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Conference Call Transcript

GTCB - Q2 2005 GTC Biotherapeutics, Inc. Earnings Conference Call

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GTC Biotherapeutics, Inc. - Chairman, CEO

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Sam Rebotsky

SER Asset Management - Analyst

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PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the GTC Biotherapeutics, Inc. second quarter 2005 earnings conference call. My name is Carlo and I will be your coordinator for today's presentation.

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 prepared remarks. If at any time during this call you require audio assistance, feel free to press star zero on your touch-tone telephone and a conference coordinator will be happy to assist you.

It is now my pleasure to turn the presentation over to your host for today's conference, Dr. Geoffrey Cox, Chairman and Chief Executive Officer with GTC Biotherapeutics. Please proceed, sir.

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

Thank you, and good morning everyone.

Welcome to the conference call and webcast to discuss the second quarter and first six months of the 2005 results for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB. I'm Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics.

With me today is Tom Newberry, our Vice President of Corporate Communications, and Jack Green, our Chief Financial Officer, is taking a long planned and well deserved vacation today.

Our results for the second quarter were released earlier this morning. 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 antithrombin program. I will then provide an overview of the financial results as well as comment on where we stand with respect to our expectations for 2005, then have some further prepared remarks about the status of our other programs before opening the meeting to questions.

As is 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 our expectations for future achievements are forward-looking statements based on management's current anticipations.

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We urge to you 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 which are described in detail in the Form 10-K and Exhibit 99, our actual results may differ materially from our current expectations.

Let me start by making some comments about our progress with ATryn®.

We continue to focus on achieving a positive outcome to MAA's review of our filing for marketing authorization approval for ATryn®, our recombinant form of human antithrombin. And I know that our investors want to get a renewed sense of our progress on this important program.

To quickly summarize the important regulatory events in Europe, we filed a Marketing Authorization Application, or MAA, with the EMEA in the first quarter last year and received what is called a Consolidated List of Questions at the end of June 2004. It's a normal part of the process and we responded to the questions in December last year.

We then received a list of Outstanding Issues at the end of March. We had further meetings in April with representatives of our rapporteurs, the member countries taking the lead in the review of our filing, and as a result of these very constructive and positive meetings we were granted an extension to respond to the Outstanding List of Issues by July the 8th. We actually completed our response on July the 6th.

Our expectation is that our responses will be reviewed by the EMEA with an opinion determined by the end of October. This includes allowance for the vacation period in Europe that occurs in August when we do not anticipate significant progress in the review process.

If, as we hope, we receive a positive opinion from the agency, there is an additional official confirmation at the MAA by the European Union which takes a further two to three months positioning us for marketing approval around the end of the year.

The continuing of the review process that will lead to the determination of the opinion includes inspections of our farm operations, inspections of the contract facilities where ATryn® is purified, and the facilities where some of our clinical work was performed. The inspection portion of the review process has now begun and I'm sure you'll understand that I cannot comment further on the activities of the inspectors.

I believe that our response to the Outstanding List of Issues was both thorough and well supported. The List of Issues was focused primarily on the purification process starting from milk and ensuring that we have validated assays in place to track the removal of potential contaminating proteins as well as on defining the product release specifications.

Remember that the regulatory authorities have never before seen a recombinant protein derived from milk.

Our response has required some additional laboratory data and good analytical work all within what would be expected to confirm the robustness and consistency of any recombinant protein manufacturing process. I continue to be optimistic about the MAA approval process and our plans to launch ATryn® in the first half of 2006.

In preparation for commercial sales, we've continued our discussions with potential partners. Just to recap, our focus in these discussions is on establishing a partnership that assists in the development of ATryn® for larger market acquired deficiency indications while allowing GTC to participate in the growth of this product.

Remember, acquired deficiency is where antithrombin is being consumed as a result of a patient trauma.

This has led us into a number of discussions with both pan European and regional pharmaceutical companies. One of the potential pan European partners has progressed into late stage negotiations.

Our recent financing provides with us a stronger negotiating position in these partnering negotiations including the option to launch ATryn® ourselves if appropriate terms cannot be established. While business development discussions such as this are inherently unpredictable, I'm encouraged by the progress we have made and I believe we have an opportunity to successfully reach an attractive partnering agreement.

Our plan is to initiate clinical development in an acquired deficiency indication in the first half of next year. Of course, this is a central strategic objective of this program to continue to expand the market opportunity for ATryn® into larger acquired deficiency indications that would be difficult to serve with limited supplies of plasma-derived material.

The specific indication will be dependent on our strategic objectives and those of our partner. We'll remain interested in the areas of severe burns, coronary artery bypass surgery and disseminated intravascular coagulation or sepsis.

Interesting data on the DIC, or sepsis indication, is being presented this week at the International Society of Thrombosis and Haemostasis conference in Sydney, Australia. The data in this study suggests that the anticoagulant and anti-inflammatory properties of antithrombin have a therapeutic benefit in patients that have been subject to an experimental model of sepsis, when antithrombin is provided at super-physiological levels without the presence of heparin.

One of the reasons our recombinant antithrombin product was attractive to Dr. Jilma's team for this study is that it does not contain residual heparin. Most of the plasma-derived antithrombin products do contain residual heparin from their manufacturing processes.

We will aim to conduct further studies in the indication we do select in a way that will yield data that can be used in both Europe and the United States.

Turning our attention to ATryn® in the United States, we have begun the recruitment process into the multinational study of the heredity deficiency indication that the FDA has agreed to. This study requires us to perform a trial of an additional 17 patients undergoing high-risk procedures such as surgery or childbirth.

The results from these 17 patients will be added to the results we obtain from the 14 patients we studied for our European filing. This group of 31 will be compared to an historical control arm of 35 patients with a similar profile to the active arm that have been treated in the past with plasma-derived antithrombin.

We have expanded our physician and patient registry and have identified a number of potential candidates to include in the study. Our plan is that enrollment will be completed around the middle of next year.

Remember that the completion of this study is expected to form the clinical base for filing a Biologics License Application with the FDA around the end of 2006.

In summary, we've made very good progress in advancing ATryn® towards approval in Europe and with a pivotal study for the United States. This is a transforming moment for both GTC and for production of biologics used in this technology.

The approval of the transgenically produced first protein will demonstrate that we can commercialize proteins using this technology that are difficult to express as well as those proteins that will be required in large volumes.

Now before I begin reviewing our quarterly financial results, let me make a few remarks about the financing transaction which we completed earlier this week.

The objective of executing this limited financing at this time was to maintain a responsible cash position and to ensure that we have the ability to maintain the momentum of the development and commercialization of ATryn® both with the U.S. hereditary deficiency study and the expanded development in acquired deficiencies. Our enhanced balance sheet will also strengthen our position in partnering negotiations.

In addition, of course, we will continue to carefully manage our expenses and cash. Our financial results reflect our careful management of cash.

While I do not plan to review all the details that can be found in our press release, a few comments on our cash position and expenses are useful.

For the second quarter we utilized a net \$5.8 million of cash, somewhat lower than the \$6.6 million we used in the first quarter, excluding the effect of our financing in January and the \$2.4 million of debt refinancing with GE Capital. We expect to use approximately a net \$20 million of cash excluding financing for the year.

The net cash use projection includes cash collections of approximately \$12 million for the year, including collections from partnering arrangements, of which approximately \$5 million either been collected or are anticipated under existing contracts. We anticipate finishing the year with approximately \$20 million of cash and marketable securities, including the proceeds from our financing transactions and partnering activities.

Our cost of revenue and operating expenses totaled \$8 million this quarter, slightly higher than the \$7.5 million in the second quarter of 2004.

Increases in research and development to support our MAA filing and to initiate the pivotal study for the U.S. were mostly offset by reductions in our selling, general, and administrative expenses.

These results are in accordance with our overall strategic financial objective, which is to keep a careful watch on our cash position and structure GTC's needs and resources according to the demands of our business and the progress is of our programs.

Now, I opened our presentation on this conference call discussing the progress of ATryn®. ATryn® is more than the first transgenically produced protein to be submitted for regulatory approval, it's also a product which we believe has the potential to establish large markets that expand beyond the current market for plasma-derived antithrombin.

We estimate that we can build a 500 to 700 million dollar market for ATryn® by opening up the U.S. market to a robust supply, expanding the clinical use of the product into acquired deficiency indications that would challenge the supply capabilities of plasma-derived products, and penetrating the current sales of plasma-derived products with our secure source of recombinant material.

One of our marketing advantages in Europe will also be a uniform, consistent, product approved throughout the European Union compared to a country-by-country status for each of the current plasma products with none of them available in every country.

Our near term focus in people, activities, and finances is executing this vision. However, we have not lost sight of the broader application of our technology to important therapeutic proteins, particularly additional recombinant plasma proteins such as recombinant human alpha-1 antitrypsin and recombinant human albumin programs and also in large-scale antibodies.

The AAT program, like the ATryn® program, is being considered for congenital, or hereditary deficiency indications and other clinical indications. Hereditary deficiency of AAT is a common genetic cause of emphysema and chronic obstructive pulmonary disease.

Because of this close tie to respiratory conditions, we continue to investigate pulmonary delivery as well as the traditional intravenous formulation.

In our development discussions for recombinant human albumin we have noted that both Invitrogen and Serologicals have established control herds of standard cattle in Australia in order to provide a more secure source of bovine albumin from the animal's blood for use in cell culture media. We believe that our source of human albumin from milk, a much safer starting material, will be of great interest to those in the industry who wish to avoid the use of blood-derived products.

We will advance these programs as resources become available.

During the quarter we established transgenic animals in our CD137 program and induced lactation at significant expression levels. You'll recall CD137 is an agonistic antibody that stimulates the immune system to recognize and respond to solid tumors.

We believe this product will be required in very large volumes once it successfully completes clinical studies and therefore it is well suited to our technology. We have submitted an application for a second small business innovation research grant to obtain additional funds to support our activities in this program in 2006.

We also recently entered the collaboration agreement with Scancell, a private company based in Nottingham in the United Kingdom to develop their SC101 antibody to the Lewis (y/b) antigens, which are overexpressed in many types of cancer cells, and we view that as a potential treatment for a broad range of tumors such as breast, colorectal, and lung cancers.

Like CD137, we believe that SC101 will be required in large volumes upon successful completion of clinical studies, a natural fit for our transgenic technology. We're beginning the first step in this program of demonstrating transgenic production of SC101 with Scancell.

You may recall that we have developed a close working relationship with the National Institute of Allergy and Infectious Disease in our malaria vaccine program and we've developed transgenic animals. The NIAID has informed us, however, that no additional funding has been committed beyond mid-August 2005 due to current budgetary constraints.

They are keen to maintain their relationship with us. They've informed us that they remain very interested in our technology for both our malaria vaccine and other potential applications where cost of goods or development of difficult to express proteins is an important factor.

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GTC and the NIAID are discussing opportunities to continue preclinical activities in the malaria vaccine program without incurring significant additional cash expense.

With regard to our program with Merrimack Pharmaceuticals production of MM-093, the current contract for the clinical supply was successfully completed in the second quarter of 2005. The negotiations for the further supply of MM-093 to Merrimack for the next stages of their clinical development program are in progress.

In support of all our programs, we have recently been allowed claims in a significant new patent for our Tangential Flow Filtration technology for recovering recombinant proteins from milk. Using this TFF technology enables the removal of lipids, or fats, casein, and other milk proteins resulting in a clarified material which could be directly applied to standard purification systems, typically chromatography.

This is important in reducing to practice the commercial production of proteins using transgenic technology. Our position is unique and not subject to any existing cross-license agreement providing additional patent protection and potential licensing opportunities to GTC in the U.S. until 2023.

In summary, we've had a strong quarter advancing ATryn® both in Europe and the United States. We are committed to achieving our timetable for obtaining a positive opinion for ATryn® in October with full approval around the end of the year, completing our partnering negotiations, establishing ATryn®'s commercialization strategy over the next few months, launching ATryn® in Europe in the first half of 2006, selecting an acquired deficiency indication and initiating clinical development in the first half of 2006, and completing enrollment in the clinical study of hereditary deficiency in the United States in the middle of 2006.

We believe that these events will be important in unlocking the value of all our programs for both difficult to express and large-volume products.

So I very much look forward to updating you on our progress during the coming months as GTC continues on its transition to becoming a commercial products company. The Company is truly energized by the progress we have made and the opportunities available for us. We look forward to this time of transition with real optimism.

So thank you. I'll finish this part of the presentation and we can now move over to any questions that you may have.

QUESTION AND ANSWER

Operator

Thank you, sir. [OPERATOR INSTRUCTIONS] One moment, please. Sir, our first question is from the line of Curt Daniel with Fortis Bank.

Curt Daniel - Fortis Bank - Analyst

Thank you for this presentation. Just a quick question on the cost of goods. Can you give me some guidance on cost of goods of producing ATryn® in a goat?

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

Well, of course, we don't, that's proprietary information, and I'm sure you understand that we don't actually talk about precise cost of goods as such.

We're very confident that we will have very competitive cost of goods with this product as we move forward with ATryn® into commercial production. Typically, transgenic production is very effective at being able to produce large volumes of therapeutic proteins at very economic cost of goods.

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It's one of the features and one of the strengths of this technology, and it's also reflected in the lower capital cost of goods, lower capital uses of cash to be able to provide the type of capacity required for this type of volume of production. So we are very confident that we will have a competitive cost of goods position in this marketplace.

Curt Daniel - Fortis Bank - Analyst

And I have a second question on your alpha antitrypsin program. Are you going to cross-license or co-develop this with Pharming, you know, as PPL alpha antitrypsin program in terms of IP or technology development?

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

We are aware of Pharming's access to some of the intellectual property of PPL. We have not had specific discussions with Pharming.

We know the people at Pharming very well. We regard them as good friends in this technology space. But this is a program which we feel we can independently pursue.

Curt Daniel - Fortis Bank - Analyst

Okay. Thank you very much.

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

My pleasure.

Operator

Our next question is from the line of Sam Rebotsky with SER Asset Management.

Sam Rebotsky - SER Asset Management - Analyst

Good morning, Geoff.

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

Good morning.

Sam Rebotsky - SER Asset Management - Analyst

You have made an awful lot of accomplishments for a small company, and I just wanted to sort of discuss your cash. You've paid \$2 million in this quarter to Genzyme?

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

We paid actually \$2.4 million in April. Remember, there was an outstanding loan of 4.8 million of which 2.4 million was paid in April, and towards the end of the first quarter, we actually had refinanced that part of the loan for \$2.4 million with GE Capital.

We already have a loan arrangement in place with GE Capital. So we refinanced that 2.4 million and we still after further loan payment due to Genzyme in April of 2006 for 2.4 million.

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Sam Rebotsky - SER Asset Management - Analyst

I see. And you speak of ending the year with about \$20 million.

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

Yes.

Sam Rebotsky - SER Asset Management - Analyst

And you talk about going forward with the ATryn® with your introduction. That would seem to require an awful lot of cash, or this partner that you're seeking. What are, how are you going to go about, if you don't find a partner, do you expect to raise additional funds on your own?

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

I think the question's an excellent one. Clearly the objective of our partnering discussions is to not only seek a partner who can help us from a point of view of sales and distribution of the product, but is also prepared to commit financial support to the continuing development of ATryn® in one of these acquired deficiency indications which we have not made any particular decision on at this juncture. And clearly that's an important part of the partnering discussions which we have at this moment.

The general approach which we have taken with all our programs at this juncture is to take a very measured approach to the way in which we initiate new development programs. We certainly will not initiate programs unless we have a clear runway in terms of financial resources in order to be able to do that in a way which is appropriate to our cash resources.

The types of programs, however, that we're looking at with regard to acquired deficiencies, at least in the initial phase for ATryn®, are not highly expensive programs. We would be looking to do some pilot studies or maybe physician-sponsored studies which could be done in a relatively modest fashion from a cash perspective, but will provide good data to us which will help us both to define the type of dosing regimen that we require, which is likely to be different from the acquired deficiency indication, the type of end points that we should be trying to look for in more expanded studies, and also to define the patient profile that we can include in these types of studies to be successful.

So, you know, I think that we will progress quite cautiously, Sam, and we certainly are not going to rush into these things and cause ourselves to be short of cash.

Sam Rebotsky - SER Asset Management - Analyst

Clearly you've progressed very cautiously, and you've covered a lot of different areas. I'm trying to sort of get from a bigger picture, does it make any sense, and I'm sure the board discusses, does GTC fit with a bigger company with more resources and an ability to market products for all the research that you're looking into, if an appropriate valuation could be put on GTC to be part of a larger entity. Have you been thinking about that with all the research that you've been doing and your accomplishments?

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

Well, let me first of all say that we're not involved in any of those discussions at this juncture. I think as a company and as a responsible board, we always continue to look at and address what our options and what are the best, what is in the best interest of our investors as we move forward, and I'm sure we will continue to do that over coming months. I think you make an interesting point.

It's not part of our strategy at this moment. Our strategy, where we're at, at this juncture, is to remain an independent company, to progress our programs forward, but certainly we recognize the value of finding partners who could help us to support in a more timely fashion the development of the larger indications which are so crucial to unlocking the value of ATryn® and the follow-up programs.

But it's an interesting comment you make. But we're not involved in any of those discussions at this juncture.

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Sam Rebotsky - *SER Asset Management - Analyst*

Good luck on achieving your goals.

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

Thank you very much indeed.

Operator

And, sir, our next question is from the line of Leland Gershell with SG Cowen.

Leland Gershell - *SG Cowen & Company - Analyst*

Hi. Thanks for taking my question. Two questions that I have. One is, could you review the potential upcoming milestone payments that you may receive for signing partnerships in the next few months? And also to review the potential, I should say the time line for development in the acquired deficiency that you may be pursuing.

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

That's a good question. The first one of course is something which is part of our current negotiations so it's not something I particularly want to talk about in the public domain as such. However, we have quite regularly said that one should not expect that they're going to be very large up-front payments in this program.

I think this year we've projected, as I said in my comments on the financials, that we're projecting further 7 million from various partnering discussions and arrangements this year. But I think the most important part of any negotiation which we're involved in at this moment is the contribution which the potential partner is prepared to make to the further clinical development of the product, and so I think that one has to look at the package in it's entirety rather than just up-front payments, and that's certainly the way in which we're looking at that at this moment.

We also want to make sure that we engage a partner who is truly committed to the timely development of ATryn® in a program which we want really the partner to feel is very important to their own strategic positioning as well, so that we really do see the performance in the development of the value of the product.

With regard to timing, I think it's reasonable to assume that depending upon which indication which we may approach, but a clinical development program which would lead actually to an expanded indication is probably going to be the order of three to four years in order to be able to complete into Phase III studies. So it's that sort of time line, but that's still something which we obviously would need to define a little more clearly once we have established which clinical indication we want to aim for.

Leland Gershell - *SG Cowen & Company - Analyst*

Great. Thanks for taking the question.

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

My pleasure. Thank you.

Operator

Sir, our next question is from the line of George Marshall with Boenning Scattergood.

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George Marshall - Boenning & Scattergood, Inc. - Analyst

Does your 500 to 700 million dollar market for ATryn® include Japan and the Far East?

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

That's a very interesting question, actually. It probably doesn't at this moment, but I think that we feel that we have a real opportunity to be able to establish that type of sales revenue out of Europe and the United States.

But you do raise a very interesting point, that antithrombin is a very significant product in Japan, and it actually is approved in Japan, my understanding is for disseminated intravascular coagulation. So we have already started to put out some feelers regarding potential partnering in Japan.

Clearly, that's one where we wouldn't take it through ourselves, but we would be looking for an actual Japanese company to help us through that process, and we would assume that we would need to do some clinical development in Japan as well to be able to support that. But I think it's something which is a little further down the track from our primary targets which at this juncture is Europe and the United States.

Remember, in the situation which exists today with plasma-derived products, first of all, in Europe, the plasma-derived products are quite limited on the number of countries in which they're approved. We're the first antithrombin product which has ever gone through the centralized procedure, and so we will get access to the whole 25 countries of the European Union.

In the United States there is only one supplier of plasma-derived product which is Bayer's Thrombate, and that has been available in the past in relatively limited supplies. So you have a very, very large valuable market here in the United States which really is quite underserved at this point in time, and we feel that that's a tremendous opportunity for us.

So we feel actually pretty good about that projection as being realistic, but it clearly needs supporting by expanded clinical data in order to be able to achieve those sorts of figures.

George Marshall - Boenning & Scattergood, Inc. - Analyst

Thank you very much.

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

My pleasure.

Operator

And again, ladies and gentlemen, as a reminder, you may press star one to submit a question. And, sir, we have no further questions at this time. Back over to you for any other remarks.

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

Thank you very much indeed. And I thank all of you for joining us this morning.

We obviously look forward to what we believe will be an exciting few months through to our next call, which we expect to be in early November. So please stay tuned, and we look forward to speaking to you then. Thank you very much indeed. Have a good day.

Operator

Ladies and gentlemen, we thank you for your participation in today's conference. This concludes your presentation, and you may now disconnect.

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