Transcript of the Management presentation on

NCE and NDDS

4 pm, March 15, 2007

Corporate Participants

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Uday: Good afternoon everybody. We have actually three sets of participants today. So, I will again wish good afternoon to people in the hall. We have participants joining us through the web cast and the audio call. Welcome to our management presentation where we are sharing some details on the NCE and the NDDS pipeline. Our hosts are today are Mr. Dilip Shanghvi, Chairman and Managing Director of Sun Pharmaceuticals, Mr. Sudhir Valia, Wholetime Director, and Mr. Sailesh Desai, Wholetime Director. This call will be recorded and the web cast replay of this call will be available for another 15 days until 30th of March. Just as a caution, we would be making quite a few forward looking statements in the presentation today and I think people need to view these statements in conjunction with the risk that the business carries. During the presentation, we will make an effort to answer all the questions that are asked but if the time does not permit then I request all of you to please send in your questions to either me or to Mira and we will get back to you. I now invite Mr. Dilip Shanghvi to start the presentation.

Dilip Shanghvi: Thanks to all of you. Thank you Uday. When we announced the demerger of the Innovative research company, we shared with investors that 30 to 40 days before the company gets listed, we would give some details on the innovative products that we have been working on since last few years. In addition may be to the caution which Uday stated, I would be making some forward looking statements. I also wish to make an additional statement that everyone of the statements that I am making is based on our understanding of the product today but that as innovative product development evolves, there are unanticipated risks involved with each of these products and if any of these products encounters a roadblock, then what happens to the product would depend on the kind of the roadblock. So, that is something that we need to keep in mind all the time. These are not necessarily the only products that we are working on. These are the products that we have reasonable clarity about our intellectual property protection. At the same time we have reached a level where we can share some kind of timelines for development of these products. The structure of the presentation is that I would be sharing the current NCE products and development with you initially. In Novel Drug Delivery Systems I will share the different platform technologies that we have been working on in slightly more detail and cover both the technology platforms that we are working on we have shared with you earlier, and the specific projects in NDDS that we have in development. And, finally, we will give some guidelines as to the milestones for each of the product which is under active development and we are sharing here with you.

Sun-1334H is the product furthest in development, it is an antihistamine. It is being developed for seasonal and perineal allergic rhinitis and urticaria. We have completed phase I for this product mainly in Europe. Recently, we have done some studies in India. The product has been administered close to 127 human subjects and doses as high as 8 times what we presume to be the human dose have been exposed to patients or volunteers and we have not seen any measurable sedative side effects. Currently, the product is undergoing phase 2 study for seasonal allergic rhinitis and we hope to finish this phase 2 study by may be end of this year. Along with the human studies, the chronic studies which are required before the approval of the product and also may be before longer term chronic administration of drug is approved, are currently ongoing. From whatever that we have seen out of the studies that are completed in humans, we know that the product is once a day, it has very rapid onset of action compared to the other products in this area. Its efficacy is comparable to Cetirizine over a 24-hour period on a wheal and flare model. It is clearly non-sedating and we have not seen any cardiac toxicity in this product until now in any of the subjects. As I mentioned, we have dosed those patients significantly high level of single dose administrations. We plan to initiate phase 3 studies for this product next year. As all of you know, antihistamines are a fairly large market worldwide and most of the current products which are in market will see potential expiration of patent within next one or two years. So, in a way, the opportunity is that when the product comes to market there will not be many actively promotive products. So, in a way it is a relatively noncompetitive area. The challenge is that since most of the products would be genericized, for getting a sensible reimbursement pricing we will have to develop

appropriate clinical outcome data justifying the premium that an innovative product will command and that will possibly mean significant investment in phase 3 clinical studies as we move along.

Sun-461 is a soft steroid. It is used for treatment of asthma as well as COPD. For this product we have done some acute toxicity studies and some of the studies are ongoing. We expect to dose this product in humans sometime in 2008. Let me try and explain some broad differences between soft and hard steroids or the classical steroids. Classical steroids have anti-inflammatory property, but when they are systemically absorbed, they produce significant systemic side effects and after that they are inactivated and excreted as inactive metabolite. Soft steroids on the other hand have affinity for the receptor and have activity at the site of action, but it is inactivated in plasma immediately on its absorption leading to significantly reduced systemic side effects and then the inactive metabolite is excreted. These are animal studies data and in lung edema which is a surrogate for the asthma model, we found that the ED_{50} or the effective dose for the 50% of the animal level for our product is more or less in line or may be slightly less potent than fluticasone as well as budesonide, but where it is significantly superior is that the effective dose 50% for thymus involution is significantly higher. Its effective thymus involution dose at 50% is 5 mg per kg compared to 0.36 mg for fluticasone. So, in terms of therapeutic index it is a significantly safer product. Therapeutic margin of safety is 23 times for our product compared to four times for fluticasone. The other side effect which is generally seen with steroids is glycogen deposition. Also Sun-461 has significantly lower glycogen content compared to fluticasone and at 3 mg dose which is a very high dose with almost 0% thymus involution compared to close to 50+% thymus involution for the other currently marketed products. As you have seen, steroids are a large market. We hope to file IND and dose the first human subject in 2008.

Sun-44 is a pro-drug of gabapentin, and gabapentin, as some of you would know has significant bioavailability related issues and it is very difficult to develop a once-a-day product of gabapentin. This product is in early preclinical study. We have done some toxicity studies and the product comes out very safe and we should be able to file this product IND sometime in 2008. Let me try and explain the meaning of this chart that you see here in the beginning. With Gabapentin, the problem is that since it uses an active transport mechanism, the absorption of gabapentin is linked with the availability of the active transporter in the GI tract. So, when you give 50 mg you are able to absorb more or less the entire amount of gabapentin, but when you give 100 mg, because of the time required for regeneration of active transporter, you do not achieve high level of absorption and when you give 2000 mg per kg to the animal, even though it is 40 times more in terms of dosing, the blood level achieved is only may be 8 to 9 times more than the 50 mg dose. Compared to that Sun-44 has a more or less linear kinetic profile which means that we can develop a much longer working product that is once-a-day with this product. There are other companies working on a pro-drug for gabapentin. XenoPort is one such company which is working on a pro-drug of this product and we believe that Sun-44 is a superior product than the XenoPort product (which is in active development) because its toxicity profile is significantly superior, its LD_0 is comparable to gabapentin and its LD_{50} is two and half times than the XenoPort product. Clinically, as we see, we should be able to make a much more consistently available product allowing us to develop a much higher blood level than what is generally feasible with gabapentin. It is also because of its absorption profile and amenable to once-a-day dosing. Gabapentin is generic as all of you know and even as a generic it is a very large product. So, if we are able to introduce this product as a patent protected product with superior efficacy, we see a significant potential. We will be beginning, as I said earlier, phase 1 study for this product in 2008.

Sun-09 is also another pro-drug of a muscle relaxant and it also offers similar level of benefit over the existing product like our pro-drug for gabapentin offers. As you see the Cmax as well the AUC achieved with our product is significantly higher than the product it is competing with, and we see that the benefit, the overall therapeutic efficacy, the side effect profile as well as the performance of the product. The current market for products of this class is only USD 200 million; however, what is interesting is that

there are around 1.5 million patients under active treatment for this product in U.S. as well as in Europe. So, if we are able to bring a superior product to market and if we are able to charge sensible pricing for this product compared to the other innovative products which come to market, the market can be significantly different than what we see for the current generic product.

We have shared this with you earlier, that as a platform technology we are working on dry powder inhalers and we are working on two oral drug delivery systems, one gastric retention system and a matrix system. I will give more details about both the oral drug delivery systems. Then we have shared with you that we are working on anticancer products using targeted drug delivery using nanoemulsions, and we are working on biodegradable injectable systems.

The device that we have in development right now is suitable for asthma as well as COPD, but it can be modified for systemic delivery of drugs to the lung. It is a very simple, easy to use device, with a three-step operation, open, inhale, and close, compared to 7-8-10 steps of the currently marketed dry powder inhalers depending on whose product you will look at. It is small, it is convenient to carry; it is a multiple but single dose device which means that individual dose is packed separately in the device and the device is being developed with the current U.S. F.D.A., as well as the European regulatory guidelines for the inhalation device. It is important to understand this, because more than three or four European dry powder inhalers and MDIs are currently not marketed in U.S. because they do not meet the U.S. guidelines which are very stringent. The device is designed and engineered to give a visual, audible, and tactile feedback, which means that you get a sound when the device is activated, you get a feel when the device is activated, and the patient is inhaling the dose so that the mistake is minimized. It delivers the uniform dose over a range of patient efforts. So, what I think we are trying to say, is that most of the devices have variable drug delivery based on flow rate of the inhalation. What we have tried to do is that irrespective of the flow rate of the person who is inhaling, the drug delivered will be more or less constant, and this is important in asthma as patients who are under severe asthmatic attack, will have very low flow rate because they cannot breath deep and they cannot breath at a high rate. So, it is at this point of time that they need the highest amount of drug, but if your device does not deliver that level of drug, then the patient benefit is significantly compromised. The design of the device is such that it will never double dose, because sometimes you may load the device once and forget that you have loaded, then you load again. And then when you inhale, then you might get twice the dose, but the device will not permit that kind of an oversight by the patient. It has a fail safe counter so that patients know how many doses remain and what is most important is that compared to the current devices in development or in market, it will deliver significantly higher level of the drug to the lung. So, if we can have a device which can have steroid-sparing effect for the patient, it can be of significant benefit for the patient. It is easy to use by children, adults, as well as old people. So, in a way it is very easy for doctors to explain to the patient how to use and the device is fool-proof, all kinds of fools. So, your probability of making a mistake and getting wrongly dosed or not getting dosed is very, very low with a device and that is the focus for our design team in developing this product. It can be used for delivering combinations of existing steroids and bronchodilators and it can be also used for delivering other NCE. The timelines that I am sharing here are the timelines that we have in mind for developing innovative formulations of the existing marketed products of other company, but superior to what is there in the market. And since the regulatory path for registering this product in regulated and semi-regulated markets are different, we will be in regulated markets much later than the semiregulated market. And in semi-regulated market, we expect to be in the market in the year 2009, and we expect to file the NDA in 2011 in regulated market. So, in a way it is also the philosophy that we generate cash flow while we move along with the product.

Gastric Retentive System is for those kind of products which have an absorption window, which will not be absorbed in colon or may be in lower part of the intestine, may be it is because of the poor solubility or degradation in the alkaline environment or it is a transport mechanism or reduced solubility; so, any of

the reasons. The device or the dosage form that we have in development will float, will expand compared to its original size, and it will have mucoadhesion. These are the technologies that people have also used in the past. Our product is a multilayer dosage form, floats immediately on administration, it will swell up to 8 times its initial size, it will maintain its physical integrity, and it is flexible and soft so that it will not hurt the stomach. It will allow us to develop once a day product for improving patient compliance, it will reduce the side effects and allow us to develop different kinds of release profile, IR plus SR, or SR plus SR. There is a small video film about how the device works or how the dosage form works.

(Video presentation)

There is a difference between the way he speaks and I speak. So, we have a product that has gone through human clinical study, baclofen GRS is the product. Very shortly it is likely to be marketed in India. We have completed phase 3 studies and it has received approval. We have completed the pre-IND meeting with the U.S. F.D.A., and we hope to file the IND in the next few months. The clinical outcome that we saw for the product in India broadly indicates that once-a-day product is preferred by almost all the patients compared to the three-times-a-day product that they used to take, but what is more important, is that we could very easily switch all the existing patients on three-times-a-day dosing to once-a-day dosing without any dose titration; so, we could switch patients to exactly the same dose. It was found to be as effective in terms of statistics because of very small sample size. However, we believe that if we have large enough sample size, we could have found statistical superiority and efficacy. However, the product is clearly statistically superior in terms of reducing sedation which is a major problem with baclofen and we did not encounter any unanticipated side effect because when we develop a new type of a dosage form for the first time, there is always an anxiety and stress that you have.

The other system that we have is a Wrap Matrix system, it is an oral control-release system, it is suitable for all types of products, but especially suitable for drugs which are highly soluble or given in very high doses. Its performance is pH independent, and it is capable of being made in different kind of release profiles, immediate release plus slow release; immediate release, slow release, then immediate release; slow release plus immediate release; and the benefit as I see of the product attribute, of its being capable of making different types of release profiles, is that we can then make a product which will be very difficult for generic companies to copy because it will be difficult to make a bio-equivalent product. The other benefit is that you need very limited amount of excipient to make the formulation. Typically for a slow release product you need around 50% to 60% excipient of the dosage form that you wish to make, whereas this product with very high dose up to 1 g, 1.5 g, can work with only 20% excipient. So, for products which are otherwise difficult to make into a once-a-day product, we can use this technology for making those products. These are the classic benefits of a slow release product, but the benefit for this product is also that it has very little food effect. There is also a video film about how the technology works.

(Video presentation)

We have a product using this technology in market, we are marketing it in India and we have also filed a number of ANDAs using this technology. So, as I said, this technology is difficult to mimic but at the same time it is capable of mimicking bio-availability or bio-equivalence requirement for large number of difficult-to-copy products. If you are familiar with currently patent-protected control-release technology, then the technology which will come closest to this product would be geomatrix® system. However, we believe that from both convenience, as well as features point of view, this is possibly the best technology for slow-release products in market.

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Nanoemulsion is a technology that is being worked on. I will not be sharing any specific product that we have in development using this technology, because we have not yet filed patents for those products. However, we have some very interesting innovative approaches which avoids or reduces usage of toxic excipients, gives a significantly safer profile for cytotoxic products because of the use of non toxic excipient, increases circulatory life of the drug improving targeted delivery, allowing higher dosing to be given to patients, reduces hypersensitivity of the excipients, and does not use any new excipients.

Biodegradable injectable system. We are using this system for manufacturing and marketing leuprolide injections or leuprolide depot-injections for the last three years. Now we have developed superior technology which will allow us both claim patents as well as bring better products to market. So, our product will not require large needle sizes because it can possibly be injected through very small needles. And most important, is that we believe we can scale this up to kg scale. We dont use any toxic solvents for manufacturing the product and these are easy-to-reconstitute kind of products. We have a GnRH analogue in current development and clinical studies are planned in India. We will also be filing 505-B2 for this product in both U.S. as well as in Europe where there is a similar option, which is possible. And, for somatostatin analogue, I think we have a product for which clinical trials are already on the way. In animal studies, our product was found to be equally comparable, but clearly non-infringing to the innovative product.

Next is Tobra plus Dexa eye drops. This is a product that our ophthalmology business is marketing in India, but this is a significantly better product than the product which is there in the U.S. and European market. European product is a suspension of dexamethasone, our product is a solution and it is generally given to patients after surgery. Unlike a suspension, which can feel irritating and gritty, a solution does not. Because our product is a clear solution, it is something which patients as well as doctors prefer. We had a pre-IND meeting with the U.S. F.D.A., and we will be filing IND for this product shortly.

So, these are some of the timelines that we wish to share, so that we have also the commitment to pursue the product in terms of timelines that we have for ourselves. Sun-1334H is, as I said, in phase 2 and we hope to begin the phase 3 next year. For Sun-461 which is a soft steroid, we are currently doing pre-clinical studies. We will be filing IND as well as the first human dose in patients next year. Sun-44 and Sun-09 also are in pre-clinical studies right now but we will be filing IND for these products in 2008 and also begin phase 1 study for this product, but we do not believe that we will have to do a phase 2 study for Sun-44 and Sun-09, because drugs are very well known; so, we can directly go on to the phase 3 study. If we run it efficiently, we can may be do it a little bit faster.

What I think is important for me to also point out here is that philosophically we have taken an approach of relatively low risk, if you consider the risk of potential failure for these products. Because they are all marketed products, a lot of things are known about these products, I am talking of Sun-09 and Sun-44. The risk of potential failure is relatively low. What it means is that it may not get the kind of clinical outcome that we are looking for, but the drugs getting some unanticipated side effect has a very low probability. Antihistamine as a class of drug is very well known, there is a very high level of regulatory understanding about this product and we know what are the potential risks about product sedation, cardiac toxicity, and that is something that we can watch all the time. We do not expect any unforeseen event or a side effect to hurt this product. Soft steroids, people have been working on, generally the risk is they may not work, but its failure on account of having unanticipated side effect is not a major issue. And if does not work, then we can possibly drop the project after phase 1 which is not a very large commitment of financial resources.

So, what this potentially low risk profile of every product that we have in development allows us, is ability to develop the product furthest into development and then license, and license only if it is necessary

because for say Baclofen, we possibly do not need to license because it will need may be around 100 people and we can market it ourselves in the U.S. and license possibly for European markets. Dry powder inhalers, as I said, will go into phase 1 study this year and for semi-regulated market, may be in phase 3 study in 2008, but we feel reasonably comfortable that including validation of device and all large number of other things which we are likely to do, we will be able to file this product in 2011. And the risk of potential failure of this product is not very high. It may not deliver the kind of benefit that we think it is likely to deliver, but the product failure is not a great possibility, because even if it does not deliver steroid-sparing effect, then also the device is significantly superior to all devices which are in market and possibly superior to most of the devices which are in development right now. So, from that point of view the risk is relatively low. When I am saying low, you should keep the context of the first statement which I made, is that all of this is risky, but within risky this is relatively low risk. So, baclofen GRS – its worked, it has worked in India, so we do not expect to see unforeseen events taking over the product in the U.S. We may have to spend more than what we think we will have , but the product will come to market. It is a very interesting market; around may be a million patients in the U.S., with very limited number of doctors using this product and even if we do sensible valuation of the kind of per day cost of treatment for all new products coming to market, it is a very attractive product. Biodegradable injectables, I think are interesting products, relatively low competition business, both as generic as well as innovative products, and we understand the technology, the manufacturing issues, and I think the product has potential. TobraDexa is a niche product. We have no other major products in ophthalmology right now that I can share with you, but it is an interesting product and we believe that can become very successful in the international markets.

This is the new logo for Sun Pharma Advanced Research Company, a logo for SPARC Limited. Thanks for coming and attending this presentation, and if you have any questions, then we will be very happy to respond to your questions.

Katya Naidu: They say the dry powder inhalers have a damaging effect on the lungs. How true is that?

Dilip Shanghvi: Damaging effect in what context?

Katya Naidu: In the sense a lot of doctors do not prefer to prescribe them for kids because on the long run it might have an effect whatsoever.

Dilip Shanghvi: I think what you are asking is the preference of doctors in India to prescribe inhaled products. As such, the use of inhaled steroids in India is significantly lower than the U.K. U.K. is the market with highest preference of inhaled products. However, in all developed markets, let us say, U.S., Europe, and Japan, inhalation as a route of administration of drugs for asthma and COPD is more or less fully accepted, and I am not aware of any extra damage that DPI will cause compared to the MDI. As a matter of fact the largest product in this area is the Advair of GSK which is a more than $3.5 billion product and that is a dry powder inhaler.

Question: Can you explain more in detail about this nanoemulsion technology though you have said that the patents have not yet been filed, but the roadmap of these two products and what is the size? Something more about this?

Dilip Shanghvi: I can explain the technology, I will not explain the products, but the technology broadly is that most of the anticancer products are difficult to solublize and because of this nature of product, have to be solublized in excipients which are very toxic to humans or to animals, whoever it is given. At the same time all the anticancer drugs have toxic affect to all the cells that come in contact with them. The nanoemulsion does two things; it reduces or avoids the usage of the toxic excipients so that the side effect on account of excipient is reduced. The second thing is that the particle size of the emulsion is

such that it will not be leaked into the normal capillary. The capillary porosity in the tumor area is slightly higher than the capillary porosity in the normal organs. So, the particle size of the nanoemulsion is designed such that it will not leak into the normal capillary, it will only leak into the cancer area; so that you will have three to five times higher concentration of the anticancer compound in the tumor sites compared to the normal organ. This is the technology that we are trying to use for developing a new delivery system of a currently marketed product.

Question: Is this technology being used in the product currently available in the market?

Dilip Shanghvi:There are nanoparticle based products in clinical development right now. Our product is different from their technology, but using the basic and similar scientific concept.

Nimish Mehta: About the NCE, Sun-1334H, can you give us which is the closest competitor or which is the closest product right now in the market whether patented or generic type? And also if you can give us some competitive landscape in terms of other products being developed or in development right now which one of them is in the later stages.

Dilip Shanghvi: There are two products which are patent-protected in the market, Cetirizine and desloratidine. Cetirizine patent expire in 2007 end. Desloratidine patents expire very long but people have filed para 4 generic applications for desloratidine and we believe that they will win the case. So, we expect generics of desloratidine to be in market in 2009 or 2010. There are currently no other patent protected antihistamines in the market. There is a metabolite of Cetirizine called levocetirizine which has recently been licensed by Sanofi from UCB and that is in clinical development right now in the U.S., it is expected to come to market in 2009. So, as I see, that is the only anticipated product that we will have to compete with, in the U.S. I am not very familiar with Europe as well as Japan. There are many more antihistamines in Japan than they are in other parts of the world, but currently U.S. is possibly the largest antihistamine market in the world.

Nimish Mehta: How is it better than say levocetirizine as well as desloratidine, the current product NCE that we are talking about?

Dilip Shanghvi: We believe it is superior on account of both, onset of action and efficacy. At the same time in terms of side effect, it does not have sedation.

Pawan Nahar: Good afternoon sir. First, congratulations for this wonderful presentation. I have a few questions, first more on the basics. (1) If you could just give us what is the budgeted spend on the pipeline you have? (2) What is the size of the team right now? (3) Maybe I'll ask later.

Dilip Shanghvi: We expect that in the next three years, we will spend something like $60 to $75 million for initiating and completing studies during this period. At the same time what we have announced and what we plan to do is split the company with around $45 million cash flow into the company, but we think that we should be able to license product in such a way that we will be able to continue to fund that business. The second thing is, I think you asked about number of people. We have 150 scientists, I think it is there in the presentation.

Pawan Nahar: Okay. You said that you would be able to license to fund the business any time?

Dilip Shanghvi: I think philosophically we will try and licence at the last point at which we can, because we can possibly get a better valuation and that is near the end.

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Pawan Nahar: So you are giving $45 million to the company and you think that your spend will increase to $75 million in three years?

Dilip Shanghvi: That is correct, $60 to $75 million.

Pawan Nahar: So, hopefully in the interim you will get much. Second is, on the Sun Pharma Industries, I presume have the right in India and the other 26 countries for marketing for these products?

Dilip Shanghvi: Actually, I think all the financial and other details we would be sharing at subsequent point of time when companies are actually demerged, but this presentation I think I would like to keep focus on the products.

Pawan Nahar: Sure. Could you finally just explain that Wrap Matrix technology, I just wanted to understand. You have two layers, one is the drug, the other is polymer perhaps; what is the use of that polymer there?

Dilip Shanghvi: So, let me explain conceptually what is happening in Wrap Matrix. When any patient takes a tablet and the tablet is a matrix tablet; matrix means there is a matrix from which the drug is eroding. What happens when the tablet erodes is that, it erodes from all the four sides of the tablet. In the Wrap Matrix what happens is that you have a non-permeable coating on three sides of the tablet and you have erosion taking place only from one side from which the explodable layer has removed the fill. So, it allows you to develop product with very limited amount of excipients because you have drug actually getting released from less than 25% of the surface area and ultimately drug release is linked with the surface area from which you release the drug. Did you understand?

Pawan Nahar : So basically, it will be more like a slow release kind of a thing.

Dilip Shanghvi: It is a slow release product. Only thing is the technology for slow release is very different from what is there in the market right now.

Pawan Nahar: Any drugs in the market using similar technology?

Dilip Shanghvi: I do not think there are. There are Geomatrix® products. If you see Paroxetine CR in the U.S., it is a Geomatrix® product, but this technology is significantly easy to work with than Geomatrix® and much more consistent in tablet-to-tablet profile.

Pawan Nahar: This is my last question. You already have that ophthalmology solution in the market in India. What is the kind of just a simple market share you see in of that molecule here, for the combination or any broader matrix you would like to use.

Dilip Shanghvi: I think India as a market would possibly not give you the sense of what product can become in the U.S., but this product in the U.S. is around $150 million as a suspension product. So, we can possibly get 40%, 50%, 60% of the market, but that is a product that we will need to give to somebody to market because we do not have a ophthalmic field force.

Pawan Nahar: Fine, thank you, and best wishes.

Vikram Sahu: Three questions from me. I will restrict my questions just to the products in accordance with your wishes. First with Sun-1334H, could you give me a sense of the clinical trial design please in phase 2 as well as the end-points of the trial. And also what came to my mind whether the 127 patients was in phase 1 or was that the phase 2 trial please?

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Dilip Shanghvi: 127 patients is phase 1. The current clinical trial design is a multiple dose trial with placebo, with a view to…we are still blind to the overall who is taking what, but the idea is to see the event and the resolution of the seasonal allergic rhinitis event in the patients. And when we will un-blind the trial we will see which is the most effective dose and whether it is superior to placebo or not. So, there is a dose which is lower than the dose at which we think it will work. Then there is a dose which we think will work, and the re are two doses higher than the dose at which we think it will work. And we have not seen any significant sedation in the phase 2 study until now, but it is still blinded.

Vikram Sahu: So the tag line is once daily? With the DPI, could you give me a sense for what the lung deposition is, please? What lung deposition rates are?

Dilip Shanghvi: We do not know the lung deposition because we have not done a human study yet. What we know is the T2 fraction which is an in vitro surrogate for the lung deposition. And compared to the normal product which will have a T2 of around 20%, we are currently getting around 40% T2 level.

Vikram Sahu: And a final question. This is early as yet for your clinical development program. What attrition rates have you been facing when you are looking at moving products or thinking of moving products in pre-clinical and into clinical trials? The failures, I guess we dont see on the outside looking in.

Dilip Shanghvi: There are I think quite a few products that we thought will reach clinic but have not because we saw some problems on the way. Because this is the first set of products that we are developing clinically, we have not seen any attrition as yet. But at the same time, let me try and explain you that philosophically the approach that we have taken is that in the worst case the product may not produce the benefit that we think it can, but the probability of failure on account of unanticipated side effects is relatively lower on account of the selection of the nature of product.

Visalakshi C.: What is your estimate of the addressable market size on each of the technology platforms that Sun is currently working on? And specifically with respect to the GRID platform, how many products would you be working on right now? Could you give us some kind of timeline in terms of when the first product will hit the market?

Dilip Shanghvi: For GRID product I think is the first product which is in development is Baclofen and we have given a timeline for that product. We are working on both Wrap Matrix as well as GRID for other products, but as I said we have not reached either the development or the clarity on the acceptability of technology where we need to optimize the product a little bit. We are not able to share which are those products. But now that we have shared these products with you, we will then keep on giving you quarterly updates both on existing products as well as any new product that we see a human clinical timeline approaching, so that we will share and that is the idea. For all of these products and the products in development in Sun Pharma Advanced Research Company, we will give much more information about products than what we are giving for Sun Pharma products.

Visalakshi C: My question was also on what could be the addressable market size if you look at each of the technology platforms, for us to look at some valuation?

Dilip Shanghvi: It is a difficult question. Not only difficult because it is all encompassing question, but also because it is . . . Let me give you an example, not that we are working on this product, but let us say furesemide. If you look at furesemide, it is a $35 to $40 million product worldwide, but if somebody can make a better furesemide tablet, then currently the tablet which is selling at 2 cents a tablet will then sell at $2 a tablet, and then the market changes from $50 million may be $2 billion. So, it is difficult to

give market value in terms of addressable market for a delivery system product. You will use delivery system only to enhance a currently marketed product. But I think if you see the number of products which can possibly be introduced as once-a-day product and there is clinical justification, then that is a very large universe and which means that there is an opportunity for people to look at developing once-a-day product in those areas. The therapeutic window option is not a big market opportunity because the products with therapeutic absorption window are relatively smaller. So, GRID system would, in that way, have a relatively lower market. But where we see an unanticipated opportunity is that many products which companies have not brought to market, but they can use this technology to bring to market because of what they can do to their product and that also is a very large market.

Visalakshi C: Finally, one question. Would you look at licensing any of the technology platforms and co-development as an option?

Dilip Shanghvi:Yes, I think we would look at various options including licensing technology as licensing of technology. We will look at co-development of product along with licensing of technology. So, we are open to various options.

Rajesh Vora: Mr. Shanghvi, if you could give your thoughts on Sun Pharma's capabilities in NCE and NDDS research that you have developed over the last few years vis-à-vis where do you stand in terms of the global R&D capabilities and how are you trying to bridge the gap if any, and why does Sun Pharma as you sound confident about the game plan and the strategy. If you could share your thoughts on that?

Dilip Shanghvi: It is difficult for me to answer the first part of your question. All I can tell you is that the teams that we have been working for specific project would possibly have both the technical and scientific depth comparable to equivalent groups working on similar products in different companies. I will not be able to judge overall scientific capability of this company versus other companies, but I do not think that is our approach also. We know where we need to strengthen and there are a large number of areas where we have very limited capability compared to some of the international players. At the same time, in a number of areas I think we are comparable, in some areas, we are even better. And where I think as a company on a consistent basis we will be able to deliver is by our ability to look at relatively low risk, but potentially high return kind of product opportunities which can then allow us to fund relatively higher risk and higher return businesses and product opportunities. I hope I have answered because clearly I cannot tell you how we compare with Pfizer, because first of all I do not know what is the technical capability of Pfizer, but I can tell you that our team which is working on the DPI today will be comparable to the Glaxo team working on their DPI.

Rajesh Vora: That is good enough. And in terms of benchmarking, do you look at other companies outside in terms of where do you see SPARC Limited five years down the line if you have to pick any company today or any R&D company today anywhere in the world. Is there anything that comes to your mind?

Dilip Shanghvi: Difficult to answer.

Rajesh Vora: Thank you so much and all the best.

Sameer Baisiwala: Dilipbhai, a couple of questions. First of all on Wrap, may be I did not quite understand. Did you say that metoprolol would be an NDA based filing?

Dilip Shanghvi: What I said is that we already have metoprolol in Indian market based on this technology, because that is an important point for F.D.A. that when you bring in any new technology,

then F.D.A. looks at that technology for its ability to deliver consistent benefit to the patient and potential risk with failure. So, we have enough understanding and we have now been making this product for a few months so we know when the product will not fail on account of any manufacturing or technical glitch. But what I also said is that we have filed a few ANDAs using this technology, which should come to market when may be when we win the litigation or when the products are approved.

Sameer Baisiwala: And is it fair to assume that these ANDA-based products would be part of Sun Pharma or would it be part of SPARC.

Dilip Shanghvi: They will be a part of Sun Pharma. There will be a certain amount of licensing and other royalty arrangements, but they will be Sun Pharma ANDAs.

Sudhir Valia: The research company will have only focus of research, not manufacturing or marketing.

Sameer Baisiwala: Again, coming back on Wrap, how do we see your NDA-based pipeline for this technology platform or is it going to be largely focused on a follow on generic kind of products?

Dilip Shanghvi: No we will use this technology for developing new delivery-system based products, combination products, for which I think the system allows itself to be used very well.

Sameer Baisiwala: And there are a few candidates that we are working on right now. For both Wrap as well as for GRID, what kind of exclusivity would you be getting in the U.S. market, one year, three years, for NDA-based filings?

Dilip Shanghvi: I mean I am not very sure, but what I understand of U.S. is that once we do clinical study for a new delivery system, then we will get a three-year new dosage form exclusivity. But the key here is that we should be then able to develop a product which is difficult to mimic, but that's a premise where you are visualizing that you dont have any other patent protection, but while doing clinical study or anything you see any benefit which you can patent, then you also get that patent protection.

Sameer Baisiwala: So, three years is the minimum, it can go more than that?

Dilip Shanghvi: Three years and 30 months stay.

Sameer Baisiwala :There is some final question on your antihistamine compound. When would you be sharing the clinical data in different forums?

Dilip Shanghvi:I think there are two things; one is we will continue to update investors on progress of each of these products and also we will start presenting about this product once we have the phase 2 data in various scientific forums, possibly publish about these products as we start getting this information.

Anju Ghangurde :Mr. Shanghvi, could you give us an indication of the competitive scenario for the dry powder inhaler and given the fact that most of the companies who are in the asthma segment also develop their own DPI. So to what extent does that limit the market? And the final question, does the experience reiterate the fact that Indian companies can develop new drugs at a fraction of the cost?

Dilip Shanghvi:There are fairly large number of companies who do not use their own devices. So, it is for example, Novartis; it does not have its own device, but it has products in development using licensed in devices. But, broadly what you say is correct. Most of the companies would work on their own device.

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Anju Ghangurde: Does the experience reiterate the fact that Indian companies can develop new drugs at a fraction of Western cost?

Dilip Shanghvi:I think whether we were an Indian company or an American company, we would have found a way to develop a product at lower cost. I think the approach makes the difference and not the nation of origin. Clearly, we have lower costs in India for scientists but also large amount of costs for all of these products in terms of clinical studies and others, would be done internationally. So, I do not think that the benefit that we will get is because we are in India. But yes, we have to be careful with cash flow, be careful with where we spend the money and what kind of projects that we choose for development.

Pawan Nahar : Sir, a repeat question here. For you personally, how much of your time would be spent, let us say between the two companies, what would be the proportion?

Dilip Shanghvi: I am currently spending around 50% of my time for research which is both for Sun as well as Innovative Research team. The effort is to increase the overall percentage of time spent on research compared to what I do in other parts of business. That is not dramatically going to shift, but we will get more structured in terms of appropriate people in different companies, may be start separating scientific resources at the head of the function level; so that there will be a greater accountability and responsibility for delivering timelines at operating level, because I do not think I can do product development. I can only look at broad issues.

Pawan Nahar :That actually links to the next question. Would you use ESOPs in the new company?

Dilip Shanghvi: We will. I think that is possibly one of the reasons why this is a more appropriate structure.

Pawan Nahar: And from 150 people at this moment, what is the number you envisage in three years like you are talking about the $75 million spend?

Dilip Shanghvi: I think the lab may be around 100 to 125 people in the next three years.

Pawan Nahar: In the innovative company?

Dilip Shanghvi: In the innovative company. We will also add people in the Sun Pharma Research Group.

Pawan Nahar: Okay. Broadly, can we assume that for Sun Pharma Industries, for most of the complex technology, now you will be dependent on SPARC?

Dilip Shanghvi: Yes I think broadly what you say is correct. I mean it will still have its own capability for making generic slow-release product. So, we will have people for making generic equivalents in Sun Pharma Industries.

Pawan Nahar :Basically, there is a clear revenue model for SPARC as well.

Rahul Sharma: Sir, within the costs which we incur on R&D as well on whole entity and split entity, over time remains same or related will it be a substantial markup?

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Dilip Shanghvi: No there will be some increase because we are expecting significant R&D spend on our investment on the existing Sun Pharma not dramatically going to go down and we would be spending lot more money on research than what we are spending on innovative products.

Neelkanth Mishra: I was reading a broad estimate of some research on average or median cost of doing phase 1 and phase 2 today would be about $40 million or in that average cost. Given that you will have phase 1 and phase 2 done for three products and $60 million that is half the cost. Could you give us a flavor of where you see this lower cost coming in?

Dilip Shanghvi: I think some of the phase 1's that you talk of, possibly are for type of drugs we are not working on. So, it is difficult to answer, but I think when we have shared this number of $60 to $75 million, then that includes taking products may be even if we include part of the phase 3 cost for 1334H.

Neelkanth Mishra: Follow on, on the risk aspect. You mentioned repeatedly that you would not see any unforeseen risks on the safety aspect. But again the research shows that only about 20% of drugs fail because of safety, and rest is the product efficacy and economics. Any flavor you could give, on how the products that you are working on could reduce the risk in that aspect?

Dilip Shanghvi: Not from what we know. That risk I think is an inherent risk.

Nimish Mehta :Just to understand the revenue model for the NDDS technology platform , you said it to be more in terms of filing ANDA with some better features that is what is going to drive the revenue here, and on the other part it would also generate revenue by licensing of this technology to the companies who are developing products. Am I correct in my understanding or is there something else also that we need to understand?

Dilip Shanghvi: What we said is we will use this technology for developing new delivery system products and that is one revenue model which will require clinical trial and which will be then brought to market. The second is that we can use this for filing generic ANDAs where meet a product equivalent to a product in the market. The third is you can license this technology for somebody else who has his own product. That he can use this technology or we can develop his product using our technology. So, these are the revenue streams.

Nimish Mehta :Are we developing any N.D.A. under current technology?

Dilip Shanghvi:Yes, we are.

Nimish Mehta: Okay. If you can share anything else?

Dilip Shanghvi: Whatever we can share, I think we have shared today and what I have shared is we will keep the investors updated on a quarterly basis.

Sameer Baisiwala: Dilipbhai, a couple of followup questions. One is for DPI. As I understand that two types of differentiation of much superior device. One is in terms of the way it is being used, the convenience, and whether the fact that more drug is being delivered to the lungs. Which one do you think is a more powerful driver?

Dilip Shanghvi: I think clearly steroids sparing or reducing effect is a powerful driver and that would from a clinical and medical point of view be a much more important benefit. But all the other features that we are building into the product will we believe make the device and the overall clinical outcome significantly better and the patient satisfaction with the product significantly superior. So, I think that also is

something that should help the product. I mean, if you have seen doctors explain to patients how to use the device, then that is an effort. Every respiratory specialist spends significant amount of time on explaining how to use the device properly to the patient. So, if you have a relatively easy device to use in which you have all the benefits that are currently not available, I think from both patient and doctor point of view that also is a very important benefit.

Sameer Baisiwala : For the lead-compound, I think we have indicated 2011 as N.D.A. filing timelines. Is 2011 the N.D.A. filing milestone that you set yourself for the DPI compound?

Dilip Shanghvi: Yes, DPI product, what we have said is the N.D.A. filing will be 2011, but we will start generating revenue from 2009.

Sameer Baisiwala: So when would IND filing take place?

Dilip Shanghvi:IND should be filed by 2007, we are talking of initiating clinical trials in unregulated markets. So, I think sometime in the beginning of 2008 or so we should file the IND when we have more details.

Question:I have a question from the web cast. The question is you mentioned that Sun DPI delivers more drugs to the lungs. Does it address the issue of steroid-induced laryngeal candidiasis which is encountered due to the deposit of drugs in the lungs.

Dilip Shanghvi: Actually, laryngeal candidiasis is because of the local immunity modifying property of the steroid. Because when a patient inhales the steroid, a part of it gets deposited on the entire respiratory tract and also goes into the stomach. So, the drug which has stuck on to the laryngeal tissues induces what you call immunity reduction in those tissues making the tissues prone to any kind of opportunistic fungal infection and that is what leads to the laryngeal candidiasis. My understanding is that because we will deliver lower level of the drug and also the particle design that we have of our product, the deposition will come down. However, whether it will have reduced laryngeal candidiasis or not, is something we will learn only when the product goes into clinical trial. I think we can go for the next question.

The next question is who are the competition for TobraDexa ophthalmic solution. We are not aware of anybody developing a similar product. However, we have not done very detailed analysis of potential competition.

The second question I think is which Indian and MNC pharma companies will be comparable in terms of R&D pipeline and NDDS technology? We would not know that.

What are the chances of being laden with a court case in the case of NCE and NDDS, you have explained now.
That also we do not know. But we believe we have reasonably strong intellectual property right for all of these products.

Which is the global R&D company which we admire and would like SPARC to benchmark?
I think we like many companies for what they are able to deliver. However, it is difficult to name any specific company right now.

Can you comment on easy efficacy of your DPI versus other DPI, that is Vectura's DPI which is also being developed with Novartis, NVA-149?

We believe our product is both from usage as well as convenience point of view better than Vectura device but may be that is because we are developing this product. So, we have to wait till both the devices come to market.

How do you conduct testing on humans at your labs? Who are samples? Do you tie up with hospitals for monitoring this?

Yes I think all the clinical trials that we do, are mostly done by CROs and they are done in hospitals. Currently, most of the clinical trials have been done in Europe, the phase 2 study is being done in the U.S. We have done some phase 1 work for 1334H in India.

So, thanks for your interest in what we had to share with you today. Thank you.