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## Conference Call Transcript

**GTCB - Q2 2006 GTC Biotherapeutics, Inc. Earnings Conference Call**

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Good day, ladies and gentlemen, and welcome to the Q2 2006 GTC Biotherapeutics Earnings Conference Call. My name is Tony, and I'll be your coordinator for today. At this time, all participants are in a listen-only mode, and we will be conducting a question-and-answer session towards the end of this conference. [OPERATOR INSTRUCTIONS].

I'd now turn the presentation over to Dr. Geoffrey Cox, Chairman and Executive Officer of GTC Biotherapeutics. Please proceed, sir.

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

Thank you very much indeed and good morning everyone and welcome to the conference call and webcast to discuss the second quarter and first six months of 2006 results for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB. I'm Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics and with me today is Jack Green, our Chief Financial Officer and Tom Newberry, our Vice President of Corporate Communications.

Our results for the second quarter released earlier this morning, I hope that you have had the opportunity to review this release prior to our call. I want to begin this earnings call by making a few comments regarding our achievements, progress and plans for our antithrombin program and Jack will then provide an overview of the financial results. I will then have some further prepared remarks about our plans for the future for GTC and our transgenic production technology generally as we leverage this important inflexion point in GTC's development and then we can take questions at that juncture.

First of, we 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 anticipations. We urge you to read the Safe Harbor statement noted in our most recent Form 10-K filed with the SEC entitled, important 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, our actual results may differ materially from our current expectations.

So, let me start by making some comments about the regulatory turnaround in Europe and our ongoing plans for ATryn. GTC reached an historic first in early June when the Committee for Medicinal Products for Human Use of the European Medicines Agency or the EMEA completed the re-examination and issued a final positive opinion for the use of ATryn in hereditary deficient patients undergoing surgical procedures. We would like to tell you, that just yesterday on the basis of this opinion, the European Commission formally approved ATryn.

So now, we can confirm that ATryn is officially the first drug derived from transgenic production to be approved anywhere in the world. ATryn is also the first recombinant antithrombin product approved anywhere in the world and the first antithrombin product, whether recombinant or derived from the human blood supply, that has been approved through the centralized EMEA procedure for all 25 countries of the European Union.

This is a very special moment in time. This is not simply the approval of the first product for a small developing biotech company, it also represents the regulatory pathway to developing difficult to express or high-volume therapeutic proteins using our technology.

Clearly this unlocks the value of ATryn not just in the HD indication, but also in the larger indications and the market opportunities, which we are now embarking on with our partner, LEO.

Furthermore and importantly, it is the key to unlocking the value of our entire product portfolio by the external partner programs and our internal proprietary products.

Our objective is to move forward with commercialization not only of ATryn, but also of our portfolio of transgenically derived products generally. We recognize this as a very special opportunity for GTC and one which we intend to grasp and use wisely.

Let me return specifically to ATryn. We are working with LEO, our European partner, to proceed through the steps necessary for the commercial launch in the hereditary deficiency indication. This includes transferring the market authorization to LEO and establishing reimbursement prices in each of the individual countries of the European Union. This will take several months, and reimbursement times vary greatly from country-to-country. LEO is targeting an initial launch on a country-by-country basis starting in the second quarter of 2007. In the near term, our sales of ATryn to LEO will be driven by the development of the clinical program in disseminated intravascular coagulation or DIC, associated with severe sepsis.

DIC is the widespread formation of clots within blood vessels and often results from the consumption of a patient's native antithrombin by the mechanism of septic infection. DIC is a major unmet medical need with 220,000 cases a year in Europe and about half of those patients die, and this is similar to the situation in United States, where there are an estimated 250,000 cases of DIC associated with severe sepsis each year.

LEO originally had interest in this indication based in part on a number of research studies that support the therapeutic potential of antithrombin to mitigate this mortality. Since sepsis is a complex condition, LEO submitted the Scientific Advice from EMEA to define the clinical program. Scientific Advice results in non-public written guidance that is used to evaluate the data that results from the clinical program. You may recall that we had also obtained the Scientific Advice in the hereditary deficiency indication. And this was a feature of the regulatory process that was useful during the successful reexamination.

The request for Scientific Advice was based on the strong supporting evidence from a subset of analysis of the Kybersept trial. It's a trial, which was carried out by Aventis some four or five years ago. That analysis suggested that using plasma-derived antithrombin may be effective in DIC provided the patients are not treated concomitantly with heparin. As a result, the key feature of the request for advice is that the patients in the active arm that are to receive ATryn are not to receive concomitant heparin.

LEO has just obtained the Scientific Advice which does incorporate this concept and provides guidance for Phase II study. We've not had the opportunity to discuss further details with our partner at this stage.

The Phase II study goals are to explore efficacy and safety and to establish the appropriate dosing regimen in preparation for a Phase III study. There will be a minimum of 200 patients in the Phase II study including the control group that receives the standard of care.

The last patient is planned to be enrolled approximately 12 months after the initiation of enrollment, which is projected to start by the end of this year. The design of the Phase III study and the numbers of patients will be depended on the outcome of the Phase II study.

The United States for which we retain exclusive commercialization rights, we are continuing the Phase III study that we anticipate will form the basis for a Biologics License Application or BLA with the FDA and to request approval for marketing in the hereditary deficiency indication. This study includes an historical control arm of at least 35 cases with a similar profile to the active arm. We are re-examining the outcome for hereditary deficient patients that have been treated with plasma-derived antithrombin. The active arm will include an additional 17 hereditary deficient patients that are undergoing surgery or childbirth. Remember the results of these 17 patients will be added to the 14 that were submitted to the EMEA to establish a total active arm of 31 patients.

Our current scheduling of patients projects that the last patient is to be enrolled in the first quarter of 2007 and this timeline together with the collection and analysis of data, indicate that we should expect to file the BLA within six months of the last patient enrollment.

We will also be submitting the childbirth results from these ongoing Phase III study to the EMEA in 2007 for consideration expanding the approved label in Europe to include childbirth. In light of that being little to no-dose in the guidance for plasma-derived antithrombin products in childbirth situations, we believe this data will represent a significant addition to the body of knowledge for the treatment of pregnant patients and represent a commercial advantage for ATryn in this patient population.

We believe that the addition of the US market and the later addition of the acquired deficiency indication both in Europe and United States and the rest of the world will drive ATryn sales to very significant levels, potentially in the order of \$500 million per annum.

In the longer term, we are also interested in developing ATryn in Japan and the rest of the world. In addition, we are seeking partnering opportunities for additional products. Remember, we are interested in establishing partnerships where GTC meaningfully participates in the commercial opportunity of the product. Having the first approval supports this more expansive objective for our partnership opportunities. And I look forward to updating you about our partnering opportunities as they progress.

I am also pleased that we have completed our recent financing despite the choppy market conditions, which maintains the financial health of the Company and provides the opportunity for us to maintain the momentum in our key programs. I would now like to ask Jack to review our quarterly results, including our cash position.

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**Jack Green - GTC Biotherapeutics - CFO**

Thank you, Geoff. Our press release provides significant detail about our financial results for the second quarter and the first six months. I would like to focus on few of the numbers that I believe to be most pertinent to Geoff's discussion.

We ended the second quarter with approximately \$19.4 million of cash and marketable securities. Excluding the \$2.4 million note payment made to Genzyme in January, we have a net use of cash for the first six months of approximately \$14.4 million. Remember that the Genzyme note pay-off was refinanced through expansion of our credit facility with GE Capital with proceeds received in December 2005. Our expectation of net cash used for the full year, exclusive of the Genzyme note payment, remains in the range of 21 to \$25 million or between 7 and \$11 million for the second half of 2006.

We expect the net cash used to decrease in the second half as LEO begins paying us for ATryn clinical material as well as for the additional \$2 million milestone payment for formal EC approval of ATryn.

As Geoff has previously mentioned, last month we completed a registered direct placement of 12 million shares of common stock raising an additional \$17.5 million in new equity, approximately \$16.2 million after expenses. The stock was priced at market or a \$1.38 per share and included 10-year warrants to purchase 7.8 million shares at an exercise price of \$1.4145 per share.

On a pro forma basis, adding the net proceeds of the 16.2 million from our July financing to our end-of-quarter cash balance, we effectively began the third quarter with \$35.6 million of cash and marketable securities. Although, we don't have a definitive forecast of our 2007 net cash utilization, we believe that it will be similar to 2006, and therefore, we believe that our current cash resources will be sufficient to fund the Company into 2008, during which time we anticipate completing a number of further value creating events. These potential value creating events include commercial launch of ATryn in the EU, filing the BLA on ATryn, filing for the expanded label in Europe and LEO's completion of enrollment in the DIC Phase II study.

Our cash receipts remain strong. We were paid \$1.4 million in the second quarter for our supply MM-093 to Merrimack Pharmaceuticals for their clinical program as well as \$1 million from LEO as a milestone for the positive opinion. Most of this does not appear as revenue on our financial statements due to the required policies of revenue recognition on multiple element contracts. However, assuming MM-093 continues to advance in its clinical program and with expected payments for supply of ATryn to LEO, I am encouraged by the prospects for growth in our top-line in future periods.

Our cost of revenue and operating expenses increased by \$1.5 million in the quarterly comparison and by \$3.1 million in the first half comparison; of that, research and development expenses increased by approximately 700,000 in the quarterly comparison and by \$2.7 million in the year-to-date comparison. These increases in expenses were driven primarily by the cost of our Phase III study for ATryn in the U.S. and the

cost to produce additional batches of ATryn including qualification batches for use in the Phase II DIC study in excess of the maximum selling price to LEO. These initial production costs are not indicative of what we expect for future production, as our volumes increase. Partially offsetting these increases in the year-to-year comparisons, the lower costs on the EMEA effort for ATryn as well as reduced expenses on the CD137 development program.

The increase in costs of revenue in both the quarter and six-month comparisons reflects increased activities in the expansion of our external program with Merrimack Pharmaceuticals. The increase in SG&A expenses year-to-year reflect the impact of implementation of FAS 123R, accounting for share-based payments, including the cost of implementation as well as the higher legal costs.

Our total net loss for the quarter was \$9.1 million compared with \$7.1 million in the second quarter of 2006, a loss of \$0.15 per share in both periods. Our net loss for the first six months was \$17.6 million or \$0.29 per share, compared with \$15.2 million or \$0.33 per share in 2005. The per share results reflect an increase in the weighted average number of shares outstanding from 45.8 million shares for the first six months of 2005 to 61.1 million shares in the first six months of 2006. These increases reflect the issuance of 21.4 million shares of common stock in offerings in 2005. After completion of our July 2006 financing, we had approximately 73.4 million shares outstanding, 93 million on a fully diluted basis.

To summarize, we believe that we are well positioned financially to support the development programs in growth for both ATryn and GTC, in general. Geoff?

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

Thank you, Jack. This has been an excellent quarter for GTC, and this has carried over into the current third quarter as well. It's valuable to summarize the progress we have made with our key objectives and plans both for this year and for next. First of course, is the positive opinion from the CHMP for ATryn together with all the supporting implications for the future of the program and GTC's entire portfolio. Secondly, is our announcement yesterday of the granting of the marketing authorization for ATryn by the European Commission following the positive opinion. These two events triggered two milestones payments from LEO totaling \$3 million. We will now initiate the transfer of the MAA to LEO and then reimbursement negotiations can be started.

ATryn launch in Europe is targeted for Q2 2007. We have refinanced the Company and secured our ability to maintain our forward momentum. Our ATryn enrolments supporting a BLA submission is planned to be completed in Q1 next year and submitted to the FDA within six months after that.

LEO has received Scientific Advice for the DIC indication from the EMEA and they began to move forward by year-end with the Phase II DIC study. Enrollment in that study is planned for completion in 2007.

These all represent a significant list of accomplishments in future goals over the next 18 months for ATryn as we progress to building a significant business opportunity around this product. However, I also want to remind you of the broader picture, which opens up for GTC. We have two key strategic areas, which we plan to focus on for the future.

Firstly, the production of recombinant versions of plasma proteins, which of course, ATryn is the first; we plan to define our development program now for alpha-1 antitrypsin, human albumin, and potentially other plasma proteins, and we will actively seek partnering opportunities for these products.

Advancing these plans have been limited in the early part of the year whilst we focused on ATryn approval. We also believe that monoclonal antibodies will be a focal point of our strategy for the future and our technology does have unique and relevant characteristics, which we believe are important to this class of proteins.

We already have produced CD137 monoclonal antibody in transgenic goats, and we'll move forward with defining the clinical program for this antibody and we will seek to add to the portfolio with our own proprietary products and through partnering.

Our objective is to develop a portfolio of therapeutic proteins in the area of critical care. We also recognize the importance of partnering in order to help finance the development of these products and that will be an important part of our strategy for the foreseeable future. It is our plan to develop our own commercial capability in the United States as the opportunity arises, and we will aim to maintain U.S. commercial rights in our partnering arrangements.

We have a lot to do to define, plan, and execute the strategy for the future. With ATryn approval a done deal, we are going to look to that future with real confidence and excitement, and I look forward to updating you on our progress.

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

## QUESTION AND ANSWER

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### Operator

[OPERATOR INSTRUCTIONS]. Your first question comes from the line of [Roy Friedman with Edith C. Blum]. Please proceed.

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### Roy Friedman - Edith C. Blum - Analyst

Hello. Good morning, Geoff.

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

Good morning, Roy.

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### Roy Friedman - Edith C. Blum - Analyst

First question is regarding LEO's rollout for the HD indication in Europe, can they launch when the majority of the major EU countries have inked reimbursement agreements or do they have wait for everyone of the member countries? And if it is the former, could we see a partial rollout a little bit earlier, say in Q1 '07 rather than Q2?

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

I think that's an excellent question and I think the Q2 timetable is an appropriate projection at this juncture. Clearly, we have got quite a bit of work to do before that in order to get them MAA transferred to LEO and then they can start their reimbursement discussions, but our expectation is that they will carryout reimbursement on a country-by-country basis and initiate the launch in those countries also on a country-by-country basis. So, we certainly don't have to complete reimbursement in all 25 countries of the European Union, and there will obviously be some priorities which will be set by LEO, that's still a work-in-progress at this juncture and obviously, we would be happy to update you as and when we have further information in that respect.

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### Roy Friedman - Edith C. Blum - Analyst

Okay. Turning to the DIC indication, based on the scientific guidance from the EMEA, what is the standard of care that ATryn will be compared to and will that include plasma antithrombin?

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

The answer to the latter part is no, but the standard of care actually is something which has still got to be defined from the advice that we have received, as I understand it from the EMEA. So, that is -- in fact, we only just received -- or LEO only just received this advice this week and we literally have not had a chance to sit down and go through this in detail with them to get their perspectives on that advice. The standard of care is somewhat variable on a country-by-country basis and therefore it will need to be determined in the protocol and that's also a judgment which LEO will make as we progress forward, but it won't include plasma-derived antithrombin in the control arm. That's not the -- certainly wouldn't be the plan.

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

Okay.

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

By the way, I would make the comment that we will be -- I believe that and I think it is reasonable to expect that once LEO have defined the design of the study and the protocol for the study, and hope that, that will be logged on to one of the websites such as clinicaltrials.gov and so on and so that you will be able to see the type of information, which is normally released in for public domain around these types of protocols. So, that's obviously something which is a little bit down the track at this moment.

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

Okay. Shifting to the U.S., at what point does GTC start thinking about an acquired deficiency indication and is there a strong case to be made for hedging the Company's debts by selecting an indication other than DIC sepsis?

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

That also is an excellent question, but if I just remind you of the terms that we have of the deal with LEO is that the Phase II data, which LEO is financing as a whole of their clinical study, that data will be available to us -- for us to be able to use in the United States as well. In the Phase III study, we do have the option of being able to include U.S. patients in that study and we will certainly want to make sure that we have our own discussions with the FDA, ensure that, that study is designed in such a fashion that we can use that data in the United States as well.

So that is certainly a plan and the way in which the collaboration is defined with LEO, we do have input into the study, so that the study does meet the clinical practice, which we would want in the United States. So, we would plan to be able to use that data in United States and LEO will either finance that themselves or we do have the choice of being able to contribute with financing and obviously the return will depend on how much we finance that study at that juncture, but we do have the options there.

So, I think that's the best way we can go at this moment. Clearly, we could initiate further studies and other indications. We've talked in the past about burns and severe burns remains an interesting area for us. I think we just at this juncture have to be a still quite cautious about the amount of cost of investment in these clinical studies and I think certainly for the foreseeable future the next year or so, we would like to see the outcome of this DIC study before we kick off a range of other indications.

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

Okay. Finally regarding your comment that you made earlier on the call seeking partnerships for the other programs including human serum albumin, is Fresenius still active as your partner or would you be seeking to replace them with somebody else?

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

Well, Fresenius, we still have a continued interaction with Fresenius on that program, but they don't actually finance that program at this moment. That was a result of a decision, which was taken what some four years ago now, where they withdrew from a number of their biotech deals and retrenched to a different strategic position, and we got caught up at that juncture. But we continue to have good relationship with Fresenius and we could continue to look at ways in which we can commercialize that product and that is one of the programs together with our alpha-I antitrypsin where we have been looking to ways in which we can move that forward from a commercialization point of view, but really in the early part of this year and certainly over the last 12 months somewhat being put on the backburner, just whilst we get the ATryn approval done. So, we are now beginning to revisit those issues and define on how we want to progress that. But I think that from a priority point of view, I would probably put alpha-I antitrypsin above the albumin program at this moment.

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

Okay. That's it from me, and I'll get back in the queue.

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

Thank you, Roy.

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**Operator**

Your next question comes from the line of Phil Nadeau with Cowen. Please proceed.

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**Phil Nadeau - Cowen - Analyst**

Good morning. Congratulations on a productive quarter and thanks for taking my question. My first question is on the endpoint in the advice for the DIC indication. I know it's early in the advice, was just received, but you know what that endpoint for the Phase II would be?

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

Well, again, that is one of the things which I'd like LEO to be able to go through their own assessment of the advice and then perhaps to define that in more detail, but it certainly will increase -- include mortality and the question is whether there are other parts of that which will be included as a primary endpoint, but it will clearly involve mortality as being the primary endpoint.

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**Phil Nadeau - Cowen - Analyst**

Okay. My second question is actually on the MAA transfer. What's involved in transferring MAA? Is that a prolonged and complicated process?

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

No. First of all, as I understand it, we have to make the submission to the EMEA to transfer the MAA to LEO and then that has to be -- once that has been done, which -- the process, which takes, I believe, about a month to six weeks something like that, though I would say that, that might be a little slower this time of the year because August is not a good time of the year with [regard] duplications in Europe. But then it goes to European Commission and it is logged there. I think the whole process, it is reasonable to assume it is going to take something at the order of 3 to 4 months to complete that MAA transfer.

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**Phil Nadeau - Cowen - Analyst**

Okay. And my last question is on alpha-1 antitrypsin, is that your next most prioritized candidate internally or is there something that's even above that?

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

No, I think, actually on the -- in the area of recombinant plasma proteins that we have got animals that produce very large amounts of this protein about 20 grams per liter of alpha-1 antitrypsin, and so we are very interested in defining the clinical development program and the options and the opportunities for that and we are really beginning to return to focus on that at this juncture, and hopefully over the next quarter or so, we will be able to start to lay those plans out in a more detailed fashion.

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**Phil Nadeau - Cowen - Analyst**

Okay. What is alpha-1 antitrypsin used for today in the clinics?

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

Today, there is a significant market largely owned by what was Bayer plasma proteins, which is now Talecris, a product called Prolastin, the plasma-derived antithrombin and it is for the treatment for hereditary deficiency and there is a very large population of people who have this genetic deficiency, estimated somewhere around about 3 million people who have this type of genetic deficiency, although it is significantly under-diagnosed and significantly under-treated. I think today -- and I am little bit shooting for the hip here, but I believe Prolastin sales are something of the order of 250 to \$300 million a year at this moment, but again it is a program -- it is product which has the potential for very much larger opportunities in that patient population.

When you have hereditary deficiency, you have a very strong likelihood of developing emphysema over the years, and this is an elastase inhibitor as such, and if you smoke then that increases the likelihood of developing emphysema very considerably. So, I think we believe that there is significant opportunity to be able to enter into that market. It's a chronic condition and rather differently from the hereditary deficiency for antithrombin, where we have been looking obviously to an acute usage. This is more of a chronic usage, and patients are normally treated every one or two weeks through an IV with this -- with plasma-derived product.

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**Phil Nadeau - Cowen - Analyst**

Okay. That's very helpful. Thank you.

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

Okay. You are welcome.

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**Operator**

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

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**Sean Wu - Rodman & Renshaw - Analyst**

Hello. This is actually [Sean Wu] standing in for Navdeep. Congratulations on a great quarter.

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

Thank you.

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**Sean Wu - Rodman & Renshaw - Analyst**

I have a question regarding your Phase III. You said the -- you may have actually collaborated with them for the Phase III trial and as this certainly make a sense, do you have any kind of like temporary, tentative agreement on this regard?

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

Are you talking about the Phase III hereditary deficiency --

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**Sean Wu - Rodman & Renshaw - Analyst**

Oh, DIC, yeah.

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

Oh, for the DIC. Okay. For the DIC, I think the answer is that the design of the Phase III study and the number of patients in the Phase III study will only be able to be defined once we have the results of the Phase II study and the Phase II study clearly will help us to understand both the, some guidance, although it's not powered to demonstrate efficacy as such, but it will obviously give some guidance towards efficacy and the safety of the product and also very importantly would help to establish what the dosing regimen for the product would be. So, I think until that data is available I think it's very unlikely that we will -- we want to just try and define the details of what Phase III study will look like. We obviously have some sense of what that may look like, but I don't think that's something, which would be appropriate for us to try and give guidance on at this juncture.

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**Sean Wu - Rodman & Renshaw - Analyst**

You have -- already you have 200 patients for a Phase II study. So, I am just kind of wondering if you have manufacturing capability to support the large Phase III study?

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

Oh, yes, absolutely. Obviously, we are expanding our herd of animals at this moment in order to be able to support that and certainly we have that capacity at this juncture to support Phase II study, and we are working very closely with LEO to establish the forecast, which is required for the Phase III study. We are very confident in our ability to be able to support that. Of course, our purification is done through our partner, Cambrex in Hopkinton, Massachusetts. So, we believe we have the capacity there as well. So, that's something, which obviously we've contemplated and which we've worked very closely with LEO on and those plans are already in place.

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**Sean Wu - Rodman & Renshaw - Analyst**

So, will you be selling, [Tridyne] your clinical product through LEO, okay, how that [churns] the price difference, I am just trying to find out whether you will be selling at a profitable way or it's just one kind of agreement--?

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

No, I think actually the way in which the agreement works is they will cover our cost of clinical production, fully loaded cost of clinical production, but there is a cap on that, but as our volume increases, we clearly expect our unit costs to reduce, which is normal with capital intensive types of production, until that they will pay us not a margin, but they will pay us the cost of actual production, so that's fine during the clinical phase, obviously where we supply product for commercial use that will be done at a margin and also we will get a royalty on that product as well.

I think in terms of the production, which we have just produced to initiate the clinical studies Jack referred to, the fact that some of those costs were above, there is a cap on the costs, which I can't disclose, but there is a cap on the transfer price of the clinical product to LEO. We as a result of the dialogue in the approval process with the EMEA, we introduced a number of additional analytical procedures which were part of our qualification batches in the early part of this year that did add to our costs initially. We expect our costs to come down below that cap as we move forward and our volumes increase. So, we feel confident that that's a temporary situation.

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**Sean Wu - Rodman & Renshaw - Analyst**

So this -- you may actually -- now you are providing the material at a loss, so how will these two items recording your financial statement income or the -- it will always will be off of balance sheet than income statement?

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

Yeah, I'll ask Jack to -- I think if I understood your question is this, how will it be recorded on between the P&L and also the balance sheet? Jack, can you pick that up?

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**Jack Green - GTC Biotherapeutics - CFO**

Sure Geoff. The excess cost over and above the maximum transfer price to LEO will be expensed and have been expensed to the extent that we know we have the excess cost we have expensed those. Going forward, we will capitalize into inventory, the cost of production and will capitalize those up to the maximum transfer price to LEO to the extent if there are any cost in excess of that they will be expensed and will show up in the P&L. When we sell product to LEO then we will take those costs, those inventory costs off our balance sheet and record them in cost of sales or actually they are not P&L, that's called costs of revenue.

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**Sean Wu - Rodman & Renshaw - Analyst**

Okay.

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**Jack Green - GTC Biotherapeutics - CFO**

And that is where you will see -- that is where you'll see that line item.

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**Sean Wu - Rodman & Renshaw - Analyst**

You'll record revenue in costs of other revenue.

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**Jack Green - GTC Biotherapeutics - CFO**

That's correct.

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**Sean Wu - Rodman & Renshaw - Analyst**

Thank you very much. Okay, that's all I have.

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

Thank you.

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**Operator**

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

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

Hi, follow-up question for Jack. How many dollars remain on each of the two shelf registrations?

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**Jack Green - GTC Biotherapeutics - CFO**

The first shelf registration is no longer active. The one that we did last year became inactive when we filed our 10-Q -- sorry, 10-K this year. We filed a second shelf registration statement, essentially to put back on the shelf the same amount that was on the old shelf, remaining was \$35 million. We just utilized 17.5 million. So, there is another 17.5 million left on the second shelf and that is only the active shelf we have.

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

Aug. 03. 2006 / 10:00AM ET, GTCB - Q2 2006 GTC Biotherapeutics, Inc. Earnings Conference Call

Okay. Thank you very much.

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**Jack Green - GTC Biotherapeutics - CFO**

You're welcome.

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**Operator**

[OPERATOR INSTRUCTIONS]. Okay, gentlemen there are no further any questions in queue.

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

Thank you very much indeed. I want to thank everyone for joining us this morning and we expect to discuss our third quarter results early in November and we look forward speaking to you then at that juncture. Thank you very much indeed everyone. Have a great day.

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**Operator**

Thank you for you attendance and today's conference. This concludes the presentation, you may now disconnect. Good day.

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