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## Conference Call Transcript

**GTCB - GTC Biotherapeutics, Inc. Conference Call**

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## CORPORATE PARTICIPANTS

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*GTC Biotherapeutics - Chairman, CEO*

**Dick Scotland**

*GTC Biotherapeutics - VP of Regulatory Affairs*

**Jack Green**

*GTC Biotherapeutics - CFO*

## CONFERENCE CALL PARTICIPANTS

**Navdeep Jaikaria**

*Rodman & Renshaw - Analyst*

**Phil Nadeau**

*SG Cowen - Analyst*

**Keith Marr**

*Political Capital - Analyst*

**Sam Rebotsky**

*SER Asset Management - Analyst*

**John Davis**

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**Brian Davidson**

*SF Capital - Analyst*

**Matthew Minix**

*Joseph Stevens - Analyst*

**Roy Friedman**

*Edith C. Bloom - Analyst*

**Stephen Barton**

*Bloomberg - Analyst*

## PRESENTATION

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### Operator

Good-day, ladies and gentlemen. Welcome to the GTC Biotherapeutics conference call. My name is Colby. I will be your coordinator for today. At this time, all participants are in listen-only mode. We will be facilitating a question and answer session towards the end of this conference. (OPERATOR INSTRUCTIONS). As a reminder, this conference is being recorded for replay purposes. I would now like to turn the presentation over to your host for today's call, Dr. Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics. Please proceed, sir.

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### Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO

Thank you very much indeed. Good morning everyone. Welcome to our conference call and webcast to discuss the expected opinion from the Committee for Medicinal Products Human Use, CHMP about our lead product, ATryn. Just to remind you at the start of this, we still have not at this point in time, received the official letter or official confirmation from the CHMP. But we wanted to share our thoughts and observations with you at this stage so that all our investors were aware of the information that we have at this present time.

I am Geoffrey Cox. I am the Chairman and Chief Executive Officer of GTC Biotherapeutics. Our Nasdaq ticker symbol is GTCB. With me today are Jack Green our Chief Financial Officer; Dick Scotland, our Vice-President of Regulatory Affairs; and Tom Newberry, our Vice-President of

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Corporate Communications. Our press release on the CHMP's anticipated negative opinion was distributed earlier today. I hope you've had the opportunity to review this release prior to our call.

I'll begin the call with some introductory comments. I will then ask Dick Scotland to provide an overview of the next steps for action, both with the EMEA, the CHMP and also with the US FDA. Then I'll ask Jack Green to provide an overview of our financial position. Then I'll make some further prepared remarks before opening the meeting to questions, which you may have.

First of all, 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, these are the risks inherent in our business, which are described in detail on the form 10-K and exhibit 99. Our actual results may differ materially from our current expectations.

Early today we announced that the CHMP is expected to determine that ATryn is not approvable at the present time. I want to take a few minutes to tell you about the background to this decision and to put it into context. Remember that ATryn is the first transgenically produced protein submitted for review to any regulatory agency in the world. That put a very special burden on the GTCB and the EMEA to ensure the appropriate set of benchmarks for the first recombinant protein derived from milk have been established. While the process we've been involved in with the Agency has been long and challenging, these reactions have been very professional and productive. GTC has been asked to respond to many highly detailed questions to provide the level of comfort required to demonstrate the consistent production our highly purified antithrombin product as well as to demonstrate the safety and efficacy of ATryn in the clinical trials defined in the scientific advice provided by the EMEA.

Before I put some more context around this decision, I do not want us to forget the extraordinary efforts that have been made by so many people in GTC and by our friends and collaborators. My personal thanks to all of you. The level of professionalism, resourcefulness, scientific innovation, and sheer hard work over a long period of time has been exceptional. I can say with certainty that we have left nothing on the table. This has provided a strong base of positive outcomes from our submission and these will provide an important framework for moving our program and production technology through to ultimate success.

This submission was based on two very clear requirements. The first requirement was to establish the production criteria and specifications for producing the recombinant protein from milk. And secondly, to demonstrate the safety and efficacy of the product in the clinical trials specified in the scientific advice. This led to our clinical study protocols to assess the instance of deep vein thromboses or DVTs in hereditary antithrombin deficient patients undergoing high-risk procedures such as surgery or childbirth. In the instance of DVTs, we are required to explain for adequate medical review the circumstances and outcome. This study was defined to require a minimum of 12 patients in an open-label study using complementary ultrasound data as well as clinical assessments. In our study, we enrolled 14 patients – five surgical; and nine pregnancies, three of which were cesarean births. In addition, at the EMEA's suggestion, we submitted the data from a further five patients, who were treated under our compassionate use programs. Importantly, the clinical assessors stated that our data supported demonstration of efficacy in this patient population.

In our clinical studies in pregnant patients, we found that during contractions, fluctuations in antithrombin occurred, resulting in more frequent blood draws to adjust the infusion rates. You will remember that this is a continuous infusion of ATryn to maintain antithrombin levels at between 80 and 120% of normal. This study, which was carried out substantially adds to the body of knowledge for the treatment of this patient population. It is also important to note that all these patients were successfully treated without the occurrence of DVT's and contribute to the conclusion of efficacy.

Nevertheless, the clinical assessors considered the blood draws excessive. We agreed last April that we would use an optimized dosing formula for pregnant patients in our US study and proposed submitting this as a post-marketing commitment. However, the Agency has apparently concluded that the criteria of 12 patients in this indication has not been met, essentially discounting the data from the pregnancy patients. This is what led to the determination that our submission is not approvable at this time.

The review of our manufacturing control section resulted in satisfaction of all the significant outstanding issues related to our transgenic production platform. This is a major win for this production technology. We are pleased to be able to tell you that this also included the successful inspection of our farm and contract manufacturing sites.

The CHMP opinion is expected to include a concern regarding the potential for immunologic responses related to the potential for residual contaminating proteins. We have never observed allergic or anaphylactic responses in over 200 patients that have been dosed with ATryn and we have been unable to get any production of goat antithrombin antibodies in any of the patients, even those which have received a second dose of

ATryn. We show that ATryn is a highly purified product with less than 5 ppm of total contaminating proteins. That means that it is 99.9995% pure.

On the important issue of potential contamination with the goat antithrombin, there is a maximum level of approximately 1.25 ppm. Stated another way, goat antithrombin is a maximum level of 0.000125% of the final product. Goat antithrombin is 89% homologous. That means it's the same – 89% the same as human antithrombin and is highly unlikely to result in antibody formulation.

We believe that we can resolve the CHMP concern on these issues effectively during the reexamination process. Importantly, we have a clear path forward. A major element of our continued progress is LEO Pharma's commitment to continue the development of ATryn for an acquired deficiency indication in Europe irrespective of this opinion or the ultimate outcome of the request we intend to make for reexamination of the submission. Each of the acquired deficiency indications are far larger markets than the hereditary deficiency indication. We expect to announce the acquired deficiency selected for this development in conjunction with LEO over the next few months.

We also will continue our ongoing multinational study of ATryn in the hereditary deficiency indication, which will form the clinical basis for submission of a Biologics License Application, or BLA, in the United States. We plan to complete enrolment in the study in 2006 and submit the BLA in early 2007.

Now I want to turn the call over to Dick Scotland and ask him to share with you the procedure for reexamination under the appeal process, which takes place with the CHMP. So, Dick, let me pass that over to you.

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**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

Thank you Geoff. The EMEA provides for an appeal process for reexamination of opinions made by the CHMP. This request for reexamination will provide an opportunity for us to address the CHMP's objections and include data to strengthen our position. I would also like to give you an idea of how this process works.

Firstly, we have to submit to the Chair of the CHMP our intention to request a reexamination of the opinion that has been made. We have 15 days following receipt of the official CHMP opinion. We plan to actually file a request for reexamination early next week. Subsequent to receipt of the official opinion, we have 60 days in which to file documentation supporting our grounds for an appeal. The CHMP then has 60 days in order to give an opinion on that appeal. Under the procedures allowed for this reexamination, a new rapporteur will be assigned to the review. We may also request an expert panel, although we cannot define the composition of that panel. The CHMP opinion has no direct bearing on our regulatory position in the US. We are continuing to enroll patients in our multinational study of the same hereditary AT deficient populations. The data from this whole study, which is to include 17 patients in addition to the 14 studied for the European MAA and a comparison arm of 35 historical cases that utilize plasma-derived antithrombin products, is expected to form the basis of the submission of a biologic license application in the US.

I would now like to turn the discussion over to Jack Green to address our financial position. Jack.

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**Jack Green - GTC Biotherapeutics - CFO**

Thank you Dick. In early January, we filed a form 8-K with the SEC in which we disclosed that our cash and marketable securities were at approximately 36 million at the end of 2005. This included \$2.4 million in proceeds from the extension of our term loan with GE Capital, which was drawn down in December 2005 in anticipation of repaying our \$2.4 million promissory note to Genzyme Corporation. We subsequently did repay the promissory note in January of 2006, essentially putting our proforma cash position at about \$33.5 million to the start of 2006. This cash position is sufficient to fund our ongoing clinical study and to file our regulatory submission for ATryn in the United States.

We will also be looking for ways to both accelerate data accrual in the US study as well as to reduce non-ATryn related expenses. We expect to provide more details about our 2005 results as well as our financial expectations moving forward when we release our fourth quarter and full year 2005 results on March 6. Geoff.

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

Thank you, Jack. Undoubtedly this is a tough moment for us. But we have shown great resilience in bringing our technology this far. We will not falter in completing the job. We recognize that we will have to focus the Company very clearly and very strongly on the ATryn program. Clearly

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this focus will include the reexamination process with the CHMP, which Dick has just been defining; supporting our partner LEO, which of course, is very important to us. Their commitment to us has been extremely important over the last few days. Of course, the plan is to develop with LEO in the acquired deficiency indication. That will give us access to much larger markets. We also plan to vigorously pursue the enrollment of patients in the study for the United States and to file the BLA approval at the earliest opportunity.

In moving forward from this position are strengths that we take from the support of LEO; continued development in Europe; and our ongoing clinical studies in support of filing in the United States; and a drug that has significant value. As we develop ATryn for expanded clinical indications, we believe the product could have a worldwide annual market potential of 500 to 700 million. There will be many more people that will be helped than from today's plasma sources. Remember our focus has continued to be to develop a product, which can create a market significantly in excess of that market, which exists today from plasma-derived products. This is important not only to our investors, but also for patients that may not otherwise have effective treatment options. We recognize that we have to focus the Company very clearly and very strongly. We take heart from the remarkable commitment, persistence, and resilience of all in GTC who have come this far. I am confident that we can complete the job of getting our approvals for ATryn both in Europe and in the United States.

Thank you for listening to our prepared remarks. I now would like to ask the Operator to open this call for questions.

## QUESTION AND ANSWER

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### Operator

(OPERATOR INSTRUCTIONS) Navdeep Jaikaria with Rodman & Renshaw.

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### Navdeep Jaikaria - Rodman & Renshaw - Analyst

Good morning. Can you please also give me some – I am sorry, I missed the initial part. What was the news? Did you mention that you missed the criterion for enrollment? You didn't satisfy the inclusion criterion or exclusion criterion?

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### Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO

Yes. What we talked about was that – of course, on the scientific advice, we were required to recruit 12 patients into the study. Those were in high-risk situations such as surgery and childbirth. We recruited 14 patients into that study. We have also filed on a further five patients, which were part of our compassionate use program. Within that 14 patients we had five surgical patients and nine pregnancy patients. During the course of our clinical trial, we became aware that pregnancy patients – and I think we actually added significantly to the body of data, which is available for the treatment of this patient population who are giving birth – we observed that pregnancy patients, we often needed to give – or take additional blood draws in order to maintain the antithrombin levels between 80% and 120%, particularly during the times when these patients were having contractions. We had discussed with the Agency last April, our proposal to revise the dosing formula for our US study for this particular patient population. We proposed to the Agency, and they understood, that we would plan to include that data as a post-marketing submission as a follow-up once we had completed our US study. But when we had come to this particular moment, the Agency has excluded our pregnant patients' pregnancy data from that final assessment. They have then said we have five surgical patients, which is below the 12, which are required under scientific advice.

So it's a little ironic for us because we always believed that introducing a new production technology was a very challenging proposition. We feel that we've done a fantastic job in terms of clearing all significant issues from the final assessment with regard to our manufacturing technology. But we have this one outstanding issue with regard to the clinical data. I don't – it's my personal assessment – I don't think that there is a real concern that we can demonstrate efficacy in this population. I think that is understood and admitted by the Agency. But I think it's an administrative issue with regard to what they see as the scientific advice on the number of patients, which they are seeing under the dosing regime, which we employed during the study. I would like Dick to add any further comments you may have to that.

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### Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs

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That is actually a very good summary. I will leave it at that.

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**Navdeep Jaikaria - Rodman & Renshaw - Analyst**

Just a quick follow-up. For the US study, do you – would you be enrolling some more patients to compensate for the nine patients?

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

I think you are starting to delve into – we are still living this thing just at this moment – delving into what our strategy will be going forward. I am not quite sure that we are ready to say exactly how that will be. I think our first plan, to be quite honest, is to push very hard with the CHMP for approval under the reexamination process. That has to be our first objective. We will be pushing very hard to try and achieve success in that. I think that if we were unsuccessful in that process – and I want to speak quite clearly for everyone that there are no guarantees in that reexamination process. So I don't want to raise expectations or whatever. But clearly we intend to address those concerns in a very direct fashion with the Agency. If we were not to be successful, then we would have to consider what expectations there are from the Agency in order to be able to get the HD indication approved in Europe. We will take that decision at that juncture. In the meantime, of course, we do want to move ahead with our partner LEO once we've come to a final examination with regard to which required deficiency indication we go to. We do want to move that ahead. So these are not sequential events. These are things that we want to do in parallel. That is hugely important to us of having had that commitment and very positive support from LEO in this particular situation.

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**Navdeep Jaikaria - Rodman & Renshaw - Analyst**

Great. Thanks. I'll get back in the queue.

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**Operator**

Phil Nadeau with Cowen.

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**Phil Nadeau - SG Cowen - Analyst**

Thanks for taking my questions. My first question is your comments on immunogenicity. It sounds from what you've said that there is no evidence of immunogenicity and there is really no reason to think that ATryn would cause antibodies to be raised and as a question. And yet the CHMP seems to be putting a concern into their decision about immunogenicity. So I guess I am still unclear what it is that has raised the CHMP's concern.

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**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

I want to reiterate that we have seen no allergic-type reactions or hypersensitivity reactions in the patients that we have treated to date. That is over 200 patients. We have looked for antibodies to the active moieties, the recombinant human antithrombin molecule. We have looked for antibodies to the goat antithrombin low levels, if they are present there at all. We have also looked for antibodies to any potential residual milk protein that may be present at upwards of – up to perhaps five ppm. We, in our opinion, have not seen any immune response – immunologic reaction based upon laboratory data.

I think what it comes right down to is a combination of two things. One is the very small number of patients who have been exposed to the product. That is in particular, the five surgical patients. The Agency has to evaluate the total set of data. They look at the very small number of patients, that is five for surgical, and they look at the low number of data that we have been able to provide simply because we haven't treated that many hereditary antithrombin deficient patients. They do a balancing act. They have come down with raising a concern that we believe we will be able to address when we go through the reexamination process.

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

If I could add to that also. Over the last two or three years we have been gathering even further data from samples, which we have collected from all our patients over the years to support our position. We believe that we've got strong data, which can bring comfort to address this particular issue. We will certainly be putting that data forward again as part of our package in the reexamination. We have brought it to the CHMP's notice already. But we think that we can address that in a much – or in a very effective fashion with the CHMP as we start the reexamination process. It's a little bit – we're in a situation trying to prove a negative. That is a tough challenge.

I think again, it comes back to my general point. It's just with a new technology, there is a conservatism, which is not in appropriate. I am respectful of it. It is a reflection of some of the issues, which have arisen particularly in Europe with regard to EPO. That naturally brings their attention to ensuring that products brought into the market are safe as well as efficacious. We share always concern for patients' safety as being a priority. But we also feel very confident and very good about this particular issue. We will be addressing it in a vigorous fashion with the Agency in the reexamination.

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**Phil Nadeau - SG Cowen - Analyst**

My second question is on a concern that you mentioned in your press release. I don't recall you mentioning it in your prepared remarks this morning. That is the lack of clinical data from ATryn produced with an additional filtration step. What does that concern center around? How easy will that one be to rectify?

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**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

In our dialog over the years with various health authorities around the globe and including representatives of the EMEA, leading up to submission of our application, we have added an additional what they call a nano-filtration step in. That was added in at the request of one representative of the EMEA at the meeting that we had with them. It was explained to us that we needed to have that filter in at the time that filed our marketing authorization application. The clinical trial work that has been done to date has used a product that did not have that nano-filtration step in it. We added that nano-filtration step early into the purification process so that it would not impact the product. In addition to that, we performed a series of chemistry analyses. We performed an animal experiment to demonstrate that it did not – would not have an impact. We also conducted a human pharmacokinetic study in which we prepared this nano-filtered product to the non-nano-filtered product and we demonstrated bioequivalence.

The concern, I guess, remains – at least in the minds of the CHMP – is that we have not put that nano-filtered product into patients. That nano-filtered product is constantly being used in the ongoing clinical study because we have switched over to that nano-filtered product as a means of production. The nano-filtration step simply was added as additional assurance – as an additional step for additional assurance, even though it may not have been fully necessary based on the data that we had on viral removal steps. But we added it anyway at the recommendation of EMEA personnel. In a way, it's caught us here.

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**Phil Nadeau - SG Cowen - Analyst**

My last question is going back to the pregnancy issue just so that I understand it. Was it really the blood draws that the European regulators objected to? That is why they thought that those patients were maybe – shouldn't be included in the dataset. It has nothing to do with a pregnancy patient not going through enough trauma or anything like that?

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**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

What it really boils down to is the number of blood draws that were required per the study protocol simply to ensure that the patients remained within 80 to 120% of normal activity. We have to remember that some of these patients, when they come into the clinical trial, have AT activity levels down around 30 or 40%. So we had to boost them up quite a bit simply to restore their AT activity level. Per the protocol we had to pull blood samples at specified points in time. If the AT level was not at a set level, you would have to increase the rate of infusion. And if then, once you did that, you would then have to pull another blood sample a short period of time thereafter to show that you didn't overshoot. And if you did, you would have to reduce or change the rate of infusion again simply because these pregnant patients behave differently or respond differently. Because of their medical state, there was a lot of fluctuation in what was going on.

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**Phil Nadeau - SG Cowen - Analyst**

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I see. So what exactly are you doing differently in the US trial? Have you changed the dosing for pregnant patients or just the timing of the blood draws?

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**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

What we are doing is we have developed a new dosing formula for the treatment of these pregnant women. It's my opinion that there is very little known in the published literature as to how one actually treats a pregnant woman with even plasma AT. So what we are doing is we've added specifically to the body of data about the treatment of these pregnant women. To answer your question, what we are actually doing is we have developed a new dosing formula that is currently in use in the ongoing study. We believe that that dosing formula will smooth everything out such that these patients will be treated with ease of clinical practicality.

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**Phil Nadeau - SG Cowen - Analyst**

Okay. Thanks for taking my question.

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**Operator**

Keith [Marr] with [Political] Capital.

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**Keith Marr - Political Capital - Analyst**

Thanks for taking the question. I want to ask a few balance sheet issues. How many shares and options, etc. are – what is your fully diluted share count? I guess that is the question I am trying to----

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**Jack Green - GTC Biotherapeutics - CFO**

The fully diluted share count is approximately 70 million at this point in time.

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**Keith Marr - Political Capital - Analyst**

70 million?

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**Jack Green - GTC Biotherapeutics - CFO**

Yes, fully diluted [inaudible].

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**Keith Marr - Political Capital - Analyst**

I'm sorry?

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**Jack Green - GTC Biotherapeutics - CFO**

With options and warrants.

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**Keith Marr - Political Capital - Analyst**

With options and warrants. You have 33 million in cash currently right now.

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**Jack Green - GTC Biotherapeutics - CFO**

The cash at the beginning of the quarter was about 33.5 million proforma having deducted the 2.4 million that we had to pay to Genzyme in early September.

**Keith Marr - Political Capital - Analyst**

What did you burn last year?

**Jack Green - GTC Biotherapeutics - CFO**

Exclusive of equity proceeds from the equity offerings that we did during the year, we burned around 21 million.

**Keith Marr - Political Capital - Analyst**

So you burned 21 million last year, in just pure product development – G&A expenses and R&D expenses----

**Jack Green - GTC Biotherapeutics - CFO**

All operations.

**Keith Marr - Political Capital - Analyst**

The operations. So from an operating standpoint you burned 21 million. You have 33 – you had 33 now and you have 70 million shares outstanding fully diluted with all warrants and options.

**Jack Green - GTC Biotherapeutics - CFO**

That's correct. I should mention, the cash burn that I mentioned is net of revenue – collections [inaudible].

**Keith Marr - Political Capital - Analyst**

As you start the US trials, will you need to increase that burn. Is that----?

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

I think I would say it follows that we will take a very hard look at where we are at this moment. We are going to focus the Company very, very clearly on getting this US study done. We clearly will need to take steps to control our expenses or to change our expense base in order to ensure that we have the ability to be able to get that study done and that we have the financial resources, as Jack was describing earlier, to enable us to do that.

**Keith Marr - Political Capital - Analyst**

Do you have a----

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

I think we have a – we will develop a very realistic plan. We are confident that we can do that.

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**Keith Marr - Political Capital - Analyst**

Do you have any debt right now?

**Jack Green - GTC Biotherapeutics - CFO**

Yes, we do. We have debt with GE Capital, which is approximately \$12 million -- \$12.5 million.

**Keith Marr - Political Capital - Analyst**

12.5 million in debt. You have about \$0.46 or \$0.47 a share in cash right now per share on the balance sheet. And your burn – you think you can take that down a little bit?

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

I think where we are at this moment, we don't want to try and give cash burn projections other than that we will obviously adjust our sights as necessary and as appropriate in these circumstances in order to get this job done. We are committed to that.

**Keith Marr - Political Capital - Analyst**

Okay, great. Okay. Thanks a lot.

**Operator**

Sam Rebotsky with SER Asset Management.

**Sam Rebotsky - SER Asset Management - Analyst**

Good morning. I believe I understand what you've said. Of the five patients that were not pregnant, they were – everything was satisfactory, but that just that it's not the 12 people that you needed?

**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

I think it comes right down to the number of patients that they consider acceptable for the label that we were seeking. It comes down to, in their view, that we have five patients that we treated that were just considered surgical patients.

**Sam Rebotsky - SER Asset Management - Analyst**

But would it be fair to say that they were treated properly and everything was – just that it was not the 12, although you indicated this immuno problem, which you don't know because the size was not the 12 whether or not that problem would develop in another seven of potential patients.

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

No, I don't think – that's certainly not the message. We have no observations in this patient population, either the surgical patients or the pregnancy patients of immunological reactions. That is a more of a general concern of potential immunogenicity, which the Agency is registering – which we believe they will register in their opinion. Remember we haven't seen their final report at this moment. We certainly from our discussions, that is our belief that they will comment on that. I would agree with Dick. I think that this is a numbers as much as anything. Obviously our job is to try and deal with that in the reexamination process and see if we can change their thought process around that.

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**Sam Rebotsky - SER Asset Management - Analyst**

And in the beginning was there any thought that there might be a problem with the pregnant patients? If so, would you go forward with attempting to include pregnant patients as heavily as you did so that you won't develop that problem going forward?

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

One of the things that we're doing in this situation, we're treating a group of people who today had real problems having children if they have hereditary deficiency. I would just remind you that people who are HD deficient and they are on Cumadin or Warfarin – they ought perhaps come off those drugs during the first trimester because it is actually toxic to children. So it is a very, very challenging situation for these patients. Many of them chose not to have children, which is sad. In Europe, there has been availability of plasma products in some countries, not in all countries. Because many of the countries have approvals on a country-by-country basis with mutual recognition. We feel that it's important for us to address this patient population and include pregnant patients in that because we want to be able to bring this drug, which we believe to be a safe and efficacious drug, to these patients. We have to convince the Agency from a regulatory perspective that we have done what is necessary in order for them to be able to move forward.

In the US, I would remind you also that we have been in the situation a number of times where patients actually – there has not been enough plasma-derived product available – much shorter supply in the United States. There has not been enough product available. We've made products available under compassionate use. It is going to be very important for the patient population in the United States to have a recombinant version of this product available. So we will continue to include pregnant patients in this program.

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**Sam Rebotsky - SER Asset Management - Analyst**

So the pregnant patients were no problem. You treated everything properly and hopefully----

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

They were – excuse me for interrupting. They were – it wasn't an issue of efficacy in those patients. It was a question of the number of blood draws, which was discussed.

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**Sam Rebotsky - SER Asset Management - Analyst**

Alright. Hopefully you'll be successful going forward.

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**Operator**

(OPERATOR INSTRUCTIONS). [John Davis with Reboxlin].

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**John Davis - Reboxlin - Analyst**

A quick question. What is the local precedent for overturning the EMEA – or the panel decision. Can you give us a percentage even on that?

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

I am not sure whether we have a percentage or not. I am going to ask Dick to take that question.

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**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

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There are certain precedents for this to occur. There have been cases where, upon reexamination, a decision has been reversed. As to the numbers, I actually don't have numbers for you. I am aware of a couple of examples. We will be looking into those further just to learn as much as we can as we go through this process. I am not aware of any that have not been reversed specifically.

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**John Davis - Reboxlin - Analyst**

Do you know any that have been reversed in the last year or two?

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**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

There was one reversed in January of this year. Some information about that, I believe is available on the EMEA website.

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**John Davis - Reboxlin - Analyst**

Okay, thanks very much.

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**Operator**

Brian Davidson with SF Capital.

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**Brian Davidson - SF Capital - Analyst**

Good morning. The last caller asked one of the questions I was going to ask. Related in a way, do you feel that EMEA is over the political hurdle with respect to approving a transgenically derived product? Or is there still some sense that there may be some issue with that?

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**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

I would say that I don't see it as being a political issue in that regard. I do believe that we have addressed all the major or significant chemistry and manufacturing control issues. There is no indication that I have, based on communications we've had with the EMEA personnel or representatives of the CHMP, that that has been an issue whatsoever. It is actually not that. I think it is just a numbers game.

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**Brian Davidson - SF Capital - Analyst**

It just seems, based on my own informed opinion, it seems based on the rationale for the expected non-approval that those issues could have been raised at an earlier point.

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

Well, I don't know. It's always difficult to assess political issues. I don't think we would know one way or the other as far as that is concerned. In Europe there are sensitivities with regard to genetically engineered foods, particularly. But we've always been very careful to separate ourselves from that particular dialog. There are many recombinant proteins, which have become available in Europe. We've really have not sensed any push-back from patients in terms of the use of recombinant products and those sorts of products. In general there has been some enthusiasm to have alternative recombinant available product versus the plasma-derived product. I think Dick's previous comment is correct. I think it is the way we need to address this, particularly on the numbers. That is where we will focus our attention.

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**Brian Davidson - SF Capital - Analyst**

Lastly, what is the plan in terms of filing a BLA – timeline?

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

I think at this moment we've clearly been very focused on the EMEA submission. We are going to focus very heavily now, as we move forward as well in parallel with this reexamination process, on recruitment of patients into the US study. We hope over the next two or three months, we can give some better guidance as to how that is all coming together. Obviously that is going to be important because we want to make sure that we do that in a timely fashion and recognizing that we are not blessed with extraordinary cash resources. We are going to get to that particular point. I think it's a question of focus. We hope that we complete the enrollment in the latter part of this year. Then we need to bring all the data together and file that at the earliest opportunity.

We've got some planning to do at this moment. I can't say, as we sit here today, that we know all the answers to that. We have started recruiting into that trial. We don't usually talk about the numbers in the public domain. We intend to be pressing on with that in a vigorous fashion.

**Brian Davidson - SF Capital - Analyst**

Thank you. And hang in there.

**Operator**

Matthew [Minix] with Joseph [Stevens].

**Matthew Minix - Joseph Stevens - Analyst**

My question for you is this. While you are waiting for the resubmission information could come back, are you going to be taking any steps in fulfilling what they really want in the sense of getting that number from five to over 12 on the patient study?

**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

I think we do have the study that is ongoing. That is primarily to help us support the US application. The data from that study could potentially be used for responding to this key question the EMEA has. I guess to answer your question, I would say yes. We could potentially use data from this ongoing study to help address that issue.

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

I would just reiterate again. First, at this moment as far as Europe is concerned is to focus and address the issue of reexamination. We want to make sure that that is our priority as far as Europe is concerned. Of course, in addition to that we want very much to continue to move forward with LEO on the broader indications. In terms of short-term issues, I think that the reexamination is the focus.

**Matthew Minix - Joseph Stevens - Analyst**

Thank you. I have one more question. You are expecting that to take about two to three months?

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

We have 15 days in which to file. We are going to request a reexamination. That will – we will probably do that the early part of next week. Once they have published their opinion, I think Dick said it was 60 days.

**Matthew Minix - Joseph Stevens - Analyst**

60 days and 60 days. So a total of about 135 days [unintelligible]. Is that the max? Or could things happen earlier?

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**Dick Scotland** - *GTC Biotherapeutics - VP of Regulatory Affairs*

It's actually about 120 days.

**Matthew Minix** - *Joseph Stevens - Analyst*

Okay. Good luck. Get this stock back up there, right.

**Geoffrey Cox** - *GTC Biotherapeutics - Chairman, CEO*

Yes, absolutely.

**Operator**

Roy [Friedman] with [Edith C. Bloom].

**Roy Friedman** - *Edith C. Bloom - Analyst*

Good morning. I'd like to focus on the five ppm of impurities. Do you have any sense that you have to get that down to a specific number like three or four in order to satisfy the regulators on this? Does the additional filtration step affect this number at all?

**Dick Scotland** - *GTC Biotherapeutics - VP of Regulatory Affairs*

Based on the data that we have right now, that 5 ppm is basically the maximum. It could be up to 5 ppm. But often times, based on the types of analytical tools that we are using, the actual value would be below that. In fact, sometimes we are below the limits of detection of the assays. So that 5 ppm is on the upper end. We say, not more than, simply because if one used the limited detection for all the assays, the total of the numbers based on the number of assays, we could be up to 5 ppm. However, I would say that based on the immunologic assessments that we have done to date, we have not seen any immune response either in patients or in normal healthy volunteers that have been treated. We do not, in my mind, at the moment need to reduce those levels any further based on available data.

**Geoffrey Cox** - *GTC Biotherapeutics - Chairman, CEO*

We have not received any communication, that I am aware of, back from the CHMP that that is a requirement for us.

**Dick Scotland** - *GTC Biotherapeutics - VP of Regulatory Affairs*

That is correct.

**Geoffrey Cox** - *GTC Biotherapeutics - Chairman, CEO*

There hasn't been a request that we need to modify our process in any fashion. It was a process that we have used over a long period of time and produced this very pure product.

**Roy Friedman** - *Edith C. Bloom - Analyst*

But just to rephrase, what you are saying then, it's not that you have actually observed 5 ppm. But that would be the limit of the detection assays so that you are saying 5 ppm in order to allow for that. Is that a fair statement?

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**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

That's correct.

**Dick Scotland - GTC Biotherapeutics - VP of Regulatory Affairs**

In part, some of these questions are based on some literature that has been published by the EMEA. I believe that we have addressed those concerns. We will reiterate that in our request for the reexamination in the grounds for request for the reexamination.

**Roy Friedman - Edith C. Bloom - Analyst**

On a different subject, what will LEO be doing during the 120 days while you pursue the reexamination.

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

We've only had some initial dialog with them as this situation has evolved. Again, I reiterate that we found a very positive response and attitude to be incredibly helpful in this situation. I would say that we will continue as planned. We will continue to work with them to define the indication that we want to go forward with. I have no doubt that they will be having their own interactions in conjunction with ourselves with the Agency to define the protocols and so on for whatever indication we choose to go forward with. It's a parallel process. As far as I am aware of and speaking on their behalf, they want to continue to move aggressively forward with that program. I would say that is independent of what is happening at this moment with the dialog we're having with the HD indication.

**Roy Friedman - Edith C. Bloom - Analyst**

Okay. Thank you and good luck.

**Operator**

(OPERATOR INSTRUCTIONS) [Stephen Barton] with Bloomberg.

**Stephen Barton - Bloomberg - Analyst**

About the appeal and then the movement to the United States, an analyst earlier was asking about the cash you had available and whether you would have enough. You said you would take a hard look at that and come up with a solid plan. It didn't sound like you answered the part of the question where he asked if you had enough money on hand to handle that American testing.

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

The answer is we believe we have. Remember this is breaking news for us as well. I think respectfully we would like to have the opportunity to return to base, so to speak, and to take a hard look at what all those expenses are. I think you heard us quite clearly that we will take what steps are necessary in order to adjust the way in which we are running the Company and the programs that we have in development to ensure that we direct the resources that we have to getting this program done. I was giving you a heads-up. We can't do everything at this point in time. There will be one or two things that we will have to put on the back burner in order to do this. It's a question of priorities. We will take whatever steps are necessary in order to ensure that we get this job done. There is no way with this Company and what we have achieved over 5 years that we will allow this to block us from getting this product to market. I am absolutely committed to that personally. I know all of us at GTC are committed to that as well.

Thank you very much.

**Operator**

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At this time, there are no further questions in queue.

**Geoffrey Cox - GTC Biotherapeutics - Chairman, CEO**

Alright, thank you very much indeed. I do appreciate everyone joining us on this call with such short notice. I hope you will appreciate the fact that we've taken the initiative to share with you some of our thoughts and ideas at very short notice ourselves. We wanted to make sure that there was transparency for all our investors at this point in time. All of you knew that we were going through this process with the CHMP and were very anxious to hear news from us. I hope you respect the fact that we have shared the information at the earliest possible opportunity. Clearly if there are any changes to some of these thoughts and ideas, which we've shared with you as a result of the formal responses back from the CHMP, that we will also share that with you as well at the appropriate moment.

We do expect to release our fourth quarter and full year financial results next week – it's actually on Monday, March 6. Please look out for that press release at that juncture as well. Thank you very much indeed all of you for joining us today. We are clearly disappointed with where we are at this moment. We're also – hear it again – extremely committed to this program and to this product and to this Company. We value you as investors. We ask you for your support as well at this moment as we move forward. Thank you very much indeed all of you. Have a great day.

**Operator**

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

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