your dear ones are keeping safe amidst the ongoing pandemic.

Today, with us we have our CEO, Mr. Anil Raghavan and the members of SPARC's Senior Management team on the call.

We had shared the slides some time ago and we hope that you all have received the slides. The slides are also available on our website, i.e. www.sparc.life. These slides can also be viewed using the link that we shared earlier. We will also put up the call transcript on our website soon. The format of the discussion will be similar to what we have followed in the past, that is, 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 includes forward-looking statements that are subject to risks and uncertainties associated with our business, that could cause the actual results to differ from those projected in the presentation today.

With that, I would now like to hand it over to our CEO, Mr. Anil Raghavan for his presentation. Over to you, sir.

Anil Raghavan: Thank you so much, Jaydeep, for the introduction. Hello, everybody. A very warm welcome to all of you to the 10th Investor Update on the SPARC R&D Pipeline. Thank you so much for taking the time to be with us today.

Many of you have been regularly attending this call over the last several years. As I have mentioned in the past, your sustained support and engagement over the years have been a great source of energy for all of us at SPARC. So, I am delighted to welcome you back to this important call.

Let me briefly go over the agenda before going to my opening comments:

I plan to start off with a brief overview of our strategy, before laying out the expectations for the short to medium-term. It's important to take note of the implications of a rapidly changing marketplace and discuss the impact of perhaps a ‘once in a life time’ disruption, the COVID-19 pandemic.

Dr Siu- Yao, Global Head of Clinical Development & Regulatory for SPARC, will join us to provide a detailed update on our clinical stage portfolio covering program strategy, immediate

next steps and expectations for the next 12 months. These are programs which contribute a lion's share of our current value. We have also included a deeper dive into the market opportunity driving our clinical stage portfolio. Our head of Business Development, Michael Choi will walk us through key elements of our internal market models for some of the key projects.

Preferential access to exciting new science is a critical component of the value proposition SPARC is trying to put together. The strategic partnerships with good academic research systems are critical to executing this strategy. Dr. Rajesh Ranganathan who recently joined us from Mass General Hospital to head up our portfolio strategy and strategic partnerships will join us later in the call to discuss this important initiative.

We have quite a bit of activity beyond the clinical pipeline. We are excited about the potential of our early stage programs to elevate our profile to an important innovator in our industry. We would like to talk a bit about the thinking behind the choices we have been making to put together a pre-clinical pipeline. Key themes which drives the choice of targets and technologies. This review will also touch upon our foray into novel biologics and multi-specific anti-body programs. Dr Vikram Ramanathan who heads our Translational Development function will cover our pre-clinical choices while Dr Nitin Damle, our Chief Innovation Officer will go over the key elements of our Biologics play. We plan to conclude the presentation part of today's call with an overview of our financials and cash flows with Chetan Rajpara, our CFO.

As usual our senior management team is here with me on this call. But in the interest of time, we don't plan to make individual introductions. I will start with a few opening comments on our strategy and the progress we have made in the last twelve months before moving on to detailed program level updates. As always, we are looking forward to a very lively Q&A at the end.

So, let's start with Slide #5. We usually jump straight into project level updates in these calls. For a change, I would like to zoom out a bit to review our journey so far. Our vision to pursue a path of pure innovation hasn't been an easy one, given the challenging and still nascent innovation ecosystem in India. But at the same time, we are proud of what we have achieved so far, and our overall capital efficiency.

Let's take a moment to recap:

Since our spinoff in 2007, we have been building our portfolio with a specific focus on lower risk opportunities, mostly in novel drug delivery systems using FDA's 505(b)(2) regulatory pathway for incremental innovation. And this has led to 2 FDA approvals for SPARC products. Xelpros, our BAK free Latanoprost once daily eye drops for ocular hypertension and open angle glaucoma which is currently marketed by SUN FZE and Levetiracetam higher strengths, 1000 and 1500mg tablets for Epilepsy. We are in the process of finalizing a commercialization agreement to market Elepsia in the US. And hopefully we will have something for you very soon on this front.

Following this, we have around 10 NCE/NBEs in our pipeline, including several first-in-class opportunities. Among these we have three NCEs in clinical development, pursuing seven different indications.

We have built a robust brick and mortar infrastructure, which is quite unique among our peer group for early stage biotech companies. Most companies with early stage projects tend to be significantly more virtual, while we deliberately pursued a strategy of a strong captive capability to leverage cost advantages of our location. Today, SPARC has around 425 people around three different locations, Mumbai and Vadodara in India, and Princeton in the US. More than 350 among us are scientists with impressive academic and industry credential.

So, what does all this mean for SPARC? Two things are worth mentioning and worthy of taking notes:

So what does all this mean for SPARC? Two things are worth mentioning and worthy of taking note.

First - We have set up several near term catalysts for SPARC. We will go over these in substantial detail later in the presentation.

Second point is equally or more important. The cross bar below has a summary of capital infused into our company over the years. We have taken around 150 million dollars to build a clinical portfolio comprising 3 NCEs, across 7 indications including a true block buster opportunity. We believe it provides significant validation for a capital efficient development model which can be part of the solution as our industry struggles to answer the hard questions on drug pricing and affordability. We couldn't have achieved this without the patient and committed support from our investors including our promoters who contributed more than 90% of capital infused into this company. So, a big thank you to all of you for helping us to make this happen.

But our story is not just about the near-term catalysts or the preclinical pipeline following that. This effort has also led to a fully built up operating model plugged into the global drug discovery ecosystem. So please allow me a minute to highlight some key aspects of our competency pool and partnering model.

So, let's move to Slide #6, please:

Our model has three distinct parts which is built around a core captive execution engine. We can prosecute an early stage idea all the way to late stage clinical development primarily using internal capabilities. Our medicinal chemistry team based out of Vadodara is a contemporary chemistry group with significant computational chemistry and bioinformatics capabilities. We have built robust delivery system strength, building on the inherited formulation expertise. Over the years, we have also developed substantial Biology infrastructure spanning In Vitro biology, Pharmacology, Drug Metabolism, Pharmaco-Kinetics, and Toxicology, enabling us to de-risk

programs through good proof of concept studies and evaluate the risk/benefit balance in depth before graduating assets to clinic.

Another unique element of our model is our captive experience in scaling programs from lab to clinic and commercial operations, especially from a manufacturing standpoint. Most early stage companies have significant dependency on external CMOs & CROs in this translational phase which kind of bloats their cost structure.

Adding to this in the recent past, we have scaled our clinical development function with our Princeton operations as its base. Today we can claim a strong internal core which can design smart trials and oversee its global execution through our implementation partners. That core group has a fairly diversified set of "been there, done that" experience covering clinical development science, therapeutic depth in Oncology, Immunology and CNS, Biostats, data management, Clinical Pharmacology and increasingly of late, Biomarkers.

These core set of competencies which forms the nucleus of a cost effective 'translational development engine' is a highly leverage able asset as we look to advance and replenish our early stage roster. In that sense, it's a key element of SPARC's value.

Two other pieces here are worth mentioning: We have built a fairly effective early stage partnering program covering some of the most productive academic systems around the world. This bridge with high quality PIs and early stage start-ups give us access to good, exciting science. This also can ensure an appropriate flow-through for the captive development engine we have built.

On the other end of the value chain, we have several commercialization possibilities as we make progress with our portfolio. As of now, we are committed to remain a pure play R&D shop, focusing all our energies on the generation and development of high quality assets. Such a model assumes appropriate commercialization partners who can help maximize value of our assets. But we remain open to considering the possibility of extending our scope beyond the current R&D focus to fully capture the value of these assets. But let's park that discussion for the future.

So, let me sum up before moving on to some specific programs:

We are at an important point in our journey with a significant number of near-term catalysts and a somewhat unique operating model refined through a 12 year journey which saw many successes and some failures. While we are proud of our achievements, we are super excited about what is in store. So let's take a look.

Slide #7.

Let's start with programs in our NDDS portfolio:

These are programs which form the initial set of innovations which came from SPARC. I guess most people on this call are familiar with the first row comprising Lipodox and delivery system technology licensing deals done early on. So, let me not spend much time on that. On the approved product, I want to update on Elepsia XR, which was returned to SPARC last year by Sun FZE. We are very close to finalizing a marketing arrangement for Elepsia in the US. We aim to conclude this transaction this quarter so that we can reach the market at least by the first quarter of FY '22. And we are looking forward to a successful launch, given that the patients still don't have a higher strength, a true extended release option in the epilepsy market, so this is something which we can look forward to.

We have met many of you earlier this year to give an update on Taclantis when we received the Complete Response Letter from the FDA. At that point, we have highlighted several key issues raised in the CRL, including the FDA ask for an additional Clinical Study. We have met with the agency subsequently and interacted with them several times since then to find an acceptable way forward for the program. While we managed to find clarity and make progress on some important parts, FDA continues to maintain the view that an additional clinical trial is required to fully establish efficacy. As we have mentioned in our earlier call on this subject, we continue to believe the bio-equivalence established in our pivotal clinical trial is an appropriate and adequate bridge for efficacy, consistent with all the pre-submission expectations of the agency. We have approached the agency's dispute resolution mechanism to present our case again and recently met with the designated dispute resolution official to present our arguments. We expect this process to take additional time unfortunately. But we will continue to press hard to make an effective case based on our data and regulatory history.

We are in the process of completing two Phase-III studies in this late stage basket. PDP-716 and SDN-037. PDP-716, as you know, is a once a day eyedrop of Brimonidine 0.35% for ocular hypertension, and open-angle glaucoma. We have completed the patient recruitment for this study and we expect the read out of the top-line results in Q4 of this year. SDN-037 is a twice daily eye drop of a potent steroid for treating inflammation post cataract surgery. We have completed this study and are currently in the process of finishing the statistical analysis. We expect the top-line data to come later in this month. So, we are looking forward to finalizing the commercial arrangements for US for these assets once we have the top-line data. Additionally, we have licensed the China rights of these ophthalmic products, in addition to Taclantis and Elepsia to CMS. And we are working with them towards an NDA and commercialization of Xelpros and Elepsia in China.

These initial set of assets were very important for SPARC's journey. Not just these programs which can succeed and contribute, but also our failures as they gave us some important pointers as to capabilities we have or do not have. Important learnings about translating an early-stage promise into a marketing approval in a large market, and we are better off for that today.

But the most important and perhaps the most pertinent point here is the moderation of the opportunity around the delivery system innovation. There may still be opportunities in improving the risk benefit balance of therapeutics through better delivery. But the

reimbursement environment for such interventions have become really challenging. It is becoming increasingly difficult to build a high value sustainable portfolio around such approaches. But frankly, the pricing pressure is not just about delivery system innovation. I want to spend a minute on this topic on the next slide before moving to our current focus.

Slide #8 please.

On the charts on the top half of this slide, we have the stories of three very successful new classes introduced in Oncology in the last five years. BTK inhibitors in CLL and other B-Cell malignancies. PARP inhibitors trying to exploit synthetic lethality across multiple solid tumours and CDK-4/6 inhibitors in ER+ mBC. In all these cases, we can argue about the clinical superiority or safety of first in class products. Imbruvica in BTK inhibition, Olaparib in PARP and Palbociclib in CDK 4/6. But there can be very little argument about the advantages first in class products have in garnering market share. This is true 'across the board' and "a little bit more true" in Oncology.

At the same time, we recognize that a strategy of going after completely novel targets substantially increases the risk profile of the portfolio. But we cannot be a serious player in the pharmaceutical innovation without taking note of the broader shift in the market towards real value and demonstrable clinical differentiation. As we often say, low risk has come to mean no return, or unviable low return in this business. So, it's not just about the increasingly constraining reimbursement environment, but also about the time and complexity of generating datasets which are compelling, which are required to differentiate and make effective cases for follow-on compounds. SPARC has taken this shift to heart and made significant adjustments to the way we look to shape our portfolio.

Let's go to Slide #9 for a high-level view of how we have adapted:

We have spoken about this shift in strategy many times in the recent past. What I want to report is that we have made progress with execution of that strategy. Let me highlight a few things which are important to emphasize.

We have actively pruned our portfolio to take-out programs which don't make sense in the current environment. Not just projects targeting to improve delivery systems for better risk/benefit. But also some me-too follow-on NCE. A look at our early clinical stage programs makes this point clearer. We are pursuing Vodobatinib because we could reposition the asset as a first in class, potentially disease modifying drug in CNS while the CML part of the effort provides an important hedge. We have oriented our S1P R1 agonist to a set of dermatology indications, completely skipping its more crowded space in Multiple Sclerosis and Inflammatory Bowel Disease. We are similarly pursuing niche opportunities to differentiate in ER degradation space in mBC.

But more importantly we have rebuilt our pre-clinical portfolio around potentially "first in class" or "early enough in the class" kind of targets. We have also diversified our effort beyond our

traditional niche of small molecule chemistry to include novel biologics, multi-specific biologic entities, other conjugated entities and complex delivery systems leveraging some unique disease biology. That's a substantial shift in short time.

Let me spend a slide each on these NCEs and early stage focus before I conclude. You will have lot more detail from others later in the presentation.

Slide #10 please.

Here is a 70,000 ft. view on five of our most important, near term catalysts.

Starting with probably the most important asset in the current clinical roster. Vodabatinib in Neurodegenerative Diseases. We have reviewed the highlights of its pre-clinical proof of concept in the last edition of this call. Particularly its data in the Parkinson's disease. We have made substantial progress in additional early stage clinical studies trying to match the brain levels seen in appropriate animal models with the free drug levels in the brain in human trials. We have determined the target P2 dose and made certain adjustments to its formulation. We are currently recruiting globally for a large, 500 + patients proof of concept study, which is expected to complete in 2022. We call that study PROSEEK. PROSEEK may be the largest PD Phase 2 trial currently recruiting. We will review the Parkinson's disease landscape later in Michael's section. But let me just say this. If the Mechanism reproduces its animal proof of concept in human trials, SPARC has an opportunity to be a first in class player in a set of indications where the standards of care haven't moved in decades. That means multi-billion dollar peak sales potential in PD alone. We are also doing a smaller proof of concept study at Georgetown University in Lewy Body Dementia. LBD as you may know is a variant of PD with a substantial unmet need. We are also expanding the program to Alzheimer's disease with additional pre-clinical studies. So as you can see, we are very excited about the promise of the c-Abl pathway in neuro-degeneration and Vodobatinib's ability to realize that promise.

We have two oncology programs in this roster. The original CML studies of Vodobatinib and SCO-120 in ER+, HER-2 negative, metastatic breast cancer. We continue to see impressive response for Vodobatinib in heavily pre-treated CML patients. We have met with FDA several times to gain agreement on the pivotal protocol for registration. Currently we are recruiting the registration study for refractory CML which is scheduled for submission in early FY-23. It is also worth mentioning that Vodobatinib has been granted orphan drug designation for CML. More on this later. The second program is an early stage compound in metastatic ER positive breast cancer. Our compound is currently in early stage dose escalation studies. We hope to establish an early clinical PoC by next year.

We have previously reviewed the SCD-044 data in our investor calls. As you know, SCD-044 was a collaborative program with a French Biotech, Bioprojet. SPARC licensed Bioprojet's rights to the asset last year. Since then we have completed the IND enabling studies for its long term clinical proof of concept in Psoriasis and Atopic Dermatitis. Both projects are expected to start recruiting for Phase 2 studies in Q3, FY2021. We expect to have these proof of concept

studies read out in 2022. In addition, we are also exploring SCD-044 in Alopecia Aerata, an auto immune variant of Alopecia. This would be an investigator led trial out of Tufts University in Boston.

As we disclosed previously, we have licensed the global rights of SCD-044 to Sun Pharmaceuticals earlier this year. Sun will be responsible for the clinical development and commercialization of this asset. We have received 20m dollars in upfront payments, with a provision for additional development and approval milestones and attractive royalties. We look forward to working closely with Sun as we make progress with the clinical trials.

Last program on this slide is Phenobarbital. As you may know, Phenobarb was used as a DESI drug in multiple indications including Neonatal Seizures, Abstinence Syndrome and certain adult seizures. We have been in consultation with FDA to put together an approval path for a safer Phenobarbital over the last year and we now have clarity in terms of agency expectations for approval. This program has also been granted Orphan Drug Designation. We plan to file an NDA by end of 2022.

Siu and Michael will review these programs in greater detail in coming segments to give you additional color on the clinical plans and commercial potential.as I move to Slide #11.

I don't plan to spend much time here. We have covered most of these points in my earlier comments. But two things are worth noting. Over the years, our therapeutic focus has narrowed to certain areas in Oncology, Neurodegenerative Diseases and Autoimmune Disorders. This choice has been driven by our desire to limit ourselves to a few areas where we can invest to build differentiated capabilities in the medium term. This choice is also informed by our read of the unmet needs, our access to emerging science and our readiness to scale. So we will continue to focus on these areas so that we can improve the maturity of our capability as we go forward.

Second point is about the composition of our portfolio on the right side of this chart. We discussed the transition of our basket a little while ago. But two set of numbers underscore that point very emphatically. NDDS which was more than 80% of our portfolio five years ago is less than 20% today. And one third of our programs have the potential to be first in class drugs. That's is a very significant transition, pursuing a deliberate strategy. We feel happy we could reorient the portfolio swiftly in response to a rapidly and disruptively changing market place.

We believe as I mentioned in the previous slide, SPARC offers an attractive set of near term opportunities and an exciting bunch of early stage prospects supported by some important strategic relationships with very reputed academic investigators. Our near term catalysts are set from an execution standpoint with many clinical studies scaling at the same time. We need to execute well.

Before I close, it is important to talk about the impact of the Covid19 pandemic on our portfolio.

Let's go to slide 12.

Covid-19 impact on Pharmaceutical Development eco-system has been quite severe. As hospital systems across the world shut down or got repurposed to handle the pandemic, clinical research activity has come down drastically. First half of this chart shows the extent of disruption in terms delayed initiations, recruitment suspensions and slowing enrolment rates. Within this gloomy picture, oncology has been particularly hit as you can see from the lower left graph. But the disruption is not limited to clinical research. All aspects of translational activity have been impacted. Closed down or scaled down manufacturing facilities impacted IP supply, scaled down lab operations with an 'across the board' impact on pipeline movement, global airline restrictions impacting the supply chain, so on and so forth.

We have taken several steps early on, starting March 2020 to identify and mitigate risks as much as possible. One of the primary priorities was to protect the patients who are already in trials through a combination of ancillary support and virtualization. I like to believe we have been fairly successful in that. Similarly we have managed to maintain high lab productivity from around mid-April by ensuring safe transit and a safe working environment. Today we are at, 70% of our resources working from labs on site and 30% working from home. We have also used this period to scale the clinical trial site infrastructure so that we can scale fast when things normalize later this year or early next year. Especially for our key trials, we have been adding trial sites through virtual site initiation visits and other start up activities. So in summary, I would say that the impact has been real. Not just for us, but for the whole industry. We have been trying to aggressively mitigate and protect our timelines as much as possible. It is still an evolving situation. So we have to keep our fingers crossed on this one.

Now on to my last slide, that's Slide #13, please.

I want to highlight some key expectations for the next twelve months before I go:

We would be covering several of these project level expectations in greater detail in upcoming segments. We have quite a few projects concluding in the short-term, Taclantis which is already in regulatory process, SDN-037, which is expected to be read out anytime now, PDP-716 later in the financial year. Concluding these trials and ensuring appropriate commercial arrangements for them are important priorities. We have important clinical trials at various stages of startup or enrollment. These are trials like PROSEEK, we aim to stay on track to achieve the milestones coming up in 2022 and that's most crucial.

There are additional opportunities to advance assets in the clinics in the next 18 months or so. And we will do that in a measured manner. We want to make sure we are advancing compounds with real impact and reasonable probability of success. And I have mentioned our target partnership model several times today. And as you can see, we are pretty excited about its potential to have an impact on our portfolio. So, we will work really hard to continue to partner and to advance the existing partnered programs to later stages of development. This will continue as a high priority for all of us at SPARC.

That brings me to my last point before I transition:

With several late stage clinical trials in full recruitment mode, and some really important early stage projects in scale-up, we will continue to be in investment mode for a few more years. As I laid out, we have important major milestones scheduled for 2022 which gives us our first real shot at being financially sustainable and independent. So that leaves us with some finite options of either partnering one or more of our early stage high value clinical assets before it reaches the clinical proof-of-concept or raise additional capital. Currently, we are evaluating our options in depth and preparing for another round of fundraise, as a backup option. We hope to conclude this process and execute our plan by the end of this year. Unfortunately, I am not in the position to provide additional information at this point. But we will have a lot more to say on this very soon.

So, thanks, everybody, for your time today. Now, I will hand over the call to Dr. Siu Yao for an update on our clinical stage program. I look forward to seeing you all again on the other end of this call for Q&A. So, thanks again, and over to you, Siu.

SiuLong Yao: Thank you, Anil. My name is Siu Yao. And on behalf of myself and the entire SPARC organization, I would also like to add a very warm welcome to all of our supporters across the world. In the next series of slides, I am going to try to walk you through some highlights of our current later stage clinical programs.

Slide 15 provides some background on vodobatinib, our ABL kinase inhibitor. This is a potent and highly selective inhibitor, the specificity of which is illustrated in the diagram on the right where you can see that there are very few green circles, meaning that the drug inhibits very few other targets besides the intended ABL1 kinase. The drug has good oral bioavailability and PK, with a very modest food effect and it is devoid of cardiac QT effects.

Slide 16 is a very high level summary of some of the key aspects of the clinical development plan for this drug. There is 1 key study that contains a single ascending dose component, a multiple ascending dose component and a pivotal efficacy component shown as Parts A, B, and C, respectively. Part A was completed a while back. Part B is essentially complete but we are enrolling a few more subjects to help provide supportive safety information for Part C which consists of a pivotal efficacy component designed to obtain regulatory approval.

Slide 17 summarizes some of the results we've observed with vodobatinib in Part B of the study. We were able to share some encouraging data with you last year and this year we're very pleased to report that those data are holding up over time and with additional patients. The graphs on the right help summarize some of this information.

In the top graph you can see results for hematological response which means the proportion of subjects who are able to have normal blood counts following treatment. On the y axis are data from 2019 and 2020 and on the x axis are the response rates for each year. You can see that the hematological response rate we saw last year is maintained, or even improved, this year. This suggests that vodobatinib's effects are robust and durable.

The graph in the lower right hand corner summarizes experience with cytogenetic responses, which refer to microscopic findings that are usually used as the basis for regulatory approval. Again, on the y axis are data from 2019 and 2020 and on the x axis are the response rates for each year, and once again, there is robust evidence of effectiveness and durability.

Most importantly, perhaps, is the observation that the major cytogenetic response rate in the population that we intend to use for approval, that is, patients failing 3 or more tyrosine kinase inhibitors one of which includes ponatinib, is very substantial at 58%. In prior discussions with the FDA, this is likely to be very adequate for the purposes of obtaining an approval.

Safety for vodobatinib is summarized on slide 18. There have been 2 serious AEs, both of which were known last year, so there haven't been any new SAEs despite additional time on treatment and new subjects. Mild to moderate gastrointestinal and musculoskeletal complaints continue to be the most common safety findings and there are still no drug associated cardiac events that have been typical of some of the other drugs in the class.

A little more detail about our current plans for CML are summarized in slide 19. As we discussed, we intend to get approval with Part C of our main study in patients who are refractory to 3 or more TKIs, one of which includes ponatinib. FPI has already occurred for this study and there are a variety of centers across the world participating. Topline results are expected 3rd quarter of 2022.

Slide 20 transitions to the use of vodobatinib for Parkinson's Disease. This slide is just a reminder slide that summarizes some of the characteristics of vodobatinib for this indication. Vodobatinib penetrates the CNS well so it is ideal for the treatment of a central nervous system disorder like Parkinson's Disease. Biologically, Parkinson's Disease is characterized by the generation of synuclein inclusions and inhibition of ABL kinase results in decreases in the number of inclusions with resulting beneficial effects in many preclinical models.

We've established PK characteristics in Parkinson's patients through single and multiple dose studies and have found that the drug is generally safe and well tolerated in this patient population. Currently, a Phase 2b proof of concept study named PROSEEK is underway.

Slide 21 provides an update on PROSEEK. On the left is a reminder of the study design. Patients with early stage disease who are not on symptomatic drugs are randomized to placebo, 192 mg or 384 mg and treated for 9 months. Currently, 88 sites are involved across a variety of geographic regions and we have obtained regulatory approvals to start in all countries. Patients have been randomized in the US and EU, with India set to start shortly. Enrolment is expected to complete in the 4th quarter of 2022.

Slide 22 summarizes some of the efforts we've implemented to try to help this study accrue and make it a success. We are finishing up work on a patient website and are in the process of starting media campaigns. Additional regions are being evaluated for participation and we are

implementing changes in the protocol to make it more user friendly for subjects who are wary of visits to healthcare institutions because of things like COVID.

Finally, before we move on from vodobatinib, I want to mention that we are also studying the drug in Lewy Body Dementia, as summarized on slide 23. This disease is biologically very similar to Parkinson's Disease with many of the clinical characteristics overlapping. Investigators at Georgetown University in the US are very interested in the potential of vodobatinib for this population and we have been supplying them with drug so that they can see how the drug fares in a 12 week study. Of course, that's a very short period for a neurological disease, so the primary focus of this initial study will be on safety although there will be endpoints looking at a variety of biomarkers of response which may be associated with potential clinical efficacy. This study is expected to complete in the 4th quarter of 2022.

Slide 24 transitions to our work with SCD-044, a sphingosine receptor agonist, for the treatment of autoimmune diseases. SCD-044 is a potent, orally bioavailable compound that has the potential to have a better safety profile compared to other drugs in the class, such as fingolimod, which has potent cardiovascular effects, namely bradycardia. We are currently focusing on psoriasis and atopic dermatitis as potential indications.

Slide 25 shows a graph with either lymphocyte count results, depicted as green or orange bars, or heart rate changes depicted as red bars. Various dose regimens were tried in this study as shown going across the top of the graph underneath the title. So you can see that there is 1mg, 2mg, 2-4-6mg, 0.3-0.6-1mg and 0.2-0.6-1mg regimens. Some of the newer S1P agonists have only limited effects on heart rate, in the range of a decrease of 5 or 6 beats per minute depending on the titration regimen used. You can see that we are also able to achieve that with a titration regimen consisting of 0.3, 0.6 and then 1 mg. Importantly this regimen is also associated with a 55-63% decrease in lymphocyte counts which should be sufficient to see good efficacy, better than apremilast, in psoriasis or atopic dermatitis.

The last program I want to go over with you is our oral selective estrogen receptor degrader, or SERD, program. The biological and commercial rationale for this program is summarized in slide 26. As many of you know, hormonal therapy targeting the estrogen receptor is a mainstay of therapy for metastatic breast cancer and is used in nearly 75% of eligible cases. Unfortunately, mutations can develop in up to half of these patients. There is a marketed SERD, fulvestrant, but it must be given by intramuscular injection and it does not effectively treat patients whose tumors have developed mutations. SCO-120 is an oral SERD with activity against mutations.

Some current clinical information on SCO-120 is summarized in slide 27. The IND for this compound was filed in January and a single dose, dose escalation study is ongoing. We've studied doses up to 100 mg and there have been no significant AEs. Future plans for this program include a multiple dose study in volunteers followed by a proof of concept study in patients.

Some encouraging data from the dose escalation study are shown in slide 28 where you have SCO-120 concentration on the y axis and various groups on the x axis such as mouse

concentrations associated with efficacy in preclinical studies which are shown in green. Shown in dark blue are pharmacokinetic results following 50 and 100 mg doses in humans and in the faint orange are projected concentrations. You can see that at the 100 mg dose we are already at concentrations that were efficacious in preclinical models. We will continue to escalate to better understand the characteristics of SCO-120 but we are very encouraged by this finding.

That's my last slide. I hope all this information answers some of your questions about our late stage clinical programs, and I'll be happy to answer any questions you have later in our call. In the meantime, I'd like to transition over to Dr. Dharmadhikari who will walk you through some additional projects.

Nitin Dharmadhikari: Thanks a lot, Siu. Good morning, good evening based on which geography you are participating. It is my pleasure to give you an update on a clinical NDDS assets.

Please go and have a look at Slide #30. This slide provides a summary of our ophthalmology programs. SDN-037 is a product for the management of pain and inflammation associated with cataract surgery. The Phase-III study has been completed and the last patient out occurred in March of this year. Top-line data will be available later this month for this product. The PDP-716 program is summarized on the right side of this slide. This product is indicated for the treatment of glaucoma. Futility analysis results in October 2019 with 245 subjects demonstrated that this study was non-futile and we can continue. Enrollment has been completed and the last patient out is expected in November, with the top-line results in January of 2021.

Please move to the Slide #31 for update on the next product. This slide summarizes status of Phenobarbital injection. Phenobarbital is an old drug and it is a standard of care for neonatal seizures. Current product marketed in US is not approved by FDA and also contains preservative benzyl alcohol, which is not considered safe for small babies. SPARC wants to file an NDA for its preservative free product and we have consulted FDA through a pre-IND meeting. Development program has been worked out based on this advice. Currently we are doing CMC work and PK studies are also ongoing. We also expect to receive orphan drug exclusivity, if successful in getting this product approved.

This finishes my update. Thanks a lot. Please stay safe. And I now invite Michael for further updates. Over to you, Michael.

Michael Choi: Thank you Dr. Dharmadhikari. Hello everyone, my name is Michael Choi and I oversee Business Development at SPARC. I would like to start with a quick recap of the licensing deals we have executed over the last year. Press releases were issued at the time of signing so they may be familiar to you if you have been following SPARC. In Nov 2019, we were pleased to sign an agreement with China Medical Systems for 5 of our NDDS products for development and commercialization in the Greater China region and Taiwan. Our first collaboration in the region.

In Dec 2019, we acquired exclusive rights to SCD-044 from our co-development partner, Bioprojet and in May 2020, we out-licensed worldwide commercial rights to Sun Pharma

Industries. We are particularly proud of this deal as it is the first NCE we have successfully developed and partnered at SPARC. We will continue to collaborate with Sun Pharma on SCD-044 and expect to receive additional milestones and royalties as the product is further developed and eventually commercialized.

I would now like to move to discuss some of the key commercial opportunities in our clinical portfolio. Of these, vodobatinib in Parkinson's disease represents the largest commercial opportunity. Slide 34 describes the epidemiology of Parkinson's disease. There are currently 7 million people worldwide who suffer from Parkinson's disease and this number is expected to grow to above 14 million by 2040. Parkinson's is a disease that affects all people throughout the world. There are 1 million patients in the US, 1.4 million in Europe and over 250 thousand in Japan. Parkinson's is a chronic disease and progressive in nature and there has been very few innovations in this area in decades. More importantly, there are currently no disease modifying drugs available for treatment.

As we see on Slide 35, the economic burden of Parkinson's disease is also great. Patients will typically progress to a point where they are completely disabled and require a great amount of supportive care. The total medical cost to manage Parkinson's disease is $52 billion dollars in the US alone. Single payer markets such as Europe and Japan will have additional incentives beyond the clinical benefits alone to adopt any new drugs that can delay the progression of the disease.

Let's move to the next slide, slide 36. This is where vodobatinib comes in. Vodobatinib has the potential to be a true game changer in Parkinson's disease. As Anil mentioned, vodobatinib has shown the ability to preserve neurons and preserve motor and cognitive function in animal models. If we can replicate this effect in human clinical studies, we will have the first disease modifying drug for Parkinson's disease patients. We tested our clinical study design and expected product profile with key opinion leaders and movement disorder specialist in an independent third party study and vodobatinib was very well received. We expect that it will be used in up to 70% of Parkinson's Disease patients. In addition, insurance coverage and reimbursement is expected to be robust. It is also important to mention that this is not a market opportunity with a small number of patients requiring a very high drug price. It's a large and chronic patient population in the model of the classic large pharma blockbuster drug. Vodobatinib also offers a favorable profile vs. other disease modifying drugs in the pipeline in that it is a once a day oral formulation. Finally, we had strong portfolio of patents which should protect it from generic competition until at least 2040.

While forecasts are always hard to do, our internal analysis, which was recently validated by an independent third party research, is in the high single digit billions for peak year sales for PD alone. Our forecast for other CNS indications is quite early at the moment, but we believe it is in the order of magnitude to the Parkinson's base forecast. Lewy Body Dementia is an indication with 1.5 times the patients as Parkinson's, however, we expect that there will be high level of overlap between Parkinson's and Lewy Body Dementia patients. Alzheimer's Disease has 4 times the number of patients worldwide as Parkinson's, and we don't see as much overlap as we

do with Lewy Body Dementia. Therefore, we roughly estimate that the potential for Alzheimer's is up to 2 times the base forecast for Parkinson's Disease.

On Slide 38, we discuss the opportunity in CML. The introduction of c-abl targeting tyrosine kinase inhibitors have turned a once deadly cancer of the blood, into a manageable chronic disease. The average CML patient lives for 22 years after diagnosis. During this timeframe he or she will likely cycle through a number of different treatment options as resistance develops to initial therapy. You can see the growth rates of prevalent cases across the world on the Table here.

On slide 39, you see the progressive nature of CML reflected in the product sales of 1st, 2nd and 3rd generation TKIs. The current global market for these TKIs is $6 billion dollars. The majority of this value is not assigned to the 1st line agent which is imatinib, a now genericized class. It is driven mainly by Sprycel and Tasigna, the 2nd line agents. In addition, you can see that Bosulif and Iclusig are still growing. Vodobatinib was specifically designed to address a major unmet need in this class of TKIs, which is cardiovascular toxicity. So far, we have not seen any drug related cardiovascular events nor QT prolongation in over 250 humans who have been dosed with vodobatinib. If we can maintain this trend through development, we believe we have an opportunity to take significant share from this market. We estimate global sales in line with the 3rd generation TKIs for the end of line indication with potential upside for the 1st line indication.

Finally, I would like to discuss SCO-120 which is currently in Ph.1 for metastatic breast cancer. HR-positive, HER-2 negative breast cancer represents one of the most prevalent diseases of all cancers, affecting over 200 thousand new patients per year. The current market size is estimated to be $5 billion dollars in 2020, with CDK4/6 inhibitors emerging as the new gold standard treatment. This therapy requires an endocrine backbone, but the only SERD currently available is fluvestrant, which is limited by its poor bioavailability. In addition, mutation in ER-alpha cause resistance in 20-50% of patients. A novel oral SERD like SCO-120 can address this significant unmet need and serve a large segment of this patient population. However, it is far too early to present a reasonable forecast for SCO-120 because the exact profile of our drug and that of the competitive set is still unknown. As this market develops further, we will provide an update on the program and the market potential for SCO-120.

This concludes my portion of the presentation and now I would like to pass the baton to Dr. Rajesh Ranganathan.

Rajesh Ranganathan: Thank you, Michael. As Anil mentioned, I have joined SPARC recently, and I am looking forward to engaging with all of you at the end of this meeting, as well as in future meetings.

If we can move to Slide #42. You had sort of a preview of this from Anil, where our strategy now sort of bootstraps a robust engagement of the academic community, especially in the United States to feed our pipeline. So in addition to the internal strengths that are listed here, and the explorations that we have been doing, we are now focusing significant efforts on a search and

evaluation process to identify suitable opportunities that fit into our evolving strategy to be more focused on first-in-class new targets, that Anil highlighted previously.

So, if we can move to the next slide. We have engaged 20-plus academic institutions worldwide at varying levels of exploration, and these include Harvard tops, Washington, Michigan; MD Anderson, University of Arizona, UCSF, organizations in Israel, UK to name a few. Here we are highlighting two of the more mature relationships, one with UCSF on the left and the other with the University of Michigan on the right.

At UCSF, we have two projects ongoing, one that's focused on cancer and the second on a drug delivery platform. In both of these collaborations, we would have the option to license the asset if appropriate scientific milestones are met, and we can pursue further commercialization as we see fit.

At the University of Michigan, at the beginning of 2020, we signed an umbrella agreement to provide about $10 million over a period of three years to fund multiple projects. We are conducting our first round of due diligence evaluations of opportunities and have also initiated a second call for proposals. While we were negotiating the umbrella agreement, we also independently set up a collaboration to leverage a unique resource at Michigan, which is a collection of natural compounds and extracts from all over the world. We are conducting a screening of this collection for a target of interest in oncology to evaluated a new chemical map that can be identified.

The advantage with natural products is that they have been honed over millennia of evolution in the ongoing war between organisms to have exquisite specificity that we hope that we can take advantage of. These are just two examples. This engagement of academic is a nascent effort that will be ramped up in the coming year to augment the SPARC pipeline. And I look forward to providing more updates on this front in future meetings.

I will now hand it over to my colleague Dr. Vikram Ramanathan, to talk in more detail about our preclinical assets.

Vikram Ramanathan: Thank you, Rajesh. And good morning, good afternoon or good evening to you all, based on where you are located. My name is Vikram Ramanathan, and I will give you an update on our preclinical NCE assets.

As outlined by Mr. Anil Raghavan, we have deliberately pivoted in two ways at SPARC. We have pivoted to now focus on new chemical entities, NCEs, and new biological entities, NBEs, as opposed to primarily novel drug delivery systems. We have also pivoted to work on developing first-in-class agents, as opposed to only validated targets.

Our catalysts are in the clinic. These include compounds that Dr. Siu Yao described, including Vodobatinib for Parkinson's disease, Vodobatinib for chronic myelogenous leukemia, SCO-120 for breast cancer, and SCD-044 for autoimmune diseases, including psoriasis and atopic

dermatitis. These compounds in clinical developments should deliver for the company in the medium-term.

If we now move to Slide #number 45, shown here is an outline of the areas of our therapeutic focus in the preclinical space. We are increasingly focused on novel drugs for novel targets. My overview will outline the NCE efforts and strategy in the lead optimization phase. In oncology, we are working in two broad areas, cancer metabolism, and cancer drug resistance. In neurodegeneration, we are currently focused on Parkinson's disease, Lewy Body Dementia, and Alzheimer's disease. These diseases share a common theme, which I will touch upon. In the area of immuno inflammatory diseases, we are focusing on platform technologies for local delivery to specific organs using novel, physical and chemical approaches. These are all areas where there is an unmet medical need, and I will go over each in turn.

Moving to Slide #46. This slide shows a diagrammatic summary of cell metabolism. Normal cells have a complex network of pathways to produce the raw material needed for their growth, including glucose, amino acids, proteins, etc. Cancer cells upregulate certain cellular metabolic pathways to meet their energy needs to grow fast. They convert minor bypass pathways in healthy cells into major pathways, cancer metabolism is an active area of research and offers a novel way to target cancer cells. These upregulated enzymes in cancer cells have potential molecular targets in specific cancers. Putting the brakes on the metabolism should inhibit cancer cell growth and should complement existing therapies, including chemotherapy. Because many pathways play a role, our goal has been to identify and prosecute the right target.

I would like to move then to the second major area of our interest in cancer as shown in the next slide, Slide #47.

We are targeting driver mutations in cancer. Driver mutations are the dominant mutations that drive cancer cell growth. As you know, random mutations occur in a patient but only some of these drive the cellular changes that actually cause cancer growth. There are also some genetic transpositions that can drive cancer growth. Such driver mutations or genes give a growth advantage to the cancer cells and they outgrow normal cells. Because they are specific, presence of such driver mutations are often predictive of clinical outcome. Importantly, this means that patient tumors can be genetically profiled to enable precision medicine.

Earlier-generation therapies that target such growth drivers lose efficacy over time. The cancers develop resistance by acquiring resistant mutations in these growth drivers. About 90% of cancer deaths are attributed to drug-resistance. Our efforts are focused on targeting drug resistance in such driver mutations.

The next slide, number 48, exemplifies a target from our clinical portfolio in this respect. SCO-120 is a degrader of the ER-α estrogen receptor. It is a drug on the development for drug resistant breast cancer. The ER receptor drives cancer cell growth in ER+ tumors that first line therapies fail after some time. This is because the ER receptor undergoes mutation, making it resistant to these first line therapies. SCO-120 is designed to be active against such resistant mutations.

Because it targets specific resistant mutations, it is possible to do genetic profiling to identify patients for clinical trials and later for therapy. Our efforts in the lab focus on pursuing other oncology targets, where similarly the target undergoes a genetic mutational change, making it resistant to frontline therapies. These slides have covered our strategy in cancer metabolism and drug resistance.

I would like to now move to the topic of neurodegeneration in Slide #49. In neurodegeneration, our focus is in Parkinson's disease, dementia of Lewy Body, and Alzheimer's disease.

Slide #49 shows a diagram of the brain with the anatomic location of various neurodegenerative diseases. The abbreviations are below the figure. Different neurodegenerative diseases show abnormal brain pathology and atrophy of different regions of the brain, each disease with a specific regional pattern. From a therapeutic target perspective, there is a theme that has emerged. It is now clear that regardless of the individual neurodegenerative disease, accumulation of abnormal or misfolded protein aggregates in neurons is a common feature. This means that molecules that can speed up clearance pathways for misfolded proteins have broad applicability in this area.

The next slide, number 50, shows a diagram of the neuron that summarizes the cellular processes that are involved in neurodegeneration, which occurs due to accumulation and aggregation of such misfolded proteins. This accumulation results in choking of the normal pathways to clear misfolded proteins. It causes neurons to die and causes progressive brain atrophy, which shows up at some point as dementia. Examples of such misfolded culprit proteins are α-synuclein in both Parkinson's disease and Dementia of Lewy Bodies, amyloid β42 and tau protein in Alzheimer's disease, and huntingtin in Huntington's disease.

We are focused in the lab on identifying small molecules that enhance clearance pathways for misfolded proteins in neurons, this includes ubiquitination, which is protein quality control mechanism; autophagy and interactions for, with example, heatshock proteins.

Finally, we come to our immuno inflammatory diseases in Slide #51, which is the last slide in this section. We are working in the area of immuno inflammatory diseases with a particular focus on a couple of platform technologies for novel approaches to deliver agents in site specific manner. The first platform technology is a physical approach using nanotechnologies for site directed monoclonal antibody delivery to target organs. We have a collaboration with a US academic who has world-class expertise in nanotechnology to develop ways to deliver protein. It essentially aims at using a molecular velcro to localize the specific organs and deliver one or more proteins simultaneously. This is a collaboration that is part of our academic outreach efforts that Dr. Rajesh Ranganathan referred to a few minutes ago.

A second platform technology is using chemical approaches for site-directed therapies. Here we are developing novel-linker technologies and moieties to design innovative ways to target immune cells in the vicinity of the target organs and to access the lymphatic system. We look

forward to sharing an update on our efforts in oncology, neuroscience and autoimmune therapies in the coming time.

This concludes my part of the presentation. And I would like to invite my colleague, Dr. Nitin Damle, to give you an update on our efforts in biologics. Thank you.

Nitin Damle: Thank you, Vikram. And hello, everyone, joining in from different time zones. I am Nitin Damle and during the next few minutes, I will be discussing about a new dimension in the R&D strategy for SPARC.

We have so far emphasized and exemplified our focus on discovering and developing NCEs and novel drug delivery systems. As Anil pointed out in his presentation, we are now poised to introduce a new dimension of exploring a new biologic vista for SPARC. For the last few years, we have been developing our internal capabilities to be able to undertake biologics R&D. The goal for SPARC biologics is to create and subsequently develop innovative and differentiated novel biologic entities for therapeutic applications, primarily immune oncology and immuno inflammatory diseases therapeutic areas. We believe that these two large therapeutic areas are ideally suited for the applications of novel biologic entities or NBEs. Hence, our disease focus at SPARC has remained and will continue to stay the same for both NCEs and NBEs as you heard earlier.

Towards this primary goal, we have developed a platform for antibody-based technologies, whose application will likely yield multiple therapeutic opportunities for multiple shots on goal in the above two therapeutic areas. With NBEs, our emphasis will always stay on not only the demonstration of single agent anti tumour or disease modifying activity, but also ease with which these can be readily combined with the prevalent standards of care for the individual disease indications.

A vast majority of the biologic therapeutics have so far been antibodies, and there are now 79 different antibodies approved by the US FDA as of December 2019, for various disease indications. And this number is going to increase further as newer antibodies successfully advance through their clinical development over registration. It is quite reassuring to note that more than 70% of the world's largest grossing therapeutics have now been antibody-based therapeutics. Hence, it makes a great deal of sense for SPARC to complement this existing pipeline of NCEs and NDDS candidates with antibody based biologic therapeutics.

As shown in Slide #53, we have made a strategic decision to focus on the creation of bi-specific or multi-specific antibodies or immuno fusions. One advantage in this focus is that the technology allows for the creation of a single therapeutic entity that can confer the benefits of at least two or more antibody therapeutics. If proven to be clinically efficacious, this feature is highly desirable, especially from the collective perspective of not only patients but also prescribers and payers.

As far as anti-cancer therapeutic applications of antibodies are concerned, there is a large number of tumors associated molecular targets to choose from. Many of the obvious clinically and commercially validated cancer targets such as EGFR or HER2 or CD-22, what we now recognize as low hanging fruits have already been plucked, hence we need to focus not only on the current clinically validated targets, but also those that are promising yet not validated enough, and there are quite a few of such targets of interest. Collectively they may be derived from either tumor cells themselves or from the tumor microenvironment or the cells of the immune system. A case in point for the latter is the success enjoyed by a mono-specific immune checkpoint inhibitory antibodies targeted against CPLA-4, PD-1 or PDL-1.

In order to enable our interest in the antibody-based therapies, we have developed various capabilities at SPARC as shown on slide 54 and these include, various molecular biology and recombinant DNA technology capabilities, antibody development and engineering for humanized or fully human or antibodies, and various capabilities that allow for the large scale protein expression and purification, in addition to their structural and functional characterization.

Lastly before I conclude, we are also developing, capabilities to conjugate potent cytotoxic payloads to the above antibody-based tumor targeting agents, to create antibody-cytotoxic drug conjugates (ADC) using SPARC's proprietary drug-linker technology which is being developed in our drug discovery program. While I cannot be more specific, at this point than what I have noted so far, I do look forward to the opportunity to discuss more specifics about our NBE projects during the next year's investor update

Thank you for your attention. And I would like now to invite Chetan Rajpara, our CFO, to continue this discussion further. Chetan!

Chetan Rajpara: Thanks, Dr. Damle, for a detailed overview of SPARC's biologics. Good evening, everyone. I plan to go over SPARC's financial and cash position at a very high level. I will keep this really brief.

Slide #number 56, please. During FY '20, total income was at Rs. 866 million, equal to US$ 12.2 million. While total expenses were Rs. 3,990 million, equal to US$ 56.3 million, resulting into a net loss of Rs. 3,124 million, equivalent to US$ 44.1 million for the year.

Let me update you on our latest quarterly financial results, which is also part of this presentation, and published and available on our website. For Q1 FY '21, total income was at Rs. 1,861 million, equivalent to US$ 24.5 million. While total expenses were at Rs. 1,294 million, equivalent to US$ 17.1 million resulting into a net profit of Rs. 567 million, equivalent to US$ 7.5 million as against the loss of Rs. 942 million in the corresponding quarter previous year. I would like to mention that Q1 FY '21 income includes an upfront payment of US$ 20 million from SCD-044 licensing deal which is a non-recurring item.

Slide #number 57, please. As far as liquidity status is concerned, cash on hand as at 7th September, 2020, was Rs. 240 million, US$ 3.3 million. For FY '21, approximately 60% of our

expenses are budgeted for the clinical cost, however, we are aggressively managing our cost and working to control our non-clinical expenses tightly. The company plans to raise a sum of US$ 125 to US$ 150 million by way of fresh equity issuance in order to meet the expenses over the next three years. The company has set up a line of credit for Rs. 2,000 million with the parent company to meet the interim fund requirements.

Since the beginning of 2020 until now, the global widespread of COVID has been a challenging situation for all the industries. The company has taken all possible measures to limit the impact of COVID in order to ensure business continuity with minimal disruption. The company has considered internal and external information, while finalizing various estimates in relation to its financial results. The company will further evaluate and actively respond to minimize its impact on the financial performance.

That's all from me today on the financial update. A big thanks to all for joining the call. I will now hand over the call to Jaydeep for facilitating Q&A. Thank you.

Jaydeep Issrani: Thank you, Chetan. And we would now like to move on for questions. We will wait for a minute or so for the questions to queue up and then we will pick up the questions at the earliest.

Moderator: Thank you very much. We will now begin the question and answer session. The first question is on line of Ketan Gandhi from Gandhi Securities. Please go ahead.

Ketan Gandhi: Sir, can you please say the status of the five molecules licensed to CMS? And when do we expect more than US$ 5 million per annum revenue from China?

Anil Raghavan: Hi Ketan, this is Anil Raghavan. I have briefly mentioned, of the five we are working on the commercialization of two programs which are already approved in the US, its Xelpros and Elepsia.. And for the rest of the programs, like Taclantis and two other ophthalmology programs which are part of this deal, US approval needs to happen first before we can start moving on the China process. So, our initial goal is to make sure that we have guidance from China in terms of any additional studies that they need to do to get these products to market. And we expect to have that in short order for these two products. But we don't have a guidance in terms of when we can actually go past the aspirational revenue number that you mentioned. For that I think we need to wait till we have more clarity in terms of the regulatory pathway the Chinese regulators would like to see. We are on early stages of this process, Ketan.

Ketan Gandhi: I have a question on PICN. Assuming success of your appeal with the FDA, from the day of FDA approval to market launch, how much time will SPARC take, especially since you have not announced a marketing partner, number of sales reps and market the product, and the time involved in manufacturing to require the large quantities? And have you written all your manufacturing constraints for PICN?

Anil Raghavan: From a manufacturing process standpoint, we don't foresee many constraints. But you have a good question. Our sense is that from the approval we may probably take six months to get the

product to market. And we have previously talked about this, March 2021 is the earliest we can come to market for the most attractive indication, which is pancreatic cancer. But a lot depends on how the appeal process with FDA goes.

Ketan Gandhi: Sir, and assuming we fail in the appeal with the FDA, we have to drop the PICN as molecule or we have some alternative?

Anil Raghavan: We are in the initial stages of this process. There are other opportunities for continuing this discussion with the FDA. But we have to take a call based on how this conversation goes. There are other avenues, but, we will cross that bridge when we reach there. Our hope and optimism is that we will be able to convince regulators and we are taking a very fair view to this process.

Ketan Gandhi: Sir, for SCD-044, who will pay for the clinical development across different indications till launch? And targeted development and launch timeline, sir?

Anil Raghavan: As we have disclosed during the deal, Sun Pharmaceuticals, which is the licensee of SCD-044 will be doing the clinical development for SCD-044 for all indications. So, the execution and provisioning of appropriate resources for that trial will be done out of Sun Pharma. And they will be in a position to advise you in terms of specific timelines. We don't want to jump the gun and make a disclosure for them. But our sense is that we are ready to move to Phase-II clinical trials in very short order on this program.

Moderator: Thank you. The next question is from the line of Pinkesh Jain from Way2Wealth Securities. Please go ahead.

Pinkesh Jain: I have a couple of questions. The first one is, can you update us on the drug SDN-021, the drug for abuse deterrence?

Anil Raghavan: We have spoken about this in the last year's investor call. We have managed to build that platform to a certain level of proof-of-concept. We have established proof-of-concept in early clinical trials. And then we have taken a strategic call not to pursue that platform, and that was primarily based on, may I say, very challenging regulatory environment about opioids, even if it is for abuse deterrent formulations. So, we believe that in finding appropriate marketing partnerships that justifies the cost of development is going to be a difficult proposition. We did not talk about this in great detail, but we are repurposing that platform in the overdose prevention setting. And there is an early clinical trial which is currently going on at the moment, that is SDN-118 in depression. So, our intent is to use the expertise and knowledge gathered through that experience in another context. And I think once we have the proof-of-concept, we will have more to say on that. But at the moment, we have decided, as we have indicated in our earlier investor call, not to pursue the development of SDN-021.

Pinkesh Jain: Okay. So fair to say that we have repurposed this platform for SDN-118, while completely dropping out of the 021, correct?

Anil Raghavan: That is correct. Well, it is not a full repurposing, but we have used the principles of that platform to come to an overdose prevention. Because the design objectives or these two platforms are different, I mean, in overdose prevention you want to keep the overall exposure under a certain fable toxicity threshold. So, in that sense, the design objective is different but the principles which we used in abuse deterrent formulation is being reused in this program.

Moderator: Thank you. The next question is from the line of Girish V. from Bank of America. Please go ahead.

Girish V.: First question on the SCD-044. So, if you could actually elaborate on the selectivity of this Sphingosine phosphate modulator, how is it compared to the others that are coming in the market like Ozanimod and Etrasimod? And why doing this in psoriasis and atopic dermatitis against other indications like IBD?

Anil Raghavan: Basically SCD-044 is part of a second generation set of S1P1 receptor modulators. And this product is very selective to S1P1. And in that sense, it's better in the selectivity profile to its peer group of Siponimod, Ozanimod and Etrasimod**.** So, what we have learned from these earlier products which followed Fingolimod is that the cardiac safety issues that plague Fingolimod can be managed through smart titration programs and better design. And we have demonstrated that in Phase-I trials as we have communicated in earlier disclosures, and also in Dr. Siu's session today. So, our intent is, if you look at the therapeutic space in dermatology, we believe that the oral interventions in dermatology are still a very attractive opportunity and it is less competed in this class, because only Etrasimod is being pursued in dermatology. So, in terms of intensity of competition for this class, dermatology is probably lower. And we believe that opportunity space, as you can see from the Apremilast's recent transaction with Amgen, still high or reasonable efficacy or an oral treatment in both psoriasis and atopic dermatitis is of high unmet need and potentially high commercial value.

So that has been the thinking behind the preclinical development program targeting these dermatology indications. And that has also informed the choice of our partner in terms of going with Sun Pharma. But at the same time, Sun, in addition to looking at the dermatology indication, I am hoping will take a look at additional indications, particularly the one that you talked about in IBD. But those are things which we hope the partner would pursue and they will be in a better position to talk about that.

Girish V.: Right. And let's say in a fair case, presuming trials with a partner go successful, when is the earliest we can see something on the commercialization bit from this molecule?

Anil Raghavan: Well, I will stay away from making a commitment on behalf of our partner who owns this program at the moment. Not fair for me to set expectations for a clinical program which they are running.

Girish V.: Right. And just second one on, actually I think you spoke about the biologic side, a couple of work you are doing on building technology within SPARC on ADC, bi-specifics and things like

that. But just in a very overarching question, given that you are one of the, let's say, new player entering this space, which is already crowded, I mean, what kind of challenges are you seeing and benchmarking your platform with the other established players?

Anil Raghavan: Look, first of all, going back to your assertion that this space is already crowded. We don't have the same view about both these two modalities that you mentioned, bi-specific antibodies or antibody drug conjugates. I mean, if you look at bi-specific antibodies, we have very few approved bi-specific program, actually only one approved antibody program that also is not a full bi-specific program. And so, we believe as a field its very, very nascent. And also, if you look at antibody drug conjugates, we are seeing some movement now after many years of struggle in terms of trying to deliver super toxic toxins on antibody targeted platforms. So, we believe that ADC essentially crossed a certain threshold in terms of establishing viability. And there is a vast set of opportunities, both in terms of targeting and also playing with different kinds of toxins. So, internally, we are a bit more optimistic about differentiated spaces that we can operate in both bi-specific antibodies and also ADCs. And we don't have the view that it's already a completely consumed real estate.

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

Manish Jain: Thanks for giving a very, very deep and very insightful presentation. Starting on PD Vodobatinib, just wanted to know when we look at indications such as PD, ALS, dementia, LBD, Huntington's and Alzheimer's, few questions like, for which of these indications are you currently hiring patients? Second question is, whenever in case there is a failure in one of the indication for the molecule to progress further, will it impact the progress of the other indications, basically, how independent are they? And rough timelines of the same.

Anil Raghavan: Sure. , thank you so much, Manish. And there is a lot to unpack on that question, so let me start with the order in which we are approaching these clinical programs. Parkinson's disease was the first indication that we have approached and the reason why we approached Parkinson's disease initially is that it is the area where there is most maturity in a preclinical setting, thanks to the work of Dr. Ted Dawson at Johns Hopkins and others who followed him in this pursuit of this target. So, we have now a Phase-II clinical program currently recruiting. And as we mentioned, as Siu covered this in his presentation, it's a 500 patient-plus trial. We went through with an extensive target dose determination last year to get to some level of confidence in terms of the dose that we are pursuing. And we also did some adjustments with the formulation based on that understanding and triggered the accrual of those patients. And we are in early stages, we are at around 50-plus patients in a 500-plus patient study. And we hope to conclude, COVID permitting, sometime in 2022. So that is the first study. And for this study we are collecting a significant number of samples, I mean, additional samples for biomarkers and I will come to that in a minute.

The second program is an investigator-led trial with Dr. Moussa and others at Georgetown University. This is in Lewy Body Dementia, and this is a smaller trial. It is primarily designed to look at safety of Vodobatinib in Lewy Body Dementia patients. But at the same time, it has

some important biomarkers which it will look at, so it has the potential to create biomarker driven proof-of-concept for Lewy Body Dementia. And our foray into Alzheimer's is early stage, in the sense we have early animals data on biochemical responses of Vodobatinib in AD animal model. And we are following that up with more robustly designed animal models later this year. So, our intent is to come up with a fairly attractive proof-of-concept in animal systems, like we did in the case of Parkinson's disease for Alzheimer's by end of this year.

So, now to your trickier question in terms of, if you fail in one indication, would that mean a failure for all of this? Well, there are pathways and processes which are similar in these processes, like Vikram and Siu mentioned earlier about autophagy and some of the other processes which are impacted by an ABL inhibitor. But at the same time, there are differences in the biology of these diseases. If you take Parkinson's disease and Lewy Body Dementia, the culprit ggregating protein is α-synuclein. So, in that sense, there are similarities between these diseases, while there is a whole different set of proteins at play in Alzheimer's disease. So, we need to see what happens in the Phase-II setting. I mean, this is a large trial. And we will have a wealth of information in terms of how the PK and PD correlates, responder classes with some kind of biomarker profiles if you have made progress with the samples that we are generating. So, I don't want to dwell deep into what could be rescue options if you fail. But I think we will have a wealth of information on the broader impact of this class on patients with this setting. And that can be useful. And also, it doesn't mean failure in one class of diseases, which is Parkinson's and Lewy Body Dementia may not necessarily mean failure for Alzheimer's.

I hope I addressed everything that you had in the question. Please highlight if I have.

Manish Jain: Yes, this is good, Anil. The only thing is, so essentially traditional indications like dementia, Huntington's, ALS, you will add once you have the basic data from the patient setting?

SiuLong Yao: Maybe I could clarify a little bit and give an analogy. So, the way I would give you an analogy is, you can think of oncology. Oftentimes you have a mechanism of action in oncology and we develop a drug to treat that mechanism of action. But the role of that mechanism, amongst many mechanisms that involve the disease or that are involved in the pathophysiology of disease can differ somewhat from disease to disease. For example, if your drug fails in lung cancer, it does not mean it's going to fail necessarily in breast cancer. Although, depending on the reason for failure it could be, for example, bioavailability or pharmacokinetic reasons, that might affect all the different indications. But if it's a biological reason, and the biology is different from disease to disease, failing in lung cancer does not mean you are going to fail necessarily in breast cancer. So, I hope that's a little bit clearer.

Manish Jain: Yes, this is very helpful. In fact, just a housekeeping question on this. At this stage, I don't know whether is it relevant to have a backup for 706 like you all had 954, or…?

Anil Raghavan: We have a backup program on Vodobatinib. But at the moment, we don't see any trigger for initiating or advancing a program into clinic because Vodobatinib is behaving well so far. So, we will have to wait for what happens with the program.

Manish Jain: Perfect. Moving on to the second question for Vodobatinib on CML. Essentially similar question to PD actually, that on Slide #19 you have given the three phases CP, AP and the blast phase. Similar question, what if it fails on one, can you still pursue the other? Because we have seen similar cases in other molecules.

Anil Raghavan: So, I will defer to our hematologist onboard, Dr. Yao.

SiuLong Yao: Yes, we can. So oftentimes, an example as you may know, that the doses are different for different types of CML. And so, you have three distinct types here, we will probably end up having similar doses or we may have different doses. And if we require higher doses, for example, in an accelerated or blast phase, whether it will respond to the higher dose will be different. So, it does decrease the odds a little bit, but we have seen really good activity so far to date, as we mentioned during the discussion. And so, we do expect that we will get one of those cohorts to work.

Manish Jain: And just a related question, typically just trying to understand the advantages that SPARC has through the orphan drug classification, can we file a rolling NDA? Can we file an NDA even when you have completed one of the three AP, BP or CP phases?

Anil Raghavan: That's possible, Manish. These three phases, like I said, are three different indications. As soon as we finish the chronic phase, which is probably "the easier to recruit" part of the trial, we hope to file. The timeline that Dr. Siu mentioned in his presentation and Michael mentioned in his set of slides was based on assumption that we will be going in with CP to begin with, and then augment the label with AP and BP as soon as we complete those trials.

Moderator: Thank you. The next question is from the line of Pinkesh Jain from Way2Welath Securities. Please go ahead.

Pinkesh Jain: I was dropped out of the call. So, my next question was that we have created this backup option of raising funds of almost $125 million to $150 million. So, we have taken into consideration the fact that the monetization of these late stage clinical assets will also happen before the end of this financial year.

Anil Raghavan: Well, at the moment we are evaluating those as separate options. But we have to take a view on this based on the real options we have on the table. And as I said, we will have more on this soon since we are committing to do either of this or both of this before the turn of the year. So, stay with us on this question and we will have more information for you in the coming months.

Pinkesh Jain: Okay. And lastly on the Elepsia scene, so how confident we are this time of finalizing this marketing agreement in US?

Anil Raghavan: Well, we are fairly confident and our intent is to have an update for you very soon on this.

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

Ketan Gandhi: Sir, this fundraising $125 million to $150 million, it will be done in one shot or it will be during next three years?

Anil Raghavan: No, our intent was to understand the cash requirements for the portfolio for the next three years, that is up to these catalyst events that we have spoken about through this presentation and capitalize the company now for that phase. So, in that sense, we are talking about single raise now, if we go down that path, and then pursue these catalysts in the next three years.

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

Sameer Baisiwala: Very good evening to everyone. Good to connect on your annual briefing. Sir, the question is on Vodobatinib for CML. Can you speak a bit more about the Phase-III clinical plan? And where I am coming was, the total patients that you are looking for and is it only refractory patients or would you also be trying for non-refractory patients? And third is, for multiple ascending dose, MAD, is it part of Phase-II or is it part of Phase-III?

Anil Raghavan: Samir, let me attempt an initial answer and then I can get the clinical team if we need additional points here. So, this program doesn't fit into the traditional Phase-I, Phase-II, Phase-III kind of classification. We are looking at a protocol which started off with a single ascending dose study, and then scaled to a multiple ascending dose study on the same protocol to determine the dose for a registrational trial. And then the Part C of that program essentially is designed for registration in refractory setting. So, in an earlier slide we talked about specific numbers, it's essentially in the 50 patient range each for CP, AP and blast phase. And these will be three different cohorts. And then these patients need to be followed through for a longer period of time. So, that period would be somewhere in the range of five years post response, and depending on the sustainability of response. And we intend to also start a trial in early stage CML, which is essentially a comparative study against imatinib. And we have already consulted FDA on a design for this program and there is a consensus on what kind of design we should pursue in this setting. But FDA would like us to accrue a certain number of patients in this current study, in refractory study so that there can be confidence on the safety of the doses that we are proposing. And we expect to start the study sometime either later in this year or early part of next year so that you will have a parallel study in primary CML, against imatinib. I hope I addressed your question.

Sameer Baisiwala: Yes, this is very helpful. And just a follow-up on this. So therefore, on Slide #19, the patients that you mentioned, are roughly about 150 total, so all of that put together is what you have for Phase-III clinical trials?

Anil Raghavan: For refractory, yes, for three different indications, the CP, BP and AP.

Sameer Baisiwala: Okay, great. And when you do disclose the headline data, as you said this year or very soon, that would be single ascending dose?

Anil Raghavan: No, the top-line data for this is going to come in 2022 and that is for CP for Phase-III. I mean, for multiple ascending dose study, we had published early stage PK studies and responses. But for the registrational study our intent is to complete recruitment of that study sometime in the first half of next year. And then there is a one-year follow-up for response. So, which means that we will be in a position to go to the agency with that data somewhere in 2022.

Sameer Baisiwala: Okay, great. This is very helpful. And the second question is, you also mentioned that there were two serious adverse events with this product, I mean, how do we read that?

Anil Raghavan: Let me go back to that slide. This is essentially in the early part of this study. And we believe that this is not directly related to the drug. And probably, Siu, you can review those events in a little bit more detail.

SiuLong Yao: Right. So, the events we kind of discussed last year, both events consisted of basically, I would say, progression of disease. When you make assessments clinically, there is not always a clarity as to whether the drug is causing the event or the progression of the disease is causing the event. In those cases, we believe that it's been progression of disease that's been causing the event. One patient, for example, had some bleeding. We believe that the bleeding was due to the underlying chronic myelogenous leukaemia. Unfortunately, that patient, for example, did not respond to the treatment, and so the disease progressed. However, the investigator, which is normal, the investigator could not know for sure whether it's due to the disease or whether it's due to the drug. So, in order to be conservative, generally, we attribute it to the drug under that circumstance. But like I said, there has been no new serious adverse events. And if this was a concern with the increased population that we studied, we wouldn't have expected to see that. And as already mentioned, there has been nearly 250 subjects exposed at this point, and we haven't seen anything else. So hopefully that's helpful.

Moderator: Thank you. The next question is from the line of Krishna Prasad from Franklin Templeton. Please go ahead.

Krishna Prasad: Sir, first on the ophthalmic portfolio, what has been the market performance for Xelpros? And also, maybe if you can share what kind of peak sales you are looking for the other two late stage ophthalmic assets.

Anil Raghavan: So, I would probably hand over this question to Michael. Michael, can you comment on this?

Michael Choi: Yes, I can't comment on Xelpros, but on the other two, PDP-716 and SDN-037,we gave an update on that last year, the markets for both are $400 million and $180 million respectively. In terms of the forecast, I think I would just prefer not to say because we are in discussions with partners for licensing and I don't want to disrupt those discussions by giving any sort of forecasts. So, I think I would just have to revert back to the guidance that we gave last year.

Krishna Prasad: But the expectation of an equity raises of $125 million, $150 million that builds in some extent of in-licensing revenues from these two assets?

Anil Raghavan: Yes, it does capture licensing revenues.

Krishna Prasad: Right. And also, on this refractory CML, around the time that you would probably get to the market, what kind of opportunity do you really expect there given that some of those currently in the market also would probably go generic by then? I mean, can you just talk about that?

Anil Raghavan: We believe, as Michael pointed out earlier in his comments, we believe that there will always be a niche for a safer product which provides broader mutational coverage. And in fact, if you want a proof point for this, the fact that the Novartis is pursuing a third-generation product now to follow nilotinib into the market, when both imatinib and nilotinib are going to be generic, is an evidence that people who are in this field for so many years still see an opportunity for a branded option. And we are looking at a more difficult set of patients. And also, if you look at the profile of Vodobatinib, Vodobatinib is by far the safest TKI we have seen in this space. So, given the advanced stage of these patients and cardiovascular issues they carry for these kinds of settings, we believe that it's going to be a fairly attractive option. Granted, it is not going to be as attractive as the neurodegenerative opportunities if we are successful there, but that is a significant opportunity.

Krishna Prasad: Finally, one clarity. When you say line of credit of holding company, so you are referring to which company?

Chetan Rajpara: It is the parent company which is Sanghvi Finance Private Limited. This is a bridge till the time we raise some funds, or we monetize some of the assets, and it is a short-term loan basically.

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

Manish Jain: Just one clarification. I wanted to know, in Phenobarbital have we received orphan drug designation or we are likely to?

Anil Raghavan: We have received the orphan drug designation. I mean, I can see where this confusion might have come. What Dr. Dharmadhikari was referring to is that we will be able to realize the orphan drug exclusivity if we get the approval. The process is that you will get a designation that it is an orphan drug, and once we get the approval then the benefits of that designation will accrue. What he was referring to in his earlier comments was that we will have the orphan drug exclusivity once we have the approval.

Manish Jain: Got it. And till that point of time, just getting the designate to early on, what advantage do you have?

Anil Raghavan: The designation is like a candidate for exclusivity. If you follow that up, I mean, there are some advantages like say, for example, you don't have to pay the PDUFA fee. But the most important part here is, given the nature of this program you have a potential for seven-year exclusivity on this program.

Manish Jain: Perfect. And second thing was, you just referred to Asciminib of Novartis besides the cardiovascular safety for 706 in CML, what are the other advantages that Vodobatinib has over Asciminib?

Anil Raghavan: Clinical setting for our product is different from ABL-001's clinical setting. I mean, we are going to be the only product with data on patients who have failed on three lines of therapy, where one of them is Ponatinib. And ABL-001 is not pursuing that patient popuation, they are essentially going with two lines of failure and comparing with bosutinib.. We believe it is a significant difference to have data on last line setting with a safe product where the current option is chemotherapy and the life expectancy is very short.

And what we are seeing is remarkable, I mean, if you look at the three lines of failures, including Ponatinib, we are seeing fairly robust responses compared to very low response that you typically get with chemotherapy. And in fact, if you go back to earlier slides, you have some numbers there. We are excited about the impact it is having on these patients who actually don't have much options at the moment.

Manish Jain: Okay. Just a final clarification there. In the past we have seen FDA waiving the one-year follow-up to be done, especially in these kinds of things 706 is addressing. What are the kind of things that we as investors need to watch out where in a good scenario there can be a waiver for that one-year follow-up?

Anil Raghavan: We may not look to have a waiver for long-term follow-up on this, because it gives you a real-world evidence on the durability of response. And that can be a significant advantage for the program going forward. But what you may be referring to is, how soon we can actually go to a submission. I mean, that is an ongoing discussion with the FDA. And this is an open label study, in the sense, you will have visibility to responses as we accrue. And we will have a conversation with FDA in terms of if there is an opportunity to move to a submission earlier than we now know.

Moderator: Thank you very much. That was the last question in queue. I would now like to hand the conference back to Mr. Jaydeep Issrani for closing comments.

Jaydeep Issrani: Thank you, Raymond. And thank you, everyone, for being on call today. We tried to address all the questions that were put up. In case there are additional questions, you can send it to us on email and we will respond to your questions. Thank you once again, everyone. And stay safe.

Anil Raghavan: Thank you.

Moderator: Thank you very much. On behalf of Sun Pharma Advanced Research Company Ltd., That concludes this conference. Thank you for joining us, ladies and gentlemen. You may now disconnect your lines.