

# FINAL TRANSCRIPT

**CCBNStreetEvents**<sup>SM</sup>



## Event Transcript

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

Event Date/Time: Dec. 10. 2002 3:15PM ET

**CCBNStreetEvents**<sup>SM</sup>

[streetevents@ccbn.com](mailto:streetevents@ccbn.com)

617.603.7900

[www.streetevents.com](http://www.streetevents.com)



# FINAL TRANSCRIPT

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

## CORPORATE PARTICIPANTS

### Paul Freiman

Neurobiological Technologies - President and CEO

## CONFERENCE CALL PARTICIPANTS

### Peter Hall

CCBN - SVP

### The first question is

## PRESENTATION

### Peter Hall - CCBN - SVP

Welcome to the CCBN Virtual Healthcare Conference, co-sponsored by RedChip Partners and Lippert/Heilshorn & Associates. My name is Peter Hall, and I'm a Senior Vice President here at CCBN, and I'll be serving as the moderator for this portion of the Virtual Healthcare Conference.

I'd like to take this time 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 will present these questions during the Q&A at the end of the company's prepared remarks. Should I have more questions than time allows, please be sure that we will forward all questions to company management who will respond directly to each of them.

Our next presenting companies - company is Neurobiological Technologies, ticker symbol NTII. Neurobiological Technologies is an emerging drug development company focused on the clinical evaluation and regulatory approval of neuroscience drugs. The company's strategy is to in license and develop early and later stage drug candidates that target major medical needs and which can be rapidly commercialized. The company's experienced management team oversees the human clinical trials necessary to establish preliminary of efficacy and seeks partnerships with pharmaceutical and biotechnology companies to complete development and marketing of it's products candidates.

Representing Neurobiological Technologies today is Paul Freiman. Mr. Freiman is the President and CEO. Mr. Freiman, you may begin your presentation now.

---

**Paul Freiman** - Neurobiological Technologies - President and CEO

Thank you very much, and hello to my audience.

My first slide is entitled, "Crossing the Finish Line." And I'd like to spend a minute on this because it's only a title slide. But the fact is that every biotechnology company is in a race with many other companies that develop products. We happen to be at the stage of having a developed drug approved in one part of the world and, hopefully, soon to be approved here. So, it's a real thing.

The forward-looking statements many of you've seen before. Essentially read it carefully and take what I have to say about the future with a grain of salt.

The company overview is that we were set up to develop neuroprotective drugs. Drugs that were protecting the degeneration of nerve cells as a template as was mentioned, was in-license compounds to develop them in the house and to out-license them to a pharmaceutical company.

We've in-licensed four drugs and two are still being actively pursued. One is called Memantine, which is truly a read (ph) product. It's been approved for the treatment of Alzheimer's in Europe. And in the United States, our partner, Forest Laboratories (Company: Forest Laboratories Inc.; Ticker: FRX; URL: <http://www.frx.com/>), will be filing an NDA this month. It's also being developed for diabetic neuropathy, which I'll speak about soon. The second product is an orphan drug called XERECEPT, which is being developed for a peritumoral brain edema.

And the last point on the overview is that we indeed are an experienced management team. I've been in this industry for 40 years and was the CEO and Chairman of Syntex Corporation when we sold it to Roche (Company: Roche Holding Ltd.; Ticker: ROHHY; URL: <http://www.roche.com/>). My medical director worked for us at Syntex and has successfully brought the drug to the markets. So, the experience is there.

What is Memantine? It's in a class of compounds called NMDA inhibitor antagonist. I won't bore you with the science. But essentially, the third bullet is really important in that it restores the function of damaged nerve cells, and I'll explain in lay terms how this works.

What happens in cases of Alzheimer's, or stroke, or many conditions that effect the brain. Well, the brain is insulted (ph) either by a physiological condition or a blow and it causes neurotransmitters, like the formulas in your brains are really chemicals that speak to each other. These neurotransmitters occurring in abundance. One of them is called glutamate.

# FINAL TRANSCRIPT

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

When glutamate is hyperexcited, too much of it springs out. It causes cell death. And cell death, as the cell is dying, it talks to the next cell and says, "I'm dying." And the next one says, "I'm dying, too." Memantine interferes in this process. And if any of you are scientists and would like more information, I'll handle that in the Q&A session.

Let's look at the product itself. Memantine is - in its first indications for Alzheimer's disease is a very large market. As the world ages, the condition becomes more and more prevalent. The product was approved in Europe in May of this year. And unlike the United States, in Europe, when you get a central approval, you still must go around to each country and negotiate the pricing schedule with each - with each country since the government tends to be the payer of healthcare. The product has been approved to this point in price in Germany, in Austria, Denmark, and Netherlands, UK, and Norway. And it's moving south in Europe. And in the next few months will be - should be approved in about every country of that continent.

In the United States, Forest Laboratories is our partner and they will be re-filing a new drug application, that's what an NMDA means, this month. I'll tell you why in a few minutes because it's a great story. The product is marketed by Forest Labs here, Lundbeck in Europe, and Merz in Europe. Merz is a company who first synthesized and discovered the product. And we have a strategic alliance with all these parties.

If you look at the current Alzheimer's therapy, there are only three drugs out there. The big one is Aricept by Pfizer (Company: Pfizer Inc.; Ticker: PFE; URL: <http://www.pfizer.com/>), but Novartis (Company: Novartis AG; Ticker: NVS; URL: <http://www.novartis.com/>) and Jansen, part of J&G (ph), have products in the game. They're all in the class of drugs called acetylcholinesterase inhibitors. They're very mild treatments for mild conditions of Alzheimer's disease. I can truly say that the marketplace in physicians and patients are satisfied by this therapy.

If you look at how we stack up against these compounds, we are a different class of drugs. We're not an acetylcholinesterase inhibitor, that's the AChE inhibition. And that's important to say that the drug works through a different pathway. It has been approved in Europe in moderate to severe Alzheimer's disease as opposed to the mild approvals that have been given to the competitive products. This is also what we're going for in the United States, at least initially.

The current therapies achieve moderate results. I don't want to downgrade competitors, but I've had Alzheimer physicians tell

us that the drugs are no more effective than green M&Ms, or that sometimes they prescribe the product for the families as opposed to the patient.

The side effect profile looks pretty good compared to the AChE inhibitors. And this drug has been around for about 20 years in Europe. There's a sizable safety database and as we've conducted our very well controlled clinical trials in this country and in Europe, we've seen nothing new pop up. So, we're very comfortable this large body of information that we have.

The last bullet is the most important, and that's that the product has cocktail potential. What does that mean? Forest Laboratories ran a phase three trial using the market leader, Aricept, in combination with our drug, a cocktail versus a placebo versus Aricept alone. The results - top line results were announced in October and they were fabulous because for the first time, we saw rather than a slowing of the decline of Alzheimer's, an absolute flattening of the disease and in certain measures of improvement. That is a phenomenal result.

For those of you that follow either Forest or our company, you'll see that they made a major announcement about this yesterday where they gave the complete results of the trial along with a press or a medical conference today, which can be found on their Web site. This just underscored how important this combination of products is going to be in treating the disease. We believe that it can become the standard of care for patients with Alzheimer's.

Moving along now, the second indication is something called diabetic neuropathy. This is a condition that occurs in about third of the patients with diabetes. It's the extreme pain in the extremities and it runs from chronic to acute. It goes on for a long time. Sometimes you're free of it. When it is acute, however, it is so painful that patients have described it as wrapping an electric wire around their limbs. We think that about three-and-a-half million patients roughly worldwide, we perform - we, NTI, performed a Phase IIB trial, which the FDA looked at and said, this looks pretty good to us. It will be acceptable as one of two pivotal trials that the FDA requires for the approval of a drug.

So, a second trial had to be done and Forest Laboratories is performing that. Actually, this month the last patient out of the trial, not in the trial but out, will have been recorded. It takes about a quarter - let's say, three to four months to analyze the data. So by the spring, you should be seeing some results in this field, in again, the same marketers.

# FINAL TRANSCRIPT

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

The current landscape, this is really interesting because even though this is a widespread condition, there are no drugs currently approved to treat it. Oral therapy is – that's being used today is being used off label. The market leader is a drug called Norantin, which is an antiepileptic drug. And if you look down at the chart, you'll see that the drug back in '97 was selling at not quite \$300 million. It was flat as a board for years.

Then, it started to climb when a study came out showing that it worked in about half of the patients with diabetic neuropathy. That was a big breakthrough because there's nothing else around. This disease does not respond to normal analgesics. And you can see what's happened to the drug. There's about \$2 billion in sales in there. And at least half of that has to be for neuropathic pain and probably more. So, it's a market that we're going into.

And what we've seen with our product, Memantine, are very similar results to Norantin's, but it's probably a better side effect profile. We believe that reducing pain 50 percent in half of the patients is a great breakthrough. We expect Forest to be quite competitive with this product once it's approved.

If the clinical trial is as we hope, and we'll be analyzing that this spring, we should see a filing for an NMDA this year for this indication.

Moving along to our second product, XERECEPT, is an orphan drug being used for peritumoral brain edema. What is peritumoral brain edema? It's really when a patient has a brain tumor and undergoes chemotherapy and radiation, you see a leakage from the blood vessels in the brain, which causes swelling. And this liquid, this fluid has no place to go. It's trapped between the skull and the brain, and it causes immense pressure.

The incidents of brain tumors in the United States is 30,000 primary tumors and 120,000 metastatic tumors. There's a very inexpensive steroid that works quite well that's called Dexamethasone. The other alternative seems to be drilling a hole in the skull and relieving pressure. We have used this product in peritumoral brain edema in a series of small trials, and you can see the summary of these trials in the next slide. Essentially, we saw that the product was well-tolerated, that it relieved the neurological symptoms of these patients, and they felt better. So we've decided to move ahead with the Phase IIB/III trial to substantiate the fact that we can reduce Dexamethasone and perhaps eliminate it from the therapy, and look at the long-term safety aspect of the trial.

If you look on the next slide at Dexamethasone, you see – those of you that know what steroids side effects are like, they're very

serious. There's chronic wasting – muscle wasting, osteoporosis, personality changes, et cetera. That doesn't seem to be the case with our product in several years of looking at it.

We also have found that there's a lot of literature out that shows that Dexamethasone may actually interfere with the brain tumor therapy by preventing apoptosis, which is the proliferation of blood vessels. In fact, ATRF enhance (ph) brain tumor therapy VRCRF1 and CRF2 receptors.

The next slide, which shows a couple of graphs, is very interesting. On the left side, you see a whole series of tumor cells listed. And along the side axis where it goes from zero to 100, you see the percent of tumor cells that survive radiation. So, the higher the number, the worse the condition. You can see that when CRF is given, that's the plain white box, you reduce the amount of cells that survive. You increase the sensitization by the numbers on the right hand side.

The great example is the one on human glioma, which is a brain cancer, shown as A172. We get about a five times improvement increase in radiation sensitization. That's quite a remarkable finding. We're moving ahead to a Phase IIB/III trial. We'll be going into the FDA this month, and like (ph) ran (ph) out all the details behind this.

So in summary, XERECEPT has completed three months (inaudible) in two species of animals. The FDA required that. We've completed a new manufacturing process and have packaged materials for a clinical trial. We intend to resume that trial program and we're going into the FDA to establish a final strategy.

Let me move to a significant of our collaborative partners. For those of you that follow the pharmaceutical industry, you know that Forest Laboratories is one of it's stars. It's really a company that's stepped up and doing a great job. They have partnered several products or Lundbeck of Denmark has partnered several of their key products to Forest. And there's a nice working relationship there. We're working with them in Europe as well as Merz.

So, how does the cash flow? The way things work is that Forest Laboratories and Lundbeck will sell the product, pay a royalty – rather sizable royalty to Merz, the German company who discovered the product. And then in turn will share their royalties with us unevenly. It depends on the therapeutic regimen. And let me give you some feel for this because all of these terms are wrapped around secrecy agreements that I cannot unveil to you at this point in time.

# FINAL TRANSCRIPT

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

So if you look at the financial impact slide, you can see that essentially for Alzheimer's disease, well, we never did any work. The work was all done by Merz and by Forest. We will receive somewhere around one percent of the sales - one percent of sales. In diabetic neuropathy and a condition called AIDS dementia, we would be receiving about 13 percent of sales. And you might ask, you know, is this going to be a big product or a small product? All I can say is that we're moving into two huge markets that are tremendously underserved. In the case of Alzheimer's with relatively weak drugs, all in the same class. In the case of diabetic neuropathy, with one competitor. I think that's a great stimulus for a good company like Forest to go out and succeed.

If we look back for a moment, we were broke. I mean, really strapped for cash back a few years ago. We have about \$7.5 million in the till. Our annual burn rate is closer to \$4 million now. The cash will replenish itself through a series of milestone payments and royalty payments that we will start receiving from Europe very shortly. Our stock price has been all over the lot (ph). It's been hanging mostly around two to \$2.50. In the past four weeks or so, it's taken a real pop where we find ourselves somewhere the \$6.00 range today. And there's a lot of activity on the stock in the last few days. Much of it is based on the Forest Laboratories press releases and medical conferences.

If we look at the balance sheet, it's - for a company our size, there are only eight people. I neglected to say that. We're a small company. We're a virtual company. And we work with a team of outside consultants that I've worked with much of my career and who provide us great services that we couldn't afford within the company. We pay them by the day, by the hour, by the week, by the month. So, I think we're running the company in a very frugal way. We're located in a low rent district of the San Francisco Bay Area. Out here, paying \$1.75 a square foot is pretty low priced. So, we're in great shape financially. And it's my feeling that we will move into positive cash flow in 2003 and that we will not look back in terms of wanting to raise more equity.

So in summary, we believe we have a small but very innovative product pipeline. We see sustainable cash flow coming to us, which should be reasonably sizable. We've gotten an European approval, which is great validation, we have a fine partner in Forest, and within a matter of days, we'll be resubmitting an NMDA to the food and drug people. We have milestone in royalty payments coming to us, a nice balance sheet. And we're currently looking at strategic alternatives. What I mean by that is that we are a small company. One of the opportunities that I see for us is to sell ourselves. We might need to add a few

products to our pipeline to make that more (inaudible). We are exploring those alternatives today.

So we have a biotech company that actually has a product and one that could be quite exciting. So I'm going to turn this back over to the moderator and be willing to accept questions from the audience.

Thank you all so very much.

## QUESTIONS AND ANSWERS

**Peter Hall** - CCBN - SVP

Thank you, Mr. Freiman. We do have several questions.

### The first question is

ask you to elaborate on the relationship - the strategic alliance you have with Merz, Forest, and Lundbeck. I know you mentioned it in the presentation, but this question asks you to elaborate exactly on the details of that.

**Paul Freiman** - Neurobiological Technologies - President and CEO

It's a very complicated tri-partied (ph) arrangement. Going back to 1998, Memantine came out of Merz. The patent - the composition matter of patent expired in 1995. Merz took out used (ph) patents in stroke, in Alzheimer's disease, and in vascular dementia. A group of scientists up at Harvard were doing work on the NMDA receptor. They found Memantine which sort of met their profile and the university patent the product for diabetic neuropathy, oral neuropathies age-related dementia and (inaudible) disease. We received that license.

So, here we are two companies with the same product going down a parallel track. The basic difference is that they had money and we didn't. We were flat broke. They are a fairly wealthy private German company. So, we hooked a deal and they threw a couple of million dollars into our company to keep us going. We did some more trial work. They loaned us some money, which we repaid. We returned our rights to Harvard - to Children's Hospital at Harvard, who in turn re-licensed it out to Merz.

As a consequence of that, we share both milestone and royalty payments based on the therapeutic indications. The actual terms you will never see. That comes under a secrecy agreement. But

# FINAL TRANSCRIPT

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

the rough terms, I think you can get a feel for in looking at the slide that I referred to earlier which has about a one percent royalty on Alzheimer's and about a 13 percent royalty on diabetic neuropathy. So, you've got to do your own calculations with regard to market size, and penetration, and things of that nature.

I hope that's helpful.

---

**Peter Hall** - CCBN - SVP

Sure.

Next question asks specifically about the R&D costs associated with XERECEPT: will - and specifically, will there be a large increase in R&D costs?

---

**Paul Freiman** - Neurobiological Technologies - President and CEO

Well, we've seen that pop up in the last two quarters. The - we've had to manufacture product from scratch, get it validated for FDA approval, and things of that nature, and it's quite expensive. We have about another half-a-million dollars ahead of us on pre-clinical costs and probably another three million dollars ahead of us on clinical costs. So, let's say three-and-a-half to \$4 million spread out over three of our fiscal years, because I would expect XERECEPT to be - the trial to be completed about 18 months after the first quarter of this year. So we'll tack on let's say a million-and-a-half dollars - not quite, let's say a million-and-a-quarter dollars per fiscal year in addition to any other R&D costs.

Now, all of the Memantine costs are being born by Forest and by Lundbeck in Europe. So, there is no costs there. Let's say that we ought stay close to that \$4 million a year mark going forward. At the end of the third year, it will drop off and it should be a money machine frankly.

---

**Peter Hall** - CCBN - SVP

Next question comes from the Web asking: when will neuropathic pain trial results be announced?

---

**Paul Freiman** - Neurobiological Technologies - President and CEO

We would expect them to be announced in the - somewhere around the March to April timeframe. The last patient came out this month and it takes about three to four months to analyze data. So we're all sitting and waiting. We would anticipate since

we've done two trials already on neuropathic pain, and this is a larger trial, that the results ought to be affirmative. But you never know until it's done.

---

**Peter Hall** - CCBN - SVP

Sure.

A follow up question, and I think you commented on this in your presentation, but the question we have is, the last month we've seen a lot of movement in the stock and an increased in the trading of the stock. And asked, "What's going on?" I think you did mention that, but any further elaboration on it?

---

**Paul Freiman** - Neurobiological Technologies - President and CEO

Well, we are really coasting along in a lot of ways on the wind, the draft of Forest Labs. I personally have been spending a lot of time out on road shows, talking to audiences and they seem quite (inaudible) at this point in time of a company that has a product in biotechnology instead of a technology. And as a consequence, we've seen our base of investors really start to expand.

I worked with one investor who said, you know, it seems to me, Paul, that this is like the movie, "The Perfect Storm." You know, once in a 100 years, all the elements come together to conspire for such huge waves and such a big storm. Well, everything seems to be coming together at this time for us. And, of course, there's clouds in the horizon. The FDA might not approve our product. But the odds are looking pretty good in our favor that we have something that can generate a lot of bucks.

---

**Peter Hall** - CCBN - SVP

Well, that's terrific. And we'll keep that analogy in mind. We actually are out of our allotted time, but if you want to make any last minute concluding comments or summary comments, we'll welcome them at this time.

---

**Paul Freiman** - Neurobiological Technologies - President and CEO

I'd just like to end by stating that this is a little jewel of a company with experienced management, with cash in the bank, and with a product in the market. And the best is yet to come so keep your eye on us please (ph).

# FINAL TRANSCRIPT

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

**Peter Hall** - CCBN - SVP

Thank you so much. Thank you, Mr. Freiman, for your presentation. Thank you, listeners. To listen to the next Webcast, please close your media player and return to the agenda page. You may access that at [www.ccbn.com](http://www.ccbn.com), [www.redchip.com](http://www.redchip.com), or [www.lhi.com](http://www.lhi.com) and click on the agenda page for the appropriate presentation.

Thank you very much.

## DISCLAIMER

CCBN reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES CCBN OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

©2002, CCBN, Inc. All Rights Reserved.