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Conference Call Transcript

GTCB - Q3 2006 GTC Biotherapeutics, Inc. Earnings Conference Call

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PRESENTATION

Operator

Good day ladies and gentlemen and welcome to the Third Quarter 2006 GTC Biotherapeutics Incorporated Earnings Call. My name is Eric and I will be your coordinator for today. At this time, all participants are in a listen-only mode. We will be facilitating a question and answer session towards the end of the conference. If at any time during the call you require assistance, press * followed by 0 and a coordinator will be happy to assist you. As a reminder, this conference is being recorded for replay purposes. I would now like to turn Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics. Please proceed sir.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Thank you very much indeed and good morning everyone and welcome to the conference call and Web cast to discuss the financial results of the third quarter 2006 for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB. I'm Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics. With me today are Jack Green, our Chief Financial Officer and Tom Newberry, our Vice President of Corporate Communications.

Our results from the third quarter were 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 call by making a few comments regarding the strategic transformation which is taking place in this company and Jack will then provide an overview of the financial results for the third quarter and discuss the proxy vote to approve the \$25 million investment by LFB Biotechnologies. I will then have some further prepared remarks prior to opening the call to questions.

First as usual, let me remind you of our Safe Harbor statement for this call and of the SEC Safe Harbor provisions. Please note that certain comments today about future events or 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 10K 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 10K and subsequent 10Qs, our actual results may differ materially from our current expectations.

So this call takes place at a time which is both exciting and challenging for GTC. Over the last six months, the company's fortunes and opportunities have been truly transformed, catalyzed of course by the approval of ATryn by the European Commission. In June, we received a positive opinion from the European's Medicines Agency or EMEA for ATryn and in early August, the full MAA approval, just three months ago.

This is a special time in the history and progress of this company. It's special because the decisions we take and the strategies we define and our execution of those strategies will be crucial to the creation of a significant, vertically integrated company which is our overarching objective and the one that we believe will bring the greatest shareholder value.

Few companies in this industry have this opportunity and we recognize that. We're excited and energized by the challenge which it offers. It was just 12 months ago that we entered into our collaboration with LEO Pharma, based in Copenhagen for the marketing and further development of ATryn in Europe, Canada and the Middle East. In July, we obtained additional financing for the company and arranged a direct offering and then in late September entered into a broad strategic collaboration with LFB Biotechnologies for the development and worldwide commercialization of recombinant versions of plasma proteins and monoclonal antibodies using our transgenic production technology.

Our initial focus with LFB will be on Factor VIIa. This collaboration includes a commitment by LFB to invest \$25 million into GTC. Today, we have the elements necessary to realize our vision for the company's future with our first fully approved product, two excellent and committed strategic partners, a healthy balance sheet and a growing portfolio of proprietary products in development for valuable markets enabled by the unique characteristics of our technology platform.

So let me provide some more detail on these key points starting with the ATryn program and the LEO partnership which remains a key focal point for us. Our first step in the commercialization of ATryn in Europe is for the MAA to be transferred to LEO and this request and supporting documentation has been made to the EMEA and we're awaiting confirmation of the transfer which we are expecting in this quarter. LEO will then begin reimbursement negotiations in selected countries with a view to initiating launch on a country by country basis, starting in Q2 next year.

In the third quarter, LEO received scientific advice from the EMEA for the design of the phase two study for the treatment of disseminated intravascular coagulation or DIC, in severe sepsis and that study has now agreed and patient enrollment planned to start by the end of this year. LEO is beginning the process of IRB approvals to initiate the study. The study is a comparative dose ranging study to explore the use of ATryn excluding the use of concomitant Heparin against the standard of care which may include Heparin, antibiotics and fluid supplements. This is not a statistically powered study but it is expected to provide guidance as to the efficacy of the product as regards survival benefit as well as dosing requirements which could form the basis of the design of the phase three study to follow.

It is planned that recruitment will take approximately 12 months and the results are likely in mid-2008. This is an important study because it is a demonstration of a significant acquired deficiency indication for ATryn and its success, we believe, will form the basis for a very large market opportunity for ATryn on a worldwide basis. We believe that the prospects for the success of ATryn in DIC are strongly supported by the subset analysis work done at the KyberSept study by Dr. Wiedermann as well as other confirmatory papers that point to the need to administer Antithrombin without the use of Heparin in this indication. The KyberSept study was a large study performed by Aventis with plasma derived Antithrombin some five or six years ago.

Alongside this clinical development activity, we are also manufacturing products to support the commercial launch in Europe, the ongoing phase three study for BLA in the United States and supply the needs of the DIC phase two clinical program.

In addition, although the scale of our current process is adequate to meet these objectives, we recognize that we need to scale up our manufacturing process further to meet the long term requirements for this product, including the phase three DIC studies and to leverage the resulting economies of scale. That work is ongoing and is planned to be completed over the next 18 months in readiness for the start of the phase three DIC study.

As an aside, while we're talking about manufacturing, you may have seen the announcement last week that Cambrex is selling some of its operations to Lonza, including the Hopkinton facility where ATryn is purified. We are assured by Cambrex that this will not cause a disruption to the manufacturing of ATryn and we look forward to continuing our manufacturing with Lonza who we know quite well.

Finally, in the ATryn segment, let me tell you about our pivotal study in the United States in the hereditary deficiency indication which leverages the data which we have submitted successfully in Europe. As a reminder, the FDA asked us to add a further 17 patients in the active arm to the 14 we recruited for the European study. This of course is a rare disease with recruitment rates that are difficult to predict and they have been slower than in our previous studies. Our forecast is that the recruitment in this active arm will be completed in the first half of 2007 and the BLA filed in the second half of 2007. The comparative arm to this study is a so called historical study in which records of patients previously treated with plasma derived product are examined for outcomes. This comparative arm is progressing satisfactorily and is not expected to be the rate limiting step in this submission.

Let me now turn to our recently announced strategic collaboration with LFB Biotechnology for the development of Factor VIIa and potentially other recombinant plasma proteins and monoclonal antibodies. I'm going to ask Jack to describe the financial structure of the deal, particularly the equity investment which is subject to shareholder approval and which a proxy statement has been recently mailed to shareholders. Our contract with LFB of course, is already effective on signing but it is important that we take this opportunity to establish GTC's financial stability and the support of a strategic partner who is committed to the long term investment of money and supporting infrastructure to the central focus of our proprietary programs. The long term value creation opportunity of this collaboration is very significant and I strongly recommend your support for these proposals.

The first product selected for the collaboration is transgenically reproduced recombinant human Factor VIIa. Factor VIIa is a clotting factor in the coagulation of blood. LFB has been conducting research in this program for some time and has already demonstrated that Factor VIIa is correctly expressed in a transgenic system, providing an excellent starting point. We would also be able to use the clinical and regulatory infrastructure that LFB has established in Europe for their plasma derived products. GTC is also planning to develop submittals for the U.S. and other countries, building on LFB support and this is similar to the approach being utilized in our relationship with LEO for ATryn. LFB will be paying for supply of product for clinical studies as well as sharing in the cost of developing the transgenic production and purification capabilities. We will have the opportunity to share equally in the profits from commercial sales, support our vision of building a vertically integrated company. We are retaining exclusive commercial rights in North America to this and subsequent products of collaboration.

Factor VIIa is a protein that is useful for the treatment of hemophilia which is principally caused by a number of genetic conditions that may lead to excessive bleeding. A recombinant form is available from Novo Nordisk called Novo Seven dominates this market and has been reported to have achieved worldwide sales of about \$845 million in 2005. The volume of Novo Seven to support these sales was about one kilogram. Independent market analysis estimates that the market potential for recombinant Factor VIIa will grow to annual sales of \$2 billion over the next six year. The sales of plasma derived Factor VIIa products are small at less than \$20 million. The application of transgenic technology may enable the production and pricing of Factor VIIa at more appropriate levels for broader utilization in current markets as well as extending its use to the treatment of the unmet needs of patients in an expanded number of countries and to the treatment of other acquired bleeding conditions, including hemorrhagic stroke, trauma and surgery. The collaboration plans for the initial indication to be in hemophilia. Severe hemophilia is a substantial market with 35,000 patients in Europe and about 21,000 in the United States. There is a worldwide incidence of about 1 in 5,000 males. This disease principally occurs in males since the genetic condition is linked to the X chromosome.

An important subset of this patient population -- in fact, ten to 15% -- develops inhibitors which are antibodies that significantly decrease the efficacy of Factor VIII in case of hemophilia A patients and Factor IX for hemophilia B patients. For these patients, Factor VIIa is the treatment of choice. Earlier today, these patients were only treated when their condition presents bleeding problems. An improved cost structure may encourage prophylactic treatment of this patient group as well as enabling treatment of patients in a broader range of markets. The current planning is to initiate studies in those hemophiliacs with the antibody condition.

At this point, I'm going to ask Jack to provide an overview of our Q3 financial results and also to remind you of the key elements of the LFB investment for which we are seeking your approval. I will then have some further comments on our other programs and some closing comments.

Jack?

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

Thank you, Geoff. Revenues were approximately \$700,000.00 for the current quarter, a 42% decrease from the \$1.2 million in the third quarter of 2005. Revenues for the first nine months of 2006 totaled \$3.3 million, a 6% decrease compared to the \$3.5 million in the first nine months of 2005. The revenues in the third quarter were primarily from the program with Merrimack Pharmaceuticals for the production of their MM-093 product.

We deferred \$2.6 million of revenues in the third quarter, primarily related to cash received from LEO for successful approval of ATryn in the EU as well as cash received from Merrimack that was not recognized as revenue in the current quarter. These deferred revenues will be recognized as revenue in future periods in accordance with our revenue recognition policy for multiple element arrangements.

Third quarter revenues in 2005 included the completion of the program with Elan as well as the ongoing Merrimack program. There was no deferral of revenue during the third quarter of 2005. The revenues for the nine month results were primarily due to the program with Merrimack. We deferred \$5 million of revenues during the first nine months of 2006 primarily related to cash received from LEO and Merrimack that will be recognized as revenue in future periods. Revenues deferred in the first nine months of 2005 totaled approximately \$700,000.00.

Total cost of revenue and operating expenses were \$11.1 million in the current quarter, a 44% increase from the \$7.7 million total in the third quarter of 2005. Cost of revenue and operating expenses totaled \$31.4 million for the first nine months of 2006, a 26% increase from the \$24.9 million for the first nine months of 2005. These cost increases were driven primarily by production of supplies for both the Merrimack and ATryn clinical programs. The increase in cost of revenue in both the third quarter and nine month comparisons reflect increased activity in the expansion of our external programs including the costs associated with revenue that was deferred. Please note that we are required to recognize the cost of these programs in the quarter in which they are incurred even though some of the revenue will be deferred to future periods.

Research and development expenses increased by approximately \$2 million in the quarterly comparison and by \$4.8 million in the year-to-date comparison. These increases were primarily driven by the cost to produce additional batches of ATryn including qualification batches for use in the phase two DIC study that were 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 were lower costs on the EMEA effort for ATryn as well as reduced expenses on the CD137 development program. The increases in SG&A expenses year-to-year reflect higher legal costs in support of intellectual property and new business transactions.

The total net loss for the current quarter was \$10.3 million or \$0.14 per share, compared with \$6.7 million or \$0.14 per share in the third quarter 2005. The total net loss for the first nine months of 2006 was \$27.9 million or \$0.43 per share compared to \$21.8 million or \$0.46 per share for the first nine months of 2005. These increased net losses included the significant impact of the deferred revenue in the third quarter and first nine months of 2006. The per share results were affected by an increase in the weighted average number of the shares outstanding from 49.4 million shares for the third quarter 2005 to 71.7 million shares in the third quarter 2006. The weighted average shares outstanding increased from 47 million shares for the first nine months of 2005 to 64.6 million shares in the first nine months of 2006. The increases in weighted average shares outstanding primarily reflect the issuance of common stock and financing transactions that improved the cash and marketable securities available to reach significant milestones in the product programs. GTC had approximately 73.6 million shares outstanding as of October 1st, 2006 and 93.1 million shares on a fully dilutive basis.

We ended the third quarter with approximately \$29.3 million of cash and marketable securities compared to \$36.2 million at the beginning of the year. Exclusive of the registered direct placement of stock in July 2006, we used \$6.3 million of cash in the third quarter. Excluding the repayment of a promissory note made in January 2006, in addition to the July 2006 registered direct placement, we used approximately \$20.7 million in the first nine months.

Assuming a successful shareholder vote on the completion of the investment by LFB, we anticipate ending the year with a pro forma of 50 to \$54 million of cash and marketable securities. This is consistent with our previous projections for a net cash utilization of 21 to \$25 million for 2006, excluding financings and the promissory note payment.

Our cash forecast includes projected fourth quarter 2006 cash receipts from our ongoing product supply commitments with Merrimack and the sales of ATryn clinical supplies to LEO.

Let me now say a few words about the LFB investment and the ongoing shareholder vote. LFB will invest a total of \$25 million in GTC of which \$6 million was completed in October and an additional \$19 million is dependent on the approval of our shareholders. We have reviewed the details of the financing with you in our previous conference call on the LFB collaboration and the details are available in our previous press release as well as in the proxy statement which has been mailed to the shareholders. This investment is very important to us. If completed this year, we will then have approximately two years of cash including the funds to move not only the Factor VIIa program forward with LFB, but also to progress the development of our pipeline. The investment will take the form of preferred stock, common stock, and convertible debt. Upon the completion of the stock investment, LFB will own the equivalent of approximately 18.2 million common shares or 19.9% of our outstanding equity post-transaction.

In addition, they will purchase a \$2.3 million convertible note which will convert into common shares subject to the contractual limit of 19.9% of total equity. The preferred stock pays no dividend and carries no liquidation preference. The equity financing is priced at market as of the date of the agreement with no discount and it included no warrants. Most importantly, it will be done with a strategic partner who will be collaborating with GTC in the strategic development of our product portfolio.

The special shareholder meeting is scheduled for December 5th, to shareholders of record on October 23rd. We are asking for approval of an increase in authorized shares to 200 million shares which will provide long term flexibility to support the company's development and for approval of the LFB investment to exceed 20% of the shares outstanding prior to any investment by LFB, even though LFB will only own 19.9% upon completion of the transaction.

We have begun mailing the proxy statement to our shareholders with the intention of obtaining shareholder approval before the end of the year. We believe that these are attractive investment terms which provide the company with financial stability and the resources to create shareholder value through the development of our product portfolio and we strongly recommend that our shareholders vote to approve it.

Geoff?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Thank you, Jack. Now let me take a few moments to review our programs. Let me start with CD137 which is an immune modulator which we believe has the potential to be used in a broad range of indications including solid tumors and autoimmune diseases. We have developed transgenic animals that produce this antibody at high levels and we have recently been awarded a further SBIR grant which will assist in the aim of moving this program into the clinic over the next two years.

This is an exciting program with the potential to address major markets. Our current plans are to focus initially on the oncology indications and we would also seek partnering arrangements in order to support both the clinical and financial needs of this program. As we have discussed previously, we have transgenic animals that produce large volume of alpha 1 antitrypsin in their milk. We are now moving this recombinant plasma protein into a preclinical program with a view to treating patients with a hereditary deficiency of alpha 1 antitrypsin. This is one of the largest genetic disorders. It's poorly diagnosed and can lead to emphysema later in life. Since it's a chronic disease, patients are treated on a weekly basis. Our intention is to move this program into a clinical setting over the next two years.

Our focus is in our proprietary pipeline where we can determine the direction and progress of the programs and where we believe we will derive the largest shareholder value. We will also continue to pursue externally partnered programs on an opportunistic basis where our transgenic platform provides a compelling rationale to advance a product into clinical and eventually commercial supply. In these situations, we will seek to participate as a value added partner in the development of the program.

Our intellectual property, in addition to our demonstrated expertise and obtaining approval of products derived through transgenic production technology is a compelling value that we bring to both our internal and external partners. The recently granted broad patent in the United States for the production of therapeutic proteins in the milk of transgenic mammals provides us with the dominant intellectual property in the United States until the year 2021.

I hope that you can tell from everything going on that we're very excited about our transformation, catalyzed by ATryn's approval in Europe and validated by the commitments made by two important strategic partners. This, in combination with our renewed financial resources, will enable us to pursue our growth strategy. Over the next two years in pursuing this strategy, we're planning to first of all, launch ATryn in Europe through LEO in the second quarter of 2007, file a BLA in the United States for a hereditary deficiency in the second half of 2007, assist LEO in initiating the DIC phase two study by the end of 2006, assist LEO in completing enrollment in the DIC phase two study by the end of 2007, obtain the results of the DIC phase two study by mid-2008, initiate the DIC phase three study after receiving further EMEA scientific advice, explore ATryn partnering opportunities worldwide, particularly in Japan, establish clinical production in the Factor VIIa program, complete preclinical work Factor VIIa with LFB, supply product for LFB to initiate clinical studies by the end of 2008 and complete preclinical evaluations in both the CD137 and alpha 1 antitrypsin programs.

We look forward to communicating these exciting goals and opportunities with the investment community. We began a high level effort earlier this week at the Underberg [Tobin] conference in New York. Next week, we'll be presenting at the Rodman and Renshaw conference in New York, followed by the Cowen conference in London. At the end of this month, we'll be presenting at the Lazard conference in New York. In addition, we have already begun a series of one-on-one meetings with fundamental long term institutional biotech growth investors. You can tell, the transformation that is taking place at GTC is building momentum and I firmly believe that this is the right path to deliver maximum shareholder value. I very much look forward to updating you on the progress of our ATryn program in the United States and for DIC as well as our relationship with LFB and the recombinant Factor VIIa program.

Thank you for listening to our prepared remarks and I now ask the Operator to open the call to any questions.

QUESTION AND ANSWER

Operator

Ladies and gentlemen, if you would like to ask a question, please press * followed by 1 on your touch tone telephone. If your question has been answered and you wish to withdraw your question, press * followed by 2. Please press *1 to begin and stand by as we compile a list.

Your first question comes from the line of Roy Friedman with Edith Blum. Please proceed.

Roy Friedman - Edith C. Blum - Analyst

Good morning, Geoff.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Good morning, Roy.

Roy Friedman - Edith C. Blum - Analyst

Let me start with some questions for Jack regarding the revenue and deferred revenue from the Merrimack program. If the program for MM-093 were impaired for any reason, would you be required under GAAP to move some deferred revenue from the balance sheet to the income statement?

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

Yes, -- we are required right now to spread some of this revenue over the term of the agreement. If the agreement were to terminate for any reason, then we would pick up all of that revenue at that time. So it's kind of a strange thing that would happen that we get a bolus of revenue if the program were to terminate but that's exactly what would happen.

Roy Friedman - Edith C. Blum - Analyst

Okay. By my calculation, GTC received about \$1.3 million in cash from Merrimack during Q3 including the amounts classified as revenue and the amounts classified as deferred revenue. Can you verify that that's at least close?

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

That's approximately right.

Roy Friedman - Edith C. Blum - Analyst

Okay. Geoff, can you clarify whether the AAT program will be conducted with LFB or whether it will be conducted independently by GTC and what the issues are involved in that decision.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Well, I think we have the options to do both those and we've made no decisions on that at this juncture. Certainly in our discussions with LFB, they've expressed significant interest in the alpha 1 antitrypsin program and the contract and collaboration with LFB allows us to present that to LFB as a potential collaboration program. We've made no decisions on that at this present time and we would like to advance some of our development work a little further before we decide which direction to go as far as that's concerned but it has been an important topic of conversation between the two parties.

Roy Friedman - Edith C. Blum - Analyst

Okay. Turning to the ATryn program with LEO, can you provide any kind of very rough guidance for in-market sales during the first 12 months that the product is marketed?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

I have not done that in the public domain and I think that that's a little early for us to be able to project that in quantifiable terms. I think it is important to say though that this product will be launched in selected countries, not in all countries, 25 countries of the European Union initially. There will be a -- these countries will be done over a period of time so they won't all be done right on the front end and some of that will be determined clearly by the timing of getting reimbursement from those countries. Remember, although we've got approval in 25 countries of the European Union, reimbursement takes place on a country by country basis. I think that as I've said to many investors, it's important to recognize that the hereditary deficiency indication itself -- it's a rare condition and a modest market and therefore on its own will not drive GTC to profitability. I think that it should be seen very much alongside the DIC indication, give us tremendous opportunity to introduce this product into the marketplace with key opinion leaders and I think we will get a better perspective of what those figures will look like as we progress during the second half of next year and I'd be happy to give guidance at that juncture. I think it's a little early for me to try and project that. Although we have some hopes and expectations, we have not really disclosed that in the public domain.

Roy Friedman - Edith C. Blum - Analyst

Okay, fair enough on that. A follow up question for Jack -- does the 50 to \$54 million guidance for cash at year end include the proceeds of the \$2.3 million loan from LFB?

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

Yes, it does. It does include the full \$25 million and part of the \$25 million is the \$2.3 million convertible debt.

Roy Friedman - Edith C. Blum - Analyst

Okay, thank you very much. That's it for me.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Okay, and Jack, just as an addition to that, it's payable, I think in early January. Is that correct?

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

The third tranche of the investment which is approximately \$4.5 million is payable in the first week in January which is why we use the term pro forma when we talk about year-end cash. The actual note proceeds and the second tranche of the investment will be received shortly after receipt of shareholder approval which we anticipate will be in December.

Roy Friedman - Edith C. Blum - Analyst

Okay, thanks for the clarification.

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

Thank you, Roy.

Operator

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

Phil Nadeau - Cowen and Company - Analyst

Good morning. Thanks for taking my question.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Good morning, Phil.

Phil Nadeau - Cowen and Company - Analyst

My first question is on the comparative arm in the U.S. phase three trial. In your prepared remarks, you made a comment suggesting that that won't be the rate limiting factor in the completion of the trial. It was my impression that that comparative arm was really just a look at an historical database. Is my impression wrong or are you actually aggregating or enrolling patients in the trial that are being currently managed by standard of care and so there are actually new data from those patients being accumulated during the course of the trial?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

We're talking about the [inaudible] deficiency indication you're talking about, is that correct?

Phil Nadeau - Cowen and Company - Analyst

That's right.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Yeah. No, this is -- these are patients who have been treated in the past with plasma derived products and the data which is being accessed for us is largely in European hospitals. These are patients who have undergone similar procedures to the ones which are included in our active arm. In other words, they're both surgical procedures and pregnancies and so there are no active elements to that at all. The patients are recruited under a protocol though and so this is done in a very appropriate fashion to make sure that it is a real comparative arm. In other words, it's intended that you can't design the study in such a fashion that you can cherry pick the results, if you understand me, which would be an inappropriate comparator. So this is a defined protocol and of course, you have to get patient permission to access records and all those sorts of things so it has some complexities to it but we are proceeding quite well with that and we believe well on schedule with that particular study.

Phil Nadeau - Cowen and Company - Analyst

Okay, so --

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

And there are 35 patients required in that particular arm.

Phil Nadeau - Cowen and Company - Analyst

Okay. The patients that are in that arm, are the characteristics of those patients dependent upon the exact patients that are enrolled in the active arm? So if you have --

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Yes. I understand what you're saying. It's the same inclusion criteria in terms of their background and everything else so it is a comparative arm.

Phil Nadeau - Cowen and Company - Analyst

Okay, but --

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Does that answer your question?

Phil Nadeau - Cowen and Company - Analyst

Yes, my question may have been a little more specific. If you have one patient -- if the next patient enrolled in the active arm is a trauma patient, does that then trigger a look into the database for a trauma patient or is the match in patient criteria between the active arm and the control arm more --

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

I understand what you mean. I think the answer to that is it's not controlled in quite that fashion but we are aware from this first study that we did that we probably have what, 60% pregnancies or something like that as a percentage versus surgical patients. If you remember, in the first arm of the 14, I think we had nine pregnancies and five surgicals and so I think we're likely to see a similar sort of percentage in the ongoing active arm for the United States as well so I think that we will aim to try and keep a similar sort of pattern in the way in which this is conducted and of course, we do this actually through a CRO so that it is done in an arms length fashion, if you understand me.

Phil Nadeau - Cowen and Company - Analyst

Okay. That's great. That answers my question. And then my second question was on the DIC phase two trial. It sounds like Heparin can't be in the ATryn arm but Heparin can be used in the standard of care arm. Are there any other -- first of all, is that correct and then second, are there any other medicines that are allowed in standard of care that can't be used in combination with ATryn?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

The standard of care in sepsis is actually, is not particularly well established as such. It generally focuses around antibiotics and maintaining fluids and in some cases, physicians, depending on the location, do use Heparin and so that's the way in which that protocol has been designed. Of course Xigris also could be used but it's not in this particular protocol so we will be -- the study will be designed against Antithrombin for action on its own versus the standard of care in that particular location so I think that that's -- but as I said, it's not a well defined standard of care in the first place.

Phil Nadeau - Cowen and Company - Analyst

Okay. You, in your prepared remarks, cited the trial where a similar design had been used. What were the results of that trial?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

That's the KyberSept study which is actually being published and the follow up subset analysis which -- there's a number of people who have looked at this including Dr. Wiedermann -- and that actually is being published as well. That original analysis, which I don't actually have the reference for the KyberSept study which is done by Aventis, was close to 3,000 patients and it's a study which actually failed in its totality but in the subset analysis which Wiedermann looked at, he looked at those patients who had been treated without the use of Heparin in conjunction with the plasma derived Antithrombin and in that subset, he found that there was a significant improvement in survival, statistically significant improvement in survival, in those patients where Heparin was not used concomitantly with Antithrombin and I can -- Tom Newberry can certainly provide those papers to anyone who cares to be interested in that, but it's very important and quite compelling documents and I think that when the Aventis study was originally done, there was quite a lot of surprise that it did fail and I also would remind you that a number of the plasma derived products in Europe already have DIC as part of their label although they haven't been supported by well controlled clinical studies in the way in which the Aventis study was intended to be and also DIC is actually approved in Japan as well for plasma derived product.

Phil Nadeau - Cowen and Company - Analyst

That's very helpful. Thank you very much.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

You're welcome.

Operator

As a reminder ladies and gentlemen, if you would like to ask a question, please press * followed by 1 on your touch tone telephone.

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

Sean Wu - Rodman & Renshaw - Analyst

Hello, good morning. This is Sean Wu in for Navdeep. I have a couple of questions. One is about your revenue and the cost of revenue. It looks like you made quite an active margin here. This is not historically what has happened so what happened this quarter which you have such a big discrepancy here, \$1 million?

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

Well, as we had mentioned Sean, we had in addition to the revenue that was recognized, there was also about \$2.6 million of revenue that was deferred and that is due to our accounting policy that requires us to defer revenue over -- for multiple element contracts -- over the future elements of that contract.

Sean Wu - Rodman & Renshaw - Analyst

So don't you have a matching thing? You match your expense with revenue, right? So you don't defer your expense?

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

Well, we take the expense for conducting these programs in the quarter in which they incur and we recognize as much revenue as is allowable under our policy, but in some cases, you have a situation where the revenue and the expense are recognized in different quarters. Accounting principles require us to be conservative when it -- in both booking revenue, that we have to book -- rather, revenue over these future multiple elements that are in these contracts but it also requires us to recognize the expense in the quarter in which it's incurred.

Sean Wu - Rodman & Renshaw - Analyst

[inaudible]

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

So that gives us what -- the phenomena I think you're seeing in our third quarter margin.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

I would just comment that it is confusing and -- but this is what the general accounting practices are and we're not the only company that has to deal with these particular issues and we deal with it in a consistent fashion with the way other companies deal with it.

Sean Wu - Rodman & Renshaw - Analyst

So I have a question. Do you have any kind of milestone or anything related to the [inaudible] phase two trials in the fourth quarter?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

No. From what I remember, it's the milestone which we're paid from LEO will be on the successful completion of the phase two study so that's a milestone which I think we would expect to see, or hope to see, in the first half of 2008.

Sean Wu - Rodman & Renshaw - Analyst

Is it fair to say this 1.6 million of cost of revenue, that we shouldn't see such a high level in fourth quarter?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Excuse me. I didn't understand that.

Sean Wu - Rodman & Renshaw - Analyst

No, I'm just saying this high level of cost of revenue should not be duplicated in fourth quarter, right?

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

Well, what would drive the cost of revenue would be activities on the external programs in particular and if we are doing significant activities, for example on the Merrimack program relative to producing clinical material, you'll see a significant cost of revenue.

Sean Wu - Rodman & Renshaw - Analyst

Okay.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

But you see the cost of manufacturing as it's happening, Jack. Correct? You know, we would incur those costs as they happen.

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

Exactly.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

The revenues will come at a later stage and so on, as according to the elements of the contract.

Jack Green - GTC Biotherapeutics, Inc. - Chief Financial Officer

That's correct.

Sean Wu - Rodman & Renshaw - Analyst

Okay, so you need to scale up your production of ATryn over the next 18 months. It looks like you have started using rabbit in addition to the other one for production of, at least for Factor VIIa. Have you considered using rabbit for ATryn or you'll stick with --

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

No, absolutely not. We've established the production system for ATryn with our goat platform. Our goat platform remains our primary production platform. In the particular instance of Factor VIIa, LFB has done some previous development work in transgenic rabbits. Factor VIIa is not a large volume product in quite the same way as ATryn is. As I remind you, the billion dollar product today from Novo Seven supplied by - just a keynote product -- so it's a scale of production, the size of product which can be perfectly appropriately addressed through rabbit production but rabbits wouldn't be at all appropriate for the ATryn product. As we see forward to acquired deficiencies at the meeting of the market opportunities which we believe we will have with acquired deficiencies, particularly with DIC indication, we're talking about hundreds of kilos of product and that certainly will require the goat platform to establish all the analytical and support procedures and so on for goats and that's certainly what we'll stick with for that product.

Sean Wu - Rodman & Renshaw - Analyst

That's my misconception. I thought the rabbits were easier to produce the [inaudible] platform.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Well, I think it's just a question of volume. A rabbit will produce about ten liters of milk a year whereas a goat produces somewhere between two and three liters of milk a day and so it's a very different volume altogether.

Sean Wu - Rodman & Renshaw - Analyst

I see. May I ask a final question?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Mhmm.

Sean Wu - Rodman & Renshaw - Analyst

Yesterday you said the current market for Factor VIIa is about \$845 million and it's going to grow by, to \$2 billion by 2012. I know you expect to see some prophylactic use of this drug if we don't have more drug available. Is this now actually the market is constrained by the supply limit or --

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

I don't actually have any information on Novo Seven's pricing or -- I know what their pricing is but I don't know what their manufacturing capabilities are and so I really can't answer that particular question. I think we are confident with the technology which we have that we can produce a cost effective product without limitations of production capacity and I think the objective of what we see at this moment is to be able to price this product in a way which it can get broader utilization in a larger number of countries. There are many countries who don't use Novo Seven today because it's such an expensive product and also there are limitations to the way in which it's used in the prophylactic basis in the hemophiliac community and also there are a number of trauma situations including things like cranial bleeds where the product can be used hopefully in a broader fashion once we've done the clinical development work. So I think we feel there is a lot of opportunity to develop the market further and clearly, Nova Nordisk will be competitive in that marketplace but it's a very large market and therefore, we feel very good about our opportunity to have a very significant product in that marketplace.

Sean Wu - Rodman & Renshaw - Analyst

Thank you very much.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

You're very welcome.

Operator

As a reminder ladies and gentlemen, for more questions, press *1 on your keypad.

Your next question is a follow up question from Roy Friedman with Edith Blum. Please proceed.

Roy Friedman - Edith C. Blum - Analyst

Regarding the DIC program, if Xigris is not allowed in the protocol, does that mean that the protocol is restricted to less severe cases of sepsis that are outside the approved label for Xigris?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

No, there are particular -- there is a very clear definition in the protocol of the patients which can be recruited into the study. One of the things which -- and I don't claim to be an expert in this, Roy -- but LEO have taken the best advice of clinicians in the world who treat these types of conditions and people who have been involved in previous studies and there has been a lot of work that's been done over the years in terms of defining the patient population in an appropriate fashion and many studies which failed in the early years of sepsis development and I understand failed because they didn't define the patient population very clearly. I'm not able to disclose to you as to what those definition of parameters are other than to say that this is a study which has got very clear protocol, definitions, of which patients will be included in the study and that I think is going to be important to the way in which the success of this study is seen so -- but I can't say any more than that.

Roy Friedman - Edith C. Blum - Analyst

When the phase two trial starts, will we have that information?

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Maybe not. I think that LEO regards the design of the study in which they've taken scientific advice from the EMEA as being proprietary so, and subject to confidentiality, so we are -- we respect that and obviously it's an important element to the way in which they conduct the study and I think that that will be fairly closely controlled.

Nov. 02. 2006 / 10:00AM ET, GTCB - Q3 2006 GTC Biotherapeutics, Inc. Earnings Conference Call

Roy Friedman - Edith C. Blum - Analyst

Okay, thank you.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

You're welcome.

Are there any other questions?

Operator

There are no more questions at this time. I would like to turn the call over to Mr. Geoffrey Cox.

Geoffrey Cox - GTC Biotherapeutics, Inc. - Chairman and Chief Executive Officer

Thank you very much indeed everyone. Thank you for joining us for this presentation this morning and for the discussion and questions which came after it. We look forward to our next conference call which will be to discuss the fourth quarter results and that will be early in 2007. We look forward to speaking with you again. In the meantime, thank you very much for joining us today. We wish you all our best wishes for the holiday season. Take care.

Operator

Thank you for your participation in today's conference. This concludes our presentation. You may now disconnect. Have a good day.

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