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CELL THERAPEUTICS INC

Form 425

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The following presentation was given on June 17, 2003 by Dr. James Bianco of Cell Therapeutics, Inc. (CTI) in connection with the announcement of the proposed business combination between CTI and Novuspharma S.p.A.

Cell Therapeutics, Inc. Conference Call

June 17, 2003

OPERATOR: This is Premier Conferencing. Please stand by, we're about to begin. Good day everyone and welcome to the Cell Therapeutics, Inc. 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, CEO and Director. Please go ahead, sir.

JAMES BIANCO, PRESIDENT, CEO, & DIRECTOR, CELL THERAPEUTICS: Thank you. Welcome. My name is Jim Bianco and I'm excited to announce today, what I hope you'll agree, is one of the strongest combinations to be announced in the biotech arena; that being the merger of CTI and Novuspharma. With me this morning are members of our management teams, both at CTI and Novuspharma, including Dr. Spinelli, the CEO of Novuspharma, as well as our Chief Operating Officer, our Chief Financial Officer and our Head of Research, Jack Singer.

As you'll note, this presentation contains forward-looking statements. The statements in this presentation are based on our 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.

The next slide tells us about additional information. Investors and security holders are encouraged to read the proxy statement/prospectus for more information concerning the proposed merger as well as other relevant material filed with the SEC. The proxy statement/prospectus will be available on filing at the SEC web site or from CTI at www.cticseattle.com.

So, let me begin. We believe the strengths of the combined phase III product programs, along with the potential cost savings, operating synergies and strong balance sheet make this a smart strategic and financial transaction for both CTI and Novuspharma. This transaction marks the third cancer-related product addition to our pipeline since 1998 and it's consistent with our 2x5 strategic objective, which targets filing two NDAs every five years. We believe, like our acquisition of XYOTAX in 1998 and TRISENOX® in 2000, Pixantrone and the synergies of Novuspharma's expertise will create significantly greater value for our combined shareholders and, importantly, our customers.

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Now, let me describe why we are so excited by this opportunity. I'm going to start by reviewing the synergies that we anticipate from the proposed transaction. First, and foremost, Pixantrone is one of the most exciting phase III candidates we have seen which, based on the strength of its phase II data, could be eligible for fast track status and could be submitted for its first NDA in aggressive lymphoma as early as 2005.

Secondly, there are significant sales and marketing synergies between Pixantrone and TRISENOX[®], both here in the U.S. and abroad, that can be realized as a result of this combination. For example, as we expand the TRISENOX[®] label, both here in the U.S. and in the EU, with a potential regulatory filing for MDS next year, the introduction of Pixantrone in non-Hodgkins lymphoma, could provide a significant revenue build for our hematology P&L, allowing the company the opportunity to develop a significant presence in the blood related cancer space. And I'll elaborate on that later.

Third, this transaction provides the combined entity with a strong balance sheet with a pro forma cash balance of \$230 million as of the end of March clearly adequate resources to take XYOTAX to an NDA filing and potentially into market. The cost savings of approximately \$18 to \$20 million per year as a result of operating synergies between the two companies is accretive to our P&L both in 2003 and in 2004 was another critical component of our decision, while at the same time allowing us to build complementary expertise in cancer drug development.

And, lastly, a stronger European presence that will give CTI and Novuspharma more global access to patients, physicians and capital markets, allowing us the opportunity to continue to evaluate our strategy as it pertains to growing the TRISENOX® franchise in Europe and as it pertains to our XYOTAX commercial strategy.

For those of you who are on the call who are not familiar with CTI, we marketed our first commercial TRISENOX® in the U.S. and Europe for a severe form of leukemia. We posted triple digit growth in 2002 and expect this growth rate to continue through 2004. We have forecasted \$24 million in net sales this year and we are comfortably on target to meet that objective. In addition, TRISENOX® has shown encouraging responses in clinical trials in blood-related cancers such as MDS and multiple myeloma and we believe that additional label expansion to these indications could drive peak sales for TRISENOX® in excess of \$150 million. In addition to TRISENOX®, we are also developing a potentially safer, more effective version of paclitaxel called XYOTAX, which links the active ingredient in Taxol® to a novel biodegradable polymer and, as you may know, XYOTAX is in pivotal trials for non-small cell lung cancer and we anticipate initiating a pivotal trial in ovarian cancer in conjunction with the GOG in the fourth quarter of this year.

As you saw from our announcement yesterday, based on the strength of the clinical data, the FDA in phase I and phase II the FDA has granted XYOTAX with fast-track status in non-small cell lung cancer. We have also applied our polymer technology to the second largest class of anti-cancer agents, the camptothecins. CT-2106 as we call it, or PG camptothecin, is currently in phase I and, as we also announced, a decision has now been made to advance with the phase II early next year. Our research coverage includes CIBC World Markets, Lehman Brothers, Piper Jaffray, Wells Fargo, Punk Ziegel and Delafield Hambrecht and we are currently traded on the Nasdaq under the ticker symbol CTIC.

Let me move on to review Novuspharma. As I mentioned, one of the key attractions for us in this transaction is their Pixantrone drug candidate, which is currently in a pivotal trial for NHL, non-Hodgkins lymphoma. Pixantrone is the next generation, potentially safer, more effective anthracycline. This product's profile is consistent with our overall portfolio strategy of acquiring well-defined, chemotherapy agents that have an improved activity, meaning anti-tumor activity, and potentially an improved safety profile. At the end of the first quarter, Novuspharma had approximately \$120 million in cash. They are located in Milan, Italy. They were spun out of the oncology drug division of Boehringer Mannheim and Hoffman-La Roche, and as such, they have expertise in predevelopment, pre-clinical, toxicology, pharmacology and early clinical development. Their research coverage includes Lehman Brothers, Banca IMI and Caboto. And they are currently traded under Nuovo Mercato in Italy.

I am going to talk a little bit about the specifics about the proposed combination. This transaction, as you have read, has been unanimously approved by the boards of both CTI and Novuspharma. The merger is subject to, obviously, shareholder approval from both Novuspharma and CTI shareholders. Now, we know that the majority of the shareholders have entered into voting agreements from Novuspharma to vote in favor of this merger, and obviously, another subject of the merger agreement is approval of CTI's application to list the shares on the Mercato exchange.

We expect this transaction to close in the fourth quarter of this year, and we have established an integration team, outlined an integration plan, really to implement the operating and cost synergies that were identified during the planning of the merger. We anticipate the year-end cash position of the merged company to be at

approximately \$160 million prior to any additional revenues that may be realized from potential corporate licensing agreements.

Under the agreement, Novuspharma shareholders will receive 2.45 shares of CTI common stock for each Novuspharma ordinary share or approximately 16 million shares. And this represents approximately 31 percent of the fully diluted outstanding shares of CTIC prior to the conversion of our convertible debt. The combined entity is expected to trade on both the Nasdaq and the Nuovo Mercato. Novuspharma will have two seats on the board of the merged entity. Dr. Silvano Spinelli, their current CEO, will join the board as an Executive Director. And Dr. Eric Platzer, who is Novuspharma's current Chairman of the Board, will join as a non-executive Director. A third independent director, to be mutually agreed upon by both companies, will be appointed to the board of the merged entity.

In addition, we're pleased to announce that Dr. Spinelli will join our management team as Executive Vice President of Development, and will continue on as the managing director of the European operations in Milan.

The main reasons for this transaction are pretty compelling when you look at this side by side comparison of the two companies. While everyone else was focusing on the universe of biotech companies, most of which had appreciated significantly in value, we believe we found a true value, which was, for the most part, not quite as visible to the U.S. investors, and to some extent to even European investors. The strategic fit between these two companies is uncanny, both with regards to our therapeutic focus in hematology and oncology, and in particular, to developing the next generation of safer, potentially more effective, chemotherapy agents, designed to make cancer more treatable.

Our pipelines are truly complementary. Combined, we would have one marketed product, two Phase III products in pivotal trials, and several products in early to mid-stage clinical development. This enhanced pipeline, combined with a strong balance sheet and strength in development and commercial capabilities, alongside a stronger EU presence, places CTI among a relative handful of biotech companies with the resources to become a significant commercial entity in the oncology space.

Combined, our core competency synergies would provide capability across the entire spectrum of drug discovery, development and commercialization, ultimately giving us more control of these aspects of our value chain, resulting in significant cost savings and leverage, as we position ourselves to grow a commercially successful cancer company.

As I mentioned, Novuspharma was previously the oncology drug development division of Boehringer-Mannheim and its staff has an extensive track record in cancer drug development. As a result, the merged company will establish the Milan facility as its center of excellence for pre-development, pre-clinical and early clinical development activity. In addition, the Milan facility will become CTI's European headquarters.

Novuspharma's European presence, vendor and customer relationships will be critical in expanding the commercial prospects for TRISENOX® in Europe as we set our sights on extending the label into MDS, while assisting in the management of our ongoing clinical development efforts in Europe for, not only Pixantrone but our other products, such as XYOTAX and PG-camptothecin.

The corporate headquarters will remain at CTI's facility in Seattle, Washington. In addition, the Seattle facility will be the center for target validation and discovery, Phase II to Phase IV clinical development and commercial activities including sales and marketing.

So let me elaborate a little bit on the portfolio synergies that we see from this transaction. We believe the competitive landscape in the blood-related cancer space represents a significant opportunity for us, with relatively few mid-size or large pharma competitors and relatively

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few approved agents for conditions like MDS or, for example, there are no approved chemotherapy agents for aggressive non-Hodgkin's Lymphoma at this time.

With TRISENOX[®] gaining traction in blood related cancers like MDS, Pixantrone provides us a unique opportunity to leverage our growing presence in the hematology market. Phase II data for Pixantrone suggests that this novel drug candidate could become the anthracycline of choice for the treatment of aggressive lymphoma. The drug could also find a role in treating breast cancer and prostate cancer, which would provide additional synergies with our XYOTAX product program.

As you may know, XYOTAX is in pivotal trials in non-small cell lung cancer and, as I mentioned, a pivotal trial in ovarian cancer is expected to start later this year.

Lastly, CT-2106 or polyglutamate camptothecin is also expected to have utility in solid tumors, such as colorectal cancer and small cell lung cancer.

Let me move on to describe the products that are in development in more detail. One of the main reasons that we got excited about this transaction is that Pixantrone is similar, in many respects, to TRISENOX[®]. For example, we gained access or acquired TRISENOX[®] at its pivotal stage of development. TRISENOX[®] had a compelling clinical response database and an acceptable safety profile.

Similarly, Pixantrone has generated encouraging high rates of complete tumor response and overall responses in aggressive non-Hodgkin's Lymphoma, and even in the indolent non-Hodgkin's Lymphoma, coupled with the ease of administration and a side effect profile that could prove superior to existing cancer cycling.

In addition, it provides a potentially quick regulatory route to approval since we believe it addresses an unmet medical need in the treatment of relapsed aggressive non-Hodgkin's lymphoma. An indication for which there are currently no approved therapies. Thus, allowing it, like we forecasted for TRISENOX[®] and, as you heard yesterday, XYOTAX, to qualify for fast track designation from the FDA.

Preclinical studies show that Pixantrone was the most active of the anthracyclines tested, both as a single agent and in combination treatments, against lymphoma. As such, much of the clinical effort has been exploring the utility of this agent in a variety of lymphomas at various stages. More than 170 patients in approximately seven phase I and II clinical trials have been treated to date. And, as you can see, that data from this chart is quite impressive whether it be in combination regimens for relapsed/refractory non-Hodgkin's lymphoma where complete remissions and objective responses are seen in more than half of the patients. For example, in the CHOP regimen, where doxorubicin is replaced with Pixantrone, or in other combinations in aggressive relapsed lymphomas where you, again, you see majority of patients experiencing not only high objective responses but, in fact, complete remissions. The same impressive activity is seen, again, in the indolent non-Hodgkin's lymphoma setting where all six patients of the six evaluable had a major response, including five complete remissions.

While the combination data with Pixantrone are among the most encouraging reported in the medical literature, what really excited us about this product and what got our experts equally as excited was the single agent data with Pixantrone in the relapsed, aggressive, non-Hodgkin's lymphoma setting, demonstrating that this is one of the most active agents of its class. It's important to recognize that once patients received a threshold accumulative lifetime dose of anthracycline, for example 300 to 400 milligrams per meter squared of doxorubicin, they are typically not eligible for further treatment with this class of drugs because of the high risk of cardiac complications, which typically is reported in excess of 50 to 65 percent of patients, including this complication called congestive heart failure. In this phase II trial, all but one patient, as you can see from these slides, had maximum anthracycline exposure, with most patients being resistant to their last treatment regimen.

I think as you go down the chart you can see why we're excited about the prospects for Pixantrone and this disease. The ability to induce such a high rate of complete and partial remission, among this advanced group of patients, with some of those responses lasting as long as 17 months, is

unprecedented among any

single agent therapy reported to date. We believe these data will provide a compelling argument for a fast-track, single agent pivotal trial in relapsed, aggressive lymphoma.

So the summary for Pixantrone is that the high rates of long-lasting responses is clearly unprecedented for this agent. It was well tolerated. Neutropenia is the predominant side effect, which is typically manageable with growth factors, which is common to the class of anthracyclines. Most notable in this study, in particular, is that 85 percent of these phase II patients had received prior anthracycline exposure, which typically would have made them ineligible for further anthracycline therapy and despite the exposure to cumulative doses of Pixantrone in the 1,000 milligram range or higher, there was a very low, only 10 percent instance, of cardiac events and, in our view, that is just very impressive and unprecedented for this class of agents.

So we believe the strength of this phase II data provides a clear route for U.S. registration strategy. Based on regulatory discussions of others, we believe a single pivotal trial in third line aggressive non-Hodgkins lymphoma yielding a response rate of 30 percent or more and a time progression greater than three months, with an acceptable safety profile, as has been demonstrated in their phase II effort in approximately 100 to 120 patients, would be adequate for submission and for approval. As I mentioned, we also believe this indication will qualify for fast-track designation and anticipate initiating that pivotal trial in the first quarter of next year. With enrollment taking approximately 12 to 14 months, we would be in a position to file an NDA in the second half of 2005, with approval potentially in early 2006. A phase III study in combination with Rituxan in relapsed indolent lymphoma is currently underway in the EU, which we believe could expand the label and market applications and provide additional commercial upside to the prospects of this product into this other large market opportunity called the indolent lymphomas.

It's probably been a while since you've reviewed the data on anthracyclines, so let me give you the information that we looked at when making the decision on the prospects for this product. Anthracyclines clearly are the standard of care treatment for lymphomas, both non-Hodgkin's aggressive and indolent lymphomas, when relapsed. They are the standard of care in leukemia and front-line breast cancer and now in the relapsed hormone refractory prostate cancer setting as well.

The market is currently about a \$500-plus million market, and the two products that are the market leaders, if you will, in Europe, it's epirubicin, and in the United States is doxorubicin. As I mentioned, the major limitation of both of these two marketed agents is cardiac toxicities when patients have received a certain cumulative lifetime dose. So that once a threshold has been reached, they cannot be retreated with this active class of agents. In addition to this limitation, as a result of their severe corrosive nature, they must be administered through a central heart catheter since, if they come in contact with the skin, they can cause severe ulcers and necrosis.

As part of our due diligence on Pixantrone, we conducted a limited market survey among lymphoma specialists testing the various product attributes and determining the key product drivers. Based on the product profile that I summarized and the registration strategy that we proposed in the third line, aggressive non-Hodgkin's lymphoma setting, the results of that survey demonstrated that if approved in the third-line setting, Pixantrone could gain significant penetration, not only in third-line usage, but even in second-line multi-agent uses.

Well, surprisingly, half of the participants in the survey would substitute it for doxorubicin in the top regimen for front-line treatment. The attitudes on Bexaar® and Zevalin were very interesting and clear that supportive data in the indolent non-Hodgkins lymphoma setting that this product would also begin to penetrate use into that segment as well.

In total, we have conservatively forecast the product could achieve U.S. peak sales of \$150 million in our current model. Needless to say, with anthracyclines being the cornerstone front-line treatment for breast cancer, and due to the overlapping cardiac toxicities that limits the use of Herceptin® in combination with an anthracycline, the potential ability to combine Pixantrone, which was accepted in front-line breast, could

provide significant upside to the commercial prospects for this agent, which we currently have not worked into our model.

I'm going to briefly walk through CTI's programs, just as an update for those of you who may not be as familiar with Cell Therapeutics. And I'm going to start by talking about TRISENOX®. As I mentioned earlier, we acquired TRISENOX® through the acquisition of PolaRx in early 2000, filed our NDA, received FDA approval and launched the product in the fourth quarter of that year, initially for a limited label in a severe form of leukemia called APL. Much of the product growth potential resides in the encouraging response data that has been reported in the higher incidence blood-related cancers, such as MDS and multiple myeloma.

It is from the potential for these two extended indications that we have seen triple-digit growth in 2002, and expect that growth to continue this year. The upside surprise potential next year is our plans to evaluate data from recent clinical trials in approximately 200 patients, to support the U.S. and an EU registration for MDS. If successful, we believe that TRISENOX® would have U.S. sales well in excess of \$150 million.

I'm going to briefly review some of that data that was presented at the MDS and myeloma conferences. We saw a 32 percent long-lasting response rate in about 120 patients with MDS, both high- and low-risk varieties, with the drug being well-tolerated. And, as you recall, 81 percent of the patients who responded were transfusion dependent, became transfusion independent and that was long lasting in some cases, up to two years. And the thought-leaders really encouraged us to complete the enrollment in those trials and submit that data to both regulatory agencies for an indication in MDS and we are currently in the process of putting that task force together.

We also announced very encouraging response rates in multiple myeloma with an overall objective response rate of 40 percent of patients, despite their having failed Thalidomide and Velcade and we expect more exciting data to come up on at ASH this year. Actually, some 30 some odd abstracts that I know that are in the works. So, we anticipate to have a lot of visibility on TRISENOX® in these blood-related cancers.

The estimates shown here on this slide for 2003 and 2004 are from CIBC World Markets. We set our net sales guidance for '03 of \$24 million and, as I mentioned previously on the call, we are comfortable and well on our way to hit that target. We have not yet provided guidance for 2004 sales.

Clearly, with an expanded label in MDS we would expect this growth chart to change substantially to the upside beyond 2004.

While most analysts consider the potential blockbuster in our pipeline to be XYOTAX, I just want to remind you not to underestimate the combined revenue and earnings growth potential of an expanded TRISENOX® label and a Pixantrone approval in the aggressive non-Hodgkin Lymphoma setting. Now, clearly, the most commercially attractive candidate in our pipeline is XYOTAX. By conjugating paclitaxel to this polymer, XYOTAX is designed to take advantage of the fact that blood vessels in tumor tissue are different than blood vessels in normal tissues in that they have openings or pores that can trap large molecules like polyglutamates. And that has the potential, as we have seen, to allow more of the chemotherapy to be trapped in the tumor tissue than in normal tissue adding to the potential for improved effectiveness and less side effects.

And unlike marketed or experimental formulations of paclitaxel, the polyglutamate polymer gets into the tumor cell through a different route and it's selectively metabolized by enzymes abundant in active tumor cells. So these two unique properties provide XYOTAX with a profile that is completely different than standard formulations of paclitaxel. And this is our target product profile, as you can see, compared to not only paclitaxel but what is becoming clearly the taxane leader in the space right now, at least on a growth basis docetaxel, or Taxotere®. We now have treated over 450 patients to date. We have not observed the frequency of neutropenia, severe allergic reactions or the typical so-called taxane related toxicities. The neuropathy that we have reported has been seen predominantly in patients who have received extensive

prior taxane therapy and typically over very prolonged treatments with XYOTAX at very high doses. So this is a very encouraging product profile that continues to bear fruit in a now very extensive clinical experience.

I think the fact that patients don't lose their hair on XYOTAX confirms that their blood levels are clearly lower than what could be accomplished with standard formulations of paclitaxel. As you know, XYOTAX was recently granted fast track designation by the FDA and we're going to read you directly the, what's on the slide came out directly from the FDA letter, and that was because in advanced non-small cell lung cancer in PS 2 patients that disease is incurable with available therapy offering only modest benefit. And because XYOTAX, actually they said CT-2103, has the potential to demonstrate improvement over available therapy in these patients, based on anti-cancer activity observed in the phase I and phase II clinical trials. So given the product profile that we have been developing, we've initiated a robust pivotal trial program in lung cancer and, to be initiated later this year, in ovarian cancer. And unlike generic reformulations, our trials are specifically designed to demonstrate superiority over marketed taxanes. Our phase III programs are approved under the FDA's special protocol assessment process and they will test XYOTAX in over 1,500 patients. And, as I mentioned, unlike generic formulations, we believe if our phase III trials prove successful, XYOTAX has the potential to be rapidly adopted in treating non-small cell lung cancer, which would save not only health care costs and time but will add to patients' quality of life while extending their survival.

I'm going to briefly review our plans, again, and reconfirm our status that we are on track with our phase III program. As you know, in our plans for registration in lung cancer we've chosen to focus our effort on the PS2 subset of patients with lung cancer, primarily because the strong phase II data supporting the likelihood that XYOTAX could be superior to existing approved paclitaxel therapy in the treatment of that subset of lung cancer patients. This was recently validated by the FDA's review of that data and the granting to us of fast-track status. This subset accounts for 25 percent of 170,000 patients with non-small cell lung cancer in the U.S. and these patients typically have, spend almost half of their time in bed as a result of their cancer and they typically poorly tolerate current chemotherapy. In fact, clinical trials show that they only tolerate two treatments on average, that their cancer progresses within six weeks and, unfortunately, half of these patients die from their disease in as quick as two and a half months. We believe that XYOTAX's potential improved tolerability profile will allow patients to receive more therapy, control the progression of their disease and, therefore, extend their survival.

That belief is based on the encouraging data that we presented as update at ASCO in the phase II study amongst elderly phase II patients where single agent XYOTAX was well tolerated, 50 percent received four treatments and 30 percent received six or more cycles. Tumor progression was delayed significantly and an increase in median survival was reported, which was encouraging, especially when compared to a recent randomized trial of paclitaxel. Side effects of XYOTAX in that study were also encouraging, especially in light of the anticipated side effects that accompany standard paclitaxel therapy. Now most analysts project that XYOTAX peak sales revenue could reach or exceed \$500 million and, obviously, we have expectations that can exceed the analysts and hopefully we can deliver on those. We expect to submit an NDA for XYOTAX on target in late 2004.

Our current phase III trials in non-small cell lung cancer are outlined here. You should note that if XYOTAX is successful in achieving its primary end point of improving median survival compared to Taxotere®, in the second line treatment setting, or proving superior to combination Taxol®/platinum in front-line PS2, or even single agent gemcitabine or navelbine in PS2 front line, XYOTAX would be positioned to become the taxane of choice in treating advanced non-small cell lung cancer across the entire treatment spectrum from front-line to second-line salvage therapy. By ASCO next year, we could be in the enviable position that Genentech enjoyed this year when they reported their Avastin data as we target reporting the first of three clinical studies and late in the first half of next year.

Let me briefly move on to some of the clinical data in ovarian cancer. You've seen some of this data at ASCO and at the Society of Gynecological Oncology. It's a 100 patient study of XYOTAX standard dose amongst relapsed and refractory ovarian cancer patients. These patients, as you recall, fell between anywhere

between 2 and 12 prior chemotherapy regimens, clearly a very advanced group of patients. Similarly, when XYOTAX was applied in combination with platinum in a phase I trial, XYOTAX was demonstrated to be better tolerated at much, much higher doses, as high as 270 milligrams per meter squared, with platinum and importantly, high rates of anti-tumor activity were reported, including in patients who had taxane- or platinum-resistant ovarian cancer.

While direct comparative trials are obviously planned or in progress, I just thought it would be useful to frame our preliminary experience with XYOTAX to that reported for other agents typically used in treating this disease. The data shown here for paclitaxel or Doxil® or Topotecan are from the package insert or a recent cooperative group comparative study of patients with platinum-sensitive disease in a second line setting. So, that is in contrast to the XYOTAX data, which is also platinum-sensitive disease, but this is in a third-line or advanced setting.

And you can see the response data compares favorably, as does the occurrence of side effects, and it was based on these data that the GOG selected to study XYOTAX and compare it to a standard paclitaxel-containing regimen in front-line phase III, which is scheduled to begin in the fourth quarter of this year. As you may know, the GOG is the premier cooperative group that sets the treatment standards for ovarian cancer in the United States. And based on their interest and their review of the phase I and phase II clinical data, we anticipate them initiating this trial on schedule, late in this year in the fourth quarter. And that is a phase III trial, comparing XYOTAX/platinum versus paclitaxel/platinum amongst 1200 patients with the endpoint being similar, or noninferior progression-free survival, but with a superior side effect profile compared to that combination.

I'm sure you're interested in what, if any, impact today's combination or merger announcement will have on our target of venturing into an ex-U.S. partnership for XYOTAX in the first half of the year. And let me just tell you, over the past six months we have experienced significant validation in our XYOTAX phase III program, not only by the GOG adopting XYOTAX for ovarian cancer, but the increasing enrollment rates in our phase III lung cancer trials, coupled with the FDA designation of fast track, has led to a significant growing interest among some of the leading, multi-national pharmaceutical companies.

Now, I mentioned in our prior calls that we had reached tentative financial terms on a potential ex-U.S. deal. But I also commented that there was the prospect of our choosing to pursue a potentially larger strategic global relationship if the right partner and the superior economic terms could be agreed to. With the recent validation on our registration product, the strategy, and product potential in lung cancer, the ability of XYOTAX to replace current marketed taxanes indication is significant, and we believe, could benefit from a strong, global major marketing partner.

The combined product and financial strength that the Novuspharma combination, coupled with the prompting of multi-national pharmaceutical companies' interest in worldwide access to this product opportunity, has convinced us to re-evaluate our prior direction of focusing solely on an ex-U.S. partnership and now, extending those considerations in a more meaningful way to the prospects of a more global relationship.

So, in summary, we believe there are abundant product and financial synergies associated with the proposed combination of CTI and Novuspharma. In addition to the portfolio synergies that I elaborated, these synergies include the potential for label expansion into a large market indication like MDS, with a stronger presence now in the EU, where we will begin to re-evaluate commercial prospects for TRISENOX® and that territory, which could have significant impact on our sales forecast for this product next year and beyond. And, similarly, increasing our EU presence will facilitate the management of our pivotal trial efforts collectively across our three main products. Especially when one considers that 45 percent of our enrollment is stemming from Western Europe.

The addition of Pixantrone to the product pipeline strengthens our presence in the U.S. hematology market and allows us to leverage our existing TRISENOX® customer base when we launch and introduce Pixantrone. We see synergies in early stage development in the, and in European clinical trial management have a similar benefit on our CT-2106 program. We also have a couple of promising new targets in

preclinical development as a result of the merger, which we will not get into today but will be happy to take off-line with our chief scientist.

Remaining development programs will be assessed and prioritized by our integration team with the goal of pursuing only those that add value and minimize the costs related to their development. This is an exciting transformation transaction, transforming transaction for CTI, Novuspharma, and our shareholders as it positions our company to become a significant provider of novel, less toxic and more effective treatments for cancer with one of the strongest late-stage cancer product pipelines made up of proven classes of active chemotherapy agents. It provides us two products from which we believe we can grow a significant commercial presence in the hematology market and another global product, which we believe may have blockbuster potential.

The realizable cost synergies, strong cash position, and combined core oncology development competencies of this transaction coupled with the retention of all of our rights to our products provides us with the flexibility to maximize the commercial prospects with XYOTAX.

So, on that note, I appreciate your spending a long time to hear why we are so excited about this transaction.

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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 and the proposed CTI/Novuspharma merger. 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: 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, and its Current Reports on Form 8-K. 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) will file 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 when it becomes available and other relevant documents filed with the SEC because they will contain important information.** Security holders

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may obtain a free copy of the proxy statement/prospectus (when it is available) 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.

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.