



## **Catalyst Pharmaceuticals Partners, Inc. (CPRX)**

Price: \$3.23 (12/18/07), Market Cap: \$40MM (12/18/07)

Rating: Market Outperform; Target Price: \$9

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### **Panel of Experts Discuss the Promising Potential for Vigabatrin in Addiction – Transcript Attached**

- We hosted a call with four experts in the addiction therapy field to discuss positive results recently announced from an investigator-led Phase II trial in Mexico evaluating vigabatrin for the treatment of cocaine addiction. The experts present on the call were:
  - Dr. Jonathan Brodie, professor of psychiatry at the New York University School of Medicine and co-principal investigator for the Phase II trial.
  - Dr. Thomas R. Kosten, Professor of Psychiatry and Neuroscience at Baylor College of Medicine and former Professor and Chief of Psychiatry at Yale University and VA Connecticut.
  - Dr. Thomas F. Newton, a professor in the Department of Psychiatry and Biobehavioral Sciences.
  - Dr. Eugene Somoza, is Professor of Clinical Psychiatry, Psychiatry Department, College of Medicine, at the University of Cincinnati and Director of the Cincinnati Addiction Research Center (CinARC).
- We observed the following key points from the expert panel:
  - Dr. Kosten stated that the bar to success set in this trial was very high, and it was achieved. Dr. Kosten has previously generated data indicating that achieving abstinence for three weeks is a strong indicator of a patient remaining abstinent for a substantially longer period of time.
  - All of the doctors on the call viewed the trial results as positive, with Dr. Somoza stating that the results “exceeded expectations”.
  - It was also a general opinion that the secondary outcome measures would strengthen the results released so far. These include drug abstinence throughout the duration of the treatment period and reduction in cocaine use. Dr. Kosten did point out that he would expect observations of psycho-social improvements to take longer than the three month timeframe of this trial.
  - Dr. Somoza believed that the main limitation to the trial was the frequency at which urine samples were taken (twice per week). He stated that due to the short half life (~5.5 hours) of benzoylecgonine, the primary metabolite of cocaine assayed in abuse testing, it was possible that patients negative due to the timing of cocaine use. Dr. Somoza did provide the caveat that any false negative would be expected to be equally weighted between vigabatrin and placebo treated patients. Additionally it is our view that the patient population had no incentive to “trick” investigators in this study, especially given that patients had likely been long time abusers of cocaine.
  - It was the consensus of the panel that more frequent urine sampling would be preferable in future trials and would allow a more quantitative assessment of cocaine abstinence.
  - When discussing the future for vigabatrin the doctors all expressed the opinion that vigabatrin is the most promising developmental therapy that they have seen: Dr Newton stated that he would be surprised if vigabatrin was not a success based on the animal and clinical data available to date. It was

Dr. Somoza's opinion that the animal data were "incredible" and he believes that the drug would likely be active as a treatment for addiction to all stimulants.

- A replay of the call will be available for one week and can be accessed by dialing (888) 203-1112 or (719) 457-0820 and providing the passcode 3405806.
- Today's call reinforces our confidence in vigabatrin's potential to become a leading therapy for the treatment of addiction to numerous stimulants, including cocaine and methamphetamine. We reiterate our Market Outperform rating and 12-month target price of \$9 on Catalyst shares.

## **RODMAN & RENSHAW, INC.**

**Moderator: Elemer Piros**  
**December 18, 2007**  
**10:00 a.m. CT**

Operator: Good day, and welcome to today's Attenuating Addiction - Benchmarking Catalyst Pharmaceuticals Vigabatrin conference call. As a reminder, today's call is being recorded. At this time I'd like to turn the call over to Elemer Piros. Please go ahead, sir.

Elemer Piros: Yes, good morning, thank you very much for joining us on this conference call. The purpose will be to examine a clinical trial, a Phase IIa investigator sponsored clinical trial of vigabatrin. And we are joined by one of the co-principal investigators of the study, Dr. Jonathan Brodie who is a Professor of Psychiatry at NYU. And we have asked a panel of opinion leaders in the field of addiction, namely Dr. Thomas Kosten, who is a Professor of Psychiatry and Neuroscience at Baylor College of Medicine. Dr. Thomas Newton, Professor of Psychiatry and bio-behavioral sciences at UCLA, and Dr. Eugene Somoza, who is a Professor of Clinical Psychiatry at the University of Cincinnati to join us to evaluate the study, and to put it in historical perspective and to discuss the challenges that are apparent with addiction studies both in cocaine, methamphetamine or alcohol addiction.

Gentlemen, once again thank you for joining us, and I'd like to turn over to Dr. Jonathan Brodie to set the clinical trial up for us, and perhaps discuss the primary endpoint and the results that have been obtained and publicly available to date. Dr. Brodie?

Jonathan Brodie: Thank you. This is a double blind, placebo controlled, parallel design, efficacy study using vigabatrin in the treatment of cocaine dependent subjects. And this was a follow-up to two open label studies that had been done previously that suggested that, in keeping with the animal studies, there were promising outcomes from these prior studies.

In this study, the primary objective was to assess the efficacy, dependent upon a single primary outcome measure, which was three consecutive weeks of negative urine tests for cocaine use without any slips allowed, and these weeks had to be the last three weeks of this nine-week trial. The trial was conducted with a ramping up of vigabatrin over several weeks, similar to our previous trials in which they started off with one gram a day, and then two grams and then three grams a day maintained for four weeks. And then deescalated down to nothing over the last two weeks of the trial. So at the end of the trial, they in fact had no vigabatrin.

What we found was of the 103 subjects who were enrolled, that 43 completed the trial, that is completed all of the nine weeks. These were people who were parolees from either prison or from the judicial system who had access to cocaine 24 hours a day, seven days a week. They had to report to their normal parole officer once a week or participate in the trial and show up twice a week to get their medicine. The medicine was the vigabatrin dissolved in orange juice, and this was dispensed by the research pharmacist.

They had to provide samples under direct observation. That is, they provided urine samples under direct observation in the bathroom, and this was maintained for the entire course of the trial. Of the 43 subjects who completed the trial, it was about equally distributed between the two arms, the placebo and the treatment arm. Of the 18 people who completed the trial with negative urines, that is achieved the primary outcome result, 14 of them were in the treatment arm, and four of them were in the placebo arm.

Of this group of subjects, they were the 40, which represented 28 percent of the treatment arm, which had 49 subjects, and seven percent – 7.6 percent of the placebo arm, which had 53 subjects. This was done in a block design randomized fashion in which none of the investigators knew either the design or the assignment completely through the trial. To address a question that has come up, the unblinding is done after the data set was locked, the assignments were e-mailed to the site where an independent statistician evaluated the data. After it was already ascertained that they'd been checked out, the assignment of subjects in fact checked out against the randomization.

And with that, I'll stop.

Elemer Piros: Dr. Brodie, where did the data analysis take place actually?

Jonathan Brodie: The primary analysis was done at the Nathan Kline Institute for Psychiatric Research.

Elemer Piros: What was the rationale behind deescalating the dose towards the end of the study?

Jonathan Brodie: Well what we did, the rationale was very simply this is the way we had done it in our original pilots when we had no idea what to expect.

Elemer Piros: Someone ...

Jonathan Brodie: Well there's a further rationale, the further rationale was that we have every reason to believe that on the basis of the pharmacokinetics of the enzyme inhibition that in fact one can maintain blockade of the target with a much lower dose than the initial.

Elemer Piros: Could you talk a little bit about the target and why vigabatrin might be potentially useful as we have seen it in this initial randomized placebo controlled study?

Jonathan Brodie: Yes, sorry, this is an irreversible inhibitor of the Gaba transaminase, which is the major enzyme for removing Gaba from the synapse. And as such, it actually blocks it, it's almost a suicide inhibition, and this causes the accumulation of Gaba in the pre-synoptic terminal.

Elemer Piros: OK.

Jonathan Brodie: Now as opposed to most of the drugs that have been used which target the receptors, this in fact targets the enzyme, and as such you wouldn't expect to get tolerance. The second thing that happens is that this drug is sort of different from most of the other Gaba or Gaba agonists, the drugs that had Gaba agonist activity not only in its target, but the fact that the Gaba is typically not released into the synapse. When you

have high amounts of Gaba, of course that tends to modulate the effects of dopamine and the increases in dopamine that would be seen when you get pleasurable stimuli, and so what you find here is in fact this does not seem to inhibit the normal pleasures, at least in animal experiments associated with sex, with rats, with – I'm sorry, with eating, and as such, and people also don't typically fall asleep if you have high amounts of Gaba and synapse, it would be like sedating.

What happens here is that only when a drug abuse triggers the change from tonic to burst firing, you get this pre-synaptic Gaba dump, if you will, that is caused by the action of this drug vigabatrin, and that's really what makes it quite different from most of the other – from all of the other drugs with which I'm familiar that change Gaba activity.

Elemer Piro: And the fact that you – how customary it is to look at an addiction study and examine the primary endpoint as the last two or three weeks of the treatment period, when you examined the literature, was this a unique approach, or is this more of a typical way of looking at the effectiveness of the drug? And could you please also tell us some of the secondary endpoints that you are about to examine? And would there be for example a comparison between treated and placebo when we look at the overall timeframe of nine weeks?

Jonathan Brodie: It is neither unique nor is it necessarily typical, but the other members of this panel are far more versed in that than I am. Dr. Kosten years ago had shown that if you could get three weeks of continued abstinence, that in fact that was a very good predictor of a six-month outcome, and I'm sure he can elaborate on his studies that have been confirmed in other laboratories as well.

The other reason for choosing that particular endpoint was that it was set up to be a very high bar, Steven Dewie, my colleague and I said, let's just test this drug and see whether or not it's going to be clinically useful. Now what does this mean? Well if somebody is, for example, an alcoholic and drinks seven days a week, and you've reduced them 22 percent by having them go down to five days a week, he's still a drunk. Whereas if we could get someone abstinent, then there is a chance at rehabilitation, and into the society.

And indeed in our second clinical trial, the open label trial of the 18 people who completed drug free, 17 of them actually got jobs, and this was in fact to us a measure of both clinical utility as well as social efficacy. So we wanted something to be clinically useful. It is something that we could measure objectively, and because it is

such a high bar, we could use a relatively small sample. And since we have – we're doing this study on a shoestring, that mattered.

Elemer Piros: Right. I'd like to ask the panel, and mostly Dr. Kosten since your previous studies were brought up by Dr. Brodie, to provide us some sort of a background if you look at historical studies, what's the best way at least for other drugs or when we include also vigabatrin to ascertain the impact of a particular drug on addiction? Dr. Kosten, maybe you could go first?

Thomas Kosten: Certainly. Well I think I'd emphasize what Dr. Brodie said, that three weeks of continuous abstinence in what's a relatively short trial is a pretty high bar, and I think all of us in the field would applaud any opportunity to find a medication that can sustain that in such a short period of time, that these are generally chronic patients who have a recurrent disorder that usually the best they can sustain on their own is a few days of abstinence, and in some patients they can't even manage a few days.

And certainly the patients he's working with in Mexico have no lack of supplies of cocaine, and have it probably at a fairly bargain price compared to what it is in the United States, since most of the cost is getting it over the border into the United States. So it's a hard population, easy availability, inexpensive drug, and three weeks of abstinence in a life of a cocaine abuser is a relatively long period. So that's the first thing I'd emphasize, and I think that the information that we have that if you can attain three weeks of abstinence, and again like this is a relatively short-term study, the odds are that you could still be abstinent six months later.

Now having said that though, this does not necessarily mean that if you in fact discontinue the medication you'll be abstinent six months later, I mean just like as we would say with hypertension, when you stop an anti-hypertensive drug, and your blood pressure goes back up again, you generally will then say gee, this is a really effective medication, while you're taking it, it works. No one would think that after you stopped your anti-hypertensive if your blood pressure went up that the anti-hypertensive was a failure, because in fact gee, your blood pressure went back up.

I mean these are chronic disorders, it takes months and years to get these patients back on their feet. We hope eventually that we can get them completely medication free, that we can get them free of their illicit drugs, you know, that that's the target we have. But I don't think that anyone thinks at this point that we can have a three-

week or a two-week or some kind of miracle cure in a few days as if this is pneumonia that we give penicillin and that's it. And you know, and even with pneumonia and penicillin, people do get recurrences. So I think that's the important perspective I'd like to put this in is this is a first study, this is a study that's taken a relatively high bar, and indicated that gee, this really does look better than a placebo.

I don't know of any other medications that in fact have taken this particularly difficult criteria and said yes it works, there are other medications that have shown efficacy. The efficacy has generally been measured more along the lines in what Dr. Brodie was referring to is a reduction in use, that is the people don't stop altogether, but the amount that they use decreases.

When you do that, my experience with the Food and Drug Administration has been if you are not able to show a two to three-week period of sustained abstinence, that then what the FDA is going to be asking for, and this is based on alcohol studies, opioid studies, is that you also show a significant improvement in psychosocial functioning, that is other things in your life get better.

Now you can't expect again that to happen in a brief trial. But to just, you know, I've been talking for a while, so to just summarize, I think that the bar that they've set of three weeks of abstinence is in fact a high bar, it's difficult to attain that, they did attain that, there's every expectation that looking at other ways of examining the outcome, either reduction in use that you would show that significant also. I don't expect that in eight to 12 weeks you can expect somebody to change their lifestyle and have significant medical, psychosocial or other kinds of improvements, that that in fact is the kind of thing that does take months, and usually sustained treatment.

So I applaud the study, I think it's an – a remarkable effect that has not been attained by any other medications that I know of, and is not an easy one to attain.

Elemer Piros: Yes. Dr. Brodie, could you please help, and then we forgot to mention this, what were the baseline characteristics of this population, i.e. what was their average cocaine use?

Jonathan Brodie: We haven't analyzed that yet, but they were all– if the previous studies are any indication – they averaged about 10 years of use, typically anywhere from one to seven or eight grams a day of coke, and they tend to use it habitually, i.e. daily as opposed to binging.

Elemer Piros: And I'm sure you've got some sort of an entry criteria, was there a minimum number of – or a period for which a person had to be an abuser? And was there a minimum daily usage that would qualify a person for the study?

Jonathan Brodie: Well typically – they had to meet the diagnostic criteria, the (DSM), the diagnostic statistical manual, (DSM) for criteria for cocaine dependence, and they had to be dependent on cocaine and not co-dependent on anything else. That typically means that they have to use it to the point where it's interfering with their life, they have to use it to – on a – on a regular basis, and so these are really very severe users. We expected that in the past that their mean time to relapse was about a day and a half, if they wanted to stay clean, and of course there's a wide variation. But they were motivated to stop.

Elemer Piros: Dr. Somoza, do you concur with Dr. Kosten and Dr. Brodie on – that the bar has been set very high here, and therefore the outcome pending obviously confirmation from the secondary endpoint, and in a larger study later on, was a successful one?

Eugene Somoza: I totally agree, I think this – surely it is looking very, very good, it kind of exceeded my expectations. There are still some questions, however, in my own mind.

Elemer Piros: OK.

Eugene Somoza: For example, I would like to know whether these – this population of patients were using cocaine by smoking it or by snorting it, do we know anything about that, Jon?

Jonathan Brodie: We should have it, most of them I believe smoke it, but we'd have to go back to the original records, which I have been barred from looking at until the data were locked.

Eugene Somoza: Right, so that would be very interesting, because in the United States of course the vast majority are smoking it, and that's a harder disorder to treat, smoking than snorting.

Elemer Piros: You're referring to "free basing", as it's known.

Eugene Somoza: Yes, right, it gets to the brain a lot faster, and so it's more reinforcing. The other thing that, you know, I'm a little troubled with, and you know, let me just toss it out here, is you know, essentially everything is based on those 18 patients that actually were abstinent. And so we have to be pretty sure that we got it right for the safety in patients. And as four of them were from placebo and 14 of them were from the vigabatrin arms.

But a lot is riding on the accuracy of those 18 patients, and particularly, you know, they measure the urine twice a week, now twice a week is, you know, it's a long time between urines from the perspective of the half life of benzoylecgonine, which is what they measure. The average half life is around 5.5 hours, and so I just made a really quick calculation, that basically the question is, what is the chance of having undetected uses of cocaine during this period of time?

Jonathan Brodie: I think that's a fair point, we would have liked to have done it three times a week, and the reason we didn't do it three times a week was simply a matter of logistics of getting people to participate in the study, they got no incentive, there was no money involved in participating in this study, in fact it was more onerous than if they had their normal parole, which was one day a week. Traveling in Mexico City is really very difficult, and we ended up compromising and having them come in two times a week.

The question of since we're not doing quantitative benzoylecgonine, and there is a detection, a lower detection limit, the chances that anybody on a consistent basis is going to slip through would mean that they cleverly were trying to get around the detection apparatus, and these are people when they use, they use, they just drop right off the wagon.

So the notion that you can't detect it in three to four days is of course not true, you typically can, what you can't do is do the trends that you would do with more frequent dosing, or with more frequent testing, and quantitative benzoylecgonine.

Elemer Piros: So if there are any weakness – potential weakness – I'm asking this question to the overall panel, to everyone essentially, on quantifying the metabolites or the qualitative measurement, which one would be a more stringent method? Dr. Brodie, if you could just start up, please.

Jonathan Brodie: Oh, you want me to speak to that?

Elemer Piros: Yes, please.

Jonathan Brodie: I mean it's not a matter of stringency, it's a matter of what it is that you're trying to do. One of the things that quantitative testing does is it allows you to handle missing data better, because you can ask the question is it going up or is it going down? And it also takes care of the neighboring testing, i.e. do you have a spill over? If somebody used once and they tested positive on the second day, was it because of a new use, or was it because of the old use washing out?

So there's different advantages and, you know, disadvantages, this is very simple to do, and could be done outside of a laboratory setting.

Elemer Piros: Dr. Somoza, so with qualitative testing, what is the – what is the Achilles' heel of qualitative testing versus quantitative if there is any?

Eugene Somoza: Well qualitative essentially means that if the quantity of benzoylecgonine is over 300 nanograms per mill, that means they're positive, and it's below – it's negative. And like for example just to give you an idea, if somebody were to – suppose you see them twice a week, say half a week apart, you know, you make it so it's fairly even, that means there's 3.5 days between testing. They could – if they used shortly after you saw them last time, by the time you see them this time, they could have used to a level of 19 million – 19.6 million nanograms per mill, which probably would kill them, you know, so you probably wouldn't see them then.

But anyway, the huge level, and still be under 300 when you see them now. So I think it's very easy actually, you know, so they could have used less the next day, for example if you saw them on a Thursday, they probably could have used a Saturday, and still you know, so long that it would be negative.

Jonathan Brodie: They were seen on Monday and Thursday.

Eugene Somoza: Monday and Thursday, OK, so it's Monday what's three or four days, I guess, right? Thursday, Friday, Saturday, Sunday, Monday, only three days, right. Anyway, the point is that it's not that hard to have undetected uses, and that's ultimately what – on the other hand, you know, having said that, obviously this is a randomized study, so you would expect them to fall equally into the vigabatrin and the placebo group.

But then when you started going down in the number, we're not really talking about under three anymore, we're talking about 18, these particular 18 patients that happen to have been abstinent at the end. You know, were they really abstinent or were just undetected uses?

Jonathan Brodie: Excuse me, 43 patients completed the nine weeks, 43.

Eugene Somoza: Right. And all the time, 18 were abstinent.

Jonathan Brodie: For the last three weeks, that's ...

Eugene Somoza: Right, and those are the ones that essentially the results are all about, really those 18 that were abstinent. And the question I'm asking, you know, how sure are we that they were really abstinent? And if – say you are protected by the randomization process, but you know, with small numbers like 18, it could be unbalanced, I mean there's some probability that just randomly, you know, and also let's assume that they all used, but some you detect and you some you didn't detect, that you know, randomly that would not normally fall evenly into both groups, and they didn't. So certainly it's likely, it's very likely that, you know, that Vigabatrin is better.

But I think there's still that – at least in my mind certainly the nagging question about that.

Elemer Piros: Dr. Newton, we haven't heard from you. Do you have a particular opinion on this particular topic?

Thomas Newton: Well more frequent testing would probably give you more complete data, but I think that, you know, Eugene's point that randomized provided protection against having it being one group or the other is true. I

would like to ask, a relatively large number of patients completed this entire study, what was their motivation for staying abstinent?

Jonathan Brodie: Well they didn't have to stay abstinent?

Thomas Newton: Well what was their motivation for showing up then?

Jonathan Brodie: Most of them – when I interview for people in the prisons and these – and for earlier studies, it was that they had no life, they had no – they felt that they had no chance of changing a cycle of addiction, criminality, incarceration, recidivism and over and over again. And the word has been getting out about these other trials, so down there there's a kind of mystique that there's a – there's a hope.

Elemer Piros: And Dr. Brodie, I think you mentioned previously that the only compensation that these subjects were receiving is their car – or travel ...

Jonathan Brodie: ... their travel expenses, and a – and a meal, I think it was about \$7 or something like that, or basically a day.

Elemer Piros: And the authorities didn't find out about what the outcome of these individual patients ...

Jonathan Brodie: No.

Elemer Piros: ... were at the end of the study? Are they protected in that regard?

Jonathan Brodie: They are protected, but in fact that use, per say, is not criminality, if used for criminality, none of these people who were in prison would ever be paroled since cocaine is distributed practically at mealtime, cocaine in prisons is just endemic.

Male: Hey, can you comment a little bit more on that? How long were people in prison before entering the trial?

Jonathan Brodie: Well it started we had to change in the middle, because of the change in governments, and the change in the prison administration. But we started out they – these were people who had been incarcerated, but they met the DSM4 criteria. And then just as they were ready for discharge, they had the opportunity to participate in a trial, they were told that. There was – no prisoner was used in the trial.

So they signed up, and they didn't know – and they had to give a urine sample, and they didn't know that if the urine sample was not dirty, they were not going to be in the trial. But not only did they have to give a history of cocaine use dependence, but they also had to be actually actively doing it.

After they were discharged and on parole, they were then re-consented and they had the opportunity to come into this program where they would have to be tested and get medication and be examined, and there was a whole series of secondaries which I can get to, twice a week, or they could go to their normal parole once a week and they could go at any time, they could leave the program and just – they would only have to go once a week to their normal parole.

Male: Can you say why it is you decided to select this population?

Jonathan Brodie: We did this at the request of the – of the Federalies, this was a population that they have had a great interest in trying to break the cycle, for them it was much more social than anything else. They had followed with great interest the two open label studies that we did with this kind of hard core population, most of whom were hourly staff, of whom were drug dealers in Mexicali.

And so the director of the prison, who was sort of an enlightened gentleman by the name of (Adiano) said this would be terrific if we could somehow do this, this would really help, you know, the country. And so this enlightened gentlemen was of course eliminated in the changeover in the election with 20 subjects down, so the social worker who had been assigned to us, and who also keeps everything from – is the Chinese wall between the authorities and the subjects –suggested that we get the people who are addicted and going to be sentenced to give them the opportunity of being on parole to go on parole to participate in this program.

So they – the criteria were all the same except they were – they were not incarcerated first.

Elemer Piros: Right. Dr. Kosten, if I may ask you please, how different this population is from the general addict population, if you will. And again if it's a more difficult population to work with than one wants to ascertain the efficacy of an entire addiction drug?

Thomas Kosten: Well I think that this is a population that is not easy, I don't think that everything I can hear about this population it seems to me that their motivation for treatment, as Thomas Newton was asking, is actually a little surprising. We have trouble retaining people this long in treatment, now some of that may simply reflect the poor efficacy of our treatments, although if that was the simple answer, then you'd expect the placebo group to have ...

Male: Right.

Thomas Kosten: ... a greater dropout also.

So to some extent, something's different about the Mexican population that they're working with them and the United States population in that they do have better treatment retention than we generally see. For us to get treatment retention, that is as good as that, we usually have to build in some sort of contingency where what we're doing is we're not paying them to – or, you know, giving them \$5 a week or something, to clean up, that is they can keep using cocaine, but we have to usually give them some sort of subsidy or contingency to get them to simply show up to give the urines, and – so that we have an outcome measure.

So that's – I think that's a difference. Now it may well be that, you know, Mexico is different than the U.S. in terms of their standard of living, and you know, I'm just – it's hard for me to account why it is that they had better retention than we generally get. But all that being equal across your placebo and your active group to some extent it's irrelevant, that is they showed up and you found the difference between the two treatments.

So the patients are somewhat different somehow, I'm not sure how, they seem to have just as severe cocaine abuse, certainly if they're smoking cocaine, they certainly have availability, which if anything is probably easier in Mexico than the United States. My experience with working with say former prisoners compared with those who don't have a criminal record is that generally the people who get arrested and go to jail are a more difficult population to work with, and have less motivation and less, you know, they generally only do things practically

speaking when either significantly enticed or coerced, there doesn't seem to be either one of those things present in this study.

So it's a difficult population, is my summary, and that bodes well for it doing well in a U.S. setting, but as I said, to get this level of participation and treatment retention in the U.S., we'll probably have to build in some incentives.

Does that answer your question?

Elemer Piros: Yes, that's very good actually. Dr. Somoza, in your experience, do you see larger attrition rates than what we've seen roughly 60 percent in U.S. based studies?

Eugene Somoza: Well I know our studies have all been about 50 percent, so I thought – I thought that it was actually lower than you saw, and I don't know, maybe Thomas Kosten has been different. But generally we get, you know, 50 to 70 or 75 percent. But of – but of course we may be paying a bit more than they were paying them. We actually have not done ours with contingency management, we – but we do pay them for coming to the visits, and – you know, and so that we can actually look at the urine and see what's in there.

So I thought this was actually on the low side where, you know, so I kind of disagree with Tom on this.

Thomas Kosten: This is Tom, so I can address that a little bit again. When I said contingency management, and you know, and Eugene's talking about, you know, paying them to show up, contingency management is perhaps an overstatement of it, yes we give them something for coming, pay their transportation, and if they don't show up, they don't get that money.

So – and we've had experience with as few as, you know, 30 or 40 percent of the people left at the end of the study. So I didn't mean to suggest that this was a dramatic difference, and I agree – and the other thing of course is Eugene seems to be particularly charming and does get better retention than some of the others of us do.

Elemer Piros: And maybe that's why Dr. Somoza is more suspicious of – or thinks about people becoming sophisticated in when they use cocaine, and when they would have to show up for a day of urine test, i.e. if someone is more or better compensated, maybe it may – there may be a higher degree of motivation to trick the test, wouldn't there be?

Male: You know, we tell them up front, and reiterate it that at some level we're not – we don't care if they use or not, that's not the point, we want them to be present so that – to see that the medication works, and for that we need to actually analyze their urine. So that we're really paying them to show up and give us their urine, and also we do self reports where we actually ask them how much they used for each day even when they weren't, you know, in between the three times that we measure their urine. So at the end we actually get what they say they – how much they said they used for each day of the clinical trial, and then of course a subset of that we actually get urine.

Jonathan Brodie: This is Jon Brodie again – we also did that in this trial so that among the secondary objectives are the – were the psychosocial measures, including the subject retention, the use report, the severity of addiction using the (ASA) and light, the cocaine craving using the craving questionnaire, mood indices (Ham A and D), and the (CGI), both self and observed. So all of these measures were obtained on these people.

Male: Now ...

Jonathan Brodie: It's just that we got to those data yet.

Male: ... it's excellent that you brought up the secondary measures, Dr. Brodie. I'd like to ask Dr. Kosten, Dr. Newton and Dr. Somoza if you could (define) on how much stronger this data could get with the release of those additional measures. And just for us to better understand how important those outcome measures are typically in addiction studies, the ones that Dr. Brodie just mentioned.

Thomas Kosten: This is Tom, I'll try to start the answer. I think that these other psychosocial measures generally take longer to improve than our typical three-month study would run. And some of them can improve quickly, so for example depressive symptoms can often get better, and those are the kinds of things that we hope to see, because three months with an antidepressant, for example, certainly make depression better, not that these are

antidepressant medications, but the stressors that these patients experience often relieve quite a bit when they can get sustained abstinence.

The other measures that can improve in that period of time is if people initially come in unemployed, on the course of three months they may in fact get a job, for those people that have significant legal problems, once again they sometimes can manage during that three months to have a significant period where they're not getting arrested for various charges. So it's – two issues are important, one is how bad is the base line problem? And the worse that that problem is, often the sooner that you can make it better.

The second issue is that some psychosocial changes in fact just take months to improve, family relationships may take a long time to improve, but again if they are in very poor state, that is a very say poor sets of family relationships, in a country like Mexico where often you see close family relationships, at least that's what we certainly see here in Houston with our Hispanic families. Then you can improve those family relationships quite dramatically sometimes within a three-month period.

So the bottom line of what I'm saying is that there is the potential that we will – that Dr. Brodie's study would show quite an improvement in some of these other measures, which would even be again, you know, more remarkable, certainly more proof or demonstration that this medication is having a broad effect, and when you stop using drugs for a sustained period of time, it's remarkable how many things in your life can improve.

Elemer Piro: Dr. Newton?

Thomas Newton: Well I think the most important thing is going to be a better look at drug use over time. The theory on looking at the last three weeks is that it's better to have stopped than it is to stop and then start up again, which is true. But if the medication is working to either reduce the euphoric effects of cocaine, or to reduce craving associated with cocaine or cocaine (cues), you'd expect to see kind of a gradual onset and take-off over time, and so that would be important to see.

On the other hand, if it's merely an increase in retention due to a placebo effect, then you know, perhaps the medicine causing a side effect that makes people think that they're on the medicine, and therefore the people on

the active drug retain longer, then you shouldn't see the change in use. But this is going to require a full data set to see that.

Elemer Piros: Right. What I'd like to ask from Dr. Kosten, Newton, and Dr. Somoza, maybe we could start with you, Dr. Somoza, based on what we know, and it's very limited so far, what would you recommend, how should the U.S. phase II trial look based on what we know to date? What would your recommendation to the company and to Dr. Brodie would be?

Eugene Somoza: Well I think it's not – certainly not a bad start the way they did it, this one. I think – and let me just – a couple of loose ends with what we were previously discussing, the nice thing about doing more than one, and obviously you know, more than outcome was done, and the second – they just haven't been analyzed. But at this consistency, in other words I think having this outcome to be abstinence the last two or three weeks, but trying to be sure that there will be no or very low probability of having an undetected use of cocaine, I mean is really critical (sometimes three four), I think that would be very reasonable.

I think I would also, you know, like Dr. Newton says, also due the – to the normal analysis of say both the sub rating scale and perhaps the urine at some level over time. And if you see consistency with all the things that you're looking at, rather than just looking at one that we can only see one right now, the primary, it – you get a better feeling that things are OK, they're all self consistent, they all show that it's improving at various levels. For example the (CTI), you know, that's the global impression that the – that these investigator examiners over time, one that causes you very generally how the person is function, that's very important.

The sub reports are important, partly because it minimizes missing data, it increases tremendously the amount of information, if that's consistent with the primary outcome. So I would say that I think the same kind of primary secondary outcomes that was used in this study could carry over to the American study.

Elemer Piros: And – but you would definitely have urine checked three times a week if it ...

Eugene Somoza: Right, and I would definitely do, you know, as Dr. Kosten say, I'd show contingency management to kind of really reinforce the probability that we will actually come in to give a urine and to give their sub report.

Elemer Piros: Dr. Newton, Dr. Kosten, any recommendations from you before we go to the audience for questions?

Thomas Newton: Well something that typically isn't done in this country is to look at the population of parole people, because it's a different population and hard to get into IRBs and everything. But that would in some ways make it the most comparable, and if for example a second trial in the U.S. was not quite as – was not quite as suggestive of efficacy, that would then eliminate the difference in population as being an explanation for it. Although obviously the differences between Mexico and the U.S. are large anyway.

Elemer Piros: And do you – but do you think that that particular study that you suggested, would the regulators view it as a – as a representative population of your typical addict, or would they scrutinize that study that we are not looking at what the drug would be eventually prescribed for?

Thomas Newton: Well most likely they would look at it with a jaundice, kind of as you were implying. Typically though if you do look at the patients we do enroll, Tom Kosten has a better picture than me for the exact numbers, but I would guess more than half have significant criminal histories. And so we're just not getting them, you know, on the way out the door, but they've certainly been there not too long ago.

Elemer Piros: Right. Dr. Kosten, any ideas, something you'd improve– that you would recommend?

Thomas Kosten: No, I'd concur with – both with Thomas Newton and with Eugene.

Elemer Piros: OK, thank you. Stacie, would you please check if there are any questions from our dialed in audience?

Operator: Yes. Ladies and gentlemen, if you'd like to ask a question, please press star one on your touch-tone telephone keypad at this time. If you're using a speakerphone, please make sure your mute function is turned off to allow your signal to reach our equipment. Once again please press star one for a question. And we'll pause for just a brief moment.

And as a reminder, that is star one.

And with no questions, I'd like to offer a final reminder, please press star one for a question.

Elemer Piros: While we wait, I have a couple of more. Again going back to the entire panel, how predictive – and there are two questions here essentially – when you see result as such that was reported here, how predictive these results may be assuming that everything was – that the secondary endpoints also would show consistent results, how predictive would this initial result of a final outcome would be, have you seen studies that were initially showing positive signals, and then they didn't show improvement in larger studies? And the second part of this question is what we know about the mechanism of (Ilgavatrian), would the results, positive results in cocaine addiction be generalizable perhaps to other addictions, such as methamphetamine dependence? Dr. Somoza?

Eugene Somoza: Well I would say that when you look – when you think about predictiveness, you have to look at the whole picture, and part of this is that the animal studies are incredible, I mean this substance has the best data that would be predictive of, you know, being useful in clinical cocaine. And also to answer the last part of your question, also all other stimuli, and even – it's been (planimos), it seems to be work for Opiates, for marijuana, et cetera, they've tried it on lots of different substances, that's one thing.

Then there's the – of course the secondary steps that two previous open label Mexican studies that are also highly positive, and then there's this one that's randomized, placebo controlled. So taken together, I would say that right now this is number one candidate as far as the probability of primocological treatment, except for – at least stimulants, specifically cocaine abuse.

Elemer Piros: Dr. Newton?

Thomas Newton: Well the – you know, in spite of my concerns that I mentioned earlier, it would be a surprise to have a compound with the really strong preliminary animal data, and this finding in a clinical trial to not turn out good one way or another, it would really surprise me. The second question, how generalizable is this? The animal data say one thing, but we don't know for people, the animal data suggests that vigabatrin should be good for pretty much anything in terms of addiction type drugs.

But for humans, we really don't have any data showing that if it works for one, it should work for the other, so we'll have to wait and see on that.

Elemer Piros: And there are on precedence on other agents out there, at least ...

Thomas Newton: Well the one agent would be Wellbutrin, which Dr. Kosten's group showed in a specific type of clinical trial helped people use less cocaine, and then it also helped people use less methamphetamines. So there is some precedent.

Male: Well I can say from some of the – and really anecdotal is not going to study, it's very clear that all of the animal data is not translatable, there are people who have been four pack a day smokers who responded to nothing, who responded to vigabatrin on their own, just did it – they self administered it for a few weeks. And that yet there are other people who do cocaine and continue to smoke. So clearly it's heterogeneity in response.

Male: Right.

Male: And then I think we should expect it there, there are people we know that have taken the drug religiously and have not changed their cocaine use.

Male: Right.

Elemer Piros: Yes. Before we go to Dr. Kosten, Stacie, would you please do a final check? We have about five minutes left from this ...

Operator: Sure, as a reminder, it's star one. And we do have a question from James Tong with Rodman and Renshaw.

James Tong: Hi, this is James Tong, Dr. Brodie, Dr. Somoza, Newton and Kosten, I wonder if you can comment on what this particular study can offer us in terms of maintenance dose when vigabatrin finally put in use for patients or subjects that are wishing to quit cocaine or other addiction agents. For the maintenance dose, – would we use a similar dosage, or it's going to be lower, or the spacing of those ...

Jonathan Brodie: Perhaps – this is Jon Brodie – perhaps I can answer that, because we've given this a great deal of thought, and have laboratory data. We have every reason to believe first of all that one does not need to

maintain this dose, and we would not expect it. We expect that if one just looks at the pharmacokinetics that is the rate determining step in this study, and in all of the uses of Vigabatrin is the turnover of the enzyme, i.e. de novo synthesis.

On the assumption that what you need to do is to blockade the enzyme somewhere near the order of 90 percent, then what you have is a half life at somewhere of the order of about five days for regeneration. What that means then is that you could probably give a half a gram to one gram a day, and maintain full blockade. Second if the animal studies even suggest something even more curious, which is that if you do intermittent dosing, you will in fact have a stronger effect than if you do daily dosing. We've not yet untangled that.

James Tong: Thank you.

Jonathan Brodie: The study – the study itself does not really bear on this.

James Tong: Yes, sure. Yes, thanks.

Elemer Piros: Dr. Kosten, could we circle back with you and if you could offer your thoughts on predictability for the future and generalizability of these findings?

Thomas Kosten: Well as far as other addictions go, I think Tom Newton probably made the point best in terms of bupropion, which had shown some efficacy for cocaine, then for methamphetamine, and of course as everyone knows, it's quite effective for tobacco smoking. So I think those are at least three addictions that we know it's useful for, and it's been used for all sorts of other things, not the least of which is it was initially tried around bulimia where it ran into some difficulties in terms of toxicity, but if you want to think of bulimia as a process addiction, or an addiction to food that's poorly controlled, then it's even had some potential utility there.

So I think that there are common mechanisms around these addictive disorders is quite true, and we have quite a bit of data to indicate from the animals that the Gaba systems are critically important in addictions, and we have both human and animal data to indicate that these Gaba systems, which Vigabatrin acts on directly, are down regulated, that is they're markedly less active than they ought to be in normals across a wide range of addictive disorders, so the fact that it's going to augment this system, push it back into the normal range, so to

speaking, that normalization process is going to be a common characteristic across many addictive disorders, so it wouldn't be surprising if this medication in fact had some utility for alcoholism, some utility for stimulant medications, you know, stimulants such as cocaine, methamphetamine, conceivably nicotine, this could be a broad spectrum agent in that way, either alone or in combination.

I think the generalization question about, you know, how long are you going to need to take it, what dose are you going to take them in? That's sort of the next level of addressing this, but it probably will need to be taken for, you know, more than a few weeks, and I think as Dr. Brodie said, it's not a question that's been un-thought about so far, there's been quite a bit of thought into it, and how maybe you'll even need lower dosages, that's certainly true of the antidepressants where you do often give people higher dosages of these medications, or anti-psychotic agents, and a variety of things we use in psychiatry where the dose you use for maintenance can be lower than the dose that you use for initial attainment of symptom stabilization.

Elemer Piros: Right. I think we should end on this note. And I personally wanted to thank you, all of you, and Dr. Brodie, Dr. Kosten, Dr. Newton and Dr. Somoza for joining us. To the audience, I wanted to thank as well, and if those of you who joined us late, we'll have the transcript of this conversation available hopefully within the next 24 hours, and there is also a replay of this call available I believe for one week.

And you would be able to obtain the replay information from Rodman and Renshaw. Gentlemen, again thank you very much, and a nice day to all of you.

Operator: Thank you. Again ladies and gentlemen that will conclude today's conference, we do thank you for your participation, and you may disconnect at this time.

END

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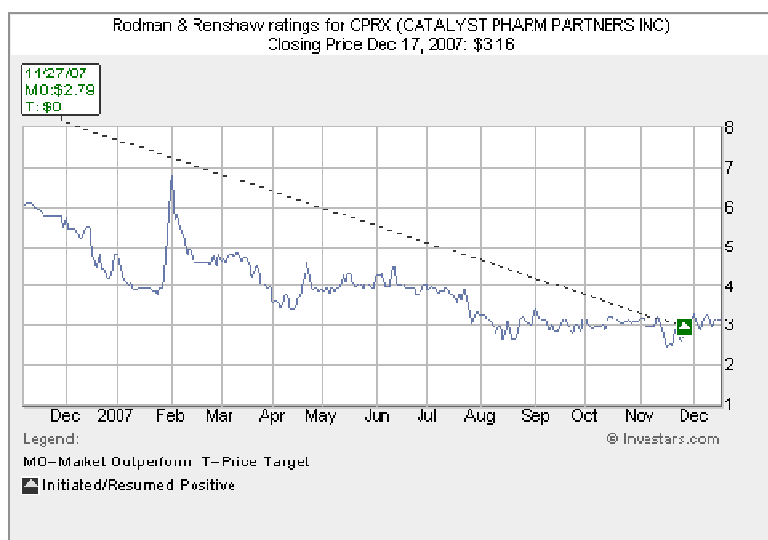
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