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Conference Call Transcript

GTCB - Q2 2008 GTC Biotherapeutics, Inc. Earnings Conference Call

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Good day, ladies and gentlemen, and welcome to the Second Quarter 2008 GTC Biotherapeutics, Inc. Earnings Conference call. (OPERATOR INSTRUCTIONS) I would now like to turn the presentation over to your host for today's call, Dr. Geoffrey F. Cox, President and Chief Executive Officer. Please proceed.

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

Thank you very much and good morning everyone and welcome to the conference call and webcast to discuss the Second Quarter 2008 Financial and Operating Results for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB. I'm Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics and with me today are Jack Green, our Chief Financial Officer and Tom Newberry, our Vice President of Corporate Communications.

Our results for the second quarter 2008 were released earlier this morning and I hope you have had the opportunity to review this release prior to our call. After some introductory comments, I will ask Jack Green to provide a summary of our financial results and expectations and I will then provide some final comments and I will then open 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 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 1A of our 10-K and subsequent 10-Qs, our actual results may differ materially from our current expectations.

This has been an excellent quarter for our business. We realized strong cash receipts from our partners, we've also secured an outstanding partner with OVATION Pharmaceuticals for the commercialization and further development of ATryn® in the United States and we've completed the preparation of the final part of our rolling BLA submission. These are all great examples of GTC's progress in its strategic, operational and financial performance goals.

So let me take you through these in some more detail.

We have now completed preparing the second and final section of our rolling BLA submission that includes all the analyzed clinical data from our US study together with the data from our previous European study. We will be issuing a press release announcing submission to the FDA later today once the FDA receives all the data.

In February of this year we announced successfully meeting the non-inferiority end point of our US Phase III study for the prophylactic treatment of hereditary antithrombin deficient patients undergoing surgery or childbirth.

This study was composed of 17 evaluable patients treated with ATryn® combined with the 14 that were treated in the European study and compared to an historical or retrospective control arm of 37 patients that have been treated with plasma-derived products for surgery or childbirth procedures. We submitted the first part of the rolling BLA at that time.

The first portion of the BLA filing led to the FDA's field inspections of our production farm operations and the downstream purification of the Lonza facilities in Hopkinton, Massachusetts. We did not receive any major findings from these inspections.

Completing the BLA submission is a tremendous accomplishment for GTC particularly since it was achieved with our own clinical and regulatory staff. If you recall, we worked through the European regulatory process primarily through contract regulatory resources. This demonstrates our growing expertise and capability in successfully managing our own clinical and regulatory affairs.

Compared to our filing in Europe which was submitted entirely on paper, this submission is a cross-linked electronic file that enables the reviewer to more easily access all the data. This should assist in the timely review of our submission.

You'll remember towards the end of last year ATryn® was designated an orphan drug and was also granted fast-track review. As a result of our fast-track status we have requested priority review and anticipate a decision from the FDA on this request as they review the complete BLA filing.

Assuming that priority review is granted, the FDA's decision on the BLA is anticipated six months after their acceptance of our filing. We're expecting an advisory panel meeting as part of this review as is the normal course of business for the FDA with products derived from technology.

A key element of our growth strategy is to build financial value in ATryn® by expanding development both geographically as demonstrated by the BLA submission, and importantly into much larger acquired antithrombin deficiency indications beyond the initial genetic deficiency submitted to the regulatory agencies for initial approval.

We have now come a very long way in realizing the strategy first through our partnership with LEO Pharma for Europe, Canada and the Middle East and now with OVATION Pharmaceuticals for the United States. LEO and OVATION both bring tremendous market expertise in their respective territories for commercially introducing the benefits of recombinant antithrombin while preserving the pricing power for the acquired deficiency indications.

OVATION is an important new partner. Headquartered in Deerfield, Illinois, OVATION is a private company primarily backed by the private equity firm GTCR Golder Rauner, LLC.

OVATION focuses on drugs for high need patient groups that historically have not been well served by pharmaceutical innovations. OVATION was formed in 2000 and its senior executives have been drawn from major pharmaceutical companies such as Abbott, Baxter and Hospira. We understand that they have been profitable throughout their history with 85% compound annual growth in revenue and cash flow.

Importantly, for the development of ATryn®, OVATION has a hospital-based sales force with a hematology and oncology biologics portfolio, they market Panhematin for the treatment of recurring attacks of Porphyria, a genetic disorder, and Elspar, an E. coli-derived form of the enzyme asparaginase for the treatment of acute lymphoblastic leukemia. OVATION also works in the area of neonatal intensive care.

OVATION has a total of about 250 employees and has been recognized with the 2007 Chicago Innovation Award and as the Scrip Pharma Company of the Year in 2006 and 2007 in the under \$5 billion revenues category.

OVATION will be responsible for ATryn®'s US launch including all sales and marketing. The agreement with OVATION provides that they will fund the anticipated clinical work for ATryn® and heparin resistance and pay us for the product used in the studies.

For commercial sales our average effective royalty percentage including the margin on our transfer price and the licensed royalty on sales will be in the low-20s.

In addition to the ongoing revenue from product sales, our agreement includes a series of potential clinical, regulatory and sales milestones totaling \$257 million. This includes payments of \$9 million for the initial hereditary deficiency indication which consists of \$3 million for closing of the agreement, \$2 million for the acceptance of our BLA filing for hereditary deficiency and the successful determination of priority review and \$4 million for approval in hereditary deficiency.

The closing of the agreement with OVATION remains on track although this has taken a little longer than originally anticipated. The required Hart-Scott-Rodino Review has been successfully completed and the legal requirements for closing are in the process of being completed.

OVATION's first interest is in developing the heparin-resistant indication that GTC has previously studied. Heparin resistance is the term applied to patients undergoing a cardiopulmonary bypass, or CPB procedure, who no longer respond satisfactorily to additional heparin.

As you may recall, heparin depends on the presence of antithrombin to have an anti-coagulant effect. Heparin is used in bypass procedures to minimize the risk of clot formation while the patient is on the bypass machine. Heparin-resistance occurs in up to 15% to 20% of CPB operations and we estimate the fully developed market in the US to be approximately \$150 million.

The initial data GTC previously developed will be valuable in establishing an agreed protocol with the FDA. We plan, together with OVATION, to discuss our clinical study proposal with the agency after the review of the hereditary deficiency indication is complete.

While we'll have a better understanding of timelines after discussion with the FDA, it is possible that the heparin-resistance clinical program can begin later in 2009.

OVATION is also interested in pursuing the indication for disseminated intravascular coagulation, or DIC, associated with severe sepsis in the United States as the data becomes available from LEO's Phase II study in Europe.

LEO is continuing to focus on the Phase II DIC dose ranging study in Europe demonstrating a strong commitment to the further development of ATryn®. We will have full access to the Phase II results when the study is complete.

DIC is a very large unmet medical need with a \$2 billion to \$3 billion market potential in the United States alone. LEO has benefited from the wealth of published patient data in this field in developing the clinical protocol.

While this study initially got off to a slower start than they had planned, LEO is taking corrective measures and I believe that their progress indicates top line results from the study in the second half of 2009. We will continue to update our timing expectations after we obtain further information and progress reports from LEO.

The currently approved use for ATryn® in Europe for surgical procedures is a very modest indication. Despite this limitation, LEO has initiated commercial sales in the UK. LEO will be applying later this year to the EMEA for a label expansion to include childbirth based on the dosing information we obtained in our US Phase III study that we just submitted to the FDA.

Childbirth comprised 60% of the procedures included in our clinical studies and is a significant portion of the hereditary-deficient treatment population.

LEO will also be submitting later this year for Canadian review an hereditary deficiency indication by using the data we have generated for the FDA.

Our relationship with LFB Biotechnology continues to be a strong example of the value of our overall partnering strategy. LFB has demonstrated their dedication to the success of our collaboration by entering into a commitment under our existing agreement to fund up to \$6 million of GTC's share of the expenses in the collaboration programs this year.

They provided \$3 million of this expense reimbursement in the second quarter. This ensures that we do not lose momentum in the Factor VIIa, Factor IX, alpha-1 antitrypsin and CD20 monoclonal antibody programs through the second half of the year.

With this funding, we continue planning to reach clinical status in the recombinant plasma protein programs in the second half of 2009. Over the next few weeks we are also expecting the birth of goats that can express the CD20 monoclonal antibody.

We are planning for pre-clinical studies for CD20 in 2009.

Two of our other partnering relationships that result in significant contributions to our financial performance this quarter - the revenue from our service to PharmAthene's Protexia program increased significantly in this quarter. Protexia is PharmAthene's recombinant form of human butyrylcholinesterase that is in animal models and human testing as a potential bio-defense product to treat exposure to nerve agents.

The Protexia product is being produced in PharmAthene's transgenic goats for which we have provided PharmAthene a license to our intellectual property. We receive service revenue for our support of their downstream processing and regulatory submission activities.

Our relationship with ProGenetics has yielded some near-term dividends. Last year we obtained rights in Europe, North America and Japan for recombinant Factors VIII and IX as well as fibrinogen for \$1 million. Factor IX program has subsequently been brought in for collaboration with LFB and LFB is committed to paying \$500,000 and funding their portion of the costs.

As a follow-up to this arrangement, we licensed fibrinogen for these territories to Pharming Group of The Netherlands for an upfront fee of \$550,000 and a single digit royalty on future commercial sales.

Overall, therefore, we believe we have positioned ourselves to gain significant future value from this portfolio of recombinant plasma proteins through our financial interests in the successful development of these products.

An important element of our partnering strategy has consistently been to engage in a mutually beneficial relationship that results in a commitment to advance the transgenically produced product, obtain near-term funding for clinical and commercial development, benefit from the access to the partners' broader functional expertise and to retain a significant interest in the future market value of the product.

Our partnerships with LFB, with LEO and OVATION meet these criteria reducing the cash burden of further development and its effect on our balance sheet while maintaining significant commercial value for GTC upon which we can grow into a significant biotechnology company.

After Jack has reviewed the financial results I'll take some time to describe some of the progress in our other partnering opportunities. So let me now pass over to Jack.

Jack Green - GTC Biotherapeutics, Inc. - CFO

Thank you, Geoff. Revenues for the second quarter 2008 were \$9.1 million, more than triple the \$2.8 million recorded in the second quarter of 2007. This increase was driven primarily by revenue from LEO for clinical supply of ATryn® and from services provided under our contract with PharmAthene.

Revenues totaled \$12.7 million for the first six months of 2008 compared to \$8.3 million for the first six months of 2007, an increase of 53%. The six month increase is also primarily due to revenues from LEO for the clinical supply of ATryn® in revenues from PharmAthene.

Cost of revenue and operating expenses totaled \$11 million in the second quarter of 2008, approximately 19% lower than the \$13.5 million total in the second quarter 2007.

Costs of revenue and operating expenses totaled \$22.7 million for the first half of 2008, approximately 15% lower than the \$26.7 million for the first half of 2007.

The lower expenses are primarily due to decreased costs in the ATryn® program combined with \$3 million of program funding received from LFB in the second quarter of 2008 for funding GTC's share of the collaboration programs, Factor VIIa, Factor IX, alpha-1 antitrypsin and CD20 monoclonal antibody, as well as the impact of a \$2.9 million inventory write-down incurred in the second quarter of 2007.

The lower expenses in the ATryn® and LFB programs were partially offset by higher costs supporting the higher revenues both from the PharmAthene program and in the cost of goods for the ATryn® products sold to LEO.

Costs of revenue increased by \$1.5 million to \$5.6 million in the second quarter, year-to-year comparison, primarily due to the cost of products sold to LEO and to the cost of increased services provided to PharmAthene, partially offset by the impact of the 2007 inventory write-down.

Research and development expense decreased year-to-year in the second quarter by approximately \$4 million to a total of \$2.7 million. The decrease was primarily a result of the \$3 million program funding received from LFB in the second quarter of 2008 as well as lower expenses in the ATryn® program.

LFB has also committed to fund an additional \$3 million of second half expenses on the collaboration programs fully funding the \$6 million of GTC's expenses for those programs for 2008.

LFB has been a very collaborative and supportive partner and has worked diligently to help advance the collaboration programs. This is an excellent example of how partners can help us advance our programs and reduce cash burn.

In the quarterly comparison, SG&A expenses were relatively flat year-to-year. Our total net loss for the second quarter 2008 was \$2.2 million, or \$0.02 per share, compared with \$10.6 million, or \$0.14 per share, in the second quarter of 2007.

The net loss for the first six months of 2008 was \$10.4 million, or \$0.11 per share, compared with \$18.1 million, or \$0.23 per share, for the first six months of 2007.

Cash and marketable securities at the end of the second quarter totaled \$12.2 million, a \$3.6 million decrease compared to the \$15.8 million at the end of 2007 and a \$0.5 million increase from the \$11.7 million at the end of the first quarter.

We were slightly cash positive in the second quarter reflecting over \$10 million of cash receipts in the quarter from collaboration partners including \$4.2 million from LEO for ATryn® products sold, \$3 million from LFB to fund first half expenses on our collaboration programs, \$1.6 million from PharmAthene for product development and purification services as well as \$550,000 from Pharming for the license to fibrinogen.

Our cash receipts for the quarter were very strong but let me remind you, as I always do, that due to the timing of program activities and the schedule of product shipments revenue and cash receipts on our partnering programs are expected to vary on a quarter-by-quarter basis and the results on any quarter are not necessarily indicative of expectations for future quarters.

We currently estimate our cash use for the second half of 2008 to be approximately \$14 million which does not include any payments from potential new partnering agreements under discussion.

Geoff?

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

Thank you, Jack. So most of the recent activity is focused on ATryn® and the other products in our portfolio of recombinant human plasma proteins. In addition to drawing investor and collaborator attention, these programs continue in their development and we are encouraged by their progress. We also have a strong interest in monoclonal antibodies, particularly as follow-on biologics.

With energy costs and presidential campaigning dominating media and legislative discussion, let me take a few moments to remind you what has been accomplished in advancing relevant legislation.

Most responsible parties now understand that the complexity of biologics and the current level of predictive certainty about the impact of any differences will require that most glycosylated proteins such as antibodies obtain some level of clinical validation beyond reference to the innovator's clinical experience.

Most participants agree that the FDA is the appropriate authority to judge how much new clinical evidence will be required for each product, there is still significant discussions surrounding the issue of how much time the original protein's market remains exclusive to the innovative company.

The BIO trade organization has proposed 14 years of exclusivity. The legislation which has progressed the farthest in the Senate, the Kennedy-Enzi-Hatch-Clinton bill and the Eshoo-Barton proposal in the House both specify 12 years of exclusivity. The complicating issue is defining a process, if any, by which a follow-on may be considered interchangeable with the innovative protein.

We believe that the next president, regardless of who wins the election, will support the passage of the legislation of the emergence from these discussions because rising healthcare costs will continue to be a high priority on the country's political agenda.

While the differences under discussion are not trivial and will take time to resolve into a single piece of legislation, most of the companies interested in participating in follow-on biologics are now planning their development based on the general outlines of the bills in Congress.

We are utilizing our established infrastructure to initiate the development of production for some of these follow-ons that have a current market value of about \$16 billion and they are projected to grow to \$32 billion over the next five to six years.

Initial discussions on partnering these programs have included some of the established generic pharmaceutical companies and I am encouraged by the interest shown in these discussions.

Our innovative antibody program for the CD137 receptor which we believe is a modulator of the immune system continues its preclinical development. This work supports our optimism about its potential utility in both oncology and autoimmune disease. We have developed both glycosylated and non-glycosylated versions of this antibody and there may be clinical uses for both these versions.

Our work on the CD137 antibody program is being funded by an SBIR grant from the National Institutes of Health. This Phase II grant has just been extended to support our work through the end of August 2009.

As you may recall over the last two years I've said I have a strategy which I believe established the platform for building GTC into a significant company. I set out that strategy as our challenge following the approval of ATryn® in Europe. This first approval of a transgenically produced drug demonstrated our leadership in this powerful technology for enabling difficult to express proteins and delivering large volumes of therapeutic proteins that reduce costs compared to traditional recombinant methods.

As we discussed in previous conference calls, we've been leveraging our strong patent position, demonstrated expertise in this technology, establishment of a low risk, high potential product portfolio and track record of successful product development to establish a broad range of partnerships that meet our growth criteria.

GTC's performance and progress in our business this quarter has been excellent. We are seeing some of the benefits of our partnering strategy in our financial results. The progress of our programs are continuing to generate significant interest in additional partnering discussions with a major agreement reached with OVATION contributing significantly to our near-term funding.

In addition, we are well on our way to gaining FDA review and hopefully approval for ATryn® in the first quarter of 2009.

I look forward to updating you on our progress as we move into 2009 with the expanded commercialization of ATryn® in the United States and our Factor VIIa, Factor IX and alpha-1 antitrypsin programs transitioning into clinical studies.

I thank you for listening to the prepared remarks. I will now ask the Operator to please open the call to any questions you might have.

QUESTION AND ANSWER

Operator

(OPERATOR INSTRUCTIONS) Ren Benjamin, Rodman and Renshaw.

Ren Benjamin - Rodman and Renshaw - Analyst

Thanks for taking the questions and congratulations on a very nice quarter. Just a couple of questions starting off with, maybe, the LEO partnership. Can you just give us an update or just some color as to how the Phase II is progressing? I think you mentioned on the call that results are still expected in the second half of '09 but are there any other details you can provide from that trial?

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

Yes. It's a little difficult to give you detailed information because LEO is very conscious of a number of these studies ongoing at this moment. So they consider quite a lot of that information to be confidential, understandably.

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But, as you are aware, these are quite complex studies and LEO has been actually quite conservative about the way in which they have designed the study to avoid some of the pitfalls which clearly have arisen in previous studies and so I think that this has been a progressive approach on their part.

They are, I think, making good -- they've made some corrections in the study and I think they are making good progress now but I think it's going to still take another two or three months before we have a real good understanding as to what these timelines look like.

Our best estimate at this moment is probably the latter half of 2009, I think, for top line results. But that's something which we are -- we will certainly be looking at as we progress over the next few months.

Ren Benjamin - Rodman and Renshaw - Analyst

Regarding the BLA submissions, if everything goes according to plan and the FDA gets all the paperwork today, what's the amount of time, if you can remind me, that it takes them to come back to you with a decision regarding priority review or not?

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

Actually, it's a fair question. I'm not quite sure -- I hope I answer you accurately because I'm not quite sure exactly whether there is a mandatory requirement around this but I think it will be dependent on a couple of things, one of which they will review the finding once it's been made and assess whether this is a filing which they will accept, obviously, and we are obviously pretty hopeful and expectant that that will be -- that our filing will be fine and will be accepted.

They may give us a priority review status at that juncture or they may delay it even a little further after that. I think it's a question of how the advisory committee timetables fit into the timetable for the priority review process as well.

So I don't think there's an absolute requirement of X number of days when they've got to make that determination but obviously we're hoping that they will make the determination as part of the acceptance of the filing.

Ren Benjamin - Rodman and Renshaw - Analyst

And the acceptance is usually 30 to 45 days? One of the two after --?

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

I think they have a maximum of 60 days but, of course, they've already seen a large part of the filing from the CMC section so it could well be within that timeline of 30 to 45 days.

Ren Benjamin - Rodman and Renshaw - Analyst

Regarding the OVATION partnership, you mention that quite a few boxes have been checked. What else is remaining to sort of seal the deal and close the deal and is there any chance that it could be further delayed?

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

I think this is just an issue where we -- when we close the deal we sign the definitive agreement which is, itself, a pretty comprehensive agreement about the structure of the financial terms and arrangements between the two companies. So there are no real issues as far as that's concerned.

There are a number of operating agreements which come out of that definitive agreement including things like the manufacturing supply agreement and quality agreements and all the other things associated with us supplying product and the commercial arrangements with LEO. And

it just takes time for the lawyers to work through all those things and get the agreement sorted out so this is just a normal course of the progress with this and we hope that this will all be completed quite shortly.

Ren Benjamin - Rodman and Renshaw - Analyst

So the \$3 million will hopefully, correct me if I'm wrong, the \$3 million will hit your balance sheet in the third quarter?

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

Yes. That's certainly our expectation.

Ren Benjamin - Rodman and Renshaw - Analyst

And then, I guess, just going to the cash burn guidance, with the cash receipts received this quarter and, I guess, the potential for LFB to give an additional \$3 million or so, I would have thought that the cash burn guidance would have gone down for the second half of '08. It just seems similar to what was previously announced in the last conference call. Correct me if I'm wrong. But can you help me sort out why the cash burn guidance is still staying fairly strong?

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

I think there's a couple of things there for a start and I'll speak on behalf of Jack. Jack's always been very conservative of the way in which he's projecting this which I'll just remind you what he said was that these are exclusive of -- that cash burn forecast is exclusive of any partnering negotiations which are ongoing which may get completed before the end of this year. So that's the first point.

The other point was that we had initial discussions with LFB earlier in the year about the potential for them to help us with some of our cash requirements and that commitment was made during the course of the second quarter. So that's what we've disclosed at this moment but we had contemplated that likelihood as part of our initial discussions.

And, Jack, would you like to add anything to that?

Jack Green - GTC Biotherapeutics, Inc. - CFO

I think that's exactly right. Those items were built into the projection that we made at our last conference call because we knew that they were happening and so we had already included those in the progression for cash receipts going forward.

What is excluded, as Geoff had mentioned from this number, is any additional partnering relative to ongoing discussions for new partnering arrangements.

Ren Benjamin - Rodman and Renshaw - Analyst

Great. Thank you very much and good luck.

Operator

(OPERATOR INSTRUCTIONS) And at this time we have no questions in queue. I would like to turn the conference back over to Dr. Geoffrey Cox for closing remarks.

Dr. Geoffrey F. Cox - GTC Biotherapeutics, Inc. - President & CEO

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Thank you everyone for joining us for this review of our financial results for the second quarter. We expect to be able to discuss our third quarter 2008 results in November and we look forward to speaking with you again.

We've just had a very nice quarter and we feel very good about the progress we're making on many fronts and, of course, we live in challenging times and we recognize that but we are very confident of our ability to be able to come through in some style. We have, I think, strong news flow going forward over the coming months and we feel well able to meet the challenges which we face at this juncture. So I look forward to talking to you again in November and updating you with our progress.

Thank you very much, indeed, everyone and have a great day.

Operator

Thank you for your participation in today's conference. This concludes your presentation. You may now disconnect. Good day.

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