FINAL TRANSCRIPT

CCBNStreetEvents℠

Event Transcript

SCLN - CCBN Virtual Healthcare Conference: Co-sponsored by Lippert/Heilshorn & Associates and RedChip Partners

Event Date/Time: Dec. 10. 2002 4:15PM ET

CORPORATE PARTICIPANTS

Peter Hall
CCBN - Senior Vice President

Donald R. Sellers
Sciclone Pharmaceuticals - President and CEO

PRESENTATION

Peter Hall - *CCBN - Senior Vice President*

Welcome to the CCBN Virtual Healthcare Conference co-sponsored by RedChip Partners and Lippert/Heilshorn & Associates.

My name is Peter Hall and I'm Senior Vice President here at CCBN and I'll be serving as a moderator for this section of the Virtual Healthcare Conference.

I'd like to remind our live Webcast participants that you may submit a question at any time by simply typing your query into the question field in the lower left-hand side of the Webcast player.

I'll present these questions during the Q&A at the end of the company's prepared remarks. Should I have more questions than the time allows, please be assured that we will forward all questions on to the company management, who will respond directly to each of those.

The following presentation will be made by SciClone Pharmaceuticals, ticker symbol SCLN. SciClone Pharmaceuticals is a biopharmaceutical company primarily focused on the development of immune system enhancers.

Its lead product, Zadaxin, is in two Phase III hepatitis C clinical trials in the U.S., a Phase III hepatitis B clinical trial in Japan, a Phase II malignant melanoma clinical trial in Europe, and two Phase II liver cancer clinical trials in the U.S.

Zadaxin has been approved for sale in 30 companies, and it has been administered to more than 10,000 patients in both clinical and commercial use, alone and in combination with antiviral and anti-cancer drugs, without producing any reported significant side effects.

Representing SciClone Pharmaceuticals today is their President and CEO, Mr. Donald Sellers. Mr. Sellers, you may begin your presentation now.

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

Thank you, Peter. That was about as good a three-minute summary of SciClone as I've heard in a long time.

The slide I'm looking at right now is the company's forward-looking statement. This presentation will include forward-looking statements - and I think it should. These forward-looking statements are not guarantees of future performance, and I think you're all aware that they are subject to the risks and uncertainties that are quite difficult to predict. But everything we're saying is based on what we know today and working off our history.

One of the tricks to being a successful biopharmaceutical or biotech company is to have a really successful regulatory strategy that will get your drug approved by United States FDA.

That really is where a lot of companies fail. What SciClone has done is first design that regulatory strategy, and then the design the studies to support it. And right now, as introduced, we are in Phase III clinical trials in the United States and in Japan. We are in Phase II clinical trials in the United States and in Europe, targeting a cancer indication. And the trials we're working with are designed to support regulatory filings on a global basis.

Our lead drug is called Zadaxin. And, again, it introduced - this drug is now approved in over 30 countries around the world, and is actively being marketed in about 10 of those.

This drug has been used safely in over 10,000 patients without any significant side effects or toxicities. And if you look at other therapies that are targeting serious viral diseases as (ph) cancers, this is a very, very unique product.

Most importantly - or as important - this drug is already generating millions in positive cash flow from our international sales, to help support the enormous costs of running the Phase III clinical trials in the United States, Europe and Japan.

To put these clinical trials into a timeline context, in Japan, our Phase III hepatitis B study is finished.

The last patient has come out of the observation phase, and we are anxiously awaiting the assembling (ph) of the data and we will have that in information available during the first half of 2003.

In the United States we are in two Phase III studies. They had been actively enrolling since about the middle of this year, and

we are online to have the last patient come out of the observation phase there by the end of 2004.

In Europe, we have a Phase II, Phase III cancer program in place, and the Phase II part of that is already enrolling, and patients are being injected. And we'll talk more about that later.

Looking at the pack (ph) shot (ph) of Zadaxin, this is the product that is being sold commercially around the world. Zadaxin is a very interesting substance. It circulates naturally in the human, and is a main component of the immune system. In fact, this is a very well conserved, or homologous product. It's in almost all animal species from the starfish up to the human, and it forms a very important component of the immune response.

We make this product synthetically in a very (ph) to (ph) a (ph) form, and inject it back into patients who have a compromised immune system, at concentrations between 50 and 100 times its normal circulating level.

So, what are we going to do with Zadaxin? We know the drug is safe and effective as a monotherapy, that is, by itself, or in combination with other drugs out there treating viruses and cancers.

We know that Zadaxin can increase the response rates of these other drugs without adding to the side effects. And this is quite different than adding other drugs together in a cocktail.

We know that it complements. We are not competing with other drugs. This is not like one interferon competing with another interferon for market share. We would make both interferons, for example, perform better.

Also, the drug's profile fits a growing consensus in medicine, that if you go to treat a very difficult disease like a cancer or a virus, you need to have a cocktail. You need to have a combination of drugs. So Zadaxin has all this going for it now.

What are we going to do with it in the United States? Well, we've elected to move as strongly and as quickly as possible into hepatitis C. There are a number of reasons for that. Probably the first and most important to shareholders would be that hepatitis C is already a multi-billion dollar market opportunity.

In the United States, Europe and Japan, where 90 percent of the world's pharmaceutical sales are located, there are 10 million carriers of hepatitis C. In fact, data shows that this is already a $1.7 billion market in 2001, and is forecasted to grow over the next decade by about $5-$6 billion, up to the $7 billion level. So this is indeed a big opportunity.

In the United States specifically, there are four million carriers of hepatitis C. And already today, there are more people dying from the consequences or the (INAUDIBLE), if you will, of the complications from hepatitis C than from HIV. Indeed, there are four times as many people infected with hepatitis C as with HIV.

The Center for Disease Control has forecasted that by the end of the decade, there'll be 30,000 deaths annually attributed to hepatitis C. This is a classic unmet medical need.

What's interesting is, also as a competitive situation, in the United States there are really only two therapies now available to treat hepatitis C - interferon, and now more interferon in its pegylated form, but still it's interferon - or the combination of interferon plus ribavirin.

There are no vaccines available for hepatitis C, and it's quite a difficult virus to create one for, so we don't expect that in the near future.

In addition to there only being two company - two products out there treating this disease, there are only two major companies playing in the field, and they are major companies. One is Schering-Plough and the other is Roche. And both Schering-Plough and Roche are selling a combination of pegylated interferon plus their form of ribavirin.

In the treatment of hepatitis C, SciClone has Zadaxin intellectual property protected. It's patent protection until the year 2015. So Zadaxin can be used in the treatment of hepatitis C without challenge until 2015 in the United States. We have similar protection in Japan and Europe until 2012, so this is a nice horizon for us.

We also know that there's a lot of interest in the hepatitis C area. But we also know that we are the only product that is not an interferon or interferon related product that is in Phase III development today. There are other therapies out there, but they are years behind us. And, we anticipate that when they do come onto the marketplace, they also will be compatible with Zadaxin therapy. So, another way to accelerate the response rates, if you will.

But how does a small company like SciClone and a drug like Zadaxin, that is virtually unknown in the United States, how

does it get into that large competitive marketplace and get such big heavy-hitters?

Well, it's quite interesting that half the hepatitis C carriers in the United States are infected with a type of hepatitis C called genotype one. There are six different genotypes and hundreds of quasi-species or subtypes. This is a very complicated virus.

But the specific information is that half the people infected have genotype one. And more than that, they've had that for a while. They carry a high viral load.

In that particular patient population, which is the majority, 70 percent of those patients that are treated failed to respond to the combination of pegylated interferon and ribavirin, whether it comes from Schering or from Roche. This is, again, the classic definition of an unmet medical need.

More importantly for us, there is no approved therapy for the people who are non-responders. These are people who take the treatment for a year, up to a year, and at the end of that therapy they are still positive for the virus.

We know from clinical studies that re-treating those people with that same combination, or any other combination, is seldom effective. Interestingly, it might be that the best treatment for those non-responders would logically extend itself to be the best treatment for all patients. But right now, as a clinical strategy, we're going after that non-responder population.

The next slide is a line graph. And rather than try and make it complicated, I want to simplify it by directing your eyes to the right-hand side of that graph. This is the last piece of Phase II data that we did before we moved into our pivotal Phase III studies.

And this data was actually completed in the early part of 2002, but only recently presented at the American Association for the Study of Liver Disease meeting in Boston, which is the largest liver congress in the world. And that was done in early November.

But the lines at the right-hand side show that in treating patients who are non-responders - these are patients who specifically had genotype one infection, had a very high viral load of that infection, and had already failed to respond to interferon, mostly interferon plus ribavirin. But these patients have been resistant to that therapy.

When we treated them with Zadaxin, at three different dose levels, they all showed a positive reduction in viral load. And the orange on your screen is the 1.6 milligram dose, which is the dose we selected to go forward on our Phase III study. So this is very, very exciting and very positive information.

In the United States, our trials will consist of 1,000 patients. We'll have two overlapping patients, 500 patient trials, 500 patients each. These are very closely guarded studies, double-blinded, randomized and placebo controlled, and covering a wide geography around America, so that there'll be a very good random sampling of the population.

The therapy is quite straightforward and simple. Zadaxin plus pegylated interferon, and we are using in this case Pegasys, the Roche form, the newest and most recently approved of the new, of the pegylated interferons. And we're comparing that to a placebo plus the Roche pegylated interferon, pegylated interferon.

This is to clearly show the value of adding Zadaxin to pegylated interferon therapy for hepatitis C non-responders.

The current FDA paradigm for approval in hepatitis C is 12 months of therapy, and determine then if the patient is negative for the virus. And then you need to wait an additional six months and see if the patient is still negative for the virus. And if they are, then you have a success. If you don't, we do not.

And this is the study design, and these are the trials that are unrolling now. We have well over 40 sites around America, and we are continuing to enroll this study, and we will let people know when it is, in fact, fully enrolled.

What can go wrong with a clinical study? Well, the MDA first looks at the safety of the drug. How does it compare to other drugs out there that may or not have the same efficacy? So even if you have efficacy, if you are a dangerous product, you may not get through the screen.

Well, Zadaxin has incredible safety profile. As we said earlier, over 10,000 patients without a single significant side effect or toxicity.

The next area that drugs fall down is in their manufacturing. This drug has been manufactured for five years in the United States to current good manufacturing practices, both for U.S. clinical work and exported to Japan for their clinical studies, where the safety criteria are not perhaps stronger, but certainly different.

We are covering ourselves in two areas. We have manufacturing approvals in two different environments right now, so we think we're pretty good on the manufacturing front.

The next thing that could go wrong is the design of your study. We have had the world's experts, leading experts involved in the design of our study, including our principal investigator, Adrian Di Bisceglie, who is the man who decided at the National Institutes of Health how to treat hepatitis C with interferon.

Roche, who provided, incidentally, the pegylated interferon for this study, about $20, $25 million worth of it with no charge to SciClone, just in exchange for data, they also endorsed the protocol. And they have been through the regulatory process with hepatitis C two or three times in the United States, so they know what to do.

We've also powered (ph) this study for statistical significance, to assure that we have enough patients in it to get to where we need to go.

Additionally, we are in an enviable position that we still qualify for an expedited review, which we would apply for when we submit the MDA. This is because we are going for an indication where there is no approved therapy currently, the non-responder group.

Changing gears very quickly, because the clock is running on me here, I want to talk a little bit about hepatitis B. I mentioned earlier in the presentation, the last patient has come out of our hepatitis B study in Japan.

Japan has a significant problem with hepatitis B, unlike the United States where it's really not a big issue. But there are over 30 million carriers in Japan, and the current therapies really are inadequate.

Our study had 300 patients in it, and they all received Zadaxin. They received Zadaxin as a monotherapy in this case, not in combination with anything. And they received it for only six months, but there was a 12-month follow-up period, so this is still a long trial.

But this trial now is ended. The last patient has come out, and we are now beginning to collect and assemble the data.

What's exciting about this is that about a year ago, we - or early, I guess, early in 2002 - we opened up one-third of the patients and looked at one significant marker, the "e" antigen. The "e" antigen conversion from positive to negative is a clear sign that that patient is going to clear the virus.

The data on those 100 patients was 50 percent better than the "e" antigen data on lamivudine, which is currently the leading product for hepatitis B therapy around the world. Lamivudine was approved in the United States with a 16 percent "e" antigen conversion rate, and our first 100 patients in a country where all patients are very homogenous, our patients showed a 24 percent conversion rate.

To put that into context, this next chart quickly shows you some of the available approved therapies for hepatitis B around the world. As you can see, Adefovir, which was just recently approved in the United States, has a 12 percent "e" antigen and DNA clearance rate, lamivudine about 60 percent. This is all after one year. Interferon and Zadaxin, the two injectable products are both 40 percent in terms of DNA negativity.

And what's really exciting for us is that if you combine Zadaxin with interferon, or you combine Zadaxin with lamivudine, in recent clinical studies, we are looking at over 70 percent sustained disappearance of viral DNA.

This is really the best data out there on hepatitis B therapy. And we'll be doing more with this in the future. This is kind of exciting news for us.

The same qualities that make Zadaxin have a utility in treating viruses also applied in the treatment of many cancers. And to prove this, we are conducting two liver cancer trials in the United States right now.

We also have in Europe a Phase II, III cancer program targeting malignant melanoma, and this is being funded and conducted by our European partner, Sigma-Tau. They are running this program right now. They have injected patients, that we are targeting a European approval for malignant melanoma.

All of this utility in cancer will be very useful in the future in expanding the utility of Zadaxin as a significant tool in medicine in the United States.

We do have other drugs in our product line. SCV-07 is a unique molecule. It's also an immune system enhancer. It has many of the properties that Zadaxin does, but unlike Zadaxin, it is not a natural substance. It's sort of a small, discrete, designer molecule.

We just recently published Phase II efficacy data - very, very positive efficacy data - in using SCV-07 in conjunction with anti-tuberculosis remedies in Phase II studies in Russia. We'll continue to do more of that study, those studies, in that area, and then expand the utility of this drug into areas such as hepatitis C, hepatitis B and cancer.

We also have a drug - two drugs, actually - CPX and DAX, which are targeted at the treatment of cystic fibrosis. It's a slightly different area, but these are novel compounds targeting a defective protein, and addressing the underlying causes of cystic fibrosis.

I want to point out, though, that at this point in time, because of the nature of our company, all of our resources are focused on the Phase III programs to get this drug registered and moving in the United States, Europe and Japan.

A very quick look at our financials. The drug, as I said, is being sold. Ninety percent of these sales are in the People's Republic of China. And there's a very simple logic for that. We've been in that market for about five years, and it's a very, very profitable market for us.

We sell the drug there, and it generates a significant amount of cash without further investment, to help support the U.S. programs. We are running about $16 or $17 million in sales this year, and I'm quite comfortable saying that. I think at this point we're very close to the end of the year, and I'm sure we'll reach those targets.

The company at the end of the third quarter had about $24 million in cash. And this is enough money to get us certainly through the next year. We are working on our cash situation, and we are carefully managing the funds that we have.

The team is a very experienced team, developing this drug. Very briefly - not a lot of time here - I could tell you, I've been in the industry for about 30 years, everything from carrying a detail bag to being president of a division in a major multinational. Dr. Rudolph, who was instrumental in developing IL-2 and atopicide (ph), two very important anti-cancer therapeutics. And IL-2, frankly, is very similar to Zadaxin in stimulating the immune system, but a much, much more dangerous drug.

I guess the point here is that we have people who know how to ask the questions if they don't know the answers. Of note, our chairman, Jere Goyan, was a former commissioner of the FDA, so we're in good stead there.

Looking ahead, we will be telling you about Zadaxin's clinical trials. We'll let you know when the Phase III trials are fully enrolled. We'll let you know, as the Japanese data comes out there in the first half of next year. And it may come out as early as the first quarter, but not the beginning of that for sure. But we certainly think we'll have it before the first half of the year is finished.

The cancer, Phase II cancer trials are open trials, and as significant or other developments occur, we will make you, make you aware of those. We are developing SCV-07 in other tuberculosis models, and I think the news will come out on those.

We look to make continued progress in the international markets, both in terms of increasing sales and, frankly, to having additional countries recognize the safety and efficacy of Zadaxin, and further approve the use of this drug in their markets.

There's always new scientific and smaller clinical studies going on. And as that data comes out, we'll present it to you.

I invite anyone to visit our Web site, sciclone.com. We have a second Web site, scicloneinternational.com, because the drug is in fact marketed overseas.

And I guess that's about the end of my presentation. I would welcome any questions.

QUESTIONS AND ANSWERS

Peter Hall - *CCBN - Senior Vice President*

Thank you, Mr. Sellers. We do have several questions. And, again, at this time, if any of our live Webcast participants would like to submit a question, they may do so, entering the question in the query field on the lower left-hand section of your Webcast player.

The first question, Mr. Sellers, asked about the opportunities that you really envision for Zadaxin in the area of cancer. Would you like to elaborate a little bit on that?

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

Well, Zadaxin, as an immune system enhancer, increases the body's CD4 count. This is a type of t-cell that's very important

if you're going to mount a successful immune response in many cancers or viruses.

So that same mechanism of action, investments (ph) in Zadaxin, is it's really an immune system enhancer, that really has utility in cancer. I think, in fact, the potential for this drug in cancer could be bigger than the potential for it in hepatitis, but that will be in the future after our approval.

Our partner, Sigma-Tau, has enough faith in this that they are funding this and conducting this 300-patient, Phase II malignant melanoma clinical study in Europe. This trial is comparing Zadaxin in combination with various approved cancer agents to illustrate the benefits of adding an immune system enhancer like this to these regimens. They believe this is an approvable indication in Europe, and so do we.

The best performing arm of that Phase II study will go on and become the Phase III in Europe. We are conducting, as I said, two apathe (ph) cellular carcinoma, two liver cancer studies in the United States to generate data in peer review journals, so the oncology communities of the world will understand the potential of this. And we do think that the data will open up many new uses for Zadaxin in the treatment of various cancers.

Having said that again, I want to bring people's focus back. And our initial target is going to be the use of this drug in the non-responder population in hepatitis C.

Peter Hall - *CCBN - Senior Vice President*

Next question, I think you alluded to this already in your presentation, but one of the questions received asks you to elaborate on probably the significance of the hepatitis B trial in Japan.

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

Well hepatitis ...

Peter Hall - *CCBN - Senior Vice President*

What those results might ...

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

Yes, yes ...

Peter Hall - *CCBN - Senior Vice President*

... those results.

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

As we said, the hepatitis B trial in Japan is quite significant. It's the largest trial we've done in hepatitis B, over 300 patients.

Incidentally, the data we have already on hepatitis B is what has enabled the registration of this product in 30 countries around the world. So we already have significant data. But the 300 patient study is very, very important for us.

Japan is an enormous market opportunity for hepatitis B. And Japanese data is important around the world. Japan, obviously, is a high science country. And the utility of this information will be applicable in many, many developing country markets, and perhaps even the U.S. market.

But our real target is to try and get this drug through the regulatory hurdles in Japan. And the first step to that is to collect and analyze this data and assemble it.

The potential is quite significant. I haven't put numbers out there, and I don't know if any of the analysts following the company have.

But, again, all I can say is that we are very excited about it. The "e" antigen conversion rates we're seeing are a fact. The 16 percent for lamivudine, the 12 percent for Adefovir are published in the Physician's Desk Reference. These are the numbers that we used to approve those drugs in the United States and Japan. And our initial looks at a third of our patients has shown our data to be 50 percent and then 100 percent, respectively, better.

So, I think there's a very important potential future for us in that product in Japan. That Japanese data will be useful.

Peter Hall - *CCBN - Senior Vice President*

Let me ask another question that gets very specific that came in, and I hope I can translate it correctly here. The question asks the following.

The 60 percent MDR-TB rate in the recent trial published at the ICAAC show, show extraordinary results. And asks the

question, do you think you will get funding by organizations like WHO for accelerated pivotal trials.

I hope I translated that OK.

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

Well, you're talking about ICAAC data, ...

Peter Hall - *CCBN - Senior Vice President*

OK.

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

... and I'm just trying to think which study they were referring to.

Peter Hall - *CCBN - Senior Vice President*

It says, just says, the recent trial published, show extraordinary results. And will you get funding by organizations like WHO for accelerated pivotal trials?

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

Well, I can't speak to whether the World Health Organization would send us money. I'd have to go back and actually talk to Dr. Tuttle (ph) - Cynthia (ph), who will present it ICAAC to find out exactly what we're talking about, ...

Peter Hall - *CCBN - Senior Vice President*

OK.

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

... to see whether this. But send that question on to us. We'll get it ...

Peter Hall - *CCBN - Senior Vice President*

Will do. We'll send them all on.

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

... we'll get a detailed answer back.

Peter Hall - *CCBN - Senior Vice President*

Actually, we're just about out of time. And if you'd like to have any summary comments at this point, feel free to do so.

Donald R. Sellers - *Sciclone Pharmaceuticals - President and CEO*

All right. Well, the only - actually, the summary comment would be sort of a recap of your introduction.

SciClone is a company that is actually making things happen today. We are in Phase III and Phase II studies in the major pharmaceutical markets of the world.

We have a drug that is actually being sold in countries around the world and has been approved by the ministry of health in over 30 countries. And we are quite comfortable with the design of our study and the progress of our company to-date.

And we think we're on to something really good here. And we'd like to have people keep in touch with us and listen as the story develops.

Peter Hall - *CCBN - Senior Vice President*

Well, thank you very much for your presentation, Mr. Sellers. We appreciate it. We appreciate our listening audience.

A reminder, to listen to the next Webcast, please close your media player and return to the agenda page. That can be accessed at www.ccbn.com, www.redchip.com or www.lahi.com, and clicking on the appropriate agenda item.

Thank you very much.
