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Conference Call Transcript

GTCB - Q3 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

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PRESENTATION

Operator

Good day ladies and gentlemen, and welcome to the Third Quarter 2007 GTC Biotherapeutics, Inc. Earnings conference call. My name is Nicole and will be your coordinator for today. At this time, all participants are in a listen-only mode. We will conduct a question and answer session towards the end of this conference.

(OPERATOR INSTRUCTIONS)

I would now like to turn the call over to Dr. Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics. Please proceed, sir.

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

Thank you very much and good morning, everyone, and welcome to the conference call and webcast to discuss the financial results at the third quarter 2007 for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB.

I'm 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 in the third quarter were released earlier this morning and I hope that you've had the opportunity to review this release prior to our call. I want to begin this call by providing an overview of our progress on our strategic and operational goals and Jack will then provide an overview of the financial results of the third quarter and then I will then have some further prepared remarks prior to opening the call to questions.

Last of all, as usual, let me remind you of our Safe Harbor statement for this call and 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 1A of our 10-K and subsequent 10-Qs, our actual results may differ materially from our current expectations.

On our last conference call, I spoke at length about our strategy for building GTC into a significant company. The importance of a well-defined strategy is that it provides valuable guidance to investors and the long-term direction and objectives of the company and the potential value of the programs in development. For many investors, our progress on shorter-term milestones and news events is an important driver in their investment

decisions, together with the guidance on the identification of emerging milestones and events. I will continue to provide guidance on all these issues in these quarterly updates.

With regard to our strategy and longer-term objectives for GTC, this is continuing to crystallize and strengthen in a way which I believe will provide a real identity and clarity to GTC's opportunities and value. The transition which has taken place at GTC enables us to focus on a coherent portfolio of products which leverage the special characteristics of our production technology, having validated our commercial scale production platform through the approval of ATryn®.

The measure of GTC is not the size of the market for ATryn® in the hereditary deficiency indication, which we recognize is modest. It is the size of the markets for the portfolio products which are largely known chemical entities and which leverage the same production platform and infrastructure as ATryn®. The uniqueness of our production technology provides a competitive advantage with these products by enabling us to produce large volumes of products at attractively competitive manufacturing costs and capital investment.

Many instances, particularly with recombinant plasma proteins, involve products that are difficult to express in any other manufacturing system. These characteristics also provide the opportunity to develop markets significantly in excess of those which exist today in indications and for geographies where the pricing of existing products precludes their development in commercialization from current technologies. All of this is supported by our unique production infrastructure and our broad and strong intellectual property position.

So, today we have a portfolio of recombinant plasma proteins with our lead product ATryn®, recombinant antithrombin, together with recombinant Factor VIIa being developed with our partner LFB, recombinant alpha 1-antitrypsin or AAT and recombinant Albumin. It is our plan to add further to this portfolio as opportunities arise to do so. Our clinical focus with this portfolio is in genetics deficiencies in hematology.

Our previously demonstrated ability to produce large volumes of monoclonal antibodies has led us into the follow-on biologics or FOBs or biosimilars space and we have initiated the first program in this strategy with CD20 monoclonal antibody, the same target at Rituxan. This is under our collaboration with LFB. We have already identified a number of further potential products for introducing to this portfolio, each with already established multi-billion dollar markets.

Let me also remind you that in addition to intellectual property covering our production technology through 2021 in the United States, we also believe we are outside the Cabilly patents and that the natural glycosylation profile of our production technology with low fucose levels has the potential to provide advantages in antibody-dependent cell cytotoxicity or ADCC.

The market for monoclonal antibodies was greater than \$22 billion in 2006 and is expected to continue to grow significantly over coming years. Some patents have already expired and many will expire over the next ten years.

In Europe, the EMEA has defined guidelines for recombinant proteins such as human growth hormone, erythropoietin, and insulin and is ahead of the U.S.A. at this time. Legislation in the U.S. Congress remains a work in progress, but it is widely believed that legislation covering FOBs will be enacted over coming months. The potential pressures of the cost of healthcare strongly supports the likelihood of these opportunities becoming a reality.

The increasing size of the population wanting to access these drugs, the drive to reduce the cost burden on payers and the opportunity for new markets are all part of the opportunity which we want to address. These are already highly competitive markets and innovators will defend these markets and are likely to introduce second generation products.

It is our plan to seek partners for these programs who have the commercial and financial capabilities to effectively compete in these markets and we are already active in seeking such partners. Our FOB strategy will provide a clinical focus in the areas of oncology and autoimmune diseases in indications where many of these products have already been developed.

So, having painted the big picture, let me now turn to our progress with our near-term milestones and objectives. High on this list is our filing for a biologics license application for ATryn® in the HD indication in the United States. We are planning to complete enrollment in the 17-patient active arm of the study in the current quarter, enabling us to provide top-line guidance on the data by year end. Together with the data on 14 patients, which provided the basis of the EMEA approval, this gives 31 patients in this active arm.

These patients include both surgical and pregnancy patients and it is expected that the pregnancy data will enable us to submit for a label expansion in Europe later in 2008. We were very pleased to be advised by the FDA during the quarter that ATryn® has been given fast track designation. In addition, the FDA has provided permission for GTC to submit a rolling BLA.

We expect to initiate that submission in this quarter, starting with the manufacturing sections and to complete the clinical and safety sections in the first half of 2008. The rate limiting step in this process is the 90-day antibody data which is collected after the 'last patient in' has been treated. Similar antibody data was supplied in the EMEA package, which was previously approved.

Our fast track designation also gives us the opportunity to apply for priority review, which we intend to do. If granted, this will lead to a six-month review process which points to a potential approval around year-end 2008 and a market launch in 2009 in the United States.

In preparation for this event, we have initiated a number of partnering discussions to support the commercialization of ATryn® in the U.S.A. and the further development of ATryn® in acquired deficiency indications. These negotiations are proceeding on plan and, although business development is a highly unpredictable process, we would like to draw these to a conclusion around the end of this year and we have included some assumptions in that respect in our current financial forecasts.

As we have noted before in these calls, we believe the U.S.A. to be a major untapped potential for ATryn® since there is a very limited competition from the existing plasma-derived product. As in Europe, the key to unlocking this potential is the continuing development of ATryn® in acquired deficiency indications. In the case of DIC or disseminated intravascular coagulation in severe sepsis, the indication which LEO is pursuing with ATryn® in Europe, we believe the market opportunity in the U.S.A. alone to be in the range of \$2 billion to \$3 billion.

This is an appropriate lead-in to transition to the progress of ATryn® in Europe. As was previously announced, LEO introduced ATryn® to the medical community in Europe at the ISTH meeting in Geneva in July and they are launching ATryn® on a country-by-country basis as pricing arrangements are established. They are initiating the first launch in the United Kingdom and then following up in other European countries over the next 12 to 18 months.

Pricing in Europe is a complex issue and LEO is seeking to achieve a premium pricing strategy overall, although price of plasma derived products are highly variable throughout Europe. Initial sales of ATryn® are anticipated to occur in the UK later in this quarter and additional countries will be added as pricing is established. LEO is also preparing a regulatory filing in Canada in mid-2008 for ATryn® in hereditary deficiency and we're planning for approval by the end of 2009. More information about LEO's branding and plans for ATryn® can be found at leo-pharma.com and you can view the product packaging for Europe on our own website at GTC-bio.com.

LEO has also initiated enrollment into the Phase II dose ranging study in DIC in severe sepsis. Enrollment to date has been slower than planned and LEO is taking steps to increase enrollment, including the opening of further sites to maintain the plan schedule. To date, 26 sites have been opened. The schedule seeks to have the last patient in to enable top-line results to be available around the end of 2008. That remains our objective and we'll get a better handle on that timeline as the trial progresses into the first half of next year.

Let me now turn to the Factor VIIa program, in which we are partnered with LFB. We are currently developing the production animals for this program, using our proprietary beta casein promoter system and that work is progressing well and on schedule. Our clinical development plans, for which LFB is principally responsible, and envision a similar clinical development program as that used for the approval of Novoseven in the treatment of hemophiliacs that have developed inhibitors to Factors VIII or IX.

The pre-clinical work, including the characterization of our production animals, together with the product characterization sufficient to support an IND is expected to take us into the fourth quarter of 2009 and into the clinic early in 2010. These are not large trials and we plan to complete a clinical package in 2012 supporting approval in this indication, which is in line with when Novoseven comes off patent. Depending on the timing and the substance of FOB legislation, it is possible that a modified clinical development plan may be defined and we will continue to monitor that opportunity.

As a reminder, today's market for Factor VIIa is \$1 billion, which is supplied by approximately a kilo of product. The market is predicted to double over the next five to six years and there is significant room to do so in broader clinical indications and other geographies. The extraordinary high price of Novoseven is a major barrier to maximizing patient access and we see that as a significant opportunity for us to exploit the cost advantages of our technology.

Competition will develop in this space, including the development of pegylated versions of this protein and including from Novo Nordisk themselves, would be strongly of the opinion that this market remains significantly underserved and represents a major opportunity for GTC and LFB to exploit.

Although ATryn® and Factor VIIa represent our priorities at this juncture, our program in alpha 1-antitrypsin is continuing to move ahead steadily. Our development objective at this time is to extend the half life of AAT to provide an attractive competitive product of plasma-derived products for IV delivery to treat patients with hereditary deficiencies in AAT.

These patients have a strong likelihood of developing emphysema over time without weekly injections of AAT. The market in the U.S.A. is dominated by ProLastein from Talecris, which today is an approximately \$225 million product. The future may lay in the development of a pulmonary delivery of this product which, in turn, may open up the opportunity of a broader range of clinical indications in which elastase destruction of the lung and resulting inflammatory conditions play a part.

I will return towards the end of these prepared remarks to provide some concluding comments, but before I hand over to Jack, let me briefly comment on our partnering strategy. We have a number of partnering opportunities, which we are continuing to advance at the present time, both in the near term as part of our planned activities for the fourth quarter and longer term for strategic development of recombinant plasma protein and monoclonal antibodies portfolios.

High on our list is to establish partners for our programs to support both the commercialization and further development of our products, including upfront and milestone payments. Our broad and well defined low risk portfolio of known therapeutic products, including late-stage opportunities such as ATryn® in the U.S.A., is an important part of our partnering strategy. We are confident that our partnering efforts will make an important contribution to sustaining the forward momentum of GTC and its portfolio of products.

At this point, I'm going to ask Jack to provide an overview of our Q3 financial results and I will then have some further comments before opening the call to further questions.

Jack Green - GTC Biotherapeutics, Inc. - CFO, SVP

Thank you, Geoff. Revenues were approximately \$2.6 million for the current quarter, a 273% increase from the approximately \$700,000 in the third quarter of 2006. The revenues in the third quarter were primarily from programs with PharmaAthene for services provided in developing their Protexia product and with Merrimack Pharmaceuticals for MM-093.

Third quarter revenues in 2006 were primarily from services provided to Merrimack. Revenues for the first nine months of 2007 totaled \$10.8 million, 228% increase compared to the \$3.3 million in the first nine months of 2006. The revenues for the nine month results were primarily due to the sale of ATryn® to LEO for use in the Phase II DIC clinical study, as well as revenue from Merrimack and PharmaAthene programs.

Going forward, we project that the primary sources of our operating revenues will be from the sales of ATryn® to LEO for use in the DIC clinical study, from partnering milestones, from the external programs with Merrimack and PharmaAthene and from LFB in the development of Factor VIIa and CD20.

Cost of revenues and operating expenses totaled \$10.9 million in the current quarter, down 2% from the \$11.1 million total in the third quarter of 2006. Cost of revenue and operating expenses totaled \$37.6 million for the first nine months of 2007, up 20% from the \$31.4 million for the first nine months of 2006. The increase in the nine month cost year to year included the cost of goods sold related to inventories sold to LEO in 2007 to support the increased revenues as well as the inventory writedown we discussed in the second quarter of 2007.

Cash and marketable securities at September 30, 2007 totaled \$21.8 million, a \$22 million decrease compared to \$43.8 million at December 31, 2006. We project cash and marketable securities at the end of 2007 totaling \$20 million to \$22 million, assuming completion of partnering transactions currently under discussion as well as projected cash receipts from existing partnering arrangements, including our programs with Merrimack and PharmaAthene.

While we have not yet finalized our budgets for next year, we anticipate a cash use on the order of \$28 million to \$30 million for 2008. We believe that our current cash resources and anticipated receipts from partnering programs, both existing ones and those in our current forecast, will be sufficient to support our operations well into the second half of 2008 when ATryn® is planned to be at or near approval with the FDA. Geoff?

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

Thank you, Jack. So, our news flow over the next few months continues to be driven primarily by ATryn®. Our emerging portfolio of products is beginning to provide a series of milestones in 2008 and 2009, which will broaden the range of news events across our pipeline. And let me take a few moments to review our anticipated news flow over the next two years.

For ATryn®, our major milestones are planned to include, firstly, initial sales by LEO in the approved indication in the UK in the fourth quarter of 2007, in this current quarter, to admission of the first section of our BLA in the United States in the current fourth quarter and the final section in the second quarter of 2008 and obtaining top-line results of the instance of thrombotic events in our U.S. study by the end of 2007 with full results available in the second quarter of 2008.

And next, entering a partnership for the further development of ATryn® in the U.S. by the end of 2007 and submission by LEO for the approval of ATryn® in the hereditary deficiency indication in Canada in the middle of 2008 with an approval planned in 2009. Also submission by Leo in the EU to expand the approved indication to add pregnant patients by the end of 2008 utilizing the data generated in our U.S. study.

Next, FDA approval of ATryn® in the hereditary deficiency indication by the end of 2008, assuming we obtain priority review status by the end of the first quarter. And followed by top-line results, the Phase II DIC by LEO by the end of 2008 and initial commercial sales in the United States in the hereditary deficiency population in the first half of 2009.

In our other programs, our planned milestones are, first of all, to establish the production system for our CD20 and the follow-on biologic by the end of 2008 and develop our regulatory strategy as the appropriate legislation is passed.

To complete pre-clinical studies with LFB and submit an IND for the Factor VIIa program by the end of 2009. Complete pre-clinical studies and submit an IND in our alpha 1-antitrypsin program in the first half of 2009 and complete pre-clinical studies and submit an IND in our CD137 antibody program in the first half of 2009.

I hope you can tell from everything going on that we are very excited about our progress in transforming into a focused products-based company with a rational partnering strategy. Our work across the range of opportunities we have, with proven therapeutic proteins, holds great promise in our goal of developing large market products with relatively low risk.

I firmly believe that this is the right path to delivering maximum shareholder value. And I very much look forward to updating you on our progress in future calls. So, thank you for listening to our prepared remarks and I now refer to the operator. Please open the call to any questions.

QUESTION AND ANSWER

Operator

(OPERATOR INSTRUCTIONS). Your first question comes from the line of Stephen Dunn with Dawson James. Please proceed.

Stephen Dunn - Dawson James Securities - Analyst

Good morning, Geoff and Jack. It looks like things are going to be very exciting for you.

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

Good morning. Thank you very much indeed. Yes, we're very much looking forward to the next few months.

Stephen Dunn - Dawson James Securities - Analyst

Yes, the prepared remarks were quite thorough. I just have some, I guess, housekeeping questions to put a finer point on things. Can you shed any light on LEO's -- I guess what -- if they've made it clear to you where their initial thrusts will be with the reimbursements. Obviously, UK is first, but are they going after the big five in Europe first or can you give me any color on the order of the countries?

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

Yes, I think certainly that's their focus, clearly, is to -- is to aim for the larger markets in Europe. Because the plasma proteins in Europe, many of them have been only approved in a limited number of countries, the pricing of plasma derived products is actually quite variable throughout Europe. And their strategy has certainly been to look for a premium pricing strategy overall. And therefore, you need to be very careful where you introduce a product initially.

In fact, rather surprisingly, the UK is a relatively high priced market. And so this is an appropriate place for them to start and to establish the pricing strategy before they move into some of the other markets. But this is something which they're very familiar with. They understand the European market very well. This is why we entered into this collaboration with LEO and we obviously are leaving it to them to develop that strategy. But we're very encouraged by the progress they're making.

Stephen Dunn - Dawson James Securities - Analyst

Okay. I guess, more of a philosophical question on partnership strategies. You -- so far you work with LEO and LFB of France. I guess, are you looking -- in the back of your mind, are you looking to just stick with those partners, let's say, for Europe for all the future indications or are you looking to spread the partnerships among different players?

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

Well, let me answer that in two parts. I think, with regard to recombinant plasma proteins, we obviously have a very strong relationship with LFB. And under our collaboration arrangements with LFB where we develop products in which we jointly finance, they have full commercialization rights in Europe, just as we have full commercialization rights in the United States. And then we share the rest of the world under the arrangements we have.

So, in the recombinant plasma protein field, that -- we probably would expect to work with LFB for the majority, if not all of those proteins. And I think with regard to any of our other -- well, with the CD20 monoclonal antibody, that also comes under the same category since we're developing that with LFB. With regard to other products which we have in the portfolio or other follow-on biologics, I don't feel that there is any constraint on us in what we do in other territories.

As far as ATryn® is concerned, we are looking for commercialization partners in the U.S. And neither LFB nor LEO actually have commercialization infrastructures within the U.S. So, we're looking for a partner who can help us to develop and to commercialize ATryn® in the U.S. and we are talking to a number of parties at this moment and we're in negotiations at this juncture.

Stephen Dunn - Dawson James Securities - Analyst

I guess where I was leading is it sort of sticks out to me that the anti CD20 is partnered with LFB, but the anti CD137 is not.

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

Yes, CD20, really, we're seeing more of as a follow-on biologic or part of the initial part of our follow-on biologics strategy. And that was a program, actually, which was brought to us by LFB. So, that's why that's within that particular structure. CD137 monoclonal antibody is a new chemical entity which we license in the Mayo Clinic and we're developing that.

And we're certainly looking to potentially partner that product, largely because the range of indications -- this is an immune modulator -- and the range of indications potentially available to that product, I think, is well beyond the resources of GTC to manage entirely on our own.

And it is a type of molecule where we feel that if we can get the support and help of a larger biotech or a larger pharma company, that would be extremely helpful in terms of being able to progress that particular program. So, I think it's unlikely that that would be brought under the umbrella of LFB.

Stephen Dunn - Dawson James Securities - Analyst

Would you view that as more -- as a combination -- a potential combination therapy?

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

That may well be so, actually. That's very interesting and that's something which we've thought about, but it's a little way off at this juncture. But it's that type of thought process round the clinical development strategy where we would find it very helpful to have a larger company who has real depth in the whole area of immune systems and immune modulation which can help to develop that type of clinical strategy. But that clearly is something which is in our minds.

Stephen Dunn - Dawson James Securities - Analyst

All right. All right, Geoff and Jack, again, congratulations and it's going to be very exciting. Thank you.

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

Thank you very much indeed [for your] question.

Operator

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

Sean Wu - Rodman & Renshaw - Analyst

Good morning, Geoff and everybody. This actually is Sean Wu standing in for Navdeep. I just have a couple simple questions. You say you are trying to get a patent for ATryn® in the U.S. and you also mentioned that ATryn®'s opportunity for HD is limited. So, are you each handle patent as a whole thing, like ATryn® for hereditary deficiency indication is also for acquired indications or just for the commercial opportunity in term of HD only?

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

No, the answer -- thank you for your question, Sean. The question is very clearly that we would certainly be licensing a partner for the commercialization of ATryn®, initially, in the hereditary deficiency indication. But in these negotiations, we are specifically requiring that our partners support the development in the broader acquired deficiency indication. So, that's, I think, a mutual interest on both sides. So, that's certainly clearly the objective, both in terms of the -- financing those programs, but also the commercial opportunity, which we're offering.

Sean Wu - Rodman & Renshaw - Analyst

Okay. I have a question -- a follow-up question for Jack. You say you are going to enter the year with \$20 million to \$22 million in cash. So, I haven't done the correlation yet, so what is your implied cash of receipts from this partnership?

Jack Green - GTC Biotherapeutics, Inc. - CFO, SVP

Okay. Well, we obviously do not want -- as a matter of negotiation -- don't want to publicly talk about what we expect from a partnership. Certainly, closing a partnership in the fourth quarter is a part of reducing that cash burn for the fourth quarter to bring us in at the \$20 million to \$22 million level. But in terms of publicly disclosing specifically what it is we expect for an upfront payment, I would -- I would -- think I would defer from doing that at this point, Sean.

Sean Wu - Rodman & Renshaw - Analyst

I think, I mean -- I guess I will have to do the calculations myself. With the cash burn -- cash -- so, what is your estimated cash burn for this year now? I know that you said you are going to have \$28 million to \$30 million for next year, so I just wanted to model in front of me -- do you have more cash burn than that for 2007, right?

Jack Green - GTC Biotherapeutics, Inc. - CFO, SVP

2007, the cash burn projected is between \$22 million and \$24 million using the -- using our current projections. And again, that's assuming the close of the partnering transaction in the fourth quarter.

Sean Wu - Rodman & Renshaw - Analyst

Awesome. Thank you very much.

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

If you remember, Sean, if I may just add to that that we started the year with a commentary on a pro forma cash burn, which included some cash income from sales to LEO early in January and also some cash which came in from the final piece of the LFB transaction.

And in fact, if you look at -- if you take those out of the equation, our cash burn, which we are projecting for next year, is very much in line with the cash burn that we have for this year. So, there's no -- this is no major change in our overall cash. I think that's true, isn't it, Jack?

Jack Green - GTC Biotherapeutics, Inc. - CFO, SVP

That's exactly right.

Sean Wu - Rodman & Renshaw - Analyst

Thank you very much. I appreciate that.

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

You're very welcome.

Sean Wu - Rodman & Renshaw - Analyst

Thank you for the clarification.

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

Thank you.

Sean Wu - Rodman & Renshaw - Analyst

I'll go back in the queue.

Operator

Nov. 01. 2007 / 10:00AM ET, GTCB - Q3 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

(OPERATOR INSTRUCTIONS). And your next question comes from the line of Roy Friedman from Edith C. Blum. Please proceed.

Roy Friedman - Edith C. Blum - Analyst

Good morning, Geoff.

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

Good morning, Roy. How are you?

Roy Friedman - Edith C. Blum - Analyst

Fine, thank you. My first question concerns the reporting of clinical data from the U.S. ATryn® trial. Will these data be reported in a press release and, if so, how much detail will be included? Specifically, will you be including the follow-up antibody data to be sent to the FDA later?

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

Thank you for the question and I'm happy to answer that. This will be top-line data, which I think we will -- we're expecting to release through a press release. So, it will be based on the initial review of the clinical data from the two arms of study, both historical -- or retrospective study together with the active arm, and that's our plan. The antibody data will not be complete until 90 days after completion of the last patient in the clinical study, so we would not have that available.

We provided similar data to the EMEA and it's a routine part of these types of studies. And we got a very clean bill of health in that whole process with the EMEA. And so, it's not a major issue in any of our expectations, but it is a required part of the safety data which all the agency are asking for these types of products these days. So, it will be, basically, just the top-line data and we will plan to do that through a press release.

Roy Friedman - Edith C. Blum - Analyst

Okay. Turning to the AAT program, you said on today's call that GTC's recombinant AAT is expected to have a longer half life than plasma derived AAT. How will this longer half life be accomplished?

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

Well, actually, I can't answer you the question to that because that's sort of work in progress, to be quite honest. And so, that's still a -- sort of a proprietary situation. I think what I said was we're looking to extend the half life of alpha 1-antitrypsin that we have, which is transgenically produced and we are not, at this juncture, at a point to be able to comment as to how that will compare with plasma derived products.

Nonetheless, it is an important aspect of us developing the IV formulation and certainly I hope over the next few months that we will be able to provide you with a better response to that particular question. But at the moment, I don't have the data, I don't know the answer. But that's clearly our objective.

Roy Friedman - Edith C. Blum - Analyst

Okay. How will GTC get around orphan drug exclusivity of a computing AAT product and could the half life be a way of getting around that?

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

I'm not aware that there is a recombinant form of alpha 1-antitrypsin which is -- which would be potentially competitive. There have been -- previously been recombinant forms of alpha 1-antitrypsin which were being developed in yeast. But to my knowledge, that program is no longer in operation. I may be incorrect.

Roy Friedman - Edith C. Blum - Analyst

Well, I was referring mainly to the program from Kamada.

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

Well, that, I think, is a -- the Kamada program that I know of, if you're referring to that -- Kamada, I believe, is an Israeli company which is developing alpha 1-antitrypsin in a pulmonary application -- and they may well have orphan drug in that pulmonary application for a -- as a plasma derived product. But I have no indication that that would constrain our ability to bring our product to market.

Roy Friedman - Edith C. Blum - Analyst

Okay. Question for Jack. Has there been any progress on recovering the \$2.9 million inventory loss recorded last quarter?

Jack Green - GTC Biotherapeutics, Inc. - CFO, SVP

We have -- we have had a number of discussions with the contractor and those discussions are continuing. But as we said in the last quarter, we did not -- we were not able to promise that we would be successful in recovering any significant amount on that. That is still the guidance I think we would give at this point in time. We're still working it, but the discussions haven't been completed.

Roy Friedman - Edith C. Blum - Analyst

Okay. All right. Thank you very much.

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

Thank you, Roy.

Operator

(OPERATOR INSTRUCTIONS). And I show no further questions at this time. I'd like to turn the call back over to Dr. Geoffrey Cox for closing remarks.

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

Thank you very much indeed and thank you for joining us in this discussion of our third quarter results. We expect that our next conference call will be to discuss our fourth quarter 2007 results early next year. We are obviously looking forward to a number of things, which are going to be happening in that intervening period, so we very much look forward to that call and we look forward to speaking to you then. Thank you very much indeed, everyone, for joining us and have a great day. Thank you.

Operator

Thank you for your participation in today's conference. This concludes the presentation and you may now disconnect. Good day.

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