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Conference Call Transcript

GTCB - Q4 2006 GTC Biotherapeutics, Inc. Earnings Conference Call

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the quarter four 2006 GTC Biotherapeutics, Inc., conference call. My name is Michelle and I will be your coordinator for today. At this time, all participants are in a listen-only mode. We will be facilitating a question-and-answer session towards the end of today's conference. [OPERATOR INSTRUCTIONS].

I would now like to turn the presentation over to your host for today, to Dr. Geoffrey F. Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics. Please proceed, sir.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Thank you very much and good morning, everyone, and welcome to the conference call and Webcast to discuss the financial results for the fourth quarter and for the full-year 2006 for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB. I am Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics, and with me today are Jack Green, our Chief Financial Officer, and Tom Newberry, our Vice President of Corporate Communications. Our results for the fourth quarter were released earlier this morning and I hope that you have had the opportunity to review this release prior to our call.

I'm going to begin this call by making a few comments regarding our progress in 2006 and the development of our pipeline and our partnering strategy. Jack will then provide an overview of the financial results for the fourth quarter and the full year and discuss our cash use projection for 2007. We'll then have some further prepared remarks prior to opening the call to questions.

First, as usual, let me remind you of our Safe Harbor statement for this call. Under the SEC Safe Harbor provisions, please note that certain comments today about future events and potential developments are forward-looking statements based on management's current expectations. We urge you to read the Safe Harbor statement noted in our most recent form 10-K filed with the SEC entitled "Important Risk Factors Regarding Forward-Looking Statements." As you know, due to the risks inherent in our business which are described in detail in item 1-A of our 10-K and subsequent 10-Qs, our actual results may differ materially from our current expectations.

So, GTC went through a transformation in 2006, catalyzed by the approval of ATryn® in Europe, the first approval of a transgenically produced therapeutic protein anywhere in the world. We now have two strategic partner relationships with LEO Pharma and LFB-Biotechnologies which enable us to further develop ATryn® and expand our portfolio of recombinant plasma proteins, as well as monoclonal antibodies. We believe that these products will build valuable franchises for us in hematology, oncology, and autoimmune diseases. We also strengthened our balance sheet in 2006, with an ending pro forma cash position of \$51 million. Over recent years, we've been primarily in the position of depending on equity financings to sustain the Company while we completed the European regulatory process.

With the approval of ATryn®, we now have the opportunity to focus on partnering as a strategic activity to help finance our portfolio of proprietary products. Not only will this strategy build on the value of our production technology through a broad portfolio of products, but also it would reduce our dependence on the equity markets for source of cash to fund our growth. There is no certainty in business development, but you can be certain of our recognition of its importance and our commitment to the process. In that regard, I'm pleased to announce that Dr. Ashley Lawton has joined GTC today as Vice President of Business Development. Ashley has over 20 years of business development and management experience, including at Celltech, RepliGen, and Genzyme, where he has successfully led product development and licensing negotiations with a wide range of big pharma and biotech companies.

Let me share with you some of my thoughts on our partnering strategy and opportunities. Our partnerships with LEO and LFB are examples of the strategic focus we have on partnering to support the development and commercialization of our proprietary products. ATryn® is partnered with LEO for Europe, Canada, and the Middle East and we'll be exploring our partnering options for commercialization of this product in the United States, particularly to support the acquired deficiency indications such as DIC. In Japan, plasma-derived antithrombin products have significant sales, and we have initiated discussions with a number of companies who may be interested in supporting ATryn®'s development and commercialization in that territory. Certainly, the interest expressed in Japan in ATryn® and our other products has changed significantly following our EMEA approval.

We will also be seeking partners to support the development and commercialization of our other products in our portfolio. This includes our commercialization rights to recombinant human Factor VIIa as well as the overall development and commercialization of our recombinant human alpha-1 antitrypsin and CD137 antibody programs. The antibody to CD137 receptor appears to have a broad range of potential indications, including cancer and autoimmune diseases, which are clearly beyond our current financial and personnel resources to exploit fully.

An emerging area of interest for us is that of follow-on biologics, otherwise known as biosimilars in Europe. These products are for large markets and there is the clear opportunity to utilize the characteristics of our production technology to produce large volumes of proteins at a competitive cost of goods. As you're aware, there is an important discussion ongoing in both the political and regulatory arenas in both Europe and the United States, and we are following this discussion closely. What seems clear is that legislation embracing follow-on biologics in the United States and Europe will come to fruition. We are planning to develop a position in this area through our business development activities.

Also included in our partnering activities will be external program relationships that provide opportunities to expand the adoption of our technology and help fund the infrastructure we have established to support commercial drug production. Our newest agreement is with PharmAthene for the Protexia product, a biodefense product, which was announced last week. Protexia is a recombinant form of human butyrylcholinesterase, a protein found in small amounts in blood plasma, and which is intended to help remove nerve agents.

This product, like Merrimack's MM-093 is a product which is enabled by the characteristics of our production technology. Both of these external programs meet our partnering criteria since there is a clear commitment to the transgenic reproduced product and we have the opportunity to participate in the financial rewards of success or development as they build on the technical and regulatory expertise we have already established. Underlying all of our partnering activities is our broad patent in the United States, which was granted in 2006 and which expires in 2021, which covers the production of any therapeutic protein in the milk of any transgenic mammal.

Now let me take a few moments to review our major commercialization programs. LEO, our marketing partner for ATryn® in Europe, will be introducing the product at the International Society of Thrombosis and Hemostasis conference in Geneva in July. While the approved indication in hereditary deficiency is a modest one, it does provide a base on which to establish key opinion leader familiarity with our product as we work towards approval in the larger acquired deficiency indications, such as DIC. The market authorization to begin commercialization in Europe was recently transferred to LEO, and they have begun the process in Europe of establishing the reimbursement prices on a country-by-country basis. We have been very pleased with LEO's collaborative efforts in defining the branding and product positioning that will support broader adoption of ATryn® in Europe.

In the United States, we're continuing our pivotal Phase III of ATryn® and the gathering of the historical comparative data from patients treated with plasma-derived products in the hereditary deficiency indication. We expect to file our BLA with the FDA around the end of this year. On

this timetable, we plan to provide an overview of the Phase III results in the second half of this year. As you may recall, we are utilizing an improved dosing protocol for pregnant patients in childbirth for the U.S. study. And this data will also be submitted to the EMEA for review to expand the approved indication to include pregnant patients in Europe.

LEO has always shared our vision of growing the market for action well beyond the current markets of plasma-derived antithrombin by establishing strong clinical data in acquired antithrombin deficiencies. The first acquired deficiency is disseminated intravascular coagulation, or DIC, associated with severe sepsis. LEO has obtained scientific advice from the EMEA and is initiating the opening of clinical sites for the approximately 200-patient Phase II dose ranging study. This study will provide the basis for the design of a subsequent Phase III trial.

We expect patient enrollment to commence shortly and this trial to be completed in approximately 12 months. We believe that data from this study will be available in the first half of 2008. LEO is responsible for conducting this trial and is paying for the material used in the study, and GTC will have access to the data for use in other territories. We look forward to continuing to work with LEO to develop the expanded clinical indication, and to build ATryn® towards what we believe is its ultimate worldwide market potential of 500 to \$700 million.

Our collaboration with LFB will focus initially on the development of recombinant Factor VIIa. Factor VIIa is a product that is used in type A and B hemophilia patients that have developed inhibitors, and we expect this to be the initial indication. LFB will be utilizing their expertise as a developer of plasma-derived products and we will enable the production system with the intent for both of us to share in the program on a 50/50 basis. Today this market is dominated by NovoSeven, produced by Novo Nordisk, which has sales of approximately \$1 billion per year from about 1 kilo of product. Independent analyst estimates are that this market will expand to approximately \$2 billion by 2012 when the last of the current NovoSeven patents expire. We plan to enter the clinic in approximately two years.

The strategic collaboration with LFB includes potential development of additional recombinant human plasma proteins and monoclonal antibodies. An evaluation of these opportunities is in process. Our portfolio of recombinant plasma proteins includes recombinant human alpha-1 antitrypsin, for which we have already established a production herd and we are in preclinical development. The current plasma-derived alpha-1 antitrypsin market is approximately \$250 million per year worldwide. Similar to the ATryn® program, our focus is on establishing a much larger market than that which exists today by offering an unconstrained supply of well-characterized recombinant product. Those with its genetic deficiency are believed to total about 3.5 million worldwide, although it is significantly underdiagnosed and undertreated. This deficiency may lead to emphysema in later life. Alpha-1 antitrypsin therapy may also have potential in other respiratory diseases such as emphysema generally and chronic obstructive pulmonary disease.

We have already discussed our intent to utilize partnerships to develop our antibody to the CD137 receptor in the human immune system. Reports suggest that our antibody has therapeutic value in modulating the immune response, potentially enabling the treatment of solid tumors and autoimmune diseases. We have established a production herd. We are in preclinical development. Both the cancer and autoimmune disease markets are very large, which would require large production quantities that our technology is well-suited to produce.

I will now ask Jack to review our financial results. Jack?

Jack Green - GTC Biotherapeutics, Inc. - CFO

Thank you, Geoff. We ended 2006 in a solid cash position with approximately \$43.8 million of cash and marketable securities on the balance sheet. The third and final equity investment by LFB in early January 2007, as well as payments from LEO for the January 2007 delivery of Phase II clinical material that was manufactured in late 2006 provided us with additional cash totaling about \$7 million, which on a pro forma basis, would put our year end cash at \$51 million, which is consistent with our previous forecast.

During 2006, we had a net increase of \$7.6 million in cash and marketable securities, including financing activities. We used \$24.6 million of cash in operations in 2006. We expect our net cash use to be in the range of \$26 million to \$29 million for 2007. The projected net cash use for 2007 includes forecasted sales of ATryn® in the approved indication and to LEO for the DIC study, as well as receipts from new and existing contracts. The 2007 cash use forecast also includes planned research and development activities in support of ATryn® and our other programs. The Phase II DIC clinical study activities in 2007 will be conducted and funded by LEO.

In December 2006, we completed a refinancing of our senior debt facility with GE Capital. This refinancing provided an additional \$2.8 million of proceeds, while extending the amortization period for a majority of the note. After the refinancing, we have a total of \$10 million of debt outstanding with GE, and we have reduced our annual debt service.

Turning now to our P&L. Revenues were \$2.8 million for the fourth quarter of 2006, compared with \$600,000 in the fourth quarter of 2005. Revenues for 2006 were \$6.1 million, a 48% increase from the \$4.2 million in 2005. Revenues increased primarily due to shipment of initial clinical supply material to LEO for the Phase II DIC study. Cost of revenue and operating expenses were \$41.8 million for 2006, 23% higher than the \$33.9 million in 2005, which were driven primarily by the cost to supply clinical material for the DIC Phase II study.

Total research and development expenses for 2006 were \$25.4 million, an increase of 20% over the \$21.1 million in 2005. The increase was driven primarily by validation costs and costs associated with manufacturing ATryn® from the current process that were in excess of the maximum selling price to LEO, as well as process development activities for increasing the scale of ATryn® manufacturing. Total selling, general and administrative expenses in 2006 were \$9.7 million, a 15% increase over the \$8.4 million of 2005. This increase was due primarily to increased patent and legal costs, the expense associated with the special shareholder vote in the fourth quarter of 2006, and to non-cash expenses associated with equity-based compensation under Financial Accounting Standard 123R.

The weighted average number of shares outstanding increased from 53.6 million shares for the fourth quarter of 2005 to 73.6 million shares in the fourth quarter of 2006. For the year, the weighted average number of shares outstanding increased from 48.7 million shares in 2005 to 66.9 million shares in 2006. The increases in the weighted average shares outstanding primarily reflect the issuance of common stock and financing transactions. The total outstanding common shares, including the common share equivalents associated with LFB's preferred stock, were approximately 88.2 million shares at the end of 2006 and were approximately 91.8 million shares upon the completion of the final installment of LFB's investment in January 2007.

Back to you, Geoff.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Thank you, Jack. Let me take a few moments to make some additional comments.

Turning first to our malaria vaccine program, we have entered into further discussions with the National Institute of Allergy and Infectious Diseases for the funding of this product. We have supplied some further material to the NIAID for evaluation for further development and we are seeking to restore funding of this program. We believe there is value to this product in the treatment and prevention of malaria, which remains one of the major causes of death in children under five years old in developing countries. Let me remind you that we are taking ATryn®'s approval in Europe as the catalyst to build a significant company, both by expanding the market opportunities for ATryn® and by building a portfolio of products which have significant value in the areas of hematology, cancer, and autoimmune diseases.

Try to share with you my vision of how this can be successfully achieved through the expansion of our partnering strategy. We believe we have already demonstrated the value of our technology in the production of recombinant plasma proteins, and these will continue to be an important segment of our Company. We also believe that monoclonal antibodies can be an increasingly important segment of our product portfolio. We have demonstrated from previous collaborations that our technology is well-suited for the production of large volumes of antibodies. In addition, it has become apparent the fucosylation achieved in the production of proteins using this technology has advantages in what is called ADCC, or antibody-dependent cell cytotoxicity. And as a natural feature of this technology, we envision exploiting these types of advantages, not only in our proprietary products such as CD137, but also in the area of follow-on biologics.

Let me remind you of some of our upcoming milestones, including the enrollment of the first patient into LEO's DIC Phase II study, which is expected shortly. An enrollment is expected to take about 12 months with preliminary results available in the first half of 2008. The introduction of ATryn® by LEO at the ISTH in July of this year. The completion of enrollment in the Phase III study of ATryn® for the United States, and our preliminary results from our Phase III study of ATryn® for the United States, which are expected in the second half of this year. And, of course, our filing of a BLA for ATryn® for the U.S. around the end of this year. I look forward to sharing with you our progress on these key milestones and our evolving partnership strategy.

Thank you for listening to our prepared remarks. I will now ask the operator to open the call to questions.

QUESTION AND ANSWER

Operator

[OPERATOR INSTRUCTIONS] Your first question is from the line of Andrew Fein of C.E. Unterberg, Towbin.

Caroline Lee - C.E. Unterberg, Towbin - Analyst

Hi, everyone. It's actually [Caroline Lee] for Andrew Fine. I just wanted to ask first of all, do you have a timeline set for finding a partner in Japan for ATryn®, and additionally if you could give us some sort of an update on how enrollment is going for that Phase III trial in the U.S.?

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Let me deal with the first one -- the last one first, if I may. Enrollment in this trial has been a little slower than we expected, but this is a rare patient population and these types of studies are always a little difficult to predict. But I would say that we're making good progress and the time lines that I've just laid out, I think, are realistic time lines for us at this juncture and we are working very hard to make sure that we execute on those sorts of time lines. I think we are progressing in very good shape. I think as far as Japan is concerned, we presented at the recent BioAsia Partnering Conference and we met with a number of companies there and there was a significant interest in ATryn® and our other products, which clearly that interest has been spurred significantly by recognition of the fact that now we have approval for ATryn® in Europe. This is a very different day now and the validation of the technology is very important in terms of moving those types of partnering negotiations and discussions forward. So I would say that we're still at the early stage in Japan at this moment, but we do have actually a number of companies who are significantly interested. Japan is notoriously slow in terms of partnering agreements, so it's tough to predict. It's certainly something I should hope to be able to update with you as we progress. We're quite encouraged by the reaction which we had in Japan recently.

Caroline Lee - C.E. Unterberg, Towbin - Analyst

Okay, thank you.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

You're welcome.

Operator

Your next question comes from the line of Navdeep Jaikaria. Please proceed.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

Hello, Geoffrey, and everybody. Congratulations on a greater year. I have a couple questions. Firstly, for your fourth quarter, your revenue and cost revenue appears to almost offset each other, so this is, I suppose the cost are in mainly the material delivered to LEO. So basically, are you now providing their material at a loss? What does the schedule look like going forward?

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

I'm going to ask Jack to comment on this, but I'm pretty sure it's a revenue recognition issue, which many companies have to deal with. If I just comment on the last piece also, about the cost issues, realize that in the initial development of the product and getting the product into the commercial arena, there is significant extra costs associated with validation of the technology, we also have process development activities for larger-scale production, which is ongoing at the moment. It's a little different to tease all those things out and we don't break those issues out separately. We do feel confident that as we move forward that our cost of production will move significantly in the right direction in terms of being able to provide a product for commercial production, which has the normal types of margins, which you would expect for biological products. I think what you're seeing here is a process at this moment and we certainly expect as we move forward to have a product that will be very competitive in the commercial arena. But having said that, I'm now going to ask Jack to talk a little bit about specifics of the first point, which you raised.

Jack Green - GTC Biotherapeutics, Inc. - CFO

Sure. So, one of the issues that we have and I think we've talked about this on previous calls is that under revenue recognition requirements, we are forced to defer certain amounts of revenue -- for which we have received cash payments in the quarter, but we cannot recognize the revenue until future periods. This has to do with the issue of having multiple element contracts. Under accounting rules, you are required to spread certain portions of your revenue over future periods, future accounting periods. And we have that situation both in the quarter and in the year in which we've deferred a significant amount of revenue in both the quarter and the year. The amount of deferred revenue we have on the balance sheet, that's revenue that we will recognize in future periods is approximately \$9 million at this point. So that is -- that's a significant amount of revenue that we will be recognized in future periods and in many cases, over a number of years.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

So those ones will not come with costs associated with it?

Jack Green - GTC Biotherapeutics, Inc. - CFO

They will not -- they will not -- the costs associated with those have been recognized in the current period. The revenue associated with those deferrals will be recognized in future periods.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

So you would have \$3.3 million at least for next year? That's pretty good. Can you just briefly review for us the deal you have with LEO? So you will receive pricing and royalty on that's sales? What's going to run the royalty you have?

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

There's two pieces for the arrangements for transferring product to LEO. One is for the DIC study, the Phase II, and later on the Phase III study. And that is transferred to LEO at a fully-burdened cost. That does have a cap on it, which we don't disclose what that is, but that does have a cap on it. And so that's just at a fully-burdened cost. We don't have a margin on the product as such.

As far as commercial sales. We have a transfer price, which includes a margin to us and we also get a royalty arrangement from commercial sales. The way we've described this in the past, if you take the margin, which we expect to have at that juncture together with the royalty, the effective royalty is in the mid- to high teens.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

Thank you very much.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

You're very welcome.

Operator

Your next question comes from the line of Roy Friedman of Edith C Blum. Please proceed.

Roy Friedman - Edith C Blum - Analyst

Hi, Geoff.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Hi, Roy, how are you?

Roy Friedman - Edith C Blum - Analyst

Fine, thanks. Let's go first to the Protexia deal. Since there are no financial terms disclosed in your press release, how are investors to judge the economic relevance of this deal for GTC? Is it reasonable to assume that the economic terms are broadly comparable to those in the ATryn® deal with LEO?

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

I think it's a different sort of deal, actually. PharmAthene is more allied to the type of Merrimack deal, if you understand me, because they actually own the product and we are producing product for them, purifying product for them and we also have a royalty arrangement, but not a royalty arrangement at the same level as we have with LEO in the case with LEO, of course, we actually own the product and therefore we are commercializing the product, or they are commercializing the product for us and that bears a much larger royalty. They're not the same in that respect. As far as the work we're doing for Protexia, we don't -- or for PharmAthene, we don't disclose the actual financial terms and arrangements, but I would say that we are making a commercially normal margin for this product on the work which we're doing for them.

Roy Friedman - Edith C Blum - Analyst

Okay. Does the Protexia deal comprise all aspects of manufacturing, including filtration? I'm asking this because GTC's 2004 license with Nexia included an option for Nexia to license the filtration technology.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Yes, we obviously do -- just remind people, the Protexia program is one which PharmAthene acquired from Nexia originally. Nexia was a Canadian company and so the technology was developed by Nexia and the herd of animals is a herd which is actually owned and controlled by PharmAthene. We're not producing this product within our own productions -- within our own herd so to speak. As far as the purification, obviously the opportunity for the collaboration not only for us to be able to purify the product and be able to use the technology and the capabilities which we've developed in that respect, but also to help support PharmAthene from a regulatory perspective, where we can bring some of the experience that we've had in terms of getting ATryn® approved. So this is a situation where I think it's a great example of us really reaching out where somebody wants to adopt and exploit the characteristics of our technology, we're very happy to do that because that encourages a broader adoption of the technology by other companies. That's why we're very happy to collaborate in this fashion.

Roy Friedman - Edith C Blum - Analyst

So it does include filtration then, the short answer being yes?

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Yes, yes.

Roy Friedman - Edith C Blum - Analyst

Okay. Switching to ATryn®, I have a technical question about the design of the U.S. trial. Recently, another company announced a Phase III study of oral heparin in knee surgery. The protocol for that study makes a distinction between proximal DVT and distal DVT, and it counts all proximal DVTs as adverse events, but it counts only some of the distal DVTs. Does your U.S. ATryn® trial make such a distinction, and if so, what is the rationale for it?

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

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I think the answer to you is, no, it doesn't make a distinction between DVTs and -- but remember, I'm not an M.D., so perhaps not the best to answer that. I'd be more than happy to make sure that your question is also addressed by our clinical people and get back to you, Roy.

Roy Friedman - Edith C Blum - Analyst

Okay.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

But there is no distinction, as far as I'm concerned. Our study in the United States is to assess the incidence of DVTs from clinical symptoms. That will be compared from the active study, which is the patients being treated with ATryn® versus patients who from historical study, in other words, we go into hospitals largely in Europe, where people have been treated with plasma-derived products, and in similar sort of surgical and childbirth situations and compare those two sets of data. That's the nature of the study. But to my knowledge, and I'm pretty confident, we don't distinct between those two types of DVTs.

Roy Friedman - Edith C Blum - Analyst

Finally, Geoff, can you clarify your comment about ADCC and follow-on biologics. I know what ADCC is, but I did not quite get what you were saying.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

The interesting part about ADCC, this has become a subject of great interest, and it really refers to the carbohydrates glycosylation which are associated with many proteins which are produced in mammalian cells, and it varies. In some instances, for instance, some biologicals have no glycosylation associated with them, which is things like human growth hormone and insulin. Other products have glycosylation, but they apparently play a very little part in the activity of the product or the therapeutic benefit of the product. And there are other proteins where this cell cytotoxicity appears to be important and related back what is considered to be a low fucose level. The technology which -- The transgenic technology which we use, appears to produce proteins with low fucose carbohydrates in a natural fashion. Many companies are trying to do this in other systems by modifying those systems to do that. That could give us some benefit in monoclonal antibodies where additional benefit from ADCC could be important.

The issue with follow-on biologics is my expectation that you will not have a situation where you can define a follow-on biologic purely by analytical purposes. I think my expectations of legislation will allow for and I expect the FDA to also want to see some fairly significant amount of clinical development and also safety criteria, but there is the potential, if you develop a follow-on biologic in that fashion, maybe also to have some characteristics of the glycosylation, which could be beneficial in relation to the originator's product. I think this is something which is still a bit of work in progress at the moment, Roy. I think this is something which I thought would be of interest to investors. This technology appears to have some real opportunities in terms of being able to leverage this particular aspect of our glycosylation using this technology.

Roy Friedman - Edith C Blum - Analyst

Thank you, that was helpful. I'll get back in the queue.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

You're very welcome.

Operator

Your next question comes from the line of Allen Seymour of Columbia Management. Please proceed.

Allen Seymour - Columbia Management - Analyst

Yes. I applaud your interest in the follow-on biologics. In particular, I'm interested in -- since most of those things are done, I think in E. coli, maybe you could talk a little bit about besides this ADCC, whether there are any other impediments to your moving ahead in this area, besides financial, I guess, is the real question.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Well, I think the impediments to financial clearly, we link the development of a strategy of follow-on biologics to a partnering strategy and so that's something which we regard as being fairly intimately linked. I think the issue around E. coli is that E. coli doesn't produce proteins with the glycosylation, which I was just describing. So you can use it fairly well for things like human growth hormone or insulin, these types of products. But it's not an appropriate manufacturing system where glycosylation is important. I think people are still considering what types of systems to use going forward.

Obviously, there's a lot of intellectual property around the use of mammalian cell culture, typical CHO cell type of production systems. We believe that we've got some advantages in that respect in terms of having the freedom to operate using our transgenic technology. We also believe, actually, we have some nice production in terms of being able to produce these proteins under the umbrella of our IP in the United States, which goes through 2021. So I think that this is still an emerging area, and I think it's a little early to say exactly how all of this is going to fall out, but I do believe that we have demonstrated very successfully in the past from a number of collaborations we've had on monoclonal antibody production for big Pharma and big biotech in the late 90s that we can produce these proteins very successfully in large volumes using our production system. I think this is an area which we should pay real attention to and one which we will certainly be updating you with as we move forward in the future.

Allen Seymour - Columbia Management - Analyst

Great, thanks.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

You're welcome.

Operator

[OPERATOR INSTRUCTIONS] Your next comes from the line of Cory Kasimov from Oppenheimer. Please proceed.

Cory Kasimov - Oppenheimer - Analyst

Good morning, guys. Thanks for taking the questions. I only have two left here. The first one revolves around the DIC Phase II study. If you could provide us with some additional detail on the design and endpoints of that study, and also how many centers LEO is expected to use to enroll the 200 patients?

And secondly, regarding the biosimilars, I too am encouraged to hear of the company's future plans for this space. And realizing that it's very early on here, can you go at all into potential strategy and who'd you be talking to, whether you'd be partnering with existing generic companies, how, where some of these companies may be of your manufacturing technology. Just any way you can expand on any of that. Thanks a lot?

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Okay. Let me just deal with the biosimilar piece first. I don't want to be too specific, because this is something that's still kind of a work in progress. I hope that'll be something I can update you with a little bit more detail as we move forward. Clearly, there are a number of fairly significant players that are developing in this particular marketplace, which we would regard as potential targets. Just sort of putting -- making sure that people understand, I don't think that we can see that the idea that we would commercialize these products alone in that marketplace,

because clearly it will be an extremely competitive marketplace, and therefore we would certainly be looking to talk to some of the companies which you can probably identify for yourselves, who would be interested in being able to bring these products through and to commercialize these products for us. So I think that's the way in which we believe that could develop, so we would really look at ourselves as being the production system for these types of products. That's where our thoughts are at this moment, anyway. We'll obviously see how that develops through the future.

As far as the DIC Phase II study, it's about 200 patients. I don't know the exact number of sites, but it's not a large number of sites, probably on the order of 15, 20 sites, something of that order and limited number of countries in Europe where LEO has a presence, so that they can actually conduct the study principally themselves. The study is based on -- it's a dose ranging study. It is not statistically powered to demonstrate benefit from regards to survival. Certainly, the Phase III study, which follows on with our expectations is that survival will be the primary end point.

This particular study is based on a DIC score and there is an international-accepted DIC score which will be important in terms of bringing the patients into the study and also being able to measure any improvements in those patients who are treated both in the active arm and obviously in the control arm. The control arm is again standard of care. The standard of care is pretty well antibiotics plus fluids. If a physician wants to use heparin in that arm, he or she can do so. Heparin is not allowed in the action arm. You've heard me discuss this before, we believe that heparin is contraindicated with antithrombin in the treatment of this patient population, and therefore it's not allowed in the active arm. We do not allow Xigris in that particular arm. It's against standard of care.

Cory Kasimov - Oppenheimer - Analyst

Thank you so much for the additional detail.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

You're welcome.

Operator

Your next question comes from the line of Roy Friedman of Edith C. Blum. Please proceed.

Roy Friedman - Edith C Blum - Analyst

Have you budgeted any receipts from Merrimack during 2007?

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Yes, we have budgeted some receipts from Merrimack, but we don't break those out separately into what would be PharmAthene or Merrimack or whatever. Yes, they are budgeted in our figures for this year.

Roy Friedman - Edith C Blum - Analyst

Okay, thank you.

Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

You're welcome.

Operator

[OPERATOR INSTRUCTIONS] Sir, there appears to be no further questions at this time.

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Dr. Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman, CEO

Okay. Well, thank you very much, indeed. Thank you all of you for joining us today, particularly since it continues to be a busy day in the markets and we really appreciate your interest and taking time with us. We look forward to be able to discuss our first quarter results, which will be in early May, and I look forward to being able to tell you about our progress at that juncture. Thank you very much, indeed, everyone and have a great day.

Operator

Ladies and gentlemen, thank you for your participation in today's conference. This concludes the presentation. You may now disconnect. Have a good day.

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