

Edgar Filing: CELL THERAPEUTICS INC - Form 425

CELL THERAPEUTICS INC  
Form 425  
October 22, 2003

Filed by Cell Therapeutics, Inc.

Pursuant to Rule 425 under the Securities Act of 1933

And deemed filed pursuant Rule 14a-12

Of the Securities Exchange Act of 1934

Subject Company: Cell Therapeutics, Inc.

Commission File No.: 001-12465

The following is a transcript of a presentation given by Cell Therapeutics, Inc. on October 21, 2003.

**Moderator: James Bianco**

Operator: Good day everyone and welcome to the Cell Therapeutics Inc third quarter conference call. Today's call is being recorded.

At this time for opening remarks and introductions, I would like to turn the call over to Dr. James Bianco, President and Chief Executive Officer. Please go ahead, sir.

James Bianco: Thank you. Good morning. Thanks for joining us. With me on the call today are members of our management team. As usual, before we get started let me remind you this call will be recorded and will be available for playback on our Web site. Any unauthorized recording of this call or use of this recording is prohibited without written consent by the company.

I'd also like to remind you as is common with presentations of this type, we will be making some forward-looking statements that involve a number of risks and uncertainties specifically regarding the future financial operating results, the proposed CTI Novuspharma merger and risks and uncertainties that could affect CTI's products and products under development including TRISENOX® and XYOTAX. And as such, I recommend that you refer to our most recent SEC filings.

In addition, as you know, we have documents referencing the proposed merger with CTI and Novuspharma on file with the SEC. And information regarding the merger can be found in our S-4 filing, either accessed on our Web site, or on the SEC Web site.

## Edgar Filing: CELL THERAPEUTICS INC - Form 425

---

As many of you are aware, we will be hosting a special meeting of the shareholders on Thursday, October 23rd to vote on the proposed merger of Novuspharma with CTI and into CTI. If you have not already voted on this matter, obviously we encourage you to do so.

So the agenda for today's call, I'm going to review the following items: our third quarter financials, and the progress we've made towards our 2003 TRISENOX® sales guidance of 24 million; feedback on key regulatory meetings that we had with the FDA on TRISENOX®, XYOTAX and Pixantrone. So it was a very busy regulatory quarter, if you will; progress on our merger with Novuspharma and near term news flow from both our pipeline and their pipeline; and milestones that we anticipate to see come up in the fourth quarter.

Let's start with the financials, I'm assuming those of you on the call have seen our press release this morning. So I'm just going to briefly highlight our financial results for the quarter. Total revenues rose \$6.5 million compared with \$4.4 million for the same period in 2002 with TRISENOX® net product sales rising about 71 percent. So approximately \$6 million compared to the \$3.5 million for the same period in '02.

Expenses for the quarter were up slightly to about \$36.3 million from \$33 million for the third quarter last year. And that was predominantly attributable to as we had been saying the rapid enrollment in our phase three effort for XYOTAX. SG&A expenses for the quarter ended September 30th were flat at \$13 million, compared to \$13 million for the same period in 2002. So we continue to track against our guidance of approximately \$30 to \$32 million, net loss quarter for 2003, i.e. the \$120 million net operating losses that we anticipate would be incurred as a single entity. Obviously, with a combined entity, as we have said, we see the prospects for some cost synergies.

Now we have implemented the headcount reductions in Seattle and the work transference to our colleagues at Novuspharma. And while that will result in a modest cost savings in 2003, we

absolutely believe we can achieve the projected 18 plus million of cost synergies between the two organizations in 2004 and beyond.

We ended the quarter with a strong cash position of approximately \$128 million on the balance sheet. And according to Novuspharma financials which they recorded yesterday, they ended the quarter with approximately \$98 million in cash. So following the shareholders vote on Thursday the combined company would have a strong cash position with over \$225 million on the balance sheet. With a targeted 2004 net burn of approximately \$100 million, the combined company would obviously be well positioned to advance our joint product pipeline including completing the pivotal trials for XYOTAX, Pixantrone and our first NDA filing for XYOTAX in 2004.

Now that net operating target does not take in account any potential revenue upside through either a XYOTAX partnership or expansion of the TRISENOX® label for additional indications, which obviously could add significantly to our 2004 forecast.

Let me move on and discuss the growth that we continue to experience with TRISENOX® and TRISENOX® sales. As I mentioned, net sales for the quarter reached approximately \$6 million. We saw our unit sales growing from about 1,393 units in 2000, the same period in 2002. It's about 2,047 units in the same period 2003.

We expected, obviously that the myeloma usage in the third quarter would be soft, following the introduction of Velcade, which is why despite an encouraging quarter-over-quarter sales run rate that we saw in the first half of the year, we were reluctant to raise our guidance above the \$24 million net target that we provided at the outset of this year. Now that softening is reflected in our patient use patterns. Currently, APL represents about 15 percent of the products use which is essentially unchanged year-over-year. In contrast, we have experienced a 50 percent increase in the MDS usage which now accounts for about 63 percent of the product use versus about 40 percent for the same period last year.

## Edgar Filing: CELL THERAPEUTICS INC - Form 425

---

We now see myeloma representing approximately 17 percent of the patient mix, compared to about 35 percent this time last year. Obviously the total number of patient starts are up since that is what's responsible for the significant increase in sales revenue quarter period-to-period.

Now based upon feedback that we've seen from myeloma experts, and sales and demand trends that are reported in September and early October, it appears that the initial Velcade honeymoon may be winding down. We anticipate that regional and national advisory board meetings that the sales force had planned in the fourth quarter, as well as obviously the increased interest we expect to see as result of data presented at ASH will drive sales in the fourth quarter to allow us to achieve and come within our forecasted goal of \$24 million.

In addition, we anticipate that our proposed merger with Novuspharma will allow us to leverage their European clinical experience, and operating presence to positively impact TRISENOX® ex-U.S. sales. As previously noted, we will provide 2004 sales guidance on our Q4 conference call, since the fourth quarter sales run rate is an important parameter for the forecast in 2004. So there are a number of key presentations for TRISENOX® at some upcoming medical conferences in the fourth quarter. These include an oral plenary session presentation this Thursday at the American Society of Therapeutic Radiation Oncology, on data that's coming out of Stanford University demonstrating in analog models that high dose radiation in combination with arsenic trioxide increases significantly the cure rate in a malignant brain cancer. And that preclinical study has prompted Stanford to initiate a clinical trial in conjunction with the NCI in glioblastoma.

We'll see a plenary session by Dr. Raza at Rush Cancer Institute on TRISENOX® in MDS at the Chemotherapy Foundation Symposium in New York in November. There are presentations on TRISENOX® and solid tumors like melanoma at the EORTC-NCI-AACR meeting in November as well.

And lastly, as always, but this year in particular, we will have a very, very busy ASH presentation calendar, which will highlight data from two large MDS trials and over 170 patients. It will highlight studies of TRISENOX® with either dexamethasone or melphalan along with vitamin C which are demonstrating a very high durable response rate in various stages of multiple myeloma. And some of that actually will be highlighted in oral presentations at the meeting as well. So we clearly look forward to the ASH event this year, as it pertains to TRISENOX®.

As I mentioned previously, we've been encouraged by thought leaders in the U.S. and in Europe to submit data to the health regulatory authorities in those two territories from our two MDS clinical trials that are currently completing enrollment. To this end, earlier this month we did meet with the FDA to explore a potential supplemental NDA for TRISENOX®. And while the discussions are preliminary we're certainly encouraged by the direction or feedback that we have received from the FDA and are currently preparing a more formal analysis of our experience in high risk patients, which we plan on sharing with the FDA later this quarter.

Given that there are currently no therapies available for MDS and the safety and efficacy results we are observing in the two trials, we believe there exists the potential to expand the product label in its disease. Clearly this would represent an unmet need and pure upside to our TRISENOX® revenue forecast. And we look forward to updating you on the progress of those discussions and our plans for any potential supplemental filing in the future.

While we're on the topic in novel agents for treating blood related cancers, this may be a good time to review our merger with Novuspharma and anticipated milestones and data flow for Pixantrone.

As I mentioned, we'll be hosting the special shareholders meeting on Thursday, October 23rd to vote on a proposed merger. In addition to the implementation of the integration plan that was

developed during the merger discussions, both groups have been busy preparing all of the listing documents for the CONSOB which will be filed on Friday following an affirmative vote from both shareholders groups. This would allow the final condition to be met, which is a listing on the Italian stock exchange, which we believe could occur in early December. Now suffice it to say the two companies have been operating as an integrated entity since early September recognizing many of the savings and synergies that we've identified during the merger planning.

We are excited about the data that we have reviewed with our colleagues at Novuspharma for Pixantrone and on the progress that we and Novuspharma had made in discussions with the FDA regarding a pivotal trial and aggressive lymphoma. For example, the FDA has confirmed that a product like Pixantrone is third line or beyond treatment of aggressive NHL could qualify under sub part H for accelerated review and approval. And they encouraged Novuspharma to submit its protocol under the special protocol assessment procedures, which we are currently with them on completing later this month.

The agency also encouraged us to investigate Pixantrone in earlier stage disease, and in combination trials with other chemotherapy agents in this in aggressive lymphomas, both strategies of which we are currently in progress pursuing, as you will here both at ASH and in our development plans in 2004. For example, we expect to see a significant amount of data on the superior cardiac tolerability profile of Pixantrone when compared to other agents in this class, in both preclinical models of cardiac toxicity, as well as in clinical evaluations of patients who have received prior doxorubicin at limiting doses. Who were then subsequently treated effectively with doses of Pixantrone. That data should be presented at the upcoming AACR meetings.

As reported yesterday by Novuspharma, they just initiated the phase II trial of Pixantrone in combination with a therapy known as the BSHAP which replaces the etoposide in the previously standard regimen called ESHAP. As you may know, ESHAP is a second blind regimen for patients who fail doxorubicin in front-line therapy, i.e. CHOP. And clearly, the phase one data

that was reported at the ISEH meetings this year, showed an overall very high response rate of 58 percent with the majority of those responses being complete remissions once Pixantrone was substituted for etoposide in that standard second line regimen.

The impressive data in the phase II trial, a single agent Pixantrone in salvage therapy for aggressive lymphomas we reported in August in the peer review journal HEMATOLOGICA. It was actually this trial experience that provided the basis for discussion with the FDA regarding the design of a U.S. pivotal study.

We also could expect a considerable amount of new clinical trial data for Pixantrone to be presented at this year's ASH meeting, including a somewhat provocative dose finding study where Pixantrone replaced doxorubicin in the standard CHOP regimen among patients who failed front line CHOP. And as such were unable to receive further doxorubicin therapy. Clearly this is the only agent based upon its cardiac tolerability profile that one would consider in retreating doxorubicin. The dose dependent complete remission rate observed in that study is outstanding. It clearly supports potential safety/superior safety and efficacy profile for Pixantrone over existing market anthracycline agents. Clearly we look forward to that study being presented at the upcoming ASH meeting.

Now that study actually paved the way for us to consider investigating a phase II study where we combine Rituxan plus Pixantrone CHOP in the front line treatment of aggressive non-Hodgkin's lymphoma, a study which we believe we can get underway early next year.

In addition to the aggressive NHL population data that will be presented, we expect to see phase I/II data on Pixantrone used in relapsed resistant indolent lymphoma this time in combination with Rituxan and the drug Fludarabine.

So we believe that the safety and efficacy data that's being generated in both single agent and combination and therapy trials, and based on feedback quite frankly from key opinion leaders that have reviewed this data in the lymphoma treatment area as well, as obviously feedback from the FDA, that we can design with a high probability of success, a pivotal trial which could be initiated early next year. And as we've been forecasting, completing within a 12 month period of time, leading to an NDA submission target for this agent in 2005.

Now our commercial team is currently reforecasting the commercial potential of this product based on the emerging data we have seen both in front line and second line failures, and quite frankly in the CHOP variant which for us was a very exciting study that Novuspharma conducted. Really underscoring the potential of this agent to replace doxorubicin in the front line therapy of lymphoma and potentially leukemia.

So let me now update you on XYOTAX. As I mentioned on yesterday's call regarding the STELLAR 4 protocol amendment, we anticipate no material change for the forecast and enrollment completion dates which STELLAR 3 completing by year's end. The amended STELLAR 4 by end of Q1, and STELLAR 2 by the end of Q2 next year. Again data analysis and release from the STELLAR 3 and two trials respectively is anticipated to occur as previously guided for late summer next year.

And our first NDA filing would file, if successful, would follow in the fourth quarter of 2004.

Now there seems to be a few questions regarding whether we would enroll additional patients on the treatment arm of STELLAR 4. Now as I mentioned yesterday, while we are not required to do so, we are planning on adding approximately an additional 50 patients to the STELLAR 4 study, such that the total eligible patients at the 175 milligram dose remain as the originally powered study at 185.

Now this is somewhat true also for the STELLAR 2, but since the percent of PS2 patients in that trial is so small, i.e. less than 10 percent, the total number of additional patients is also small at 15 or 20 patients or so. So again, given the rapid enrollment rate that we are quite frankly enjoying with these studies, this will not add materially to the forecasted completion timeline. So we really hope that that clarifies that issue once and for all.

I also wanted to take this opportunity to clarify a few questions that arose regarding neutropenia. And actually, if you go to our web site, you'll see that we added a slide that notes the reported instance of grade 4 neutropenia by drug comparator arm, and for XYOTAX. And as if you're as you will see, at a XYOTAX dose of 175 milligrams per meter squared in over 135 patients, our incidence of grade 4 neutropenia was nine percent. If we raise the dose of XYOTAX to 210, it goes to 11 percent. And at a dose of about 235, we'll be at the sample size that's somewhat limited, it's about 25 to 27 percent. But that is clearly lower than the reported instance of grade 4 neutropenia for Taxol or Taxotere.

For example, Taxol at 175 the instance of grade 4 neutropenia is 27 percent. So that's almost three times as high as what we see at our paclitaxel equivalent at the same paclitaxel equivalent dose. And grade 4 neutropenia at 235 per Taxol is 52 percent or half of the patients. Similarly, Taxotere causes 65 percent instance of grade 4 neutropenia at its approved dose.

So if you're comparing XYOTAX to Taxol or Taxotere, you would note that the other drugs would result in a higher percentage of earlier i.e. neutropenic related events including grade five related events than if you were using XYOTAX at the same dose. That is why the DMC did not observe any difference in cycle one or cycle two events in the XYOTAX arm in the 303 or the 302 study because you're comparing apples-to-apples if you will. And remember the DMC only looks at drug safety and not efficacy. So even though those events are likely to occur more frequently in the comparator arm, the DMC is only going to request an inquiry if it appears to be more frequently in the investigational treatment arm.

And so to understand why we took the dose down to 175 in the STELLAR 4 study, it helps to put in perspective the expected incidence of grade 4 neutropenia with Gemcitabine. And that, although the data in PS2s is not published in terms of toxicity yet, from the package insert, the expected instance of rate for neutropenia as a standard Gem dose is about six to 10 percent. So again if you compared XYOTAX 235 with the likelihood of neutropenia is about 27 percent to Gemcitabine where the likelihood is about six to 10 percent, again, you're going to see a handful of more earlier attempts related to neutropenia. Right, and again I think what I actually was quoted as saying was the number of patients was a single digit number of patients difference. That was the how small the magnitude was.

So by taking the dose down to 175, we can essentially assure that the expected incidence of grade 4 neutropenia should be no different between the two arms. And if the efficacy that we observed in the phase two trial with XYOTAX at 175 is repeated here, we could expect that a 22 week survival for XYOTAX compared to the expected recently published Gemzar PS2 trial survival of only eight weeks. And so that is why we made that change.

Now to dwell on this topic, but a number of our shareholders found this information very enlightening, and quite frankly very reassuring. Let me also make it clear that our primary obligation is to patient safety first, and product success second. And that may not be the popular position to take, but in ethical drug development, it should be the only position to take despite what people may write.

Also, for those of you who may be interested we utilize the common terminology criteria for adverse event recording, as is required by the FDA. And a copy of the toxicity scales grade 1 to 5 can be accessed by anybody with a desire to have accurate information by going to the NIH's website, CTC.CTEP.cancer.gov reporting guidelines version three.

I couldn't help but make a snarky comment about a snarky piece that was written.

So let me move on to discuss some of the external validating milestones that took place in September, and will take place in this quarter first. It was a landmark meeting between the new FDA and the GOG leadership. That leadership included the Chair, the Vice Chair, the Head of the Ovarian committee, the head of the Protocol committee, and the principal investigator on the proposed GOG conducted phase three trial.

And I think it is fair and accurate to say that the FDA was really taken aback by the fire power, if you will, and the commitment of GOG leadership to this project and their process at the meeting. A clear understanding of the requirements for a single pivotal trial design was discussed between the GOG and the FDA. And following the FDA's advice, the GOG plans to submit an SPA package to the agency later this quarter, and pending final comments and review period would be in a position to initiate a front line XYOTAX ovarian cancer trial. And this would represent the first time that we're aware of that a major cooperative group will hold both an investigational new drug application and a special protocol assessment agreement for a drug company's investigational drug, a move we clearly think validates the product potential by the major thought leaders in ovarian cancer.

Now further validation is supported by several publications including one on treatment of lung PS2 lung cancer treatments by Dr. Corey Langer from Fox Chase Cancer Center and one on the use of taxanes in ovarian cancer by Dr. Maurie Markman of the Cleveland Clinic both clearly and predominantly featuring XYOTAX as an exciting new direction for taxane therapy for these diseases.

At the upcoming Chemotherapy Foundation Symposium in New York, Dr. Burris will present at a plenary session data from his lung cancer study on XYOTAX 235 milligrams in non-small cell lung cancer at that dose.

Lastly following the safety review of STELLAR 3 trial we are obviously anxiously awaiting the announcement that we have completed patient enrollment in that study, a milestone which we should complete in December as planned.

Let me just briefly touch on the partnering discussions since that always comes up. Needless to say the interest among potential commercial partners for XYOTAX continues at what sometimes appears to be a tiring pace. And we are confident with the trials enrollment coming to completion that we will have no difficulty securing a commercial partner between now and our NDA filing for the product. So we look forward to what is shaping up to be a very positive event and news flow filled fourth quarter. And at this point, I think we'd like to open the call to any questions from our listeners.

Operator: Thank you. The question-and-answer session will be conducted electronically. If you would like to ask a question, please do so by pressing the star key followed by the digit one on your touch-tone telephone. If you are 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 followed by the digit one to ask your question. And we'll pause for just a moment.

And we'll take our first question from Mark Schoenebaum with Piper Jaffrey.

Mark Schoenebaum: Hey, Jim.

James Bianco: Good morning, Mark.

Mark Schoenebaum: A question. Actually there's been a lot of interest in MDS recently, and there's a recent MDS meeting in New York that really had most of the thought leaders there. Just it sounds like you've been in a lot of discussions with FDA about this disease, what in terms of a

truly approvable endpoint, and an approval trial design, where's your head on this right now? What do you think the agency expects out of a drug? What end point and what kind of trial?

James Bianco: The official party line at the FDA is going to be a randomized control survival study. That is the old FDA official party line. If you read between the lines, folks like Grant Wilson who were at the meeting, they're saying the FDA is obviously struggling with trying to come up to speed on what are more appropriate end points, for diseases where survival may not be an option, because the disease is complex, it's heterogeneous and there are no effective therapies. And so they're actually convening panels with the experts to discuss its time progression, time to leukemia transformation.

Do you need a randomized trial if you don't have comparator drugs to compare it to? Why do you have to show us compared to, for example, you know, best supportive care, that of course, you're going to, you know, if you have any intervention on transfusion independence is that going to be meaningful and beneficial?

So I think what we're hearing from them is go ahead put your data together. Look at these things that your thought leaders are telling you are important end points, like survival if you have responders, like high risk versus so called low risk. And it's really a risk benefit analysis at the end of the day. And by the time that data is analyzed and then submitted, the FDA is certainly going to be in a more educated position based upon feedback from their advisory panels quite frankly to make those decisions.

And our bet is that they will accept what the thought leaders are telling us at the end of the day. For example, high risk, the rate of transformation or survival even in a non randomized study where that group has historically shown to have a very poor outcome that that benefit if the drug doesn't have an overwhelming toxicity or side effect profile could sway their vote, if you will.

Certainly, the worse that could happen is you put in an application and it will go to ODEC. So if we do our homework correctly in terms of positioning the data that we have, consistent with what the thought leaders think are important clinically meaningful end points. Then I think that that will have a positive reception as the FDA is starting to get more comfortable with these less hard, if you will, end points than the pause up, pause down. The kind of the survival end points that they have kind of been traditionally focused on in the past.

Mark Schoenebaum: So what are your thought leaders telling you about the meaning of truly the meaning of the of transfusion independence as a clinical end point.

James Bianco: I'm going to let Jack answer that since he certainly sits in on all of these panel meetings.

Jack Singer: I think the from our perspective, rather than comment on transfusion independent per se, the best efficacy we've seen with TRISENOX® is really a very high risk disease. People are actually normally being expected to have a survival of under a year, from all of the published studies. And what we've seen is unlike the Imids, TRISENOX® really has some quite beneficial effects within this group. And you'll see data at ASH showing hematopoietic response rates in excess of 20 percent in two large studies that do translate to a survival advantage of the responders and these high risk patients.

Now these are not being targeted by the other by the Imids at all. Transfusion independence is part of it, but not the full story here. So I think our it's quite clear that in a low risk patient that's transfusion dependent which is a very small number of patients, actually that that's probably of some benefit. But if you can't translate that to the broader scope of the MDS population, you're really looking at a very, very narrow application.

James Bianco: Yes, I think that was clear Mark, that the agency was focused on risk benefit and heterogeneity of this disease. So if you carve out what the value of a red cell transfusion

independence to a low risk patient they see as being relatively low clinical value, especially if the drug has side effects. And the reason for that is these patients do very well. They don't really have the survival or the acuteness of the issues of patients who are neutropenic or have low platelet counts, and are in kind of that smoldering preleukemic states.

Jack Singer: This survival of low risk MDS is measured in multiple years. And this is an elderly population to start.

James Bianco: Right. So it was clear that their enthusiasm for the low risk transfusion, i.e. red cell transfusion approach was pretty clear unenthusiastic, especially if the drug may have side effects. And I think they were clearly more focused on this intermediate IPSS and the high IPSS population of patients.

Mark Schoenebaum: OK. Great. Thanks, I'll jump back in the queue.

Operator: And next we'll move on to Matt Geller with CIBC World Markets.

Matt Geller: Hi, Jim this is going to be a pattern here. Let's see, two questions. On Pixantrone, that class of compounds that Pixantrone has been used a little bit less over time. Can you talk about how Pixantrone is different from Novatrone? And I understand the cardio toxicity. But do you really think, and to what extent do you think that it can become a major drug and that class can become an important class of drugs. And what's the extent of potentially including multiple sclerosis for that class.

And I'm not sure if you mentioned it or not, but EORTC will you have the presence there. Are there any days when we should be going to EORTC?

James Bianco: OK. We'll start. Pixantrone is in the class anthracenediones like Novatrone is. But I'm going to say this even though I know that Dr. Spinelli is probably on the call with us. That our colleagues at Novuspharma were very crafty and quite good when they modified the so called anthracenedione nucleus so that it can have a better therapeutic index than Novatrone. The major clinical limitation for Novatrone is that it is right on the cusp of being beyond the MPD.

So when you dose that drug, some patients at the standard does will just fall apart from it and have a fair amount of toxicity. Or you won't see the response rates that are as encouraging, as they would be, for example, with doxorubicin the standard anthracycline.

In pre clinical testing Pixantrone was the most potent of its class, in both in hematologic malignancies both superior to mitoxantrone and to doxorubicin. But more importantly you had a much higher therapeutic index before you caused toxicity. And that's exactly what is being translated in the clinical trials, that you're taking these patients who fail anthracenediones who fail anthracyclines like doxorubicin. And you can dose them across a fairly wide range of doses, meaning in the dose finding studies, and not let them fall apart and get into trouble, but yet, have the clear dose response relationship where the epitome of dose response relationships are complete remissions. And I think when that data comes out at ASH especially for the group, you know, the sell side and buy side folks who are following the lymphoma market in general, will see some very impressive, very durable rates of complete remission even better than you would expect to see in a front line treatment setting with this agent. And that safety profile is underscored because these are all relapsed, all maxed out on their prior docs.

So we think that data is clearly going to be unequivocal that this product should be positioned to really be the product of choice in the anthracycline field, not the anthracenediones. So we're not talking about taking the Novatrone market. We're talking about becoming the product of choice for anthracycline use in hematologic malignancies period.

Now the other point you bring up is very, very important, even though it's not a main focus for us, but if this drug is more active in hematologic malignancies because of its design and its profile, it happens to be a better DNA intercalator in lymphocytes, than for example the other two classes of agents. Well that is the whole rational for putting it in Multiple Sclerosis in the first place. And so there is a trial that our colleagues that Novuspharma in Europe are doing with the thought leaders in MS who were attractive to not only the activity profile, but the fact that the therapeutic index, i.e. the ability to dose without having some patients just fall off the curve was very attractive. And they're exploring that in MS as well. We should hear certainly at the upcoming EORTC meeting, some data. Most of the EORTC meeting data will be either the pre clinical efficacy comparisons, between Pixantrone and mitoxantrone or Pixantrone and doxorubicin.

And Jack, what else are we doing?

Jack Singer: It's predominantly the overall story about cardiac safety which will be preclinical at EORTC and clinical at ASH.

James Bianco: Yes, there's a lot of data at ASH, Matt.

Matt Geller: Thanks a lot, Jim. And I think with Pixantrone since it's been developed in Europe and a little bit unknown here, it would be real helpful to, you know, hear more from some of the investigators, and things like that on this drug, so we can get more familiar with the compound.

James Bianco: Absolutely. In fact, we're planning on having some kind of a type of I don't want to say a coming out party, but certainly by December the two companies will be officially merged if you will. And highlighting the thought leaders in lymphoma and review that they've been doing of lymphoma data in particular as we have been having these discussions with the FDA, I think would be very useful for folks to kick the tires if you will and get the opinions first hand.

Matt Geller: Thanks.

Operator: And as a reminder to ask a question, please press star followed by the digit one. And we'll move on to Jim Birchenough with Lehman Brothers.

Jim Birchenough: Yes, hi guys, a couple of questions. Just on TRISENOX® first, can you just remind us where we're at year-to-date for TRISENOX® sales? What's left for the fourth quarter to get to the \$24 million number? And as well whether there's been any inventory stocking where inventory levels are at right now and whether they could go up in the fourth quarter.

James Bianco: Yes, Ed's going to answer that. But don't worry about the inventory levels.

Edward Kenney: Yes, hi Jim. We're at 16 million year-to-date. And that means an \$8 million fourth quarter, the fourth quarter has always been a very strong one for us. So it's looking good. There is no surplus of inventory anywhere in the pipeline. I think we've mentioned before, we're drop shipping now almost half our business. So it's going directly to a customer. There's no intermediary. And we watch the wholesale levels pretty good.

Jim Birchenough: OK. Great. And then looking at the opportunity in MDS, I'm just trying to get a sense of, you know, you're getting a fair amount off label use there, I'm trying to get a sense of what's the upside from a full label. You know, in patient terms what percent of the market are you getting? And what's still available to you from a full label expansion, do you think?

James Bianco: Yes, great question. We're doing three to three-and-a-half percent of the MDS at our current run rate. And we're doing a little bit less than five percent of the myeloma population at our current experience. So there is huge upside if we get an MDS label. I mean our—we just saw the sales forecast from Katie and the group. Across all of the MDS indications as a whole, if you look at low intermediate and high risk it's less than five percent is what we penetrated. If you

just focus on the intermediate and high risk which is what we are quite honestly going to go after, that's probably about closer to eight to 11 percent of the penetration for on an (inaudible) basis of what's out there.

So that difference is pretty substantial having an eight or 10 fold increase in the potential for on label sales could be very significant for this product.

One other thing Jim, that I'm glad you brought this up, you know, we have been focusing on the fact that TRISENOX had a relatively short product life cycle, i.e. it was only 2007 for exclusivity because APL would go essentially in late 2007. And so our investment considerations really had to make it profitable this year, and payback that profitability over '04, '05 and '06, to really justify, you know, the return on investment consideration for the product.

We now believe that we are in a position that we will receive coverage that can expand our exclusivity in all of the hematologic cancers potentially out to 2018. We should get final verification of that if not this quarter, early next year. And clearly, that is allowing this team to go back and revisit product life cycle planning for this product, not just in hematologic cancers. But as we're now starting to see in combination with chemotherapy or radiation therapy in solid tumors, may in fact provide a very significant upside model for us that we're currently exploring. We certainly will update you and the street as we get more clarity on that program.

Jim Birchenough: OK. Great. And then just one final question, just on XYOTAX just flushing out the maintaining of timelines for STELLAR 4. I guess it's safe to assume that the 50 patients that are going to be added represent 50 patients that got 235 and you now need to replace with 175. I just want to know if that's a fair assumption. And then, you know, given that, how long did it take you to enroll those 50 patients? When will you start enrolling these patients, these next 50 at 175? Just take us through how we get to timelines being maintained.

James Bianco: Sure. First of all, it's clear there's no regulatory requirement that we need to replace any patient. That is purely the company's choice. It's not a regulatory requirement. Taxotere did not replace patients in their breast cancer study that had to come off the 100 milligram dose because of neutropenia and toxicity that went down to 75. So that I just want to make sure that this is a choice purely for homogeneity and make sure that we have the retention of the appropriate power of the study.

And we enrolled 50 patients in two weeks on this study. And so the enrollment rate is extremely rapid. And so the amendment in the U.S. is purely a paper amendment which means that IRB's will sign off on it, and there should be absolutely no down time. And then certain European territories we could take up to four weeks for getting IRB approval on the amendment. The amendment was actually just signed off by the steering committee this morning because I saw all of the e-mails last night. That amendment will go in likely what's today, Tuesday? It will probably go in Wednesday or Thursday of this week. So that means effective next week in U.S. and Western Europe, everyone will be on 175. Anyone new in the study will be being enrolled at 175.

And then in certain other territories like Latin America, Portugal, et cetera, where they have different IRP requirements, it may take up to four weeks. But again, we're doing the math and we're saying if we're doing 50 patients in two weeks from an enrollment perspective, even if that because we had two months on the other end Jim that nobody knew about, we had February and March. And we were expected to complete in January internally and so we have eight weeks of float, with more than eight weeks of float, that we're working off of. And we think that even if we utilize that eight weeks up, we're still on the original time table.

Jim Birchenough: OK. Great. Well thanks for taking my questions.

Operator: And we'll move on to Edmund Debler with Millennium Partners.

Edmund Debler: Yes, thanks so much for taking my question. I just want to go back to the cash position that you had kind of gone through that pretty quickly. How much money you have, also after the merger? And the timeline to how far that will take you in terms of, you know, next year, the burn, related to the burn.

James Bianco: Yes, we had I think we had about 127.7 million in cash and securities available for the sale at the end of this quarter. Novuspharma had approximately on an as converted basis to dollars, about \$98 million. So combined balanced sheet, it's somewhere around \$225 to \$226 million pro forma.

We anticipate that the combined company burn rate in 2004 will be approximately \$100 million net. That assumption works off of the required finishing of all three phase three trials for XYOTAX. The GOG running of the phase three study in ovarian cancer for XYOTAX, the majority of the enrollment for Pixantrone in it's pivotal trial in the U.S. And that TRISENOX sales will grow somewhere to within where the analyst numbers are. I think the numbers on the street are anywhere between 32 and 40 million in that range. And so that's a conservative kind of revenue side of the P&L if you will. And makes no other assumptions with regards to other significant sources of revenues coming in to the company.

And that is affected because we were able to recognize about 18 to 20 million of cost synergies for the two companies coming together. And obviously the significant cost savings that Novuspharma will have on not conducting the very large indolent lymphoma study that was initially in their plans, given the fact that the pivotal trial in aggressive could actually supplement that from an NDA perspective.

So if we had told or forecasted previously that we should end the year on a combined basis with about 175 million in cash, and we're clearly running at a rate to come in above that for a

combined balance sheet. So we should be in a very strong cash position to get through some of the key major events for us next year.

Now obviously 2005, it's a little harder than the crystal ball, because if XYOTAX is successful in this phase three, you're obviously going to have the commercial partnership that's going to provide additional revenue. Additional product support, marketing support, et cetera, that would totally change the P&L to the positive and our balance sheet to the positive.

And obviously if TRISENOX® label gets expanded in 2005 and/or we launch XYOTAX and finish the Pixantrone studies, all of those are clearly upside to the revenue forecast. So right now, we feel very comfortable that we're well capitalized to certainly see us through 2004, and in to some key milestone events in 2005.

Edmund Debler: Great. That was my question. Thank you so much.

James Bianco: Thanks, Edmund.

Operator: At this time, there are no further questions. I will turn the call back over to Dr. Bianco for any additional or closing remarks.

James Bianco: Well obviously it's been a busy couple of days. Some folks asked us just in closing, you know, why didn't we put the announcement out about the STELLAR 4 amendment today. Obviously that is never a choice when we have material information and we have completed our due diligence. We report that as soon as we know what the answer is to the Street. We don't withhold that type of information especially when it's material. There was no other reason other than that. We would have loved to have obviously had one call instead of being here at 3:30 in the morning two days in a row to do it twice. But clearly, a lot of good progress across the clinical, regulatory and the financial front.

We look forward to the merger shareholders meeting on Thursday. We are presenting at the Techvest Rodman & Renshaw conference on Wednesday. And we look forward to obviously providing a little bit more color and clarity to our XYOTAX program which we are extremely as we put it yesterday, even more bullish on following some of the review that happened late last week. So thank you all again for joining us this morning.

Operator: And that concludes today's conference call. Thank you for your participation. And you may now disconnect.

\*\*\*

#### **CAUTIONARY STATEMENT REGARDING FORWARD LOOKING STATEMENTS**

This presentation contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The forward-looking statements contained in this presentation include statements about future financial and operating results, the proposed CTI/Novuspharma merger, and risk and uncertainties that could affect CTI's product and products under development. These statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein. For example, if either of the companies do not receive required stockholder approvals or fail to satisfy other conditions to closing, the transaction will not be consummated. In any forward-looking statement in which CTI expresses an expectation or belief as to future results, such expectation or belief is expressed in good faith and believed to have a reasonable basis, but there can be no assurance that the statement or expectation or belief will result or be achieved or accomplished. The following factors, among others, could cause actual results to differ materially from those described in the forward-looking statements: risks associated with preclinical, clinical and sales and marketing developments in the biopharmaceutical industry in general and in particular including, without limitation, the potential failure to meet TRISENOX® revenue goals, the potential failure of XYOTAX to prove safe and effective for treatment of non-small cell lung and ovarian cancers, the potential failure of TRISENOX® to continue to be safe and effective for cancer patients, determinations by regulatory, patent and administrative governmental authorities, competitive factors, technological developments, costs of developing, producing and selling TRISENOX® and CTI's products under development in addition to the risk that the CTI and Novuspharma businesses will not be integrated successfully; costs related to the proposed merger, failure of the CTI or Novuspharma stockholders to approve the proposed merger; and other economic, business, competitive, and/or regulatory factors affecting CTI's and Novuspharma's businesses generally, including those set forth in CTI's filings with the SEC, including its Annual Report on Form 10-K for its most recent fiscal year and its most recent Quarterly Report on Form 10-Q, especially in the Factors Affecting Our Operating Results and Management's Discussion and Analysis of Financial Condition and Results of Operations sections, its Current Reports on Form 8-K and its filings on Forms S-3 and S-4. CTI is under no obligation to (and expressly disclaims any such obligation to) update or alter its forward-looking statements whether as a result of new information, future events, or otherwise.

**WHERE YOU CAN FIND ADDITIONAL INFORMATION:**

Cell Therapeutics, Inc. (CTI) has filed a proxy statement/prospectus and other documents concerning the proposed merger transaction with the Securities and Exchange Commission (SEC). Investors and security holders are urged to read the proxy statement/prospectus and other relevant documents filed with the SEC because they contain important information. Security holders may obtain a free copy of the proxy statement/prospectus and other documents filed by CTI with the SEC at the SEC's website at <http://www.sec.gov>. The proxy statement/prospectus and these other documents may also be obtained for free from CTI, Investor Relations: 501 Elliott Avenue West, Suite 400 Seattle, WA 98119, [www.cticseattle.com](http://www.cticseattle.com).

CTI and Novuspharma S.p.A. and their respective directors and executive officers and other members of their management and their employees may be deemed to be participants in the solicitation of proxies from the shareholders of CTI and Novuspharma with respect to the transactions contemplated by the merger agreement. Information about the directors and officers of CTI is included in CTI's Proxy Statement for its 2003 Annual Meeting of Stockholders filed with the SEC on May 14, 2003. This document is available free of charge at the SEC's website at <http://www.sec.gov> and from CTI.