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PRESENTATION

Operator

Welcome to the GTC Biotherapeutics, Inc., third-quarter 2005 earnings conference call. My name is Carlo and I will be your coordinator for today's presentation. At this time, all participants are in a listen-only mode. We will be facilitating a question-and-answer session towards the end of the group's prepared remarks today. (OPERATOR INSTRUCTIONS) It is now my pleasure to turn the presentation over to your host for today's conference, Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics. Please proceed, sir.

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

Thank you very much and good morning, everyone, and welcome to the conference call and webcast to discuss the financial results of the third quarter and the first nine months of 2005 for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB. I am Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics. With me today are Jack Green, our Chief Financial Officer, and Tom Newberry, our Vice President of Corporate Communications.

Our results for the third quarter were released earlier this morning, and hopefully you've had the opportunity to review this release prior to our call. I will begin this earnings call by making a few comments regarding our progress with our antithrombin program and our collaboration agreement with LEO Pharma that we announced yesterday. I will then ask Jack Green to provide an overview of the financial results for the third quarter and the first nine months, as well as comments on where we stand with respect to our cash expectations for 2005 and 2006. I will then have some further prepared remarks about the status of our other programs before opening the meeting to questions.

First 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 our expectations for future achievements 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, particularly Exhibit 99 entitled Important Factors Regarding Forward-looking Statements. As you know, due to the risks inherent in our business, which are described in detail in the Form 10-K and Exhibit 99, our actual results may differ materially from our current expectations.

Before we get started on my remarks about the ATryn program, I would like to direct your attention to an article about GTC in the November issue of Scientific American. This article does a good job of describing our accomplishments and challenges in the development of our technology, our Company, and for ATryn as a product. I believe that this article gives a good portrayal of the sense of transition that we feel here at GTC as we continue to advance on our near-term goal of obtaining approval from the EMEA for hereditary deficiency indications.

Unfortunately, Scientific American will not grant us reprint rights until sometime in December. However, you can see the article, entitled The Land of Milk and Money, on newsstands or for a fee at the Scientific American, website, www.sciam.com. We also have a link to their website on our ATryn update page, which you can get to from the homepage of our gtc-bio.com website.

Let me start our more formal presentation by making some comments about our progress with the ATryn program during the third quarter. First of all, let me review the background. You remember that we filed a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMEA, in January 2004. Since that time we have received and responded to both a consolidated list of questions and an outstanding list of issues. The EMEA is continuing their review of our application. We have not received any significant new questions or issues since our response to the outstanding list of issues this past July.

The agency did recently inform us that they needed to have additional time, through to February 2006, to complete their inspections of our production, manufacturing, and clinical sites and then determine their opinion on the EMEA. It is important to recognize that this is the first time the agency has seen a recombinant protein purified from milk. The agency has been particularly interested in ensuring that we have the assay procedures in place to track the removal of contaminating proteins and establish appropriate release specifications.

We continue to feel that the questions and issues we are addressing are focused on the types of items which could be asked of any recombinant protein submission, with no fundamental issues relating to the safety of transgenic technology. Our role at this point is to provide support for the review of the documentation and the completion of the inspection processes, which are occurring in parallel.

Following what we anticipate will be a positive opinion in February, the file goes to the European Commission for final approval, a process which takes two to three months. This keeps us on track towards achieving our objective of launching ATryn in the hereditary deficiency indication in Europe in mid 2006.

Yesterday, we were able to announce a very important agreement for GTC with LEO Pharma to support the commercialization of ATryn, as well as its development in a larger acquired deficiency indication. LEO is a significant and well-recognized pan-European private pharmaceutical company based in Denmark that has been in business for nearly 100 years.

LEO has about 3,300 employees, 1,000 of whom are in sales and marketing, with products focused on dermatology and critical care. Within this sales and marketing organization are over 250 sales representatives throughout Europe, the Middle East, and Canada focused on critical care applications; and approximately 200 of these representatives are dedicated to Europe.

Importantly, they have a strategic interest in critical care coagulation management with their current low molecular weight heparin product, innohep, which LEO manufactures themselves. As you know, heparin is only effective in the presence of antithrombin. This strategic interest, along with their proven marketing and sales experience and financial strength, makes an excellent fit with the ATryn program.

The market potential of recombinant antithrombin means that the development of ATryn will receive a high level of attention within LEO. LEO had revenues in 2004 of about \$850 million. LEO's profit after taxes was approximately 200 million, with about \$260 million of positive cash flow. LEO clearly understands the value opportunity ATryn provides, based on the acquired deficiency market.

LEO will provide a total of \$73 million in potential milestone payments, distributed over clinical, regulatory, and sales goals. These payments include a total of \$5 million through to the approval of ATryn for the hereditary antithrombin deficiency indication in Europe, with \$2 million of this total being paid upon signing of the agreement. Of the 73 million potential total of milestone payments, 38 million will be made for a series of clinical and regulatory achievements leading to approval of an acquired deficiency indication in Europe.

In addition, LEO will pay a transfer price for all product used either in sales or in their clinical studies; and GTC will also receive a royalty on the LEO sales of ATryn. We anticipate that the blended transfer price margin and royalty payments will be in the mid to high teens as a percentage of LEO's sales.

LEO is also obligated to fully fund the Phase II and Phase III clinical program for the selected acquired deficiency indication. We will have unrestricted access to all Phase II data for use in any filing we would choose to do in our own territories. Should we choose to exercise our option to support half the clinical cost of a Phase III acquired deficiency study for LEO's territories, we will have access to that data for any filings in our own territories, including the U.S. and Japan.

It is clear in the discussions that we have had with LEO that they both understand and appreciate this value-building concept, making both a significant financial contribution and access to expertise and resources that enables both organizations to participate in this growth opportunity. I anticipate that a final determination of which acquired deficiency indication to pursue first will be made in the middle of 2006.

The commitments by LEO to the royalty arrangements, payment for all product sales and clinical supplies, investments in sales and marketing and product launch, together with the support for the clinical costs for the acquired deficiency indication are significant financial benefits to GTC, beyond the success-based milestone payments. We believe that this is a broadbased collaborative agreement providing a strong foundation for GTC to be a significant participant in the development of ATryn.

The agreement enables us to pursue the strategy we have discussed with you a number of times, of launching in Europe and using that base to subsequently establish our own commercial presence in the United States. We continue to expect to develop a presence in Japan through a partner and expect to begin discussions there in 2006.

We have talked for sometime about creating value in ATryn through building on the approval in hereditary deficiency to develop a broader clinical program and commercialization strategy in acquired deficiencies, and this is an important step in delivering on this strategy.

Let me now turn to our progress in our hereditary deficiency clinical program for the United States. During our second-quarter call I reported we had begun the patient recruitment process, and we are continuing to accelerate the identification of both surgical and pregnant patients that will require procedures that may benefit from prophylactic treatment with ATryn.

You may recall that we are required to include at least 17 patients in addition to the 14 that were treated in the European study in the active arm. We are anticipating completing enrollment in the study by the end of the third quarter of 2006. Since the control arms of the study must be reasonably matched to surgical and childbirth procedures experienced in the active arm, we expect to complete the 35-case historical control arm at about the same time as the active arm. We are planning to submit a Biologics License Application to the FDA around the end of 2006 based on this enrollment schedule.

Let me now hand the discussion on this call over to Jack Green to provide a review of the third-quarter 2005 results as well as to expand on our views on our 2005 and 2006 projections. I will return after that to talk about the progress in our other programs. Jack?

Jack Green - GTC Biotherapeutics, Inc. - CFO

Thank you, Geoff. Revenues were 1.2 million for the quarter, an increase from the \$900,000 in the third quarter of 2004. Revenues for the first nine months of 2005 totaled 3.5 million, essentially flat with the 3.4 million reported for the same period in 2004. Future revenues may vary on a quarter to quarter basis, due to the nature and timing of milestone-based research and development revenues.

The cost of revenue and operating expenses were essentially flat in both the quarterly and nine-month comparisons. The reduction in cost of revenue was offset by an increase in research and development costs associated with the initiation of the U.S. clinical study for ATryn and the development in the alpha-1 antitrypsin and CD137 programs.

GTC's total net loss for the quarter was \$6.7 million or \$0.14 per share, compared with \$7.2 million or \$0.18 per share in the third quarter of 2004. The total net loss for the first nine months of 2005 was \$21.8 million or \$0.46 per share, compared to \$22 million or \$0.60 per share for the first nine months of 2004.

The per-share results were affected by an increase in the weighted average number of shares outstanding from 38.8 million shares for the third quarter of 2004 to 49.4 million shares in the third quarter of 2005. The weighted average number of shares outstanding increased from 36.9 million shares for the first nine months of 2004 to 47 million shares for the first nine months of 2005.

The increases in weighted average number of shares outstanding primarily reflect the issuance of approximately 6.4 million shares of Common Stock in a registered direct placement in March 2004; the issuance of approximately 7.7 million shares of Common Stock in a registered direct placement in January 2005; and the issuance of approximately 4.6 million shares of Common Stock in a private placement in August of 2005. The net proceeds to GTC from these offerings totaled approximately \$31 million. GTC had approximately 51.5 million shares outstanding as of October 2, 2005.

We ended the quarter with approximately 20.5 million in cash and marketable securities. Excluding the effect of the equity financings, we are expecting a net use of approximately \$23 million of cash and marketable securities in 2005, which reflects the \$3 million of milestone payments for approval of the hereditary deficiency indication that we now expect in the first half of 2006.

We also expect a net utilization of 21 to 25 million of cash and marketable securities in 2006, which includes supporting ATryn's hereditary deficiency clinical program for the United States as well as scale up in process development and preclinical studies in both the alpha-1 antitrypsin and CD137 antibody programs.

We recently established a \$50 million universal shelf registration to provide us with the flexibility to execute an appropriate financing transaction as market conditions develop. We believe that our projected news flow of regulatory and clinical milestones with ATryn in Europe and in the U.S., as well as our other programs, will provide for a variety of options to meet our cash needs beyond the second half of 2006. Geoff?

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

Thank you, Jack. I would like to now spend a few moments on our other programs, particularly our recombinant plasma protein programs. We are moving into further development with our recombinant human alpha-1 antitrypsin program. As you may recall, we reported to you that we have been very successful in developing highly-productive animals with expression rates as high as 20 grams per liter of milk and good milking volumes. We have already begun a breeding program to start a production herd.

One of the well-established markets for the plasma-derived alpha-1 antitrypsin is in the treatment of patients with an hereditary deficiency that are prone to developing emphysema. This is a prophylactic treatment for a chronic disease.

Our goals for the coming year are to develop a process design that will consistently deliver a high-purity product at large scale; breed further animals for the production herd; and to start preclinical studies and aim to file an IND around the end of 2006.

Recombinant human albumin program has completed production of qualification batches; and samples of this new material is being provided to potential customers. These customers are evaluating the use of our albumin product as an excipient in their drug formulations. Albumin is also used in other settings, such as being part of the nutrient mix in the media used for cell culture. Some of our potential customers are interested in this application of our product. In the longer term, we remain interested in entering the therapeutic blood volume expander indication that represents the bulk of plasma-based albumin sales currently.

It is interesting to note that MM-093, the program where we are producing alpha-fetoprotein for Merrimack Pharmaceuticals, is also a recombinant plasma protein. The alpha-fetoprotein, unlike antithrombin, albumin, or alpha-1 antitrypsin, is normally present in only trace amounts in our plasma and therefore is not a product developed by the plasma fractionation industry. This is another example of the power of our technology to enable markets for recombinant plasma proteins that are not well developed from the human blood supply.

Merrimack recently announced the completion of enrollment in their Phase II study of MM-093 as a treatment for rheumatoid arthritis, and the initiation of a Phase IIa study in psoriasis. During the quarter, we established a new contract with Merrimack to continue supplying them with alpha-fetoprotein in their expanded clinical program.

We also have a strategic interest in antibody programs, both because of the unique patent position which we hold in producing antibodies transgenically and because of the power of our technology to develop very large-scale production capacity for an order of magnitude lower capital investment than would be required in cell culture.

We now have animals that produce significant quantities of the CD137 antibody, and we have been advancing this into breeding of a herd. We also are planning on development of downstream purification processes for large-scale production, and a preclinical study program in 2006.

CD137 is an agonistic antibody that binds to the CD137 receptor on immune system T-cells, stimulating an immune response. Initial preclinical work indicates that this can have a therapeutic value in treating solid tumors. If this concept is borne out in further preclinical and clinical studies, the CD137 antibody would be required in very large quantities as a potential treatment for a variety of cancers.

The CD137 program also illustrates our ability, as a result of having an established production platform, to access in the early-stage research program -- in this case from the Mayo Clinic -- and to add value by enabling a commercial production system as a starting point for a full clinical and commercial development program.

In summary, our progress with ATryn both in Europe and the USA remains the focus of our attention in our proprietary programs. We are committed to achieving our timetable for launching ATryn in the middle of next year in Europe and becoming the first company to bring a transgenically derived therapeutic protein to market. We are very pleased to have entered the collaboration with LEO, meeting all the major criteria we set for this partnering agreement.

Remember, the overarching importance of ATryn approval is not only unlocking the significant potential of the ATryn program but also unlocking the value of our entire portfolio of future programs and opportunities. I very much look forward to the end of February, when I am optimistic we can achieve a successful outcome to the EMEA review. Thank you for listening to our prepared remarks, and I will ask the operator now to please open the call to questions.

QUESTION AND ANSWER

Operator

(OPERATOR INSTRUCTIONS) Conzance Hzia with SG Cowen.

Conzance Hzia - SG Cowen - Analyst

Thanks for taking my question and congratulations.

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

Thank you. Good morning.

Conzance Hzia - SG Cowen - Analyst

I just have one quick question and that is, are you able to provide us any guidance on how you will be recognizing any payments from LEO Pharma on your P&L going forward? Will there be an amortization schedule for this?

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

Well, I'm going to hand this over to Jack Green to comment. But my guess is that he's unlikely to make a commitment to how that will be recognized at this moment.

Jack Green - GTC Biotherapeutics, Inc. - CFO

I think, Geoff, you answered that very well. We certainly will have to amortize some portion of the payments over a reasonable period of time. But we will have to work with our auditors to make sure that we are in compliance with the revenue recognition standards of both FASB and the SEC. So we will be working that out between now and the time we recognize those payments within our P&L.

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

I would just add to that comment, we continue to be very focused on cash within the Company. Therefore, certainly the way in which we structured the arrangements around the LEO deal was very much focused on what works for us from a cash perspective, rather than trying to manipulate the agreement in some fashion to meet particular revenue recognition issues. So that is something we will work on going forward.

Conzance Hzia - SG Cowen - Analyst

Okay, great. You also mentioned partnership discussions with potential Japanese partners. I am sorry I missed this. Did you say that you have already engaged in discussions?

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

We have had some discussions, but I wouldn't really go out (indiscernible) anything more than just tentative dialogue. I think it's important to recognize that antithrombin already has a very significant market in Japan, where it is actually approved for disseminated intravascular coagulation. So it's an area of significant interest.

Why we said that we would probably initiate those discussions in the early part of 2006 is that clearly we are expecting to get EMEA approval around that time. I think that will be an excellent catalyst for us to be able to initiate those discussions and move those forward at a reasonable pace. So we certainly intend to start to engage some of -- potential partners in Japan early in the first quarter of next year.

Constance Hzia - SG Cowen - Analyst

Okay, great. Thank you very much.

Operator

(OPERATOR INSTRUCTIONS) Roy Friedman with Edith C. Blum .

Roy Friedman - Edith C. Blum - Analyst

I would like to go back over the milestone breakdown between HD and acquired deficiency. Did you say this morning that 38 million was for acquired, which would leave 35 million for HD? And is the 2 million upfront included as part of that 35 million, if my calculation is correct?

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

Let me clarify that. We are saying that there's 5 million of milestone payments through to the approval of hereditary deficiency, which -- and GTC is responsible for getting the hereditary deficiency approval in Europe. Of that 5 million, 2 million will be paid, actually, and is being paid on signing.

In addition to that, there is a further 38 million associated with meeting clinical and regulatory milestones associated with an acquired deficiency. And we haven't broken those down into any particular elements in the public domain, and we don't plan to do that. But that will be through that whole development program.

Roy Friedman - Edith C. Blum - Analyst

Okay, so subtracting the 38 from the 73, is it fair to say that 35 million then has to do with HD?

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

No, I don't think that that is -- actually there are some sales milestones in there as well on the order of 30 million. So if you add those pieces up, you get to 73.

Roy Friedman - Edith C. Blum - Analyst

Okay, thank you. Now on the blended mid to high teen royalty and transfer price from LEO, how much if any of that must be passed through to third parties for IP licenses?

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

That is a fair question, but I am not sure that is one which we would discuss in the public domain. But we are actually I think in very good shape as far as that is concerned. Of course, we own the intellectual property to our own technology. So I think that that is something which we're not really prepared to discuss at this juncture.

Roy Friedman - Edith C. Blum - Analyst

Okay, but the mid to high teens is a gross, as opposed to a net rate. Is that correct?

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

That is correct.

Roy Friedman - Edith C. Blum - Analyst

Does the royalty rate from LEO have steps to increase if sales thresholds are met?

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

Could you repeat the question?

Roy Friedman - Edith C. Blum - Analyst

Does the royalty rate from LEO have any steps in it that would increase the rate if certain thresholds are met?

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

No, it doesn't. But there is the potential, since we also have a transfer price, there is potential for increasing royalties as we move forward. But obviously that is a complex to perform and also determined by selling prices; and then obviously that is something which is yet to be determined at this moment.

Roy Friedman - Edith C. Blum - Analyst

Okay, moving to the Japanese market, would Japanese clinical studies be required? Or would they be able to use the European data?

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

I think the answer to that is, I can't answer specifically; because obviously we have not explored that at the moment. But if you look at what most other companies have to do under these circumstances is that you can use the European or U.S. data usually as the basis. But Japanese regulatory authorities normally require some clinical work to be done to ensure that there are no elements in terms of different genetics, which could be relevant to safety or efficacy issues as far as a product. That is not just relating to our product; it is relating to any product.

So sometimes those studies are done in Japan, sometimes they are done in some area, other appropriate areas of Southeast Asia. But normally there would be some additional clinical studies associated with that. I think that is why it is helpful for us, or we would expect to have a partner to help us with that particular type of clinical program.

Roy Friedman - Edith C. Blum - Analyst

Okay, is it reasonable to assume then that a possible launch there would be in, let's say, the 2008 to 2010 period?

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

I think you can speculate that; I think it is way too early for me to comment on that. I would like to get the partner first, and then we can define the clinical program. But I think that is somewhat speculative, at this juncture, on this call.

Roy Friedman - Edith C. Blum - Analyst

Okay, finally, the albumin program. That is the one program that you didn't mention today in the press release or in your prepared remarks. Is this still an active program?

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

I actually did discuss it in my prepared remarks.

Roy Friedman - Edith C. Blum - Analyst

I'm sorry. Then, I missed it.

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

Let me just briefly, just to reiterate the point, we commented that we produced qualification batches and samples from those batches were being reviewed by a number of potential clients for the use of the product as an excipient. We also have a number of clients who are looking at it for the uses in supporting cell culture media.

We continue to be interested in the blood volume expander market at a later age, but I think excipient market and the cell culture market is probably the earlier markets which we can aim for at this juncture. But that is progressing. Clearly our focus at this moment is getting ATryn approved, and we are being a little cautious about the way in which we progress some of these programs from a financial perspective, which I think is appropriate. So we need to do first things first.

Roy Friedman - Edith C. Blum - Analyst

Okay, one more detail regarding the acquired deficiency program with LEO. You mentioned that you have the option to fund half of the Phase III program. If you do that, do your royalty rates go up?

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

No, I think that that is not the benefit to us. The benefit is in the way in which the agreement is structured, we have the option to participate in the funding of that program, but not the obligation. That is a huge benefit to GTC. So depending on our financial circumstances at that juncture we can make some choices. But it means that the progression of that trial to unlocking that value of the acquired deficiency program won't be inhibited by our own financial status.

I think the important value to us is to be able to access the data, in order for us to be able to use that for regulatory submissions in the United States or other parts of the world, which we retain all rights to, as our own territories, and Japan of course. So that is a tremendous value for us to be able to do that.

Roy Friedman - Edith C. Blum - Analyst

I just assumed that if you were funding part of the program you would have some economic benefit beyond just accessing the data.

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

That is a huge -- sorry, I didn't mean to interrupt you, but that is a huge economic benefit, to be able to access the data in order to be able to submit that to, for instance, the United States, which is of the largest, most valuable market in the world, which we believe we have got a tremendous opportunity for. So I think that that is a very real value to us.

Roy Friedman - Edith C. Blum - Analyst

Okay, thanks for that clarification. That is it for me for now. Congratulations on the LEO deal.

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

Thank you. Thank you for your questions. They were very helpful. Thank you.

Operator

George Marshall with Boenning & Scattergood.

George Marshall - Boenning & Scattergood - Analyst

Ray Friedman asked my questions for the next two quarters. Thank you.

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

Thank you very much indeed. Good to hear from you.

Operator

(OPERATOR INSTRUCTIONS) Sir, we have no further questions at this time. Back over to the group for any further comments.

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

Okay, thank you very much indeed, everyone, and thank you for joining us today for the review of our financial results. We expect to be able to discuss our fourth-quarter 2005 results early next year. We look forward to speaking with you again at that time, and of course that will hopefully be a time of a really momentous transition for GTC, as we move through the approval of ATryn with the EMEA. So we look forward to that with great anticipation. In the meantime, you have a great day and thanks for joining us.

Operator

Ladies and gentlemen, this concludes your presentation. We thank you for your participation in today's conference, and you may now disconnect. Good day.

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