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Conference Call Transcript

GTCB - Q4 2004 GTC Biotherapeutics, Inc. Earnings Conference Call

Event Date/Time: Mar. 02. 2005 / 10:00AM ET

Event Duration: N/A

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the GTC Biotherapeutics Q4 and year-end earnings conference call. (Caller Instructions)

As a reminder, this conference is being recorded for replay purposes. I would now like to turn the presentation over to your host for today's call, Dr. Geoffrey Cox, Chairman and CEO. Please proceed, sir.

Dr. Geoffrey Cox - *GTCB - Ph.D., Chairman, President and CEO*

Thank you very much and good morning, everyone, and welcome to the conference call and webcast to discuss the 2004 Q4 and full year financial results for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB.

I'm Geoffrey Cox, Chairman and CEO of GTC Biotherapeutics and with me today are Jack Green, our CFO, and Tom Newberry, our VP of Corporate Communications.

Our results for the fourth quarter 2004 were released earlier this morning and I hope you've had the opportunity to review this release prior to our call.

I want to begin this earnings call by making a few comments regarding our progress with our ATryn program. And I'll then ask Jack Green to provide an overview of the financial results for the fourth quarter and the year, as well as comment on our cash burn expectation for 2005. I'll then have some further prepared remarks about the status of our other programs before opening the meeting to questions.

First of all, as usual, let me remind you of our Safe Harbor Statement for this call. Under the SEC Safe Harbor provisions, please note that certain comments today about our expectations for future achievements are forward-looking statements based on management's current expectations. We urge you to read the Safe Harbor Statement noted in our most recent Form 10-K filed with the SEC, particularly Exhibit 99 entitled, "Important Factors Regarding Forward-looking Statements". As you know, due to the risks inherent in our business, that are described in detail in the Form 10-K and Exhibit 99, our actual results may differ materially from our current expectations.

All right. Let me start by making some comments about the Company's progress with ATryn, our recombinant form of human antithrombin. You'll remember that we filed a marketing authorization application (or MAA) with the European Medicines Agency (or EMEA) early last year. And at the end of June we received the EMEA's consolidated list of questions, which are a normal part of the review process.

We responded to those questions in December and we're now in the final stages of the review process and we're continuing to plan for market approval in mid-year. We will inform investors when the EMEA reaches final conclusions in the review process.

We've also made significant progress with the FDA in establishing the pivotal clinical protocol for the United States. As you may remember, the FDA informed us in late 2003 that they were looking for a controlled study and we were concerned that this could require a large number of patients.

We have spent the intervening time in a constructive dialog with the FDA to design a controlled study that could be accomplished practically in the HD population. We submitted and amended IND application late in December to request initiation of this clinical study and the FDA has responded with a request for some refinements to the protocol and we intend to comply with those requirements.

We have proposed that the active arm of the study require 17 hereditary deficient patients to receive ATryn as a prophylactic treatment to prevent thromboembolisms during high-risk procedures such as surgery or childbirth. In addition to the data relating to the patients that were treated in the safety and efficacy study that was part of our MAA submission.

The endpoint of this study will be clinical symptoms of deep vein thromboses or other thromboembolisms. The control arm will be a review of historical clinical cases in which plasma-derived antithrombin has been used in similar clinical situations. A minimum of 35 cases will be required in the control sample.

Both the active and control arms of the study are likely to include both U.S. and European sites. We expect to begin this study in the second quarter and based on our European experience, anticipate that it'll take approximately 12 months or a year to complete patient enrollment.

An important area of near-term interest for ATryn is our commercialization arrangements to support our launch in Europe and we're continuing discussions with a number of potential partners with both regional and Pan European marketing and sales capabilities.

In addition, we continue to explore the option of establishing our own small sales force either internally or through a contract sales organization. And if we determine that one or more regional companies represent the best partnering arrangement, we may supplement this commercial capability with our own sales force for countries where the regional partners do not have a presence.

Our criteria in evaluating and developing these opportunities is, on the one hand, to consider the support offered for developing the ATryn clinical program in larger market indications, the revenue arrangements and any up front payments. Against, on the other hand, the long-term value we retain in the program and the strategic value we gain by developing our own commercialization capability.

We expect to define our commercialization strategy over the next few months, prior to regulatory approval. After approval, we will embark on reimbursement arrangements on a country-by-country basis, which can be quite variable in Europe, but which we anticipate taking three to six months.

Remember ATryn is a key program for us for several reasons --

1. We believe that there is an opportunity to develop a \$500 to \$700 million market for this product. This market will be developed by providing a safe and well-characterized product to penetrate the existing approximately \$250 million market that currently exists for plasma-derived antithrombin outside the United States (OUS).

Then, establishing a robust antithrombin market in the U.S. with our unconstrained product supply and also expanding the overall market through broad clinical development of new indications. And these potential indications all relate to acquired antithrombin deficiencies and include such indications as burns, coronary artery bypass (CABG) surgery, bone marrow transplants, disseminated intravascular coagulation and sepsis.

2. The second reason ATryn is an important program is because obtaining regulatory approval validates the credibility of transgenic technology as a viable commercial production platform. This validation is important in unlocking the value in applying our technology to a wide variety of both difficult-to-express and large volume proteins for both our internal pipeline and our external portfolio of programs.

3. And the third reason ATryn is a key program is that it establishes the application of our business model to develop recombinant proteins that expand upon the markets established by the plasma-derived products.

We are actively developing two additional recombinant plasma protein products - recombinant human albumin (rhA) and recombinant human alpha-1 antitrypsin (rhAAT), both of which I will talk about in more detail after Jack reviews our financials.

A recent research report from Goldman Sachs JB Weir in Australia illustrates the expansion of the market that has occurred when recombinant technology can be applied to a therapeutic blood protein. This report provides the sales figures for the recombinant clotting factors for the treatment of hemophilia that have been produced in cell culture technology.

Recombinant forms of Factors VII, VIII, and IX have now dominated and expanded the plasma product markets. These recombinant forms now account for \$3.0 billion of sales, compared to the \$1.0 billion of sales of plasma-derived clotting factor sales, using strategies very similar to those that we have discussed for ATryn.

We believe that we can repeat this experience as we develop appropriate blood proteins in our pipeline. GTC is well on the path towards developing a strategic position in recombinant plasma proteins and following this business model of offering a safe, highly pure, and unconstrained supply of these known chemical entities to establish valuable therapeutic markets that expand upon the traditional plasma-based business.

Let me now hand the discussion on this call over to Jack Green to provide a review of the fourth quarter and full year 2004 results, as well as to discuss our views on our 2005 cash projections. Jack?

Jack Green - GTCB - SVP of Finance and CFO

Thank you, Geoff.

* For the fourth quarter our revenues were \$3.2 million, compared to \$1.7 million in the fourth quarter of 2003, an increase of 83%.

* For the year, our revenues were \$6.6 million, compared with \$9.8 million in 2003, a reduction of 32%. The variance in revenues reflects the nature and timing of activities and milestones in both the internal pipeline and the external portfolio of programs.

* We anticipate initiating ATryn product sales starting in late 2005.

* The cost of revenue and operating expenses were approximately \$10.6 million in the current quarter of 2004, essentially flat with the \$10.5 million recorded in the fourth quarter of 2003.

* Expenses in the fourth quarter of 2004 included non-cash charges of approximately \$1.0 million for the designation of a portion of the ATryn inventory for use in the upcoming U.S. clinical trial, as well as recognition of approximately \$1.0 million of external program costs that were deferred from previous quarters.

* The cost of revenue and operating expenses for the year were approximately \$35.8 million, about 11% lower than the \$40.1 million for 2003.

This decrease was driven primarily by the nature and timing of activities and milestones in both the internal pipeline and external portfolio of programs, as well as the savings generated by our corporate restructurings in late 2003 and early 2004. These decreases were partially offset by the increased expenses of supporting the progress of ATryn in the EMEA review of the MAA.

* GTC's net loss for the quarter was \$7.5 million or \$0.19 per share, compared with \$8.5 million or \$0.27 per share for the same quarter last year.

* The net loss for the year was \$29.5 million or \$0.79 per share, compared to a similar net loss of \$29.5 million or \$1.00 per share in 2003. Per share results are affected by a high number of shares outstanding as a result of our placement of registered stock in March 2004.

* We ended the year with cash and marketable securities of approximately \$22.3 million.

* In addition, in January 2005 we completed the registered direct placement of 7.7 million shares of common stock with institutional investors, adding net proceeds of approximately \$9.7 million.

* We also recently expanding our credit facility with GE Capital by \$2.4 million to refinance the loan payment due to Genzyme Corporation in April 2005. The additional GE credit facility will be amortized monthly over 36 months.

* As previously forecast, we expect to use approximately \$25 million of cash in 2005, including partnering proceeds, as well as the expense of supporting our clinical plans for a pivotal U.S. trial starting this year. This forecast also includes manufacturing more ATryn to prepare this year for the expanded clinical studies and commercial supplies in 2006.

* If the estimated \$5.0 million cost for manufacturing additional ATryn were excluded, our expected cash burn in 2005 would be approximately \$20 million, about 10% lower than the \$22.7 million that was used in 2004.

Again, we will continue to closely monitor and control our expenses as we move ATryn through to commercialization.

Geoff?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Thank you, Jack.

Now on to our presentation on this conference call discussing the progress ATryn is making and describing how this is the first of a pipeline of recombinant blood proteins. I'd like to now spend a few moments discussing two of these pipeline programs - our rhA and rhAAT programs.

The rhA program continues to make progress and we're working with a number of potential customers. We have begun production of qualification batches and we continue to provide samples for customer evaluations.

Some of these customers are evaluating the use of our albumin product as an excipient in their drug formulations, while others are considering the rhA as a replacement for bovine serum albumin, which is used as a nutrient component in many commercial cell culture and manufacturing processes.

I'm encouraged by the progress we're making in this program and in the longer-term we remain very interested in entering the therapeutic blood volume expander market that currently represents the bulk of plasma-based albumin sales.

In our rhAAT program we're in the process of establishing clinical, regulatory and commercial development strategies. Hereditary AAT deficiency can lead to emphysema. The plasma-derived products are used as a chronic treatment for this disease. AAT deficiency is one of the most common serious hereditary disorders, with approximately 3.4 million people affected worldwide.

Clinical research work suggests that rhAAT therapy may also be beneficial to cystic fibrosis patients and in addition, we believe that the AAT product is a potential treatment for a number of pulmonary conditions, including chronic obstructive pulmonary diseases, acute respiratory distress syndrome, and severe asthma.

Recently, we have begun commercial development of rhAAT through a licensing arrangement with Dr. Eric Bernstein. Dr. Bernstein is a distinguished practitioner, researcher, and innovator in the fields of dermatology and laser surgery. His research on skin photoaging has led to the development of his own firm, DakDak LLC, which performs in vitro phototoxicology testing for large pharmaceutical companies and pursues discovery of novel anti-aging and pharmaceutical compounds.

Dr. Bernstein is developing the dermatological application of rhAAT to address the effects of photoaging. We are pleased to collaborate with Dr. Bernstein and supply recombinant material for his work.

Our malaria vaccine and CD137 programs continue in their development and I look forward to discussing more significant news on these efforts over the coming quarters.

Our external portfolio of programs continues to make progress with a focus on establishing clinical and eventually, commercial production opportunities. We are providing clinical material to Merrimack Pharmaceuticals for their clinical program with their MM-093 product, a recombinant human alpha-fetoprotein (AFP).

AFP is also a difficult-to-express blood protein, but one that is not derived from the fractionated human blood supply, since it's normally only present in significant quantities during pregnancy. Merrimack is in Phase II studies of MM-093 for rheumatoid arthritis.

As you may recall, we have two programs with Centocor, the second of these is for an undisclosed protein. In 2004, on behalf of Centocor, we produced material for extended preclinical studies. We anticipate herd expansion later this year to prepare for clinical production, assuming success of the preclinical studies.

We've also entered into a licensing agreement with Nexia Biotechnologies to enable the continued development of their Protexia product, a recombinant form of butyrylcholinesterase, as a treatment for exposure to nerve toxins, with a primary focus on biodefense applications.

It was recently announced that PharmAthene, Inc., a private company in Maryland with a strategic interest in biodefense programs, is acquiring all the assets of Nexia associated with Protexia. We are looking forward to the potential of continuing our relationship with PharmAthene for this program.

During the fourth quarter, we were also pleased to welcome two new board members to GTC, Dr. Kenneth Bauer and Mr. Michael Landine. Both of these new directors bring a wealth of experiences and perspectives to GTC's governance and development.

Dr. Bauer is an internationally recognized authority in the field of thrombosis and haemostasis, providing a strong understanding of the clinical aspects of both ATryn and our other recombinant blood programs. Michael Landine has played an important role in the development of Alkermes over many years and will bring significant experience to GTC, particularly in the areas of finance, accounting, and corporate development.

In summary, we've had a very strong year in 2004 and we're well positioned for what we believe will be a transformational year for GTC in 2005. Or progress with ATryn, both in Europe and the USA, remains the focus of our attention in our proprietary programs.

We are committed to achieving our timetable for obtaining ATryn approval in the middle of the year in Europe and becoming the first company to bring a transgenically derived therapeutic protein to market. Our plans for developing ATryn in larger market indications are progressing and we believe we have established a strong foundation on which to accelerate this development.

GTC is establishing a position in developing a broad range of recombinant plasma proteins, providing us with a pipeline of known chemical entities to which we can bring significant supply, safety, and purity advantages to expand their already sizable markets.

Our external portfolio of programs continues to make progress, providing a base of cash flow and offering encouraging opportunities for clinical and commercial production. We've always felt that our progress with ATryn will be a catalyst to this process and we are pleased to see this strategy now evolving.

So I very much look forward to updating you on our progress during the coming months, as GTC continues on its transition to become a commercial products company. 2005 promises to be an exciting year for us.

So thank you for listening to our prepared remarks and now I'll ask the operator please to open the call to any questions.

QUESTION AND ANSWER

Operator

(Caller Instructions.) First question, Phil Nadeau with SG Cowen.

Phil Nadeau - SG Cowen - Analyst

Good morning, guys, and congratulations on the progress you've been making.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Good morning, Phil.

Phil Nadeau - SG Cowen - Analyst

I actually have a few questions - I hope you'll bear with me - first on the EU market opportunity. Would you remind us how much plasma-derived AT3 was sold in Europe in 2004 and if you have some idea of how much of that was in hereditary deficiency (HD) itself, that would be great?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

I can give you our best estimate. The market which exists today of the approximately \$250 million is split pretty well between Japan and Europe, but probably weighted a bit more towards the Japanese markets.

So the estimate is probably about \$100 million for sales in Europe for plasma-derived antithrombin. And of that, I think, our sense is that the HD market, if it was fully supported -- and remember not all the plasma products have approval in all the countries in Europe and particularly the expanded market. But our estimate is that the HD is probably about 20% of that market.

Phil Nadeau - SG Cowen - Analyst

Okay and how many plasma-derived are there currently on the market?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

I think there are probably 4 or 5. The principal ones are from people like LFB with Aclotine. There's also a product from OctaPharma. Grifols also has a product on the market. I think those are the principle ones and there's also a product in Italy as well. But there are probably about 5 suppliers in Europe but many of those suppliers in fact are quite limited, from a geographical perspective, in terms of being able to sell product outside particular countries.

Phil Nadeau - SG Cowen - Analyst

Okay and assuming that you were to -- or if we assume that you were to take this yourself in Europe, how big of a sales force would you need and what type of S&M muscle would you need to put behind the product?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Well, I think this is a very interesting question and one which we are quite engaged on at this point in time. And we think that if our plan is, as we would expect, initially to focus on some of the larger countries where there are established sales of plasma-derived products at this juncture and that we probably require a sales force of maybe in the reach of 8 to 10 people. So this is not a large sales force.

But we've focused on centers of excellence in those particular territories and so you certainly don't need a large sales force in order to be able to launch this product. And that's why it's quite an attractive approach for us, as we potentially take our first steps in terms of developing a commercial infrastructure.

And I think its as I said in my prepared remarks, the issues which we're trying to balance out at this moment are the opportunities which some of the partnering discussions are offering to us at this moment. In terms of up front payments and support for clinical development of the product and how that is outweighed from the opportunity, the strategic value of developing on our own commercial capability, which I strongly believe is an important next step for the Company at some point in the future.

And also, obviously the benefit of keeping the value of the program in-house, particularly for the long-term, once we've established the larger indications of this product. So that's the dialog and the discussion which is taking place at this moment and one which we expect to come to some conclusions over the next 2 or 3 months.

Phil Nadeau - SG Cowen - Analyst

Okay. In the U.S., you mentioned that there was going to be a historically control arm of about 35 patients. How many of those patients have been identified and already documented?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

I think that at this moment I don't know the answer to that specifically. What we will need to do is to make sure that this will be a prospective historical study and we are aware of a number of centers where we will go for this type of information. And it will need to be carefully designed and controlled, obviously. Under the protocol you have to make sure that you don't cherry pick, if you understand me and that's why it's important that this is done in a very high quality fashion.

Phil Nadeau - SG Cowen - Analyst

Sure.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

You also have to make sure, for instance if we have a number of pregnancies and a number of surgeries within the active arm of the study, that you have a similar sort of balance within the hereditary patient group as well. So that's something, which will be defined appropriately and is defined in the protocol, in which we managed in the way in which we collect the data.

So I think that's the best answer I can give at this moment, Phil, but we certainly know where we're going to go with this data and we feel confident that we can collect the data in a good and appropriate fashion.

Phil Nadeau - SG Cowen - Analyst

Okay, just two more questions on the U.S. trial. What's the time point of the clinical measure? Is it over 48 hours or over a week? And does the U.S. trial include any ultrasound measures of DVT?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

The answer to that, with regard to the issue of deep vein thrombosis and other thromboembolisms, is through the treatment until the patient is returned to normal therapy, prophylactic therapy on blood thinners. That's my understanding, anyway, Phil.

Phil Nadeau - SG Cowen - Analyst

Okay so it's not ultrasound. It's clinical?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Clinical symptoms are the endpoint. I think there is a provision within the protocol to use whatever diagnostic approaches are necessary to confirm if there are clinical symptoms of thrombosis. That's my understanding. Remember this protocol is just being finalized at this moment. As I say, we've had further discussions with the Agency and they've asked for one or two refinements. So what I've given you is what I know of at this moment. There may be other refinements, but that's my best understanding of the situation at the moment.

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Phil Nadeau - SG Cowen - Analyst

Okay and last question for Jack. Jack, can you remind us what the difference between your net loss and the cash burn is?

Jack Green - GTCB - SVP of Finance and CFO

The difference between the net loss and the cash burn would be revenues that were deferred due to accounting rules and the difference between that and cash actually received. And the flip side of that is costs that are deferred, relative to those programs for which the cash would have been paid but the cost is deferred, in line with any revenue deferrals.

Phil Nadeau - SG Cowen - Analyst

Okay. Do you expect any change in the ratio of the deferred revenues to the deferred costs in 2005?

Jack Green - GTCB - SVP of Finance and CFO

It does vary, as these projects are operated. We have in the fourth quarter recognized some revenue on a contract for which we had revenue deferrals and that was about \$1.8 million in the fourth quarter that we recognized on one of our contracts. And we also recognized approximately \$1.0 million of deferred costs in the fourth quarter, most of which were deferred from previous quarters.

Phil Nadeau - SG Cowen - Analyst

Okay.

Jack Green - GTCB - SVP of Finance and CFO

But that does -- it depends on what status the contract is at and it will vary.

Phil Nadeau - SG Cowen - Analyst

Okay, great, thanks a lot for answering all my questions.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Thank you, Phil.

Operator

Yale Jen with Rodman & Renshaw.

Yale Jen - Rodman & Renshaw - Analyst

Thank you, gentlemen, for taking my questions. I think most of the questions have been answered. Just one follow on to two aspects. One is for the U.S. trial. How many centers probably will be participating in the trials and that's the first one.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

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I don't know that figure exactly, Yale. My guess is somewhere in the region of about 15 to 20 centers and that can be sometimes a little variable, but that was our experience with the European study. And so I think it's going to be in that sort of range.

Yale Jen - Rodman & Renshaw - Analyst

Sure, I appreciate that. Just the second one was a little bit of follow-up on the prior question regarding the opportunities that you mentioned about \$150 million probably in Japan. Is there any thought or strategy in terms of pursuing that market at the moment?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Well, certainly we're actually very interested in the potential of being able to access the Japanese market. I think, at the moment, we've got our hands full just trying to deal with making sure we effectively complete the successful regulatory process with the EMEA for production in Europe. We obviously want to get our U.S. study underway and progress that and we obviously need to sort out our commercialization arrangements for Europe. So we're actually pretty focused on that, at this point in time.

Nonetheless we actually have quite a lot of contacts in Japan. We know a number of companies who are interested in the program and there's actually a lot of interest in Japan generally in recombinant plasma proteins as a replacement for the actual fractionated proteins. So I think there is an interesting opportunity there and certainly something which we will be starting to move forward in terms of those discussions as we move through the year.

Japan tends to be fairly slow, though, in the way in which that progresses and we would expect to need to do some clinical development work in Japan in order to get approval. That's the usual sort of the pattern of the way which things are done for the Japanese market and this isn't something which is short-term.

Yale Jen - Rodman & Renshaw - Analyst

Right and would that possible to assume maybe you're looking for a partner doing a lot of those things over there, because it's a territory that may be better suited for the local players to participate in them?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

I think we're very realistic about the fact that if we want to be in the Japanese market we would need a local Japanese company to assist us through that process and that is typically the way in which companies do that, even large companies. So that would be our expectation.

Yale Jen - Rodman & Renshaw - Analyst

Sure. Thanks for taking the questions.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Thank you, Yale.

Operator

Sam Rebotky with SER Asset Management.

Sam Rebotky - SER Asset Management - Analyst

Yes, good morning, gentlemen. You seemed to conclude another year and I guess we're working very strongly on the ATryn and looking for -- you're struggling with whether you get a partner or go on your own with the ATryn and with your need for spending \$25 million for the next

year. Are there any other things that you may monetize or is there certain minimum requirements of cash for this other partner to bring in to make that decision?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Thank you, Sam, for your question. I don't know whether I would regard it as a struggle. Actually, I think this is the opportunity that we've been looking for, for many years, to have the opportunity to commercialize this product and so it's a process, which we welcome, actually.

And clearly we have to make the balance between some of the short financial benefits potentially from partnering arrangements versus some of the longer-term cash flows, which would come to the Company as we get into bigger indications for this particular product. And I think that's just a process that we have to go through and understand that.

But there is another very important part. As I mentioned during my prepared remarks is that there is a strategic value to the Company developing their own commercial capability and I'm convinced that for the Company to make its transition to being a significant company we will need to establish our own commercial capabilities.

And the question is when we should do that. And that's a judgment which we, as management, together with the board of the Company, will make that assessment over the next few months as to whether this is the right opportunity or whether we wait until we go into the U.S. market.

But I think this is a nice problem for us to have. I actually feel very good about our ability to finance the Company effectively to support what we're doing as we move forward. I think that this is a transformational moment for the Company, a time when people can truly see credibility of the platform being established, a product coming to market.

This is a great time for us to really press forward and make sure the Company grasps the opportunity to take us to the next level and I think we feel very good about the process.

Sam Rebotsky - SER Asset Management - Analyst

Well, it sounds good, but how much more funds would you need if you had to go it on your own?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

I don't think that this is a major cash drain on us. As I say, we don't need a large number of salespeople and so I think that we feel that we can do this, as we do in most things, in a relatively modest fashion, but whilst still retaining a high quality approach to it. So that's part of the calculation we do.

So I think that we're certainly not going to move in that direction of establishing our own commercial capability and put us in a major cash drain in order to do that and that's one of the judgments, obviously, that we are making at this point in time. But that's now our assessment of the situation at all.

Sam Rebotsky - SER Asset Management - Analyst

Well that sounds good. Now, on the Merrimack situation, is there any discussion about monetizing this at this point in time or are there any thoughts on when this might happen?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Could you just say a little more what you're (multiple speakers) --?

Sam Rebotsky - SER Asset Management - Analyst

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In other words, has Merrimack thought of a public offering or some other method of increasing the value of Merrimack to you?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Oh, I see. Forgive me, I have no information whatsoever on what Merrimack's plans may be in that respect and it's certainly a question which you're entitled to ask Merrimack. But, in all honesty, I have no information and no guidance to give you as far as that's concerned.

Sam Rebotsky - SER Asset Management - Analyst

Okay, well it sounds like you've been doing very good. Keep up the good work.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

I appreciate it, Sam. Thanks very much for the question.

Operator

Roy Friedman with Edith C. Bloom.

Roy Friedman - Edith C. Bloom - Analyst

Good morning.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Good morning.

Roy Friedman - Edith C. Bloom - Analyst

Can you elaborate for us on what exactly is meant by a "prospective historical control arm"? I'm not familiar with that term. I don't believe I've ever seen that one before. Thank you very much.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

I think actually it's quite a common term. What it means is that you can't decide on what patients you're going to have in the study before you've initiated the study. So you define in your protocol the process which you are going to use in order to identify patients that you're going to use in that comparative arm. And what it means is a procedure to ensure that there is a balanced approach to it and that patients are not selected to prove one point or another and that's why it's prospectively defined.

Roy Friedman - Edith C. Bloom - Analyst

Well, how does that differ from a prospective registry trial? Is it the same thing?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

I'm not -- you mean in terms of from a clinical perspective?

Roy Friedman - Edith C. Bloom - Analyst

Yes.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Well, obviously the other arm of what we're doing is a clinical trial and that's what we will be comparing the historical (multiple speakers) --

Roy Friedman - Edith C. Bloom - Analyst

No, I mean the characterization that you sometimes hear of a so-called registry trial. Is this similar? Is this control arm similar to what would be generally meant by a registry trial or is this something that's a different kind of (multiple speakers)?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

No. I think that what I've described as a prospectively determined historical study is actually quite typical for that type of study. I'm not familiar with that alternative study, which you could apply to an historical study. I'm not familiar with that, to be honest.

Roy Friedman - Edith C. Bloom - Analyst

Okay. Thank you.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Thank you for your question.

Operator

Follow-up from Yale Jen with Rodman & Renshaw.

Yale Jen - Rodman & Renshaw - Analyst

Thanks for taking these follow-up questions. Just a quick one regarding for the U.S. trials. Are you looking for potentially a Fast Track type of approval process or do you think this drug may not be eligible for that type of status at the moment?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

We have looked at that in the past. The issue in the U.S. is that Bayer, a number of years ago, got orphan drug designation for their Thrombate product and that has actually expired. And so from our perspective, the only way in which we could get orphan drug designation for our product would be for us to enter a study, which we did, as a comparative study against Thrombate, to be able to show superiority to Thrombate in some fashion.

And I think that puts us back into having to do very large, complex and very extensive studies over long periods of time and we obviously don't feel that that's a rational approach. So, I think, at this moment, we're in a normal review process.

Yale Jen - Rodman & Renshaw - Analyst

Okay, great. Thanks a lot.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Thank you for your question.

Operator

Follow-up question from Roy Friedman with Edith C. Bloom.

Roy Friedman - Edith C. Bloom - Analyst

Hi, a follow-up on the historical control arm. What is the rationale for having approximately twice as many patients in the control arm as in the active arm?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Well, actually, if you take into account that we had 14 patients in our European study, which also the data from those patients will be included together with the additional 17 patients from the study which we're planning to initiate in the second quarter, in fact there's a pretty clear balance between the two.

Roy Friedman - Edith C. Bloom - Analyst

Well, are the 14 patients from the European study to be weighted equally in the trial with the new 17 patients?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

They will be included on an absolute -- all the data from that study, both the efficacy data and safety data, will form part and parcel of the full submission to the U.S.

Roy Friedman - Edith C. Bloom - Analyst

So then we can view this as a 31-patient active arm. Is that correct?

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

That's true. Yes.

Roy Friedman - Edith C. Bloom - Analyst

Thank you.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Thank you.

Operator

And gentlemen, you have no further questions at this time.

Dr. Geoffrey Cox - GTCB - Ph.D., Chairman, President and CEO

Mar. 02. 2005 / 10:00AM, GTCB - Q4 2004 GTC Biotherapeutics, Inc. Earnings Conference Call

Thank you very much indeed. So let me just thank everyone for joining us in this review of our financial results for the fourth quarter and for the year. We expect to be able to discuss our first quarter 2005 in May and I look forward to speaking with you again at that juncture and can I just also remind you that our annual meeting this year is on May 25th at 2:00. And we shall be posting the appropriate press release advising you of location, etc, as far as that's concerned.

So, once again, thank you and I look forward to updating you on our progress in May. Thank you very much indeed, everyone. Have a good day.

Operator

Thank you for your participation in today's conference. This concludes your presentation. You may now disconnect. Everyone, have a wonderful day and thank you.

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