

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, DC 20549

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 OR 15(d) of the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): November 8, 2007

**Celsion Corporation**

(Exact Name of Registrant as Specified in Charter)

**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-14242**  
(Commission File Number)

**52-1256615**  
(IRS Employer  
Identification No.)

**10220-L Old Columbia Road, Columbia, Maryland**  
(Address of principal executive office)

**21046-2364**  
(Zip Code)

Registrant's telephone number, including area code: **(410) 290-5390**

**N/A**  
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.135-(c))

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**Item 2.02 Results of Operations and Financial Condition.**

On November 8, 2007, the Company held a conference call to discuss the matters announced in its press release of the same date, and as set forth in Exhibit 99.1 to the Current Report on Form 8-K filed on November 8, 2007. A transcript of the conference call is furnished as Exhibit 99.1 to this Current Report on Form 8-K. The information in this report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section, and shall not be incorporated by reference into any registration statement pursuant to the Securities Act of 1933, as amended.

**Item 9.01 Financial Statements and Exhibits.**

<b>Exhibit Number</b>	<b>Description</b>
99.1	November 8, 2007 Conference Call Transcript, furnished pursuant to Item 2.02 of Form 8-K

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: November 14, 2007

By: /s/ Paul B. Susie  
Paul B. Susie  
Interim Chief Accounting Officer

**EXHIBIT INDEX**

<b>Exhibit Number</b>	<b>Description</b>
99.1	November 8, 2007 Conference Call Transcript, furnished pursuant to Item 2.02 of Form 8-K

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**CELSION CORPORATION**

**Moderator: Michael Tardugno**  
**November 8, 2007**  
**11:00 am ET**

**Operator:** Good morning. My name is Darlene, and I will be your conference operator today. At this time, I would like to welcome everyone to Celsion's Third Quarter Earnings Conference Call. All lines have been placed on mute to prevent any background noise. After the speaker's remarks, there will be a question and answer session. If you would like to ask a question during this time, simply press star, then the number 1 on your telephone keypad. If you would like to withdraw your question, press star, then the number 2 on your telephone keypad. Thank you.

I will now turn the call over to Mr. Paul Henning of Cameron Associates.

**Paul Henning:** Thank you and good morning everyone, and thank you for joining us for Celsion's conference call today. The call will be archived for replay from November 8, 2007, noon today until November 15, 2007. This replay can be accessed by dialing 800-642-1687 or 706-645-9291 with a Conference ID number of 23308858. In addition, the call will be evaluable on the company's Web site at [www.celsion.com](http://www.celsion.com) for 90 days after 2 p.m. on November 8. On the call with us today is Michael Tardugno, President and CEO of Celsion, and management will give the opening remarks, and then we'll open the line for questions. But before we begin, Celsion wishes to inform participants forward-looking statements are made pursuant to the Safe Harbor provisions of the Private Securities Litigation Reform Act of 1995.

You are cautioned that such forward-looking statements involve risks and uncertainties, including without limitation unforeseen changes in the course of

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research and development activities, and then clinical trials by others. Possible acquisitions of other technologies, assets or businesses, possible actions by customers, suppliers, competitors, regulatory authorities and other risks detailed from time to time in the company's periodic reports filed with the SEC. With that, I would like to turn the call over to Mr. Tardugno. Mike?

**Michael Tardugno:** Thank you, Paul, and good morning all, and thank you for joining us for our third quarter call. As Paul said, I'm Michael Tardugno, President and Chief Executive, and I'm pleased to be here with Paul Susie, our Chief Accounting Officer, and the newest member of our senior staff, Dr. Nick Borys, Celsion's Chief Medical Officer. I want to officially welcome Nick in his short time with the company he has certainly demonstrated the commitment and professional skills consistent with what our company needs in a Chief Medical Officer. I'm confident that we, all, will benefit from his decision to join Celsion, and I look forward to working with him over the coming years.

This is my sixth conference call with you since joining the company in January. As I have said before, I look forward to these opportunities to meet with you, to share our progress, and answer your questions. Your frank and candid input is most appreciated. As always, we will make plenty of time at the end of our formal remarks to respond to your questions and suggestions. So we have quite a bit to cover this morning and to make sure that we leave time for questions, I'll get right to it.

First, I have a few comments about our third quarter financial results following which Paul Susie will provide a detailed review of the P&L and balance sheet. Our financials reflect results that are inline with our spending plans. I am pleased to report that our cash balance is favorable to the internal plan — to ensure that we have sufficient financial resources to substantially

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complete a pivotal program for ThermoDox. As an essential element of that strategic plan, we have and will continue to look judiciously for opportunities to reduce our cash burn, and will continue under Paul Susie's watchful eye to closely manage our expenses focusing only on those activities that we believe will forward our strategy and improve shareholder value. I also want to make it clear and that we continue to project that the proceeds from the sale of our device business provide us with cash sufficient to fund the following objectives:

- to substantially complete our Phase 3 liver cancer trial
- to initiate our Phase 2 trial for recurrent chest wall cancer
- to ensure a quality, validated and scaleable manufacturing capability
- to conduct feasibility studies on product pipeline opportunities
- and to kick start our business development program and commercialization efforts which by the way are progressing quite nicely.

In line with our commitment to minimize financial risks, we are exploring a secured line of credit. Its main purpose is to bridge payments from Boston Scientific in order to take advantage of any opportunity to accelerate our clinical or new product development programs more aggressively. Finally, on the financial comments, I want to be sure to state the obvious. When reading our financials, please note that year-to-year comparisons are not meaningful. We report our results according to GAAP rules with the one-time gains that can be confusing. Celsion's a different, restructured and completely refocused company than it was just a year ago. We have sold our medical device business, and along with that, any product revenue prospects for the next few years. We are now exclusively a drug

development company with a clear and executable strategy, and what we believe is a promising technology in the future. Now, I'd like to ask Paul to give you more detailed update on the financials.

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Paul Susie: Thank you, Mike. Within our continuing operations, our research and development expenses were \$2 million for the quarter, which is an increase of \$400,000 over the prior year's amount of \$1.6 million. This increase is consistent with Celsion's expanded clinical activity, in particular our special protocol assessment process for the primary liver cancer study. Additionally, our drug manufacturing cost increased as a result validating our single-vial formulation of ThermoDox and the production of the supply drug necessary for our clinical trials. Our general administrative costs were \$1.9 million for the quarter, compared to \$0.9 million for the same period in the prior year. The increase was due in part to higher salaries and benefits costs, which included accrued severance cost to terminated employees, which are largely associated with the sale of Prolieve. Additionally, we incurred higher professional fees, consulting fees, and audit fees for the quarter as compared to the prior period. Net interest income increased \$400,000 in comparison to the prior year. This is due to the higher cash balances maintained during the quarter, as well as the elimination of the loan that was previously due to Boston Scientific. With respect to our discontinued operations, our transitioning of the Prolieve assets to Boston Scientific is nearly complete. For the quarter, we reported only minor income of \$33,000, which represented expense reimbursements from Boston Scientific under the transition services agreement. Our balance sheet was substantially strengthened by the sale of Prolieve during the second quarter. Our cash balance at the end of the third quarter was \$11.3 million, and we have \$30 million in receivables remaining under the sales agreement. These amounts will provide us with the liquidity necessary to further our clinical trials. As Mike mentioned, we will continue to carefully manage our cash and focus our resources only on those activities that will forward our strategy. With that, I will now hand it back to Mike.

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Michael Taradugno: Thanks, Paul. Now, I'd like to bring you up to date on our SPA submission. As you know, we received a response from FDA on Monday morning indicating that we will be required to provide a third iteration of our protocol and supporting documents for the agency's review. The notification was a disappointment, particularly since we had conversations with FDA that suggested that our submission had the potential to be acceptable. Nevertheless, we are committed to responding on a timely and fully complete manner. In doing so, we look to receive an affirmative response from FDA by late January, if not sooner. That's our target. But as many of you know, approvals often take a number of submissions before they're accepted. But we are convinced that based on the nature of the comments that we received, it's not a matter of if we reach agreement, it's just a matter of when. On that basis, in parallel with FDA's review Dr. Borys has been working with our CROs, principal investigators, medical and clinical consultants to plan our phase III study. Our planning includes detailed time lines for rapid at start up sites, as well as identifying and enrolling high potential investigators in North America, Italy, Hong Kong, Taiwan, Korea and China. Of course, you know that China is where HCC accounts for approximately 60% of worldwide incidence rate for this devastating disease. Our goal is to enroll our first patient as expeditiously as possible following an agreement. And in doing so, we will attempt to minimize the impact of the resubmission and the delay associated with resubmission and the overall study timeline. Before characterizing the issues listed by FDA, I think it would be worthwhile to recount the recent sequence of communications. As you may recall, following our second submission in August, we expect that a response by September 18th. On that day, we receive a call from the agency indicating that a revised radiology charter was expected, and was the only outstanding issue that was needed to complete the review. At that time, we were advised that a timely submission would be acted upon very quickly. We communicated this to you.

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The revised charter was submitted within 48 hours. We were again advised that a timely review could be expected. We communicated this to you, along with an update that the agency could take a full 45 days to respond. On Monday morning, November 5, we received a fax that was dated November 2, that the agency considered our full submission and indicated that there were 11 points to address, most of which require clarification and are patient safety-related. One of which suggests however that we consider collecting related data from a small set of the study population. None of the comments or suggestions is a show stopper. They're in a process of resubmission which will address all of the FDA's comments fully, which I indicated will be submitted promptly. I want to take a minute to review the components of the FDA submission. I think this will be helpful to do so as I want to make sure that we're all in the same page as these concepts may come up in future conference calls. So bear with me. While the SPA submission is a complex and very detailed set of documents, and if I put up a ruler next to the documents that we sent to the FDA last time, I'd say they're about 18 inches deep. The submission consist of first the study protocol, which outlines the purpose of the study, the competing treatment options, patient inclusion and exclusion criteria, treatment procedure, control group, blinding, training requirements, site and investigator requirements, medical monitoring, safety committee charter, definition of endpoints — just to name a few. The submission also includes a statistical analysis plan we have referred to as an SAP. The statistical analysis plan details how the data from the study will be evaluated, and how conclusions will be drawn. A third document that's submitted is a case report form. In our case, it will be over 200 pages. And that is the — the case report form is the information that will be collected for each patient in the study. The fourth set of documents is the radiology charter, and this is a significant document as it provides a standard and controls for reading the CAT imaging that will be used to evaluate disease progress. So those are the

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four major components of the SPA. And I give them to you with some detail only because we may be talking about them in future conference calls. Beyond progressing with the FDA approval process, progress is being made on other initiatives, particularly within our product pipeline at Celsion. Let me review those with you. Some are in very early stages so I'll try to be a little bit cautious. I want to review them so you can see what's happening here with us — without overstating the work that we were doing. But these are very exciting and very encouraging developments. During the summer we announced that we've seen some early success with liposomal formulations of docetaxel, and we would be conducting confirming studies. I want to let you know that the studies have been completed, and our early review of the data is very promising. I just received the formal report this morning. As soon as I digest it and we've been through it as a team, we will be announcing the details. Last week on another program, we signed an exclusive option to conduct feasibility studies and negotiate a license for a peptide ligand that when attached to our liposome will provide active targeting capability for cancers that over express epidermal growth factor receptors. This is a very exciting technology that if successful, will provide our heat-sensitive liposome with what I like to call a "seek and destroy" capability. So on behalf of the inventing academic institution which we will reveal later, Celsion has filed (PCT) patents this past week. Once I'm sure that the patents are accepted, we will provide more information to you. On a third point, we have — recently had very productive set of discussions for a joint development agreement with a blue chip medical device manufacturer that provides for a shared responsibility to study indications using a technology known as high intensity focused ultrasound in conjunction with ThermoDox. This development has a potential to provide non-invasive heating technologies to treat a broad range of cancers, including metastatic disease. The last point I want to make on the product development update is that I wanted to make you aware that we've been conducting due diligence on Duke's technology that will allow us to

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combine imaging agents in combination with chemotherapeutics in our heat-sensitive liposome. This, of course, would be a long-term unfunded development program ... but it is of interest as it would demonstrate the further potential of our platform technology. Linked to the above two technologies that I just spoke of, this has the potential to influence how oncology drugs are used in the future. So in concluding my formal remarks, let me assure you that I will provide information as we have it, trying to balance the timing and content with your need to know what's happening here at Celsion. I'm trying not to be premature, but I continue to believe that more information is better than less and that the sooner we provide the information, the better, and I trust you agree. Lastly, in spite of the timing setback with the SPA, which we are working hard to offset, I believe that we are making progress at Celsion everyday. And everyday I continue to be more excited by the promise of our company. So that concludes my formal remarks. And I will take some questions. Operator?

Operator: At this time, if you would like to ask a question, press star, then the number 1 on your telephone keypad. We'll pause for just a moment to compile the Q&A roster. Again, to ask a question, press star-1. Again, to ask a question, press star, then the number 1 on your telephone keypad. And your first question comes from the line of Ruthanne Roussel with the Robins Group.

Ruthanne Roussel: Hi, gentlemen.

Michael Tardugno: Good morning, Ruthanne. How are you?

Ruthanne Roussel: Hi, there. Lots going on. I wonder, Mike, or whoever would be the appropriate person — I'd appreciate a bit more color on what's happening with the recurrent breast cancer study. I understand that you've just received these papers regarding it, but we — I also remember that at one point, there have been some...

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Michael Tardugno: Sure.

Ruthanne Roussel: ...there's a question of perhaps meeting with the FDA for fast-track approval for ThermoDox based on the study.

Michael Tardugno: Sure. You know, just as — a number of things are going on with the recurrent chest wall program. I think as we reported to the investment community and to our shareholders that we've seen some exciting results in terms of objective response in our Phase 1 study that's being conducted at Duke. On that basis, we decided to add additional study sites to the trial. The study sites are in the process of reviewing the protocols through their ethics committee or IRB. We expect NYU will be enrolling patients some time this month, the month of November. That the third study site, should we need it, at Northwestern, would be based on a timeline, I'm familiar with and would probably not enroll patients until after the first of the year. So we're making a lot of progress in accelerating the Phase 1 program. The goal of which is to reach the MTD. Concurrently, with all that, Duke has enrolled two additional patients and I believe they are prepared to enroll a third. Of the two patients, I have a report on — both of them are evaluable. I have a report on the first one, and Duke reports that they've seen a second complete response which is very exciting. So that's what's going on with our Phase 1 program. We — I believe I reported, in a previous conference call, that we had planned to meet with the agency to discuss the progress that was being made in the Phase 1 program, and to propose that there may be an opportunity for a fast-track — and that may be a misnomer, Ruthanne. But the program for the study program for a registrational approach would be characterized as open label. In any event, we

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met with the agency about three weeks ago. We were joined by the investigators from Duke and the investigators from New York University. In general, we ask three questions of the agency. Question number one would be, is the study population that we are considering an appropriate population? And I believe the answer we got back from FDA was generally, yes. We asked the FDA to comment on our opinion that for the study population, there is no current standard of care. I believe the agency generally agreed with us that this population is treated without any standard of care, and it's generally treated in a palliative way. The third question we asked was, considering the fact that there is no standard care for this population, would you consider a registrational study with a primary endpoint for something other than survival. And I believe generally, the FDA agreed that they would be willing to consider endpoints other than survival. So what we took away from that meeting was that we believe we have an opportunity to propose to the FDA a study design and a protocol that would be something similar or probably defined as an open label study with a relatively small population. When I say small — I'm comparing it in my mind to our 600-patient liver cancer study design, but it would be a population somewhat smaller than that. We have requested a followup meeting with the FDA. They haven't responded yet, however, we're hopeful to meet with them again before the end of the year to discuss our protocol proposal.

Ruthanne Rousset: Thanks, Mike. That's very helpful. If there are other questions, I will hop back in the queue.

Michael Tardugno: Thank you.

Operator: Again, if you would like to ask a question, press star-1 on your telephone keypad. Your next question comes from the line of Vincent Dempsey, a private investor.

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Michael Tardugno: Good morning, Vincent.

Vincent Dempsey: Good morning. How are you doing?

Michael Tardugno: Okay. How are you?

Vincent Dempsey: All right. Hi. Have you gotten any results on the Phase 1 for the liver that you that you can bring out or embellish?

Michael Tardugno: I think it's premature for us to provide you with results. The study was conducted at the NCI in cooperation with a second site in Hong Kong. The study report is being compiled as we speak. As soon as the study report is available, we will be making the information available. But it's only a limited amount of information, and our investigators would like to present this information at either ASCO or another similar conference. Normally, those type of conferences where this type of presentation is made, require that very limited public information be made available before the material is presented at the conference. So we are kind of hamstrung. I can say however that we have reached the MTD as a result, or the maximum tolerated dose as a result of the study. And that was the primary objective. I can also say that the safety profile of ThermoDox is consistent with our expectation. There was nothing out of line.

Vincent Dempsey: Okay.

Michael Tardugno: You just kind of have to bear with us on that, one of the reasons the investigators sign up for these kinds of activities with the sponsor is not only to further science, but they want to be able to present their information to a group of similarly-minded scientists in a disciplined and in an appropriate way.

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Vincent Dempsey: Do you see any venue up ahead where it could take place?

Michael Tardugno: Well, you know, it maybe a little bit premature, but I am aware of the fact that an abstract has been submitted to one major conference outside the US and the anticipated abstract will be submitted to a second major conference in the United States. Also, there will be a submission for a peer review journal for publication.

Vincent Dempsey: Okay. And one last question, if you would, are you looking at about two weeks to reply to the FDA? Do you have any time schedule on that as far as how long they'll take to get it together?

Michael Tardugno: You know, I hesitate to give you an exact date, but I would say, you're not far out of the realm of reason. If we can do it sooner, we will. The nature of these kinds of responses, even given the fact that the comments made, I think, were mostly technical in nature, just required - requiring clarification. Inasmuch as that we have two CROs involved, we have a radiology charter or radiology consultant involved. We've had a number of consultants involved with helping to design the protocol and the statistical analysis plan. We have three or four principal investigators who have an interest in the study. Dr. Borys, indicated to me this morning, that he wants to make sure that he has collaborated with all of the interested parties before resubmitting the document.

Vincent Dempsey: Okay. Well, good luck.

Michael Tardugno: Thank you, Vincent.

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Operator: You have a followup question from the line of Ruthanne Rousset with the Robins Group.

Michael Tardugno: Good morning again, Ruthanne.

Ruthanne Rousseau: Good morning. Refresh my memory please on what will be the next few steps that we can look to down the line assuming that after the SPA is approved, then presumably in the liver trials, we will have the enrollment of the first patient. And after that is there some next milestone that we can look to, or will there be a long quiet period while data is being gathered?

Michael Tardugno: No, you know, I think we have a number of activities going on within the company that are significant and important and value-creating milestones. So, approval of the SPA obviously is a very important milestone. I don't want that to overshadow all the other activities are going on in the company, but we do know that our number one priority is initiating a registrational, or pivotal trial for ThermoDox. Enrolling the first patient, as you said, would be another major milestone. Given the preparations that are going on in the company, I suspect that will be accomplished quite soon. We are following up with the FDA on our thoughts on recurrent chest wall cancer. We now have virtually every evaluable patient in the Phase 1 study having shown an objective response, a durable objective response. Based on that, I become more excited. I have to be tempered a little bit by the scientists and the medical people in our company. We will continue to work as aggressively as FDA will allow us to collaborate with them to find some way for a registrational study that we could conduct in a time frame consistent with the results as I've seen in the Phase 1 study. That would be a significant milestone. And it certainly would cause us to think carefully about our priorities in the company.

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We will be announcing in some detail, and we'll be writing a press release on it, that the docetaxel in a confirming set of studies that show us statistically significant improvement over a non-heat-sensitive liposomal formulation and a free docetaxel formulation. That's another milestone which means moving it into a pre-clinical program. We've talked in the past about our commercialization strategy. If we continue to progress in discussions in that regard, we certainly may have some information to share in terms of milestones. Excuse me, I alluded to technology that is extremely exciting, and that's the ability to take this very elegant means of increasing the concentration of powerful chemotherapeutics at the tumor site with our heat-sensitive liposome adding to it a capability, a seek and destroy capability, if you will. You know, it's a very exciting advance in the efficacy, a very good efficacy, that we believe we currently provide to improve that even further. And that would be — that's something that as soon as we've completed our due diligence, we want to find a way to demonstrate in animal studies it is an effective, even more effective way of treating cancers. There are a lot of milestones coming forward and a lot of activities in this company. And at the same time, I just want everyone on the line to know and all of our investors just to know that we continue to believe that our primary, primary number one objective is to bring ThermoDox through a registrational program, a pivotal trial. So, we will not be distracted by the other events, and that we will focus our cash resources on making that happen to the exclusion of anything else if we have to. Okay?

Ruthanne Roussel: Thanks very much.

Michael Tardugno: Next question please.

Operator: The next question comes from the line of Tom O'Brien with Catalyst Financial.

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Michael Tardugno: Good morning, Tom.

Tom O'Brien: Hi, Mike. How are you?

Michael Tardugno: Good. Thanks.

Tom O'Brien: Good, good. Just, if you would, can we go back to the RCW program and just talk about, for those of us who don't have the expertise, and the FDA lingo. Could you just describe an open label versus say, for example, a compassionate use type of label? As it relates to the RCW, given, I've seen those results. And just knowing that there is no other viable option for these poor people, how - can you just describe the two, the open label before compassionate use for me?

Michael Tardugno: I think Dr. Borys will give us a quick overview of the difference between the two.

Nicholas Borys: Thanks for your question, Tom. This is Nick Borys. I'm the new Chief Medical Officer, and it's a pleasure to be here. In regards to compassionate use and open label trials, you're asking a very technical question that has very clear definitions to the FDA, so I'll give you what I have to give you as a technical response. Compassionate use in general from a regulatory perspective is, when there's a patient that you know is going to benefit from your drug; you put them on a trial on a patient-by-patient basis. So once we've established with FDA that our drug shows some activity in RCW, there might be investigators out there that will apply to us and to the FDA and say, I have a patient here that I really think is going to benefit from your drug, and can I please enroll it? And it will be on a patient-by-patient basis. So there isn't such a thing as compassionate use protocol which you would use for regulatory purposes. Now, the second part of your question was what about

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open label trials? And that's what the Phase 2 trials are. Phase 2 trials are designed to be open label and to get an idea of how your drug works in a medium-sized population. And if you look in the oncology literature, typically that means anywhere from 40 patients, maybe to as high as 90 patients. That answers your question?

((Crosstalk))

Tom O'Brien: Yes

Michael Tardugno: Maybe to clarify a little bit more for some of the other people — the difference between a randomized study and an open label study.

Nicholas Borys: Sure.

Michael Tardugno: Okay.

Nicholas Borys: FDA and most regulatory authorities would like to see a randomized study. And what they typically mean by randomized study is they like to see how your drug compares against the current standard of care. And they like to see like one drug like, for example, ThermoDox, how that would compare against something else that's being used in those patients. And that is very difficult in our case because in the patients we're looking at for RCW, there is no standard of care. These are women that have reached a point in the point of her disease where there is nothing further that they can use. And so we believe that ThermoDox is going to be very useful for them, and we would proceed in designing trials that would be open label. And if the FDA insists on a randomized scheme, that presents the challenge for these types of trials.

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Tom O'Brien: Can we assume from what you're telling me that, given the relatively limited population that is afflicted with this chest wall cancer, would it be safe to say that to bring this from beginning to end would be cheaper and would the expense to the company, be significantly less vis-à-vis, you know, in your case, clinical trials?

Nicholas Borys: Well, if you're talking about the RCW, I think what you're hinting at is because this is a very difficult population, the FDA has a provision for what they call orphan drug status, or for some cases, that they'll do sort of a fast-track for difficult diseases or relatively rare diseases. And in those cases, an orphan drug, you'll see in the history that there are drugs that are approved based on Phase 2 studies.

Tom O'Brien: Uh-huh.

Nicholas Borys: But it's up to the companies to design very robust Phase 2 studies, to identify the patients where there's a clear definition of the benefit that's given to the patient, and that's a challenge in Celsion, and that's what we're proceeding with.

Tom O'Brien: Okay. So then your planned design is vitally important so that, you know, in theory, you might be able to use that Phase 2 as a pivotal study.

Michael Tardugno: Yes, I think, Tom, I — we'd like to get some confidence in our discussions with FDA that a pivotal study, our Phase 2 pivotal study would be accepted for registration — as a registrational trial. It's incumbent upon us, as Nick pointed out, to make sure that we design and detail a study, a robust study that the FDA would agree to. Now, generally, FDA likes to see some kind of a randomized trial with a control, and it's only in the most unique of circumstances that they allow for this open label kind of study.

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We have a unique circumstance, we really do. This is a population of people who die, and they die a very hideous death. They watch this cancer progress across their chest and there is no standard of care. By all standards and measures of the medical advisors with whom we work and treat this disease report uniformly, there is not standard of care. And ThermoDox in this Phase 1 trial is showing some remarkable efficacy. And so, you know, we will work with the FDA. We may even know where we'll — overstay our welcome, but we will work with the FDA to make sure that we put together a proposal that will be given all the best consideration in moving the ball forward. I think you asked your question of by cost. An open label study whether this or any other indication, an open label study generally requires fewer patients than a randomized controlled study, particularly a double-blinded randomized controlled study. And so we would project that the cost of a pivotal trial in RCW if in fact it were open label would be less than that of our liver cancer trial.

Tom O'Brien: Okay. Thanks, guys, for your clarity. I'll come back in the queue.

Michael Tardugno: Next question please.

Operator: The next comes from the line of Mitch Landgraf, a private investor.

Michael Tardugno: Good morning, Mitch.

Mitch Landgraf: Good morning, gentlemen. How are you?

Michael Tardugno: Good. How are you?

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Mitch Landgraf: Fine. I just like to start by welcoming Dr. Borys. Mike, thank you for your continued straightforward manner. I'll take a moment to just commend Tony Deasey for all his years of continuity and service to the company and wish him well. I have a question also in regards



to the RCW program, and I'm not familiar with what can and cannot be released. But, you know, you talked about the impressive efficacy so far, the durable objective response of everything invaluable patients in the program right now, having a second patient with a complete response. I personally endorse things that would generate a lot of interest in the market, and I just don't know — it doesn't seem to me that that information is being put out into the market by our PR company or by the company. And I'm just wondering if that is something that we really cannot do because of regulations of the study, or why that isn't going out there because I do agree with you, Mike, that the more we can build value in this company before entertaining any thought of partnership or things such as that, the better for everybody. And I'm just wondering if you could comment on that please?

Michael Tardugno: Yes, I think, you know, the decision of whether to issue press releases with regards to this kind of development is made at the company, and it's among us here at the table. And we have an obligation really to the investigators who are conducting the study, to not present their information in a way that it's inconsistent with what the scientific community's belief that it should be. If there are going to be press releases or presentations of this kind of information, we have an obligation to work with the investigators who are conducting the study. So, if you thought of that consideration it may seem to you that we are taking — I mean this great news is taking a low profile, but in fact it's not, you know, when we have an opportunity to talk directly with current investors or future investors, we're comfortable and allowed to mention these kinds of things. If we have an opportunity to speak with the regulatory agencies or companies who may be interested in a commercial relationship with us, we are comfortable in using this information.

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((Crosstalk))

Michael Tardugno: But it's not a matter of if, it's just a matter of time when this kind of information is presented and be made public in a way that it provides current investors with confidence. And it may give investors who were watching Celsion and trying to make a decision whether to get in or not, the confidence that we're a company that's building shareholder value.

Mitch Landgraf: I certainly can appreciate the line you probably have to walk between shareholder concerns and your investigator's concerns and regulations. So thank you very much, gentlemen, and please keep up the good work.

Michael Tardugno: Thanks for your support, Mitch.

Operator: Your next question comes from the line Bob Greene with Celsion Corporation.

Michael Tardugno: Hi, Bob. Are you with us?

Bob Greene: No. I wish I was.

Michael Tardugno: What can we do for you this morning, Bob?

Bob Greene: I don't know if you can answer these or not, but I'll ask them anyway. How many patients did we have enrolled in the liver cancer study?

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Michael Tardugno: Is it 28 in the liver cancer study? Oh, just a second. I'll give you an exact number. Bob, it is 32 cumulative.

Bob Greene: Can you tell us how many are still alive?

Michael Tardugno: We are not following them through survival.

Bob Greene: Okay, okay.

Michael Tardugno: But the study report will be coming out soon.

Bob Greene: Okay.

Michael Tardugno: And I want to ask you to just be patient with that. This study is not designed to project or predict a survival benefit. It's only designed as a safety study and a dosing escalation study. To ask for much more than that, we would put our investigators on edge.

Bob Greene: Okay.

Michael Tardugno: We are looking for efficacy outside of a statistically well-planned protocol.

Bob Greene: Okay. Second, this information I understand why you can't give it all, but does the FDA have the right to see that?

Michael Tardugno: Oh sure.

Bob Greene: Will they know everything that's going on with the liver cancer study?

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Michael Tardugno: Sure. In addition to that, we provide an annual report to the FDA that provides a substantial amount of detail on a patient-by-patient basis.

Bob Greene: Okay — on the chest wall...

Michael Tardugno: Uh-huh.

Bob Greene: ...I think you said NYU is going to enroll the patients this month?

Michael Tardugno: That's the current projection, you know, we're at the probably at the mercy is a wrong word. But the right limiting step here is approval by the Ethics Committee or the IRB, Internal Review Board. They review the protocol for a number of issues. Most important of which is to make sure that the study is conducted in a way that it is ethical for all the patients involved, so those reviews — ethical and safe for all the patients involved. And those types of reviews do take some time...

((Crosstalk))

Bob Greene: Okay. Back to the liver cancer, is that a one-time treatment with ThermoDox?

Michael Tardugno: It is a one-time treatment for each procedure of RFA. So if there's a single tumor that's treated with RFA, the patient gets a one-time treatment. If there is a followup treatment either because the ablation was not completed for some reason or a second lesion is found, then an additional dosing of ThermoDox will occur with the RFA treatment.

Bob Greene: Okay. We reached MTD, but I see the information that suggests the trial is ongoing, is this retreatment?

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Michael Tardugno: There is a retreatment, uh-huh.

Nicholas Borys: For the liver study? Yes. Well, there were two sets of Phase 1 liver studies. One of them is completed where we achieved the 50-milligram per meter squared MTD. And now that we have a second confirmatory trial, that is ongoing.

Michael Tardugno: Were you just talking about the NCI/Queen Mary Study?

Bob Greene: You just answered that. The trial is ongoing at the NCI, and that's what I was asking. I think that's everything I had written down. Thank you very much.

Michael Tardugno: Okay. Thank you.

Bob Greene: Uh-huh.

Michael Tardugno: No other questions?

Operator: Again, if you would like to ask a question, press star-1 at this time. And there are no questions at this time.

Michael Tardugno: So let me conclude then by thanking all of you for participating. We are - as a team here at Celsion committed everyday to improving our timelines and our delivery of results of our ThermoDox program, we appreciate all of your support and interest and involvement. And we look forward to speaking to you in the future.

Thank you very much.

Operator: That concludes today's conference call. You may now disconnect.

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