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Conference Call Transcript

GTCB - Q1 2008 GTC Biotherapeutics, Inc. Earnings Conference Call

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CORPORATE PARTICIPANTS

Geoffrey Cox

GTC Biotherapeutics, Inc. - Chairman and CEO

Jack Green

GTC Biotherapeutics, Inc. - CFO

Tom Newberry

GTC Biotherapeutics, Inc. - VP Corporate Communications

CONFERENCE CALL PARTICIPANTS

Ren Benjamin

Rodman and Renshaw - Analyst

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the First Quarter 2008 GTC Biotherapeutics, Inc. Conference Call. My name is Amanda, and I'll be your coordinator for today. (OPERATOR INSTRUCTIONS) I'd now like to turn the call over to your host for today, Dr. Geoffrey Cox, Chairman and Chief Executive Officer of GTC Biotherapeutics. Please proceed, sir.

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

Thank you very much, indeed, and good morning, everyone. Welcome to the conference call and webcast to discuss the first 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. With me today are Jack Green, our CFO, and Tom Newberry, our Vice President of Corporate Communications.

Our results for the first quarter 2008 were released earlier this morning, and I hope you have had the opportunity to review the 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.

So, we have continued to make good operational progress in all of our key programs, even in the relatively short eight-week time period that typically occurs between our fourth quarter and the first quarter conference calls. Important progress has been made in our lead program ATryn, particularly in relation to completion of our clinical studies and the filing of our BLA. We have also expanded the collaborative relationship with LFB to support the continued development of alpha-1 antitrypsin, and there is continuing progress in the development programs that are already part of the LFB collaboration.

As you may recall from our last call in February, we completed enrollment and successfully met the primary endpoint of our non-inferiority pivotal Phase III study for ATryn. Both the historical control arm of the hereditary antithrombin deficient patients undergoing surgery or childbirth that were treated with plasma-derived products, and the 17 patients in the active arm of ATryn treated patients completed their procedures without clinical symptoms of deep vein thrombosis.

While we're still in the process of gathering follow-up safety data for the treatment of the last patient, we filed the first part of our rolling biologics license application including the preclinical data and the manufacturing section.

Food and Drug Administration has begun work on this first submission and inspections have occurred at our farm production facilities and the contract verification operations at Lonza in nearby Hopkinton in Massachusetts. I am pleased to report that there were no major observations reported at either location during the inspection exit interviews.

We're working on preparing the second and final section of our rolling BLA submission that will include all the analyzed clinical safety and efficacy data from our U.S. study, together with the data from our previous European study. We remain on track, the completion of the submission midyear, currently scheduled for the end of July.

If you 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 an anticipated decision from the FDA following the completion of our BLA submission.

Assuming that priority review is granted, the FDA's decision on the BLA is an anticipated six months after the completion of our filing. We are planning for an advisory panel meeting late this year as part of this review, as is the normal course of business for the FDA with products derived from new technology.

Keeping our attention on ATryn in the U.S., we continue in late-stage discussions with a potential commercialization and development partner for this country. While we had hoped to be able to complete this negotiation by this time, our potential partner had become diverted for a time by other corporate activities. However, we now have broader interest from additional potential partners. And this additional interest reinforces our confidence that we can successfully complete a partnering arrangement for ATryn in the United States.

Our objective is to complete these negotiations this quarter. All of these partnering discussions have included interest in further development in acquired antithrombin deficiencies, primarily those associated with applications in coronary artery bypass surgery.

You may recall that we had developed clinical data a number of years ago in heparin resistance that frequently occurs in bypass surgery. Heparin is used in bypass surgery to control clotting that could occur during the procedure. Heparin depends on the presence of antithrombin to produce its anticoagulant effect.

We believe the market in the U.S. for this indication is approximately \$150 million to \$200 million. We also believe that expanding the development of ATryn to this indication broadens the opportunities and potentially reduces the timeline to market in the larger acquired deficiency opportunities.

Turning to progress of ATryn in Europe, LEO Pharma, our partner in Europe, Canada and the Middle East, is continuing to recruit patients into the 200-patient Phase II dose-ranging study for the treatment of disseminated intravascular coagulation associated with severe sepsis. The program remains focused on obtaining top line results from the study in the first half of 2009. We are supplying additional product to LEO this quarter to provide material for further use in this study. We will be providing additional updates on the progress of this study in future calls.

LEO has also made progress in the commercial launch activities having now obtained pricing in the UK, Ireland, Greece, Denmark and Sweden, and this morning we learned today, also, the Netherlands and Iceland. Remember, LEO is pursuing a premium pricing strategy for ATryn to recognize its value as the only recombinant antithrombin, and the only antithrombin product approved for use throughout the European Union.

The approved use for ATryn for surgical procedures is a very modest indication. So, it is not a product that will normally be stocked in hospital pharmacies and is likely to be sold as product is required for specific procedures. LEO will be applying for label expansion later this year with the EMEA to include childbirth by utilizing the dosing information we obtained and analyzing in our U.S. Phase III study.

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

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

Our collaboration with LFB Biotechnology has also made progress. Earlier this week, the collaboration has been expanded to include our recombinant alpha-1 antitrypsin program. Alpha-1 antitrypsin is a protein that many organizations have tried to develop in recombinant form. As you may remember from previous calls, we have goats that express this protein at up to 20 grams per liter.

Our focus has been on extending the half life of our recombinant product to at least match that of plasma-derived products, and we believe we have developed good options to accomplish this goal. We believe that there is a good opportunity to expand the current worldwide \$400 million market for the plasma-derived products through the introduction of a consistent and plentiful recombinant source that offers similar dosing characteristics for prophylactic treatment of this under-diagnosed and under-treated patient population.

Patients with alpha-1 antitrypsin deficiency suffer a buildup of elastase in their lungs, which leads to reduced function and can result in emphysema. LFB is providing financing of our activities in this program for this year, to assist in maintaining the development timelines. Our near-term target is to initiate clinical studies for alpha-1 antitrypsin in 2009.

We have also been progressing in the existing collaborative programs with LFB. The recombinant human coagulation factor, the Factor VIIa program, which is the product on which our relationship was initiated, has progressed to where animals that utilize our beta casein promoter have been developed and LFB is characterizing the resultant product in the milk.

LFB's analytical capabilities and knowledge of plasma products are important contributions to this collaboration. Our goal is to move the recombinant Factor VIIa program into the clinic later in 2009. The current marketed recombinant Factor VIIa product, NovoSeven by Novo Nordisk, was approved for the treatment of hemophiliac patients that have developed inhibitors to Factor VIII or Factor IX through clinical studies that includes a total of approximately 80 patients. We believe that our Factor VIIa product will be clinically similar to NovoSeven, and compete effectively on price in this \$1 billion-plus market.

We recently acquired rights to recombinant human coagulation Factor IX in Europe, and also the U.S. and Japan from ProGenetics, which is also supplying this product from the milk of its transgenic pigs.

LFB is working with us to develop this product as a competitor to Benefix from Wyeth. Factor IX is used to treat Type B hemophiliac patients. Similar to the situation with Factor VIIa, we believe a competitively priced alternative recombinant Factor IX product will significantly penetrate the market with the potential to expand prophylactic use improving overall patient outcomes. Because ProGenetics has already established production of this protein, we are targeting submitting an application for clinical studies in 2009.

The fourth product in our collaboration with LFB is a monoclonal antibody to the CD20 receptor that is expressed on certain cancer and immune cells. We are expecting the first animals that are transgenic for this product to be born this fall. The CD20 antibody, although somewhat different from Rituxan, has the same target specificity and with the low fucose glycosylation, which is a natural feature of our technology, it is expected to have superior antibody-dependent cell cytotoxicity, or ADCC.

While there are a number of companies trying to develop antibody similar to Rituxan, we are confident that we can utilize the cost advantage of our system to significantly penetrate the existing \$4 billion and growing market.

The CD20 antibody has the potential to be developed as a follow-on biologic. In addition to this program, we have also established a business plan to developing four to five follow-on antibodies all utilizing our existing production facilities with little additional investment required. We have been closely following the legislative developments for their potential impact on our clinical strategies for these products.

While the timetable of congressional action remains uncertain, a number of bills in the House and the Senate suggest that support appears to be building for FOB legislation, and we believe that this is likely to occur during the next 12 to 18 months. We also believe that the likely outcome of this process is legislation that would enable the FDA to determine the requirements for approval of follow-on biologics on a case-by-case basis.

As generally expected, but at least for the foreseeable future, some level of clinical study will be required for complex glycosylated proteins such as antibodies, particularly where the glycosylation has important clinical functions.

We believe our production technology will be useful in establishing the additional cost savings necessary to attractively reduce the price of a follow-on biologic for patients while achieving an appropriate return for investors.

In the early stage of development, we are leveraging our existing infrastructure with little impact on our cash requirements. We have entered into early stage discussions with a number of potential commercialization partners including interest from participants in the established generic pharmaceuticals market. I look forward to updating you on this subject as both the associated legislation progresses and our business development efforts advance.

Our broad and valuable pipeline of products provide multiple partnering opportunities through the remainder of 2008, which could have a significant impact on our financial position for the year.

I would now like Jack to review with you our financial results and our expectations for the rest of 2008. Jack?

Jack Green - GTC Biotherapeutics, Inc. - CFO

Revenues were at \$3.5 million for the first quarter of 2008, compared with \$5.4 million in the first quarter of 2007. The reduction in the year-to-year comparison was due to the timing of product sales to LEO. There were \$3.3 million of ATryn product sales made to LEO in the first quarter of 2007, to support clinical studies for ATryn, while no sales were made to LEO in the first quarter of 2008.

Excluding the product sales, our revenues from external programs increased by \$1.4 million in the first quarter of 2008, a 65% increase from the \$2.2 million reported the year earlier. The increase in the external program revenues primarily reflects the expansion of our external program with PharmAthene for the development of their Protexia product.

Cost of revenue and operating expenses were \$11.7 million for the first quarter of 2008, 11% lower than the \$13.2 million reported in the first quarter of 2007. Cost of revenue was \$1.3 million in the quarter, a \$2.8 million decrease year-to-year driven primarily by the reduced product sales to LEO and the resulting reduction in cost of goods sold compared to Q1 2007.

Research and development expense increased \$1.2 million to \$7.7 million for the quarter. The increase was primarily due to expenses incurred in support of our programs and our collaboration with LFB, the Factor VIIa, Factor IX, and our CD20 monoclonal antibody, which were primarily an allocation of internal resources.

The first quarter 2008 research and development expenses also included \$5.1 million of expense related to the ATryn program, compared with \$4.7 million in the first quarter of 2007. These expenses included cost to manufacture ATryn in excess of the maximum selling price to LEO, and expenses associated with further scale-up of the manufacturing process, as well as expenses associated with the U.S. clinical program and the regulatory approval process.

SG&A expense was \$2.7 million for the quarter, a 6% increase year to year, reflecting the impact for a full quarter of senior business development hires made in early 2007. The net loss for the first quarter of 2008 was \$8.2 million, or \$0.10 per share, compared with \$7.5 million, or \$0.10 per share in the first quarter of 2007.

The weighted average number of shares outstanding increased from 77.5 million shares for the first quarter of 2007, and 83.2 million shares in the first quarter of 2008. The increases in the weighted average shares outstanding primarily reflect the issuance of common stock in our February 2008 registered direct financing.

We ended the year of 2007 with approximately \$15.8 million of cash and marketable securities. In February 2008, we completed a registered direct placement of 6.9 million shares of common stock with warrants at market for \$0.87 per share, raising net proceeds of approximately \$5.5 million. During the first quarter of 2008, we had a net decrease in cash of \$4.1 million, which reflects the proceeds from the registered direct offering, as well as \$9.1 million used in operations, \$300,000 to pay down debt, and \$200,000 used for capital expenditures. We ended the quarter with approximately \$11.7 million of cash and marketable securities. I should mention we have no exposure to auction rate securities in our portfolio.

We anticipate that our cash and current contracted receipts will be sufficient to support our operations through the end of the third quarter of 2008. For the full year, our current contracted cash receipts are expected to total \$19 million.

During this second quarter, we anticipate in excess of \$7 million in cash receipts from our external programs and from the sale of product to LEO, which was manufactured in Q4 and Q1. This should significantly reduce the net cash used in the second quarter. We project the net cash use for the remainder of 2008 in the range of \$17 million to \$19 million, which is consistent with our previous guidance. Importantly, any upfront payments from new partnering agreements would further reduce the net cash use forecasted for 2008.

As Geoff has mentioned, we are focusing on partnering as our preferred source of additional funding for the Company. We are in active discussions with potential partners for ATryn, as well as for other products in our plasma protein and follow-on biologic portfolios. We are considering all possible sources of funding including our partnering activities.

As you know, in January we received a notice from NASDAQ that our stock had fallen below the minimum \$1 closing bid price of 30 consecutive trading days and, as such, we would be subject to delisting from the NASDAQ global market if the price per share is not above \$1 by July 15, 2008. We were given the 180 days before July 15 to restore the \$1 closing bid price for at least 10 consecutive trading days.

There are a number of possible courses of action in response to this issue. The best solution is that the stock respond to positive news and regain the \$1 level by July 15. The board could also decide to apply for listing on the NASDAQ capital market with a further 180-day period in which to restore the \$1 minimum bid price. Or, our board could implement a reverse stock split.

We will be asking shareholders at the annual meeting to authorize our board of directors to enact a reverse stock split if the board should feel it is advisable to do so within the next 12 months. The board has not made a decision to enact a reverse split and is weighing its options at this point. The board is simply asking for authority to act if it feels such an action is appropriate.

We are operating in difficult financial markets at this time and your support for this proposal is important to us as we manage our way through these challenges. Geoff?

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

Thank you, Jack. Our external programs remain important to GTC's overall development and the adoption of our technology. The program with PharmAthene for the development of their Protexia product has become a significant part of our current revenues. It is also, along with Merrimack's MM-093 product, a prime example of a product uniquely enabled by the expression capabilities of our transgenic production platform.

PharmAthene plans to enter human clinical study of Protexia in the fourth quarter, while MM-093 continues its clinical program. Participation in supporting our external partners in these clinical programs is very helpful to our cash flow.

Our portfolio of monoclonal antibody programs also includes glycosylated and non-glycosylated versions of the CD137 immune modulation antibody. The CD137 antibody is a new chemical entity, and we continue to talk with potential partners for further development of this program, while our preclinical evaluations are being funded by an SBIR grant.

Much of our clinical and commercialization activity through 2009 is focused on our recombinant plasma protein portfolio. This includes ATryn, Factor VIIa, Factor IX, and alpha-1 antitrypsin. The near-term events include, first of all, concluding an ATryn U.S. commercialization and development partner, and very importantly completing the filing of the U.S. hereditary deficiency BLA early in the third quarter. Next, obtaining a determination of priority review status from the FDA, and supporting the FDA review timeline to reach a conclusion in early 2009. And that will position us for product launch of ATryn in the U.S. later in 2009. Then, initiating partner supported development in 2009 of ATryn in an additional acquired deficiency indication, and continuing to supply product to LEO to support its Phase II study of ATryn in treating DIC associated with severe sepsis, obtaining top line results in the first half of 2009.

It is also planned for LEO's expansion of the approved label in the European Union in the second half of 2008 to include childbirth procedures. And LEO's submission in 2008 Canadian approval of ATryn for hereditary deficiency in 2009. And, finally, initiating clinical studies in the Factor VIIa, Factor IX, and alpha-1 antitrypsin programs during 2009.

So, let me make a few final comments. GTC is making very strong operational progress across a whole range of our portfolio products. However, we are living in challenging times, and much of that environment lies outside of our control. I do want to reinforce Jack's comments requesting your support to provide the GTC board with the authorization to consider reverse stock split. The board has taken no position on this issue at this time, but they need the option to take whatever action they feel is in the best interest of investors. We are very focused on returning the Company to a health financial state, and I am confident of our ability to be able to do so. We see our partnering activities for ATryn, and all the products in our portfolio as a very important part of that process.

We share your frustration that these negotiations often take longer than we would like or planned, but I can assure you that they are moving forward with a broader range of parties and products. The support of our investors is very important to us, and we thank you for that. And we do take notice of your thoughts and concerns.

I look forward to updating all of you in our next call on our continuing progress. So, thank you for listening to our prepared remarks, and now I will ask the operator to please open the call to any questions you may have.

QUESTION AND ANSWER

Operator

Thank you, sir. (OPERATOR INSTRUCTIONS) Your first question comes from the line of Ren Benjamin of Rodman and Renshaw. Please proceed, sir.

Ren Benjamin - Rodman and Renshaw - Analyst

Hi. Good morning, and thanks for taking the question. A couple of questions for you. One, the 200-patient study that LEO is conducting, when do you expect that trial to complete and for data to be available?

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

Well, I think I have said for a good while that that program started off a little slower than we would like, and LEO has taken some steps to increase the enrollment rate. And certainly we're encouraged by the progress in that respect. We're still -- or LEO is still planning for recruitment to be completed in the first half of 2009, and we hope that we will be able to have top line results fairly soon after that. So, that remains our plan, and if there are any changes to that I will certainly let you know.

Ren Benjamin - Rodman and Renshaw - Analyst

Okay, great. And then regarding the, I think it's the alpha-1 antitrypsin, you mentioned that you're looking to extend the half life of the current product and match that of plasma drug products. Did I hear that right? And, if so, what is the half life of the current product and what sort of methods are you using to extend the half life?

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

Well, I actually cannot answer the last one, because obviously that's proprietary, but we've got a number of options in that respect which we've been looking at for probably the best part of 12 months, which I think we've made very encouraging progress. We've always known that the half life of the naturally glycosylated alpha-1 antitrypsin produced transgenically is short in the plasma-derived products. And so in the IV formulation, which is our first target, we feel that it will be important for us to be able to at least match. If we can extend the half life beyond current half life of plasma drug product, that will be fine, but we wanted to at least have the benchmark of meeting the plasma-derived half life.

And so we think that we have a number of options for us to be able to achieve at least that benchmark. Obviously, as we move -- if we were to move into a pulmonary delivery, which is potentially more challenging in terms of the length of clinical development program, I think the half life would be less of an issue. But we are planning for the IV formulation, first of all, and that's certainly together with LFB now, we've got this collaboration in place with LFB for alpha-1 antitrypsin. That's our first objective.

The half life for alpha-1 antitrypsin is somewhat less. I actually don't have the figure exactly in my head as to what the difference in that and plasma-derived products is, but I think the important part is that we do need, we believe, to increase that half life in order to be able to have competitive product in that particular space.

We obviously do believe that this is a very attractive product to be able to produce transgenically. These patients who have alpha-1 antitrypsin deficiency have injections of plasma-derived products today every week throughout the rest of their lives. And they consume somewhere around about 200 grams of product on an annual basis. So, that's actually quite a lot of therapeutic protein to be injecting into somebody. And so the advances of our technology clearly are to be able to bring a product which doesn't have constraints of supply to this patient group.

We are aware that this is quite a large patient population. It is under-diagnosed. Many patients just thought to have emphysema or COPD without recognizing that they in fact have a genetic disorder, and it's certainly under-treated. And there are a large number of patients in this country and elsewhere in the world who are not treated today and don't have access to drugs. So, we think it's a very nice market opportunity for us.

Ren Benjamin - Rodman and Renshaw - Analyst

Great. And I guess one final question and you may have answered this in the past. But regarding the partnership that you would like to secure this quarter, can you give us any guidelines or any color as to what shape and form this partnership may take, and what would be the ideal partnership for you guys, if you can secure it?

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

I think we've got a reasonable sort of handle on the way in which we approach these things. We actually have exchanged term sheets with one of our partner activities at this point in time, which I've mentioned before in previous call. What we'd be looking for is an upfront payment and also some milestone payments as we progress through the development of the product, including payments for approval of the product and also for expansion in other acquired deficiency indications. And later on, also, sales milestones. And that's rather typical of the way in which we also did the LEO partnership.

With regard to the clinical development, we would expect the partner to either conduct those studies themselves and pay for them, or to pay us to do them, and to pay for the product which goes into those studies as well. So, we're interested in trying to take those costs off our P&L for the foreseeable future.

And we would also, for commercial product, expect us obviously to be paid with a margin on that product, together with a royalty. And in the case of LEO, we have an effective royalty of including that margin and the royalty arrangement of the mid to high teens, once we get to commercial scale. So, that's the same type of structure, I think, that would be looking for in a partnering arrangement here in the United States as well.

Ren Benjamin - Rodman and Renshaw - Analyst

And I guess just going a little bit further on the upfront, would the upfront be similar to what you negotiated with LEO, or should we be looking for, since it's more of a U.S. partner here and in late stage something different and higher?

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

Well, I don't want to sort of set myself up, if you understand me, but on the other hand, let me just put it in the context, that when we made the original deal with LEO, that was before we in fact had completed the studies in Europe and filed in Europe, or before we had approval. And we're obviously quite a bit further down the track. The risk profile of this product has changed quite dramatically over the last two years, having got approval in Europe, now having completed our pivotal study here in the United States and initiated the filing. So, there is a lot more for a partner to be able to review in the diligence process.

So, I hope that we can do an attractive arrangement, but also I want to be cautious about raising expectations and so it's in a fairly measured fashion. But I think that the LEO deal, or the upfront payment isn't identical for what we're looking at, at this juncture.

Ren Benjamin - Rodman and Renshaw - Analyst

Perfect. Thank you very much.

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

You're very welcome, Ren.

May. 08. 2008 / 10:00AM ET, GTCB - Q1 2008 GTC Biotherapeutics, Inc. Earnings Conference Call

Operator

(OPERATOR INSTRUCTIONS) There are no more questions at this time. I'll now turn the call back over to management for closing remarks.

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

Thank you very much, indeed, and thank you, everyone, for joining us this morning. We look forward to having you on our call again for our second quarter results, which we expect to be in early August. And just to remind you, also, that our annual meeting will be held on June 24 of this year. And so I look forward to speaking to you again and updating you on the progress that GTC is making. Thank you very much, indeed, everyone. Have a good day.

Operator

This concludes today's presentation. You may now disconnect.

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