

# FINAL TRANSCRIPT

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## Event Transcript

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

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## CORPORATE PARTICIPANTS

### Michael Martino

*Sonus Pharmaceuticals - President and CEO*

## CONFERENCE CALL PARTICIPANTS

### Peter Hall

*CCBN - SVP*

## PRESENTATION

### Peter Hall - CCBN - SVP

Remind our live Webcast participants that you may submit a question at any time by simply typing your queries (ph) in the question field in the lower left-hand side of the Webcast player (ph). I will 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 sure that we will forward these questions onto company management for them to respond to directly.

Our next presenting company is SONUS Pharmaceuticals, ticker symbol, SNUS. SONUS Pharmaceuticals is applying its expertise in drug delivery to make therapeutic drugs safer, easier to administer, and more effective. The company is focused on the development of its lead product, TOCOSOL, and Paclitaxel, a novel reformulation (ph) of one of the world's most widely used anti-cancer drugs. SONUS is investigating a number of additional product candidates using its proprietary TOCOSOL drug delivery technology in applications targeting cancer and other serious diseases.

Presenting for SONUS today is Mr. Michael Martino, President and CEO. Mr. Martino has over 20 years experience in the medical industry and joined SONUS in September 1998 as Chief Operating Officer, and was appointed CEO in July 1999. Mr. Martino, you may begin your presentation now.

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### Michael Martino - Sonus Pharmaceuticals - President and CEO

Thank you, Peter, and good morning everyone. It's our pleasure to participate in this conference.

Before beginning the presentation, I need to point out that I will make a number of statements that include predictions, estimates, and other information that might be considered forward-looking, and these are based on our expectations and assumptions that are subject to risks and uncertainties. I would

refer you to those identified in our Annual Report and Form 10-K, which are available on our Web site.

So now that I've told why not to invest in SONUS, let me turn my attention to why I think SONUS is an outstanding investment. First, we have a proprietary drug delivery technology platform that we think is very versatile and can be applied to a number of products. Second, our lead product for cancer therapy is currently in the phase two development and the data is very encouraging. Third, we have applied the technology to date to a number of additional products in the pipeline and I'll talk a little bit about those in the presentation. And finally, we have a very clean (ph) capital structure, which we believe represents upside leverage for investors.

Our mission at SONUS is to apply our proprietary drug delivery system to therapeutic drugs to make them safer, easier to administer, more efficacious, and cost effective to manufacture. Our initial focus is on molecules that are called lipophilic. That means they're soluble in oil but not in water. And the challenge is that our bodies are water-based systems. So unless these injectable drugs can be formulated in water, they aren't presented in the body in optimal form for either safety or efficacy.

With our system, we can achieve very high levels of soluble of drug loading with the active ingredient. That means we can dissolve a lot of it in formulation. The technology does not require us to chemically modify the actives which we believe could have some regulatory advantages. And it results in an easy ready to use formulation ready for injection.

For example, with our lead product, we've demonstrated that we can inject the drug in less than 15 minutes as opposed to three hours with approved formulations. We believe the manufacturing process is very efficient and low cost, and can be scaled. And finally, we believe that technology will have a potential for improving the safety and efficacy of resulting formulations and of course, that will have to be proven on a drug by drug basis.

We think this is an outstanding opportunity for SONUS. Our recent scripts (ph) report that indicated that worldwide sales of these poorly (ph) soluble compounds exceeded \$108 billion in 2000. Further, that 14 of 24 new chemical entities approved by FDA in 2001 fit this description, and more than 40 percent of our pipeline compounds in big pharma fit this description. So we think that the technology is addressing a well-documented need.

# FINAL TRANSCRIPT

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

Our strategy is to develop proprietary products through phase one or two development, to license our delivery technology for application to others proprietary compounds. And of course, we have a vision of growing with a comprehensive R&D manufacturing marketing and sales organization.

We currently have a number of products under development in our pipeline. TOCOSOL Paclitaxel is the lead product and I'll spend a good part of the presentation talking about this. TOCOSOL Chempothecin (ph) is our second product with an objective of filing (ph) an IND (ph) in this year. We are currently exploring or developing four additional compounds, two of which are in cancer, three of which are in oil-dosage form, and these are all in very large and growing markets.

Now as Peter said up front, TOCOSOL Paclitaxel is a novel reformulation of the world's leading cancer drug, Taxol and generics with worldwide sales in excess of \$1.5 billion. We believe that TOCOSOL Paclitaxel presents the opportunity for a better dose of this widely prescribed chemotherapeutic. This better dose being noted by the ability to give it much faster. We've demonstrated in our clinical studies, for example, to deliver the drug in less than 15 minutes as opposed to three hours or more required with the approved drugs. We think this clearly has convenience and psychological benefits for the patient as well as convenience and economic benefits for the physician.

We believe we've demonstrated reduced side effects and specifically, something called neuropathy, which manifest itself as tingling in the fingers or toes, or significant pain in the fingers and toes. And most often is what's called the dose remitting toxicity for the approved drugs. That is it limits the amount of drugs that can be given or the number of cycles of drugs that the patient can withstand. And finally, we're seeing very encouraging signs of anti-tumor activity.

In our clinical studies to date, we have enrolled over 100 points in phase one and two studies, have administered over 1,100 doses of the drug. The phase one study was completed in May of this year. And we initiated four phase two studies in March of this year, which are ongoing. In summary, we believe we've demonstrated to date an excellent safety profile, including the ability to administer the drug in less than 15 minutes, a significantly lower rate of neuropathy, and a reduction in allergic reactions. We also continue to see encouraging anti-tumor activity in multiple tumor types.

For example, in the phase one study, although these numbers were small, we saw outstanding to these control rates in lung, ovarian, breast, and colorectal. In our phase two studies to date,

and this data is from the dose escalation stage of the study, but nonetheless, we are very encouraged by the objective responses across the board and by the high disease control rates. And if we compare this data a little bit to some reference standards, they would be as follows.

First, for non-small (ph) lung are 22 percent objective response rate compares very well to the six percent response rate that was the basis for approval for Taxotere as a second line single agent. In bladder, our 17 percent objective response rate compares favorably to the 10 percent objective response noted in the literature for Taxol in these patients. And in ovarian, our 16 percent objective response is equivalent to that demonstrated with Taxol both as a package insert in a number of subsequent studies.

In colorectal, the six objective response rate may seem low on first observation. We would point out that it actually compares pretty favorably to the nine percent objective response rate that was the basis of approval for auxelaplatane (ph) with five (ph) (inaudible). And compares very favorably to the one percent objective rate for auxelaplatane (ph) alone. And I would point out here that colorectal tumors are not thought to be responsive to taxanes historically. So we're seeing a response rate with our - with our drug that we would not that we would not expect to see.

I'll drill a little bit into the non-small cell lung data. I would further say that our 22 percent response rate compares very nicely to a 16 percent response rate published on one study presented to ASCO in this past year, and even compares favorably to the 24 percent response rate, which was the basis for approval for Taxol and Cisplatin as a combination therapy for non-small cell lung.

Some of you may be aware that Taxol was - or Taxotere was recently approved in combination with Cisplatin for non-small cell lung. It was approved as a non-inferior drug based on objective responses. So even though the data is not yet available, we believe that the Taxotere Cisplatin data would be very similar to the Taxol Cisplatin data and we believe we compare favorably.

Our second cancer product is TOCOSOL Chempothecin (ph). Now this is not a new active ingredient. It was actually discovered in 1956 at NIH, but the early development was compromised by severe toxicities (ph). This is a very hard to formulate drug. It's what the chemist would call "sand" (ph). It simply doesn't dissolve in anything.

# FINAL TRANSCRIPT

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

Several analogs were developed that represented chemical modifications of that original parent molecule, which made it easier to formulate, but we believe that it sacrificed activity. In other words, the parent molecule was more active than the analogs and the marketed analogs have some undesirable side effects of their own. Nonetheless, they're used in large patient populations in approved indications for colorectal, ovarian, and small cell lung cancer. And the market for these marketed drugs and 2001 exceeded 750 million.

We believe that TOCOSOL is a system, which can solubilize (ph) and deliver this very lipophilic active compound. That formulation of the drug with TOCOSOL may result in increased activity due to higher concentration of the active drug delivered to the tumor cells and more drugs retained in the tumor cells. In our pre-clinical studies we demonstrated a better side effect profile than the marketed analogs. And as with TOCOSOL Paclitaxel, this formulation is ready to use, and we believe will be able to be injected in less than 15 minutes.

Shifting gears for a moment and summarizing our financial position, at the quarter ending September 30th, we had 19.2 million in cash. We have no debt. Our monthly burn is approximately 1.1 million. So we believe our current cash position is sufficient to meet near-term objectives. Nonetheless, achieving financiable (ph) milestones in 2003 or early 2004, continue to be key objectives.

We have 13.7 million primary shares outstanding, three percent of which are owned by management and the board. On a fully diluted basis, we have 60.8 million shares, 10 percent of which are owned by management and the board.

So in summary, as we look at the final few weeks of 2002, we believe this has been another exciting year for SONUS. We've made significant advances with the clinical development of TOCOSOL Paclitaxel. We've positioned the second cancer product for clinical trials. We've strengthened the balance sheet with a tight close in January that netted 12.5 million. We've signed a manufacturing agreement for TOCOSOL Paclitaxel and are making good progress with our manufacturing partner in scaling that process. And the cornerstone, TOCOSOL patent issued in October with a second patent following in November.

In terms of upcoming milestones, I would note two. The first is to continue to accelerate the development of TOCOSOL Paclitaxel. The second is to file the IND (ph) on TOCOSOL Chempothesin (ph) and position our product to initiate phase one clinical studies in 2003.

With regard to the accelerated development of TOCOSOL Paclitaxel, there are three sub-points. The first is clarification on the registration strategy and the initiation of registration studies in the U.S. And we would expect to be in a position to initiate these studies in early 2003. The second would be scale the manufacturing process so that we are in a position in 2003 to manufacture product for the registration studies with a manufacturing process that would be the basis for our new drug application. And the final objective with TOCOSOL Paclitaxel is to secure a corporate partner. We did initiate discussions on corporate partnerships just a short while ago, and while I can't speculate on where those will go or when, I can say that I've been very pleased to date with the level of interest from some potential partners that are very high quality companies.

So that concludes the formal comments this morning. I certainly appreciate your time and attention. And Peter, we'll be happy to answer any questions.

## QUESTIONS AND ANSWERS

**Peter Hall** - CCBN - SVP

Thank you, Mr. Martino.

We'll now move to the question and answer session. And a reminder to our live Webcast participants, to submit a question, simply do so by typing your query into the question field in the lower left-hand side of the Webcast player.

Our first question, Mr. Martino, ask you to explain and give an estimate as to when you expect TOCOSOL Paclitaxel to be on the market, and comment on what you feel would be the market potential for that.

**Michael Martino** - Sonus Pharmaceuticals - President and CEO

Well, of course, it's a very fair question. At the same time, what you're asking me to do is to speculate in large part of the actions of an independent government agency. Nonetheless, the guidance I would offer is that on a very conservative case, assuming that this drug is reviewed and approved as a new chemical entity, our objective would be file an NDA (ph) by the end of 2005 for approval and launch of the drug at some point in 2006.

I think a more aggressive scenario assumes that because our formulation does not change the chemical structure of an active

# FINAL TRANSCRIPT

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

ingredient that's now been on a market for some time and is well known and understood, that a more accelerated regulatory path (ph) is available to us. And in that case, it may not be unreasonable to shorten the process by about a year or a little more than a year.

In terms of market potential, we believe that that will be driven by a couple of factors. If what we're able to demonstrate is that the drug is as equivalent as the approved products, then we think the advantages of a ready-to-use formulation which can be administered in 15 minutes or less are still significant. On the other hand, if we can demonstrate in our clinical studies that there is improved efficacy verses the approved formulation, then I think our market share would be significantly higher.

In either case, we think the drug will get it's fair share of a market that is today 1.5 billion, and despite generic competition, still growing.

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**Peter Hall** - CCBN - SVP

Thank you. The next question asks you to comment on the criteria for choosing products to apply your technology to. How does - how do you go about doing that?

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**Michael Martino** - Sonus Pharmaceuticals - President and CEO

Well, once again, our focus is on formulating drugs that are very difficult to formulate. And our chemists have criteria for choosing those compounds based on our chances of solubilizing (ph) those active ingredients.

Additionally, we look at marketing issues such as market size, growth, basic drivers of demand. And we also look at regulatory issues. In other words, we consider how difficult it may be to get a resulting formulation approved and on the market. We consider all of those things for the consideration of all of those things is reflected on the pipeline I presented this morning that contains three cancer drugs, a cardiovascular drug, a anti-infection drug, and a drug for diabetes.

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**Peter Hall** - CCBN - SVP

Next question asks, does SONUS have any patents protecting the TOCOSOL technology?

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**Michael Martino** - Sonus Pharmaceuticals - President and CEO

Well, we're very pleased in both October and November - in October, to have the Seminal (ph) patent issued that covers TOCOSOL, it's basic composition, and it's application to a number of active ingredients including Paclitaxel. That was followed in November by the second patent on the technology. And in total, we have now more than 24 patent applications in the United States, a corresponding number in Europe, and primarily Japan. And we believe that our patent protection on the technology is quite broad.

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**Peter Hall** - CCBN - SVP

Our next question is on financing. Mr. Martino, someone asked, do you anticipate another round of financing? If so, when and possibly where that might come from?

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**Michael Martino** - Sonus Pharmaceuticals - President and CEO

Well, we - at the quarter ending September, we have 19.3 million in cash on the balance sheet, and we're burning about 1.1 million a month. That burn rate is sufficient to support our near-term objectives with TOCOSOL Paclitaxel. It is not sufficient to initiate clinical trials on TOCOSOL Chempothesin (ph) or the additional products in the pipeline. So I do anticipate a need for cash towards the end of 2003 or early 2004.

We're currently engaged in discussions with a number of potential commercial partners for TOCOSOL Paclitaxel. And our objective would be to realize the cash that we would need through those partnerships. Potentially, then to leverage that in the use of additional equity. Now, of course, everything else not being equal, bankruptcy is always the worse form of dilution. And so we would continue to keep our options open as 2003 progresses, and consider a wide range of options to refinance the company. But our preference would be to structure the corporate partnership as the first step. And to, in effect, refinance the company with the cash from that corporate partnership.

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**Peter Hall** - CCBN - SVP

OK. I see no other questions at this time, and would welcome any concluding comments that you would like to make, Mr. Martino.

# FINAL TRANSCRIPT

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**Michael Martino** - *Sonus Pharmaceuticals - President and CEO*

Well, Peter, again, we appreciate the opportunity to tell our story this morning. We believe that SONUS does represent an outstanding value investment opportunity. We would encourage people to contact us directly if they have any other further questions either on our Web site at [www.sonuspharma.com](http://www.sonuspharma.com) or by calling Ms. Pamela Duhl (ph) in Investor Relations. Thank you again for your time and attention everyone.

**Peter Hall** - *CCBN - SVP*

Thank you.

Thank you for your presentation. A reminder to our listeners, to listen to the next Webcast, please close your media player and return to either [www.ccbn.com](http://www.ccbn.com), [www.redchip.com](http://www.redchip.com), or [www.lhai.com](http://www.lhai.com) and click on the agenda page. Thank you very much.

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