

Thomson StreetEventsSM



Conference Call Transcript

GTCB - Q4 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

Event Date/Time: Mar. 06. 2008 / 10:00AM ET

Mar. 06. 2008 / 10:00AM ET, GTCB - Q4 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

CORPORATE PARTICIPANTS

Geoffrey Cox

GTC Biotherapeutics, Inc. - Chairman & CEO

Jack Green

GTC Biotherapeutics, Inc. - CFO

CONFERENCE CALL PARTICIPANTS

Stephen Dunn

Dawson James - Analyst

Navdeep Jaikaria

Rodman and Renshaw - Analyst

Roy Friedman

Edith C. Blum - Analyst

Donald Hudson

Hudson Associates - Analyst

Steve Turner

Due Diligences - Analyst

PRESENTATION

Operator

Good day ladies and gentleman, and welcome to the Q4 2007 GTC Biotherapeutics Incorporated earnings conference call. My name is Heather 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 today's conference. (OPERATOR INSTRUCTIONS) As a reminder this conference is being recorded for replay purposes.

Now, let's turn the presentation over to your host for today's conference, Dr. Geoffrey Cox, Chairman and CEO of GTC Biotherapeutics. Please proceed sir.

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

Thank you very much and good morning everyone. Welcome to the conference call and webcast to discuss the financial results for the fourth quarter and for the full year 2007 for GTC Biotherapeutics Inc., NASDAQ ticker symbol GTCB. I am Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics and with me today are Jack Green, our Chief Financial Officer and Tom Newberry, our Vice President of Corporate Communications. Our results from the fourth quarter were released earlier this morning and 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 our progress in 2007 and our strategic goals, including developments in our partnering strategy. Jack will then provide an overview of the financial results for the fourth quarter and full year and discuss our cash use projection for 2008. I will then have some further prepared remarks prior to opening the call to questions.

First of all, as usual, let me remind you of our safe harbor statement for this call and the SEC Safe Harbor provisions. Please note that certain comments today about future events and potential developments are forward looking statements based on management's current expectations. We urge you to read the Safe Harbor statement noted in our most recent form 10-K filed with the SEC entitled Important Risk Factors Regarding Forward Looking Statements. As you know, due to the risks inherent in our business, which I described in detail in item 1-A of our 10-K and subsequent 10-Q's, our actual results may differ materially from our current expectations.

I want to take some time at the start of this call to remind you of the strategy that GTC has been following over the last year and the significant progress we have made during that time, particularly over the last quarter. The production technology infrastructure, which GTC has developed, has some unique characteristics, which provide a significant competitive advantage in the production of certain classes of therapeutic proteins. The ability to produce proteins which are difficult to express in other manufacturing systems, has been the foundation of the development of a portfolio of recombinant plasma proteins, which is unique in its breadth, even in comparison with large companies in this space. Our production technology also enables us to produce large volumes of therapeutic proteins at competitive costs and with a fraction of the capital investment normally associated with the production of biologics. These characteristics are not only important to the production and commercial potential of recombinant plasma proteins, but also to the production of monoclonal antibodies. We are exploiting this capability not only in the development for proprietary monoclonal antibodies, but also in the development of a portfolio of follow on biologics, also known as biosimilar's in Europe, which we believe have the potential to be a very important contributor to the future of GTC and which is largely unrecognized at this time. This strategy is supported by an established commercial scale production infrastructure, which has been validated as the result of the approval of ATryn in Europe. We all recognized that the first therapeutic indication for ATryn, is a modest market opportunity. But ATryn's approval in Europe was a major step in unlocking the value of this production technology across the board range of opportunities now available to us.

Since our last call, we've achieved another major milestone with the successful completion of the pivotal clinical study for ATryn in the United States, which is providing the basis for our biologics license application as submission to the Food and Drug Administration. We had obtained permission in the second half of 2007 to submit the BLA on what is known as a rolling basis where sections are submitted as they're ready rather than the normal procedure of waiting until everything is complete before submitting the filing. The rolling submission is divided into two parts. Part one includes the preclinical and manufacturing sections, part two includes the clinical efficacy and safety data. We filed part one in late January. We did this entirely with our own regulatory resources and made the submission electronically as a single disk where subjects are cross linked to expedite review. This is tremendous progress from our European submission where we relied to a large degree on the resources of outside service providers which required submitting 60 volumes of paper. We requested priority review in conjunction with our part one submission and we are awaiting a response. The granting of a priority review would provide for a six month review time after completion of the entire BLA submission. We look forward to working with the FDA during the review process. Many of you regard the approval of the ATryn by the FDA, as a significant and important validation in addition to the approval in Europe and we believe that we are well placed to achieve that objective.

Remember, that in the second half of last year, we received so called "Fast Track" status for ATryn from the FDA along with the permission to file ATryn using a rolling BLA. We are naturally pleased that the FDA has also recognized the unique therapeutic value of ATryn as the only potential recombinant antithrombin by granting it orphan drug status. The clinical trial, which is the basis of our BLA submission, builds on the 14 patient study which formed the basis of approval in Europe. The study in the United States required us to recruit a further 17 patients into the active arm, in addition to these 14 patients. All of these patients have low levels of antithrombin in their bloodstream and a requirement of the study was that all patients had to have suffered a previous thrombosis as a result of that condition. These were high risk patients, therefore, and published research indicates that 40% to 50% of these patients could develop thrombosis in the absence of prophylactic treatment when undergoing surgery or child delivery. The primary end point of the study was the prevention of signs or symptoms of deep vein thrombosis, or DVT's, or other thromboembolisms, while these patients underwent surgery or childbirth. The protocol for the study was to remove these patients from their blood thinners, such as Warfarin or Coumadin, prior to surgery or childbirth and to bring their antithrombin levels to the normal 80% to 120% plasma levels and sustain them at that level throughout the procedure for a minimum of three days or up to 14 days according to the decision of the treating physician. Patients were observed for clinical signs and symptoms of thrombosis during the course of treatment and for the seven days following completion of treatment during which period patients were returned to their normal blood thinners. Eighteen patients were recruited into the study, six surgical patients and 12 pregnancies, of which 17 are considered evaluable. The unvaluable patient was a mother who gave birth so quickly the physician was unable to achieve the protocol dosing requirements in time. However, the mother continued to be treated and mother and baby were fine. No patients in the active arm of the study showed signs or symptoms of DVT's. Remember again these are all high risk patients and procedures.

In the US trials, the FDA asked us to conduct a non-inferiority study with a comparative arm, and it was agreed that this comparative arm would be a retrospective study with data collected under a protocol and in which HD patients with a clinical history of thrombosis had been treated with plasma derived antithrombin when undergoing similar high risk procedures in surgery and childbirth. A minimum of 35 patients were required in the study and we obtained 38 evaluable patients. Most of these patients were in Europe, since plasma derived antithrombins have been in short supply over the years in the United States. There were no observations of clinical signs or symptoms of DVT's in these patients, representing the highest bar for ATryn comparison and one that I'm very pleased we met. We believe that this comparison forms a strong platform for our BLA filing. The FDA has asked us to collect plasma samples from our patients for up to 90 days after the treatment for antibody assessment and that is an important element in the time line for completing our filing with the FDA. Collection of antibody data is standard practice for clinical trials for the recombinant proteins. Remember that we also looked for the generation of antibodies 90 days after administration of ATryn in the study we performed for our successful European filing. We are planning to complete the clinical sections of the BLA with statistical efficacy analysis and

the safety data including antibody results around midyear. We are also preparing for the inspection of our production facilities used in the production, purification and fill/finish of ATryn although the FDA has not provided any guidance regarding the timing of these inspections at this stage.

We have made progress in our partnering discussions for ATryn development and commercialization in the United States and we've initiated similar discussions with potential partners for our broader recombinant plasma protein portfolio. The focus of discussions for ATryn in the US is on the clinical and market opportunities available for the broader acquired deficiency indications. While Leo continues to develop the DIC acquired deficiency in their territories, we will have access to that data for the US. We expect to be working with our US partner on an additional acquired deficiency indication broadening the development program for this product. Partnering discussions have progressed to the exchange of term sheets. We are looking for a collaboration where the partner is committed both at the commercialization and further clinical development of ATryn. We're expecting an overall structure similar to the one which we have with Leo with an up-front payment, sales and clinical milestones, financial support of clinical development, transfer price for the product and a royalty on sales. We're working to bring these negotiations to a successful conclusion over the next few weeks. As I'm sure you're aware, time lines for negotiations such as these, can be unpredictable.

Commercialization and further development of ATryn in Europe is occurring through our collaboration with Leo Pharma. Leo is pursuing a premium pricing strategy recognizing that ATryn is the only antithrombin that is a recombinant and the only antithrombin product that has been approved for use throughout the European Union under the centralized EMEA procedure. Pricing has been established in the UK, in Ireland and Greece and launch activities will continue as pricing is set on a country by country basis. In light of the premium pricing strategy, we expect growth in the commercial revenue to be slow in 2008. Remember that our ATryn revenues consist of product payments from Leo for both ATryn that will be sold commercially and for the clinical supply that will be used in the DIC study. Leo began a phase two dose ranging study in 2007 for the DIC indication. In our last call, we reported that this study was progressing more slowly than originally planned and Leo has made a number of adjustments including expanding the number of sites to increase the rate of recruitment. Leo's objective is to have top line results in the first half of 2009. We plan to provide a more definitive update on the rate of recruitment around the middle of 2008. We believe that the DIC indication is a significant market opportunity. The recent research published in a letter in Nature authored by independent scientists at the Scripps Research Institute and Johnson and Johnson Pharmaceutical Research and Development, supports the view we shared with you in earlier conference calls that DIC and Sepsis result in both a coagulation and an inflammatory response and that both these must be addressed. Antithrombin has both anticoagulant and anti-inflammatory properties. Previous reports have indicated antithrombin has the potential to provide a significant reduction in mortality for DIC patients as long as anti-inflammatory properties are not compromised by concurrent administration of heparin.

During the last quarter, we have made good progress with expanding our portfolio of recombinant plasma proteins by licensing Factor IX, Factor VIII and fibrinogen from ProGenetics. The license covers Europe, North America and Japan. ProGenetics is a small, private company that we've known for many years and have been developing recombinant proteins in the milk of transgenic pigs. The most advanced program is Factor IX, where pigs already exist that produce where they produce this product in their milk. Our plans for this year, include the transfer of the purification of Factor IX to GTC and the initiation of preclinical studies with the objective of entering the clinic in 2009. This program has already been brought under the umbrella of our joint collaboration with LFB, our existing partner for Factor VIIa and CD-20 monoclonal antibody. The clinical development plan for Factor IX is expected to follow a similar pattern to that used for the existing recombinant Factor IX product, Benefix resulting in an estimated 80 adult patients to complete pharmacokinetic as well as safety and efficacy studies. We provided ProGenetics with a cross license to our broad patent for the production of therapeutic proteins in the milk of transgenic mammals to enable them to commercially develop the Factor IX, Factor VIII and fibrinogen products in territories outside of Europe, North America and Japan. We'll receive a royalty on any sales ProGenetics generates in these territories. The license agreement ProGenetics rounds out GTC's access to all three major coagulation factors. Factor VIIa, Factor VIII and Factor IX, the only company we believe with that claim and one that we hope to build into a broad franchise serving the hemophiliac community.

All of our coagulation factor programs are targeted on establishing larger supplies of recombinant products at more rational prices to improve patient usage. For hemophiliac patients, an affordable prophylactic treatment strategy would directly improve their clinical outcomes. Rational pricing of these products will also encourage expanded use in a broader range of potential indications. The recombinant Factor VIIa program with LFB has developed production animals which are now establishing stable integration of the transgene and progressing through downstream process development. We are targeting the completion of preclinical work and submission of an IND in the second half of 2009. Our objective for the recombinant alpha-1 antitrypsin program is to initially establish an intravenous product for the prophylactic treatment of patients with a genetic deficiency of alpha 1 antitrypsin. Remember that we established high levels of production of this difficult to express protein at 20 grams per liter of milk. Hereditary deficiency patients who are not treated prophylactically suffer from a build-up of elastase in the lung that may lead to emphysema or other respiratory conditions. We believe we have identified appropriate techniques to extend the half life of our alpha -1 antitrypsin product to enable it to be dosed in a similar manner as plasma derived products. Once we establish an appropriate formulation of our alpha-1 antitrypsin product, we can complete our pre clinical development over the next 12 months. We recently met with representatives of the

Alpha-1 Foundation where they described the very real concerns their members have with managing their treatment with plasma derived product. They encouraged us in our efforts to develop a robust supply of our recombinant product to help these patients maintain as much lung function as possible.

LFB has also been a participant in our monoclonal antibody portfolio. During 2007, we brought into the collaboration a monoclonal antibody to the CD20 immune receptor that LFB had been developing initially in cell culture. The CD20 receptor is the same target as the currently marketed product Rituxan. We're anticipating developing CD20 antibody for indications similar to those approved for Rituxan. Development of this antibody, in our transgenic product system, has the potential to result in enhanced antibody dependent cell cytotoxicity compared to Rituxan. We anticipate developing CD20 antibody for indications similar to those approved for Rituxan. We plan to have animals with this transgene by the end of this year.

And I want to take some time to talk about our developing strategy for a portfolio follow on biologics or biosimilars. I believe there is a very important opportunity and value driver for GTC over the coming years. We all recognize at the present time legislation has to be passed in Congress to enable the FDA to review and approve so-called generic versions of biologics. The timetable for this to occur is not certain. But there is a reasonable consensus that this should take place over the next year to 18 months. And clearly the upcoming presidential elections will be a factor in the timing where there has been significant investment in time and effort on both sides of the aisle to bring this about. In Europe, the procedures for reviewing biosimilars have been adopted. The driving issue is the same in all geographies. Namely greater patient access to biologicals in a time of rising healthcare costs. As I stated earlier, our production technology is particularly well suited to the production of a large volumes of monoclonal antibodies at competitive cost of goods required for the expanded use of these products in the treatment of chronic diseases and large therapeutic indications. Today the manufacturing capacity from the mammalian cell based production of monoclonal antibodies in Europe and North America is largely owned and controlled by innovator companies. Capital investment in independent mammalian cell manufacturing capacity will be in the order of hundreds of millions of dollars versus transgenic production systems which require a fraction of this investment. Today, however, a number of production companies often partner with generic companies, are developing products such as Epogen, human growth hormone and interferon which are highly active but small volume products. These are highly competitive markets which do not require significant production capacities for entrance. As such, we do not see these markets as attractive opportunities for us since they do not exploit the key competitive advantages of our technology. Our focus is on a group of monoclonal antibodies which are coming off patent over the next six to eight years. We have identified four or five of these products which today have a combined market of approximately \$16 billion and are expected to double to approximately \$30 billion over the next five or six years. We have already started to move forward with the initial development into some of these products. And this can be achieved with minimal additional expenditure at this stage by leveraging our existing infrastructure. We believe that our existing commercial production facilities and infrastructure are sufficient to support the commercial scale of production for these programs. Clearly, we do not plan to commercialize these products ourselves and we're seeking partnering opportunities with companies able to support this type of commercialization activity.

Before I hand over the call to Jack Green, let me make a few comments about our financial status. As you know, we completed a modest financing in early February which was important in maintaining the financial stability of the company. We had intentionally waited until we were able to disclose the results of our pivotal ATryn study before attempting to refinance. Unfortunately, the Capital Markets continue to be very challenging with the cause and the conditions being well outside our ability to control. However, for some time we have very consciously developed portfolios of products which we can leverage in a number of ways through partnering. It is our intention to focus on these partnering activities to support the financing of the company and the development and commercialization of our products so that we're not wholly dependent on the equity markets for sources of cash. This is a strength for the company in the current financial climate. To illustrate the growing impact of our partnering efforts, today we have already booked and included in our forecast \$15 million in prospective cash receipts from our currently contracted partners indicating another year of significant revenue growth ahead of us. We will continue to build on this strong base as we add new and expanded collaborations. I'll now ask Jack to review our financial results. Jack?

Jack Green - GTC Biotherapeutics, Inc. - CFO

Thank you, Geoff. Revenues were \$3.1 million for the fourth quarter of 2007. Compared with \$2.8 million in the fourth quarter of 2006. For the year, revenues more than doubled the 2006 levels as we continue to expand our revenue base through our partnering strategy. Revenues for the year were \$13.9 million, a \$7.8 million increase from the \$6.1 million in 2006. The year to year increase reflects payments from Leo for the supply of ATryn and the services provided to PharmAthene for the development of their Protexia product. Cost of revenue and operating expenses were \$50.3 million for 2007, 20% higher than \$41.8 million in 2006. The year to year increase included the cost of goods sold to Leo supporting the increased revenues,, the cost of advancing our Factor VIIa, Factor IX and CD20 programs with LFB. and the inventory write-off of \$2.9 million related to the ATryn batches that were rendered unusable, at a US based fill/finish contractor, which we disclosed in our second quarter press release and earnings call. One result of the lost ATryn batches is that \$3.7 million of revenue from the sale of product to Leo, is now

anticipated in the first half of 2008. We have not been able to reach an equitable settlement with the US based fill finish contractor that caused the lost inventory and have advanced the matter into the arbitration process. Obviously we have not included any potential recovery in our financial forecast nor is there any assurance of a recovery. The net loss of -- the net loss for the fourth quarter of 2007 was \$9.8 million or \$0.13 per share compared to \$7.4 million or \$0.10 per share in the fourth quarter of 2006. The net loss for the 2007 financial year was \$36.3 million or \$0.47 per share compared to -- I'm sorry \$35.3 million or \$0.53 per share for 2006. The weighted average number of shares outstanding increased from 73.6 million shares for the fourth quarter of 2006 to 78.1 million shares in the fourth quarter of 2007. and, for the full year, the weighted average number shares outstanding increased from 66.9 million shares in 2006 to 77.9 million shares in 2007. The increases in the weighted average shares outstanding primarily reflect the issuance of common stock and financing transactions. We ended 2007 with approximately \$15.8 million of cash and marketable securities on the balance sheet. In February 2008, we completed a registered direct placement of 6.9 million shares of common stock with warrants, at market, were \$0.87 per share raising net proceeds of approximately \$5.5 million. We used approximately \$28 million of cash in 2007, net of the \$4.4 million of financing proceeds we received from LFB in January of 2007. We expect a similar cash use for 2008. and this excludes the impact of any up-front or milestone payments from new or expanded partnerships not currently signed. Any up-front payments from new or expanded partnering arrangements that result from the ongoing discussions will reduce the net cash use for 2008. We anticipate that our cash on hand and current contracted receipts should be sufficient to support our operations into the third quarter of 2008. Because our cash runway is not at least 12 months, the audit opinion to be included in our form 10-K which will be filed in the next few days will include a paragraph referring to substantial doubt to our ability to continue as a going concern. This is an audit requirement based upon our existing cash balances and projected cash use but does not include projected receipts from the agreements that are unsigned as of this date. As Geoff has mentioned, we are focusing on partnering as our preferred source of additional funding for the company. We are in active discussions with potential partners for ATryn as well as for other products in our plasma protein and follow on biologics portfolios. Geoff?

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

Thank you, Jack. Now, let me take a few moments to make some additional comments on other programs and upcoming events. We are continuing with the evaluation of the preclinical development program for our CD137 monoclonal antibody, and we have developed animals which express both glycosylated and non glycosylated versions of this protein in order for us to assess the potential differences or advantages in the immune modulation capability. CD137 monoclonal antibody, of course, is a new chemical entity and this work is an essential part of our preparation for meeting with the FDA to discuss an appropriate clinical development plan and indications. We hope to have this information around the middle of this year. Our work with CD137 is being supported by an SBIR grant.

Our external program contracts have been important contributors to our cash receipts over the last year and are expected to also make important contributions in 2008 based on contracts already in place. Our contract with PharmAthene has continued to expand and support their program for their Protexia product, butyrylcholinesterase, for the potential treatment of nerve gas exposure. We are providing both manufacturing and regulatory support in addition to enabling intellectual property under our broad patent. And today, PharmAthene announced successful completion of a PK study for Protexia and their plans to file an IND in the third quarter and to commence phase one human safety testing in the fourth quarter of this year. Looking back over the company as a whole, ATryn remains a key driver of near term events. While we have expanded our involvement in a broad portfolio of recombinant plasma proteins and initiated development of a portfolio of monoclonal antibodies including follow-on biologics the focus of our therapeutic development in both portfolios is on known chemical entities where the clinical risks are low and where there are large market opportunities.

Upcoming potential news events are always an important consideration for investors, so, let me remind you of some of our strategic objectives, including, first of all, the completion of a partnering agreement for commercialization and development of ATryn in the United States. Submission of the final section of the rolling BLA for ATryn, which we anticipate to be around the middle of 2008. Achievement of priority review status for ATryn. Approval of ATryn in the United States around the end of 2008 early 2009 assuming priority review is granted. Launch of ATryn in the United States in the first half of 2009. Leo's obtaining top line results for the phase two DIC study in the first half of 2009. And completion of preclinical studies for the alpha 1 antitrypsin and CD137 monoclonal antibody programs around the end of 2008 with the potential for both programs to enter clinical studies in 2009.

And finally, before I close my prepared remarks, I want to make some comments which has not been part of my prepared remarks until yesterday. As you know, yesterday we suffered a significant decline in our share price which I believe in no way reflects the significant progress which this company has continued to make on many fronts. I'm personally frustrated and even angry on behalf of our loyal investors and our employees but GTC has developed a resilience and a tenacity over the years which will continue to serve us well. You have my personal commitment, together with the commitment of our entire management team and employees, to continue to pursue our key objectives and secure the financial health of the company. Thank you for your time today. We are living in challenging times. Your support and your encouragement is both important and appreciated. Thank you for listening to my remarks. And I'll now ask the operator to ask for any questions which you may have.

QUESTION AND ANSWER

Mar. 06. 2008 / 10:00AM ET, GTCB - Q4 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

Operator

(OPERATOR INSTRUCTIONS) Stand by for your first question. Your first question is from the line of Stephen Dunn with Dawson James. Please proceed.

Stephen Dunn - Dawson James - Analyst

Good morning, Geoff, Jack and Tom. Congratulations on the progress so far. You've done what you said you were going to do.

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

Thank you very much, Steve.

Stephen Dunn - Dawson James - Analyst

First question is a little bit of housekeeping. I didn't hear it or maybe I missed it, Leo's Canadian submission, are we expecting that in 2008?

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

Thank you for bringing that point up, Steve. We are, in fact, hoping that Leo -- Leo is actually making the submission to Canada and we obviously want to be able to use the data which we are submitting to the FDA for our BLA filing to form the basis of the Canadian submission. So, we're waiting to get all of the clinical data in as we're required for the FDA as well. So, that Canadian submission, we hope that will be made in the second half of 2008 and all being well that could put us with a -- into an approval situation in Canada in the second half of 2009.

Stephen Dunn - Dawson James - Analyst

Ok. So, to summarize, theoretically, we could have all of North America covered in 2009?

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

That's correct.

Stephen Dunn - Dawson James - Analyst

Ok. All also in 2009, I guess to summarize, I've got a number of candidates that will begin human clinical trials in 2009, hopefully. I'm counting four of them. Am I counting that right?

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

I think -- well, you tell me what you have on your list and then I'll --

Stephen Dunn - Dawson James - Analyst

Well, Factor VIIa.

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

Yes.

Stephen Dunn - Dawson James - Analyst

I have alpha 1 antitrypsin.

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

Yes.

Stephen Dunn - Dawson James - Analyst

And CD137.

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

Yes. And I think the -- Factor IX, alpha-1 antitrypsin, Factor VIIa and CD137 and I think the ones which are probably the most advanced in terms of entering the clinic are probably alpha 1 antitrypsin and CD137, Factor IX and Factor VIIa, are likely to be the latter part of 2009 in the way in which we see our current plans.

Stephen Dunn - Dawson James - Analyst

Okay. I was a little fuzzy on DIC and severe Sepsis. Now, we expect a phase three to initiate in EU in 2009. When do we foresee human trials in the US?

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

Well, the current DIC study, we need to get those -- the phase two results, we need to get those and we're hoping that Leo will complete that so we can give data in the first half of 2009 and that will enable us to be able to go both to the EMEA and also to the FDA with our proposals for the design of the phase three study. Remember, the phase two study, the principal of that is a dose ranging study with the objective of identifying the dose which is most appropriate for the design of a phase three study. And so the phase two study isn't statistically (inaudible) to demonstrate efficacy although clearly Leo is looking and we're looking to demonstrate trends to improvements in survival for these patients. The objective, if we can -- if we can do this, is to carry out a single phase three study or a combined US and European study. And the important part there, of course, is to make sure that we can address the -- the general way in which these patients are treated in the two geographies. And that's something which we've got to make sure that we can meet the requirements both to the EMEA and the FDA if you understand. So, a single designer study needs to make sure that physicians can treat their patients in both US and Europe in a way which is appropriate with standard of care. So, that's the plan of action at this moment. And we assume that those discussions will take place in the second half of 2009 and then progress to the phase three study.

Stephen Dunn - Dawson James - Analyst

Ok. So, put another way, in reality, we're going to have another first in human DIC trial in the United States but it will go -- we're hoping for it to go directly into a phase three trial?

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

That's certainly the objective. Of course, the first stepping stone is to make sure we get the results of the phase two study. And then that will form that basis.

Stephen Dunn - Dawson James - Analyst

Right, now we -- it sounded like you were pretty far along on the US partnership for DIC indication and you indicated the parameters would be somewhat similar to agreements in the past. If you could remind us, you know, what kind of parameters, with the kind of ranges in dollars, what you're looking for?

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

The important -- and then if I may just also comment, a number of these discussions which we have had in the United States, we've also encouraged partners to look at the option or the alternative or the additional opportunity of being able to develop ATryn in other acquired deficiency indications. At this moment, of course, Leo is paying entirely for the phase two study which we'll get access to those results. So, the interesting thing for us is the possibility of being able to pursue through a partner, other indications and as you know, we've done work in the past in coronary artery bypass surgery and that's certainly an area which we continue to look at as a possible area of further clinical development and that could also -- if we are able to secure a partner in the way in which we're working to at this moment, that could put us into a clinical development program which we would expect our partner to pay for, of course and again in 2009 and could bring us into the market more quickly than the DIC itself in an acquired deficiency. So, it's something which is obviously an important feature of what we're trying to negotiate in our partnering. But in terms of general structure, I think one should assume that an up-front payment is probably going to be in the single digit millions of dollars and then payment for the clinical study would include not only payment for the clinical work itself but also payment for product. And then there would also be a negotiated price for commercial product and also a royalty on sales. And yet the way in which we negotiated with this -- with Leo was also that there was a series of milestones related to progress and success on the clinical programs and also sales milestones further down the track. So, I think we're looking at a similar sort of structure. The main objective is to take the costs of the commercialization and clinical development of ATryn off our P&L and make sure the partner is bearing the cost of the further development and that's obviously very important for us.

Stephen Dunn - Dawson James - Analyst

Ok. I want to squeeze one more in before I jump in the queue. The follow on biologics or biosimilars sector reminds me very much of the old stem cell sector about four or five years ago. Well, when I started covering it and before it was really well-known on Wall Street. And what I'm seeing here is a convergence of factors both regulatory, political and the science, are all kind of converging in GTC's favor. And you know, in January, (inaudible) the statement that biogenetics are a major key long term growth opportunity for that company. And we've seen the White House and the senate approve FDA funding and requirements for approval of biogenetics. But, I guess, if you could give some color, on what you are seeing -- you are on the board of Bio. What you are seeing both in the US and Europe.

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

Well, I think actually there is a growing recognition by the entire industry that follow on biologics are absolutely going to be a reality and so I think it's a question of when rather than if. And I think BIO in their public statements have stated, and as you were quite right, I do sit on the main board of BIO, that they would like to try to see legislation passed before President Bush leaves the White House. And I think that there has been a significant shift amongst the companies within BIO in a reasonable consensus to come up with a set of conditions which would enable follow on biologics to be supported by the entire industry, providing that there is sufficient time period embraced in any legislation which would enable innovative companies to be able to protect their intellectual property for a reasonable period of time. I actually have no problems with that whatsoever and I don't think that's any constraint on anything that we're planning to do. We also have proprietary products and we expect to -- we expect to observe other people's intellectual property and we expect people to observe ours as well. So, I think that the whole principle of the pharmaceutical development is that innovators should have a reasonable period to be able to gain profits on their innovation and to be able to get a true win from those products. But most companies would be expected to be developing second and third generation products as a normal part of the development of those programs. So, I think that a follow on biologic strategy is one which actually can sit in an appropriate fashion with all of these companies and I think it's very important that the biotech industry should not be seen to be adversarial with the needs and the requirements of the patient population of the United States but should be looking to ways in which we can contribute to the management of a broader range of patients but also bring through further innovation, new products into the market place as well. And I think all of these things can work perfectly satisfactorily together.

So, I think that BIO is working in that fashion and we ourselves have had actually quite a lot of input into BIO. We've also had the opportunity to work with the local Massachusetts biotechnology council and also with Senator Kennedy's office and I think that I'm somewhat encouraged that

legislation will get passed this year. And I would actually -- since you've raised this point, just like to take the opportunity to point out to investors that the opportunity for us is a timing issue as much as anything. We have the infrastructure already existing to be able to do this within our own production operations here in Massachusetts. It's not costing us anything in the current circumstances to be able to develop these products at this present time. It is important though from a timing point of view that you get on the road to actually moving these programs forward because otherwise, the opportunity is missed and it's no good if you're going to be in the fall on biologic space being way late down the track. So, it's important that we do this but it's a value which we're able to create using the -- leveraging our existing infrastructure at really no cost at this moment but tremendous value which we have the opportunity to be able to develop further down the track and of course, a lot of opportunity for us to be able to engage companies in partnering discussions which we hope and expect will support the further development of the products and also the commercialization of these products in the market place.

Stephen Dunn - Dawson James - Analyst

Alright, great. Thanks. Looking forward to 2008!

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

Thank you very much indeed, Steve.

Operator

your next question is from the line of Navdeep Jaikaria from Rodman and Renshaw. Please proceed, sir.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

Hello, good morning, everybody. Thank you for taking my question question. Almost all of my questions have been answered by the good (inaudible) from (inaudible) and James. I just have a couple more follow-ups. One is about you said form (inaudible) (technical difficulties) the initiative is one study later this year. Are you expecting to receive any kind of milestone payment from them?

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

No, I don't think that -- actually the information which I gave you is actually in the PharmAthene press release this morning. So, that's in the public domain. And I was simply quoting from their press release. We don't -- no, I understand the question. We don't have milestones associated with that progress, but we are very happy that they have been able to successfully negotiate though to the next stage of the development of their product. Obviously it's a big steppingstone for them. And since they have become an important partner for us, one which we've very much enjoyed working with, we hope that that will be an important way in which we can continue to partner PharmAthene in the further successful development of their product. So, I think it is a good steppingstone, in one which I think it was helpful for our investors to know about.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

If they do secure a governmental contract for stockpiling (inaudible), which kind of (inaudible) rate should we expect?

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

Would you repeat that again please for me?

Navdeep Jaikaria - Rodman and Renshaw - Analyst

No, I'm just saying which kind of royalty rate will you be charging them if they have a successful commercial product which --

Mar. 06. 2008 / 10:00AM ET, GTCB - Q4 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

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

Oh, I see. Well, I don't think we've disclosed that actually. But it is a -- it is a small single digit royalty rate which is the normal sort of commercial rate that one would charge for this type of -- access to this type of intellectual property.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

Excellent. Thank you very much. So, for this year, you will be recording ATryn like a (inaudible) (technical difficulties).

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

Excuse me? Recording what -- ATryn what?

Navdeep Jaikaria - Rodman and Renshaw - Analyst

(Inaudible) Are we expecting you to -- (inaudible) (technical difficulties).

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

You're actually cutting out --.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

(Inaudible) (technical difficulties)

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

I don't know whether other people are having problems but you're cutting and out, Sean.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

Yes I think the IP phone is not working well so let me just stop here. Thanks a lot for taking my questions.

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

Okay, but if I can perhaps guess what you were asking and try and answer it, you were asking about revenues around ATryn, I think for the foreseeable future, the revenues which we will be reporting around ATryn will be a combination both of our product supply for commercial use and also for clinical use. So, that's the way in which we look at that at this present juncture. As I did comment, in order to manage people's expectations, we're not expecting under the current pricing strategy for ATryn that this growth rate will be large in 2008. Clearly, what Leo are doing is building a franchise around this product. And as they move forward into the DIC indication, it's important to be able to establish a pricing strategy which they can then manage in relation to these other indications as they move forward and so that's the process we're staying involved in at this moment.

Navdeep Jaikaria - Rodman and Renshaw - Analyst

Okay Thank you very much for taking my call.

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

Mar. 06. 2008 / 10:00AM ET, GTCB - Q4 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

You're welcome. Thank you.

Operator

Your next question could be from the line of Roy Friedman with Edith C. Blum.

Roy Friedman - Edith C. Blum - Analyst

Good morning, Jeff and Jack.

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

Good morning.

Roy Friedman - Edith C. Blum - Analyst

First I have some financial questions for Jack. Can you clarify your statement about the expected 2008 cash burn excluding new sources of income. Is the number \$28 million or is the number \$32 million?

Jack Green - GTC Biotherapeutics, Inc. - CFO

The number is \$28 million. It is the projected -- is the projected, burn for 2008 -- net burn for 2008.

Roy Friedman - Edith C. Blum - Analyst

Okay. Are there any --

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

But, Roy, if I can just add to that, remember what Jack said. That is just based on what our contracted revenues are and projected revenues from those contracts as they exist at this moment. So, any partnering arrangements we have around ATryn or other -- any of our recombinant plasma proteins or follow on biologics would reduce that figure. So, I think that's the clearest way in which we could state it.

Roy Friedman - Edith C. Blum - Analyst

Understood.

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

Okay.

Roy Friedman - Edith C. Blum - Analyst

Are there any covenants on GTC's debt that could come into play during 2008 if your book value or tangible net worth were to fall below some threshold?

Jack Green - GTC Biotherapeutics, Inc. - CFO

No, Roy. There are no operating covenants in -- as a part of our (GE) debt that are part of the (inaudible) debt instrument. So, we do not specific operating covenants. Basically GE security is the lean on the assets -- all assets except IP which is part of their security. They do not have operating covenants as part of the instrument.

Roy Friedman - Edith C. Blum - Analyst

Ok. Is your cash rock solid rather than in such holdings as auction rate securities as was the case with Bristol Meyers?

Jack Green - GTC Biotherapeutics, Inc. - CFO

I'm happy to report that our cash is rock solid. We have no exposure to auction rate securities at all. And we are very, very careful to make sure that we avoided that minefield.

Roy Friedman - Edith C. Blum - Analyst

Okay. That's good to know. Do you plan to seek shareholder authorization for a reverse split at the 2008 annual meeting?

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

Yes, that's an excellent question, Roy. And clearly, we're monitoring that situation quite carefully and we have, under the existing notification from NASDAQ until July 15 and we would like to think and certainly we would -- we're working towards our share price being restored to above the dollar level through our -- meeting our goals including our partnering arrangements and hopefully we can get there without taking any other actions. If we're not successful in doing that in terms of getting above \$1 for the required period of time which is required under the NASDAQ rules, then we obviously have a reverse split as a possible scenario but it's one which we would prefer to keep in our back pocket at this moment rather than making any decisions on it at this juncture. If we do go to reverse split, obviously we would need shareholder approval to be able to do that.

Roy Friedman - Edith C. Blum - Analyst

Right, well that's why I asked whether you were planning to put that to shareholders at the annual meeting.

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

Well, it certainly if we -- if we need -- if we plan to go that track, then we would obviously -- we would obviously do that probably through the annual meeting. And we've obviously discussed it at our board meetings and we've chosen at this moment not to take any firm decisions on that but to aim to execute on some of our key goals and if possible, restore our share price to a healthier position in its own right so to speak without having to do that. But, we do hold that in reserve as a possibility.

Roy Friedman - Edith C. Blum - Analyst

Well, isn't the proxy due out very soon?

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

Well, I think actually we have 45 days ahead of the annual meeting. And so we've probably got a few more weeks yet before we need to send out the proxy.

Roy Friedman - Edith C. Blum - Analyst

Okay. Switching over to the regulatory area, actually in the commercial area, what is the approximate premium of ATryn relative to plasma derived antithrombin in the countries where ATryn has already been priced?

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

That's an excellent question. And I don't want to shoot from the hip because I don't know exactly on -- in each country. What I would say is that Leo initially went into the market in the United Kingdom because remarkably, because UK tends to be rather aggressive on pricing. Actually antithrombin charges in the UK are high. And therefore, the pricing in the United Kingdom, I think is pretty well similar to a plasma derived product. Now, if you go into some other countries, Germany, I think is a much more aggressive priced situation. There are a number of plasma derived products available in Germany. So, it may be much more significant premium over pricing in Germany. Greece, I'm not quite sure of and the other country, Ireland, I think is similar to the UK. So, I think it's going -- the answer to your question, it's going to be variable. But, what they're trying to look for is a fairly consistent pricing throughout Europe. The fact is that we got approval throughout Europe so many of these plasma derived products which were grandfathered or approved in single countries have been able to maintain pricing structures which are quite different from adjoining countries because they can't actually be sold in those countries and therefore you've got a lot of differentials throughout Europe. But with our product, obviously they can move the product across borders so they're going to probably end up with a relatively consistent pricing strategy. And that's why they're having to take that step by step.

Roy Friedman - Edith C. Blum - Analyst

Okay. Does the recent approval of ArtisanPharma for DIC in Japan adversely affect your partnership discussions there?

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

Not really, actually. People may not be aware of that particular piece of news. But this is a different product from antithrombin, of course. But DIC in Japan is -- that indication is a little different from what is -- the way in which it is referred to in the United States. Our understanding that the trials which have taken place in Japan are -- do not have the same end point of improvements in survival. And therefore, it is a less onerous or a less rigorous end point than the one which we're expecting to have to meet in the United States. Now, we haven't gone into what's the clinical indication or what clinical type of program that we required in Japan. But I think it's unlikely that the -- the design of the clinical study, which was carried out in Japan for that product, will work -- will be the same design that will take place in the US. Now, I'm not the FDA. I can only sort of guess that but that's our assessment at this point in time. Now, having said that, the market for DIC and severe Sepsis is an enormous market. We talked about this before. There's about 0.25 million people in the United States who get DIC and severe Sepsis each year. About 50% of these people die. And so, we believe that this is a \$2 to \$3 billion market place and I think there is room for competition and for us still to be able to have very successful products. But I am not sure that the Artisan product is going to be any more quickly into the market place than our own product.

Roy Friedman - Edith C. Blum - Analyst

Well what's holding up the consternation of a partnership in Japan then?

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

Japan -- we've actually had some discussions in Japan and we're represented -- we have people at the recent Bioasia conference in Tokyo in late January. A business development in Japan is a fairly protractive process and they tend to move quite a bit more slowly than in the United States. So, we've actually had quite a lot of interest. And it's very interesting that the whole concept of transgenically derived therapeutic proteins has moved forward significantly as a result of the EMEA approval and also after the news out now that we've filed in the United States. And I think that's going to be very helpful to our partnering activities. But I don't think we're projecting that we would get a Japanese partner in the current year in 2008. I think that it would be great if we can get one in 2009 but it will take longer in Japan. And that's just not our experience. That's a normal experience for people.

Roy Friedman - Edith C. Blum - Analyst

Okay. In your view, what is the likelihood of an FDA advisory panel for the ATryn BLA?

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

That's an interesting question as well. And I can't really give any guidance on that to be quite honest. We haven't been given any guidance by the FDA at all at this juncture. Certainly, I've had people who believe that -- who have told us that they believe that we will have an advisory panel since it's a new technology. And if we do, I think we feel very confident of our ability to meet that challenge in a very successful fashion. But I really can't give any guidance. If it does happen, and we have a priority review status, then I guess it would be somewhere in the latter part of 2008 if everything sort of proceeds on the sort of schedule which we see at this moment. I don't have any other information on the matter at this moment, Roy.

Roy Friedman - Edith C. Blum - Analyst

Okay. On priority review, is there any possibility of hearing the FDA's decision on that before you submit the last module or will that necessarily wait until the last module goes in?

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

Again, that's a good question. My guess is, to be quite honest, that we will hear sooner than submission of the last module. That's our expectation. But again, we've heard -- we've heard nothing back from the FDA which is not -- there's nothing bad in that respect. I think there is a normal time pattern for hearing with regard to submission proprietary review. But we're hoping that we will hear over the next few weeks in that respect.

Roy Friedman - Edith C. Blum - Analyst

Ok. Thank you, Geoff and Jack. That's it for me.

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

Thank you, good questions, Roy. I appreciate it.

Operator

Your next question is from the line of Donald Hudson with Hudson Associates. Please proceed.

Donald Hudson - Hudson Associates - Analyst

Hi, Jack and Geoff.

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

Good morning.

Jack Green - GTC Biotherapeutics, Inc. - CFO

Good morning.

Donald Hudson - Hudson Associates - Analyst

I have a couple of questions. Number one, Factor VIII, is that a -- that's a Baxter product, right?

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

Yes, Baxter. They have a very significant market with recombinant Factor VIII.

Donald Hudson - Hudson Associates - Analyst

Yes, made in mammalian cells?

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

Yes.

Donald Hudson - Hudson Associates - Analyst

Right, and you can be more competitive in that in transgenic animals?

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

Yes. That's our belief. Factor VIII, a is from a -- from a development point of view, is later in the process than Factor VIIa or Factor IX. It's just simply the way that ProGenetics haven't moved that forward as quickly. And also, and again I was speaking a little bit off the cuff, I believe the IP for Factor VIII in the United States, is later than for Factor IX or Factor VIIa. So, that's certainly later in our development schedule and we have not developed a planning timetable around that at this juncture. But in terms of the products which for the hemophiliac factors, the products, the recombinant products which are in the market place today, is probably somewhere around about \$3 billion of those combined factors, out of a total market of about \$4 billion. And each of these products is produced from mammalian cell. And our understanding is that these are very difficult products to express in mammalian cell culture systems and we feel very confident that using our transgenic system, that we'll be able to produce these products at a competitive cost of goods. And we haven't decided what that pricing will be at this moment. We don't need to make any decisions as far as that's concerned. And certainly we don't plan -- we don't need to give up margin that we don't need to, but the opportunity for us is to be able to -- be able to treat a broader patient population including patients being treated prophylactically than is possible with products today because of that price. But also potentially be able to develop in a broader range of indications and again, today, the cost of these products is so high that that is a real problem for many patients. So, I think they've got many opportunities to be able to compete in that market place and to create an important significant franchise.

Donald Hudson - Hudson Associates - Analyst

Good, good. The other question was, I didn't hear you mention in any of the product portfolios that you'll be keeping some for your own selling, is that -- is your strategy still to partner everything you can?

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

That's actually a good question. And I certainly have talked in previous conference calls about developing our own commercial capability and you know, I think particularly in the United States, that's something in which we would love to do at some point. I think we're being fairly pragmatic about what our current financial status is at this moment. What we're looking to do is to use the value which we're creating through these portfolio products to get partnering arrangements and to bring cash into the company which will -- ensure that we don't become dependent or -- entirely on the equity markets. And so, certainly we keep -- if ATryn -- if we were not able to do a partnership for ATryn commercialization development in the United States, on terms which we believe reflect the value of that product, we certainly could take that product into the hereditary deficiency indication into the market place ourselves with a relatively small number of people, maybe a dozen or so people and we will keep that in our back pocket. I think in terms of our options at this moment though, if we can find a partner who can not only help to

Mar. 06. 2008 / 10:00AM ET, GTCB - Q4 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

commercialize and maximize the opportunity for the product but also support the further clinical development, that's a very good option for us at this moment.

Donald Hudson - Hudson Associates - Analyst

Ok. Fine. Thanks.

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

Thank you, Don.

Operator

(OPERATOR INSTRUCTIONS) And your next question is from the line of Steve Turner with Due Diligences. Please proceed.

Steve Turner - Due Diligences - Analyst

Well, congratulations on your results so far.

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

Thank you.

Steve Turner - Due Diligences - Analyst

My question has to do with production facilities. What's the time line for FDA approval on your actual production facilities?

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

Well, our -- we haven't received any advice from the FDA at this moment when they plan to come into -- to inspect. And of course remember we've got three different pieces to this. One of -- is our own production operations and pharma operations which is under our control. There we do the downstream purification with Lonza in Hopkinton, which used to be Cambrex and they purify the product for us. And they've been inspected previously on our behalf by the EMEA. And then we do the filling of the product at MedImmune in Leiden. I will just reiterate, that MedImmune was not involved in this other issue which Jack was referring to in terms of production failure. So, I just want to make sure that MedImmune's name is not impugned to that respect. But MedImmune did the fill finish for us in Leiden, and so those are the three elements and our guess is that -- the inspection of those facilities may well take place in the first half of the year. But we don't normally announce the dates of those inspections. But that's what we're planning for anyway, as far as the timing of those.

Steve Turner - Due Diligences - Analyst

Okay. And as far as the number of patients comparative to the European theatre, using your product, do you have an anticipated range? Or a target range?

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

This is for ATryn? I'm sorry, can you --

Steve Turner - Due Diligences - Analyst

I am sorry, for ATryn, yes.

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

How many patients you mean are in the United States?

Steve Turner - Due Diligences - Analyst

Well, how many patients are you targeting to be potential clients of yours?

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

Oh, I see. Well, again, that's a good question. There are reports to be somewhere between 1,000 and 5,000 and 1,000 and 3,000 people who have antithrombin deficiency. And, so, that would be -- conservatively, that would mean in the United States, probably 60,000, 70,000 people who have this particular deficiency. I would say that a lot of people don't actually know they have the problem until they have their first thrombosis. In the US, this patient population it has been poorly served over the years. Thrombate has been Intermittently available on occasions and certainly it was grandfathered on rather limited clinical data originally and there has been very little clinical development done with the product in broader indications over the years. So, I think this patient population is going to need to be developed. We obviously need to work with key opinion leaders. Some of these patients in the past have avoided having children because they've got the condition. People who were going to have elective surgery avoid having surgery because they are -- the product was either not available or they didn't want to use a plasma derived product. So, there is a lot of work we can do in order to be able to encourage the understanding of the products available.

And also for being able to treat those patients. And of course, once you understand where some of these patients are, you start to be able to develop the familial connections since it's obviously a genetic disorder. And so I think that we've got the opportunity, one which I described is -- as I believe we've got the opportunity over the next three or four years with a good partner for us being able to develop a market something in the order of 30 to 40 million in the United States prior to getting an acquired deficiency indication approved by the agency. And that's the way in which we're looking at that at this juncture. But it is going to be something where we're going to have to work hard to uncover the patients and to make sure that we can make all of the connecting points.

Steve Turner - Due Diligences - Analyst

Okay, well, thank you very much.

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

Thank you.

Operator

(OPERATOR INSTRUCTIONS) As there are no further questions, I would like to turn the call back over to Dr. Geoffrey Cox for closing and remarks. Please proceed.

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

Well, thank you very much indeed everyone for joining us this morning. You've asked excellent questions and I appreciate those questions and for you taking the time with us today. And as I said earlier, we live in challenging times. But the company is very confident about our ability to be able to really progress our programs and to be a successful and significant company. And we appreciate you as investors, your consistency and your loyalty to the company and I'm sure that we are (inaudible) and I assure you we are working very hard to make sure that your loyalty is well rewarded and we will continue to do that. Thank you very much indeed, everyone and we look forward to having you on our conference call for our next quarter results. Thank you.

Operator

Ladies and gentlemen, this concludes the presentation. You may now disconnect. Have a great day.

DISCLAIMER

Thomson Financial reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies' most recent SEC filings. Although the companies may indicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY'S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON FINANCIAL OR THE APPLICABLE COMPANY OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY'S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY'S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.

© 2005, Thomson StreetEvents All Rights Reserved.