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Conference Call Transcript

GTCB - Q1 2007 GTC Biotherapeutics, Inc. Earnings Conference Call

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Sean Wu

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PRESENTATION

Operator

Good day ladies and gentlemen and welcome to the first quarter 2007 GTC Biotherapeutics Inc. Earnings Conference Call. My name is Francis and I will be your Operator for today. (OPERATOR INSTRUCTIONS) I would now like to turn the call over to Dr. Geoffrey Cox, Chairman and Chief Executive Officer. Please proceed, sir.

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

Thank you very much, indeed, and good morning everyone and welcome to the conference call and webcast to discuss the first quarter 2007 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 first quarter 2007 were released earlier this morning and I hope you've had the opportunity to review this release prior to our call. For some introductory comments on our strategic partner programs I would ask Jack Green to provide a summary of our financial results and I will then provide an overview of our development programs 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 are described in detail of Item 1A of our 10-K and subsequent 10-Qs, our actual results may differ materially from our current expectations.

During our last conference call I said I had a strategy for GTC which I believed could provide the basis for building a significant company. The approval for ATryn® last year by the EMEA was a major achievement and the importance of this approval was not only in establishing the first very important element in building a significant commercial opportunity for ATryn® in multiple indications and multiple markets, it also established the credibility of our production technology across multiple potential products and opportunities.

To execute on our strategy of building a broad portfolio of products, it's clear that GTC needs to embark on a robust partnering program and over the last 18 months we've already initiated strategic partnering first with LEO for the commercialization and further clinical development of ATryn® in Europe and then in October of last year with LFB for a potentially broad based partnership starting with the development of Factor VIIa.

Our objective is to seek quality partners who could help to provide the financial support and clinical and commercial capabilities to move our programs forward and to exploit the range of opportunities which we have available to us. These opportunities include the advancement of our

own proprietary products, particularly in hematology with recombinant plasma proteins and also monoclonal antibodies principally in oncology and autoimmune disease, the expansion of external contracts where a clear commitment exists to the transgenic production technology and the exploitation of the opportunities which are now crystallizing in follow-on biologics, or FOBs.

We recently announced, adding to our expertise in business and commercial development, with both Ashley Lawton and Rick Finnegan joining GTC. Rick Finnegan is focused primarily on commercialization strategies for our products including through partnerships and collaborations. Ashley Lawton is focused on entering additional strategic partnerships for our proprietary programs including antibodies and the development of our strategy for follow-on biologics.

Follow-on biologics are a rapidly emerging area of interest for us. Legislative deliberations define the regulatory pathway for the review of products following the expiration patents related to an originator protein are in process. We believe that this area of protein production in commercial opportunities will become increasingly important. The cost advantage of our transgenic production technology may broadly enable development of follow-on biologics particularly in treatment of chronic diseases requiring large product volumes.

We also believe that the antibody dependant cell cytotoxicity, or ADCC, is an important characteristic of our transgenic production technology that presents interesting possibilities to those potential partners who may be interested in developing second generation forms of originator products. We see ourselves primarily as a production company in the follow-on biologics and second generation area with established pre-clinical development capabilities. We anticipate the commercialization will primarily be the responsibility of our partners.

As a value added source of supply beyond the economic and ADCC advantages of our technology, we are also able to provide a strong intellectual property position that is independent of the cell culture process patents including the patents commonly referred to as Cabilly that could otherwise inhibit development in this area.

While follow-on biologics represent a very large emerging partnership opportunity for us, our strategic partnerships with LEO Pharma and LFB Biotechnology are making important contributions to the growth of our business now and for the foreseeable future. LEO is preparing action on our proved recombinant form of human antithrombin for commercial launch in Europe in the prophylactic treatment of deep vein thrombosis in hereditary antithrombin deficient patients undergoing surgical procedures.

ATryn® will be introduced as a commercial product to hematologists at the International Society of Thrombosis and Haemostasis in Geneva in July. LEO plans to begin commercial sales shortly after this introduction as the initial reimbursement prices are set. Also, during the ISTH Conference we are planning to present the data that we have seen utilizing the new dosing protocol of pregnant patients that is being implemented in our ongoing Phase III study for hereditary deficiency in the United States. If you recall, LEO will be using this data to submit for a label expansion with the EMEA to include pregnant patients after we have completed our Phase III HD study.

LEO is conducting a dose ranging Phase II study of ATryn® in the treatment of disseminated intravascular coagulation associated with severe sepsis. The supply of product to initiate the study has already had a significant impact on our growing revenue line. The phase II study will consist of about 200 patients in a comparative dose escalation study. There's a large indication in Europe and the U.S. with 500,000 cases annually with about 50% mortality.

LEO continues to make progress in establishing clinical science. They have implemented a protocol modification to remove the potential for misinterpretation of the inclusion criteria for patients which has caused some delay in the recruitment for the first patient into the study. LEO anticipates enrolling the first patient in this second quarter with full patient enrollment expected to take approximately 12 months.

Remember, we have full access to the results of the Phase II DIC study to use in discussions with the FDA and our plan is to discuss the results of the Phase II study with the FDA in parallel with LEO's discussions with the EMEA to establish scientific advice for the Phase III DIC study with the objective to be able to do a single international Phase III study that may be used to file for market approval in DIC both for Europe and the United States.

We are continuing with recruitment into the Phase III hereditary deficiency study in the United States. The objective is to establish non-inferiority for ATryn® compared to antithrombin sourced from human plasma. There will be at least 17 patients receiving ATryn® after the 14 we already treated in our study supporting approval for hereditary deficiency in Europe. These 31 cases will be compared to at least 35 matching cases taken from hospital records of patients treated with plasma-derived products. The recruitment of the additional 17 ATryn® patients in this rare patient population has taken longer than we forecasted based on the timelines for the recruitment we experienced in the previous studies submitted for European review. We anticipate completing enrollment in the third quarter and reporting top line data in the fourth quarter and filing for approval with the FDA approximately three months later as the 90-day antibody data becomes available.

Japan will also be an important territory for ATryn®. We've begun discussions with a number of potential partners in Japan and Asia generally. I believe that this interest is due to the known use of antithrombin in DIC in this territory as well as the desire to find recombinant sources of plasma proteins. While we are still in the early days of these discussions the interest is greatly strengthened by our approval in Europe. Opening the U.S. market, expanding the clinical opportunities in acquired deficiencies, establishing partnering relationships in Japan and LEO's commitment to developing the European market is our strategy for delivering on what we believe to be an annual worldwide market potential for ATryn® of \$500 million to \$700 million.

Turning our attention to our relationship with LFB, we have begun generating rabbits with the recombinant human factor VIIa transgene using our proprietary beta casein technology. Beta casein is the dominant protein in milk and functions as a promoter for the expression of the transgene during lactation. We believe that this promoter will provide for good production of (inaudible) Factor VIIa helping to manage the herd size required for commercial production. While a planned initial indication treating Type A and Type B hemophilia with inhibitors does not require large production volumes, the potential to develop this product for bleeding associated with trauma will increase supply requirements.

Today's market for Factor VIIa is supported by only 1 kilogram of product. An independent analyst estimate of the currently approved rhFVIIa product NovoSeven from Novo Nordisk projects a \$2 billion market for this product by 2012 when the patents expire. We are preparing for a full clinical program which we anticipate will be completed as the patents expire. We believe that we can effectively compete with the NovoSeven product on price and the current price of NovoSeven is \$1,000 per milligram.

We also entered into two agreements this quarter with PharmAthene to support the development of their Protexia® product. Protexia® is a recombinant form of human butyrylcholinesterase. Butyrylcholinesterase is proposed to be used as a scavenger of nerve toxins in the blood stream. As a result, it has a significant potential as a biodefense product. In the first agreement we were providing process development and clinical manufacturing supply services for Protexia and this work has begun. The second agreement provides all the necessary access to our intellectual property that enables commercial development of Protexia from the milk of their transgenic goats. We are pleased that our technology has enabled this product which has been difficult to produce in other approved recombinant systems and is present at two small a concentration to be fractionated from the plasma supply as an economically viable production system.

As demonstrated from the partnering agreements with PharmAthene and LFB which provided access to our intellectual property, we see our patent position as a strategic asset whose value greatly increased when we obtained the first transgenic approval with ATryn® last year. While a keystone of this intellectual property is the broad U.S. patent for the production of therapeutic proteins in the milk of transgenic mammals, which is in effect through 2021, we have continued to broaden our position. We were able to gain a license to the Roslin patents for nuclear transfer technology through START licensing in an agreement we recently signed. Nuclear transfer is a valuable option to our existing microinjection technology and can provide for greater schedule predictability in developing the first transgenic animal for a protein. They also could be used to rapidly increase the herd when large capacity is required early in a development program. This license has no immediate impact on our product expenses as many of our existing programs, including ATryn®, Alpha-1 antitrypsin and the Factor VIIa proteins, were developed using microinjection.

We also have completed the patent application process for the ADCC advances that we believe our technology confers to antibodies. This builds on our strong patent position in expressing antibodies in the milk of transgenic animals as well as our independence from the Cabilly patent estate which provides us with the intellectual property foundation to establish a broad franchise in antibody products.

All of this activity has resulted in a significant increase in first quarter revenues approaching our total revenues for 2006. I would like Jack to review with you our financial results and how we are progressing on our 2007 forecast. Jack?

Jack Green - GTC Biotherapeutics, Inc. - CFO

Thank you, Geoff. For the first quarter our revenues were approximately \$5.4 million compared with approximately \$2.2 million in the first quarter of 2006, an increase of 147%. The increase in 2007 revenues resulted primarily from \$3.2 million of product sales of ATryn® to LEO for clinical and commercial use. In addition to the ATryn® sales, revenues were derived primarily from development programs with Merrimack and PharmAthene. Merrimack revenues were for the supply of their MM-O93 product which continues in clinical studies and as Geoff has mentioned our revenues from PharmAthene relate to our services to develop clinical manufacturing for them. Our revenues in succeeding quarters will vary with the demand for product supply in the DIC and Merrimack clinical programs, however, our revenues in the first quarter are consistent with our transition to a growing products-based Company.

Revenues in the first quarter of 2006 were primarily derived from the development program with Merrimack. Cost of revenue and operating expenses totaled \$13.2 million in the current quarter, approximately 23% higher than the \$10.7 million total in the first quarter of 2006. The increase was driven primarily by the cost of goods for the ATryn® product sold to LEO, by expenses incurred in the development of Factor VIIa as well as increased legal and patent related expenses.

We ended the first quarter of 2007 with approximately \$39.6 million in cash and marketable securities on the balance sheet, a decrease of approximately \$4.2 million on the quarter. The net cash use for the quarter included \$4.5 million in proceeds from the final installment to LFB's investment in GTC which was completed on January 3, 2007. We had a net cash use of approximately \$8.7 million in the first quarter exclusive of LFB's investment proceeds.

We ended the first quarter with close to \$40 million of cash on hand and we project a net cash use of between \$15 million and \$18 million for the remainder of the year which is consistent with our previously forecasted annual cash burn.

Our first quarter cash use included planned expenditures in connection with our ongoing ATryn® manufacturing campaign which is expected to be completed in the second quarter. The timing of expenses around the manufacturing campaign is expected to result in higher net cash use in the first half of the year as compared with the second half. Our forecast of net cash use for the year also includes anticipated receipts from LEO for commercial and clinical supplies of ATryn® and from new and existing partnering programs including our existing development programs with Merrimack and PharmAthene.

Our net loss for the quarter was \$7.5 million or \$0.10 per share compared with \$8.5 million or \$0.14 per share on the first quarter of 2006. Per share results were affected by an increase in the weighted average number of shares outstanding from 60.8 million shares for the first quarter of 2006 to 77.5 million shares in the first quarter of 2007. The increases in the weighted average shares outstanding primarily reflect the issuance of approximately 12 million shares of common stock in our July 2006 registered direct offering as well as 3.6 million shares issued to LFB in January 2007.

At the end of the first quarter we had approximately 77.6 million common shares outstanding as well as Series D convertible preferred stock that's convertible into 14.6 million shares of common stock. As a reminder, the convertible preferred stock gives LFB the right to a board seat but does not pay a dividend, nor does it receive any liquidation preference over our common stock.

Back to you, Geoff.

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

Thank you, Jack. Now turning our attention to our other proprietary product partnering opportunities, we're developing alpha-1 antitrypsin with an initial focus on the hereditary efficiency condition. This is estimated to be a large population with about 3.5 million people suffering from the condition which can lead to emphysema. Even so, it is significantly under-diagnosed and under-treated. This is a chronic condition and alpha-1 antitrypsin will be provided as a chronic treatment unlike ATryn® which is an acute treatment for the chronic hereditary deficiency indication. We believe the alpha-1 antitrypsin augmentation therapy may also have therapeutic value in treating additional respiratory conditions such as chronic obstructive pulmonary disease and emphysema generally.

The current market for plasma derived products is approximately \$250 million which we believe to be constrained by availability with the potential for our recombinant product to greatly exceed this market size. We are planning to begin clinical development as an intravenous formulation primarily as a replacement for the current plasma-derived products in the hereditary deficiency condition. We are interested in then developing a pulmonary formulation that may be both easier to use for patients and enable the delivery of the product to the lung for treating respiratory diseases. We have goats that produce high quantities of alpha-1 antitrypsin and we use their milk to perform pre-clinical studies while beginning expansion of the herd for clinical and promotional purposes.

We are also committed to developing our CD137 antibody which is an immune modulator with potential applications in the treatment of solid tumors and autoimmune diseases. It's an innovative antibody in license from the Mayo Clinic and we've established goats that express this product at levels that enable pre-clinical, clinical and eventual commercial quantities.

We are seeking partners for both these programs to enable us to speed development, defray the cost of advancing these programs and to help ensure that the appropriate clinical and regulatory expertise is applied. And, importantly, provide additional source of cash for our growth as a company.

We will also continue to enter into collaborations with other companies where we produce and potentially manufacture their products similar to what we're doing with Merrimack and PharmAthene. Our objective in these arrangements is to be a value added supplier from the earlier stages through clinical testing and commercialization of a protein where there is a strong commitment to development through transgenic production technology. In addition to helping the commercial production infrastructure we have developed, these programs help broaden the adoption of our technology. The financial assistance our partnering strategies intends to generate will enable us to continue to make business development and financing decisions from a position of strength. We look forward to both initiating and continuing partnering discussions with a number of companies at the Bio Convention to be held in Boston next week.

However, we did file a shelf registration statement yesterday. We simply took the opportunity to do so at this time as a prudent financial management measure to replace our previous shelf registration that expired when our 10-K was filed. We are not looking for additional equity funding at this time given our financial condition as we have a broad array of partnering opportunities to develop and we will assess our future financing needs according to our successes in these endeavors.

This call follows closely on the heels of our annual results and, in fact, our Annual Report is just being mailed to shareholders and I hope you enjoy reading about our progress.

In closing, it is perhaps valuable to reflect on the remarkable transition the Company has made over the last 12 months. At this time last year we had a narrow focus as we endeavored to achieve the approval of ATryn® by the EMEA. Today, we are setting our sights on seizing the opportunity we now have to leverage that approval to build a significant company. We believe we can exploit the validation of our production technology to develop a broad portfolio of products in different market segments supported by partnerships and collaborations such as those we have established with LEO and LFB. We are energized by the scope of the opportunity we have and we have demonstrated that we have the courage and the will to succeed. I look forward to updating you on our progress.

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

QUESTION AND ANSWER

Operator

(OPERATOR INSTRUCTIONS) Your first question comes from the line of Navdeep Jaikaria from Rodman and Renshaw. Please proceed.

Sean Wu - Rodman and Renshaw - Analyst

Hello. This is Sean who is standing in for Navdeep. I just have a couple of questions. One thing is about --- thank you very much for taking my call and also congratulations on a nice presentation and a very good quarter. I have a question for your financial projections so if this quarter you have very high revenue and it looks like you will have kind of high for next quarter also because you are still supplying materials to LEO. So going forward, do we expect to see the numbers reverting back to their historical normal because LEO is not going to make usual amount of sales in the next couple of quarters. Right?

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

Well, I will ask Jack to comment but as you know for some long time we have not made revenue projections since quite a number of our revenues are related to contracts where revenue recognition is always a little difficult to forecast but let me hand this over to Jack and perhaps you can make some comments and just re -- comment again on our cash projections if you wouldn't mind, Jack?

Jack Green - GTC Biotherapeutics, Inc. - CFO

Yes. I'd be glad to. As Geoff has mentioned, the revenue projections -- we have not commented on them in previous calls and we're not giving revenue projections at this particular point in time because of the difficulty of dealing with the accounting rules relative to revenue recognition.

But one thing that we do want to reiterate is the fact that on a quarter-by-quarter basis our revenues will vary and they will vary based upon the specific activities that are happening in regards to specific programs as well as the delivery schedule for product that is provided to our partners so that in quarters where we have product that is being provided by two partners, we will have higher revenues than those in which we do not.

So it is -- we expect that the revenue is going to be uneven and that for that reason we are not giving specific guidance on quarter-by-quarter revenue targets.

Sean Wu - Rodman and Renshaw - Analyst

Great.

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

I think it's true to say, Sean, that I think the first quarter is consistent, as Jack said in his prepared comments, that it is consistent with our transition to a growing product based company so you are beginning to see a change in the way in which the Company is moving at this juncture and obviously we hope that's the way it continues.

Sean Wu - Rodman and Renshaw - Analyst

I have a question related to your patent opportunity. It appears you have a multiple patent opportunity in also because biogenerics are heating up. Do we expect to see any kind of major announcement from the earned income soon because with -- you have specific (inaudible). Are you in any kind of serious discussion with somebody which you can reveal?

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

I think that I never make predictions or projections on when business development will come to final completion. That's always dangerous to do that. Having said that, I think it's very clear from everything that I've said that we believe that we've got multiple opportunities from a partnering collaboration perspective and we have significantly reinforced our capabilities from a business development perspective in order to be able to address that opportunity. And we've got a number of different market segments, of course, not only with our commercialization of ATryn® but also in our development programs, our proprietary products including Factor VIIa and also CD137, alpha-1 antitrypsin, but also in that area which you rightly referred to in the whole area of follow-on biologics, together with the business which we've had for some length of time with regard to external contracts. So we've got many opportunities which we can now leverage this production technology to which has now been validated by the approval of ATryn® and we feel this is an important way for us to be able to help the finance the Company, to bring resources into the Company and through the use of resources both clinical and regulatory perspective with our partners. And we think that's a very important way of us being able to have a broad portfolio of products and to keep our cash burn at a modest level. And that we think that that is a very responsible and a very constructive way for us to be able to develop the Company with our rather unique business model.

There are not many companies out there who have the range of opportunities that we have nor the type of business model that we have. And that's something which we really want to be able to leverage in these number of different directions; so the answer to your question is, yes, we are engaged in a number of discussions at this moment. We expect to expand those number of discussions. When they will come to fruition is a little difficult to predict but it's clearly not something which -- it's clearly something which we are actively engaged in at this moment and we hope to have news during the course of the year.

Sean Wu - Rodman and Renshaw - Analyst

So have you now like been more prioritized for being a partner for somebody else or developing therapeutics internally?

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

Actually I think that is a very insightful question and it's something with which we work very hard at to be able to manage a number of different programs with different partners and we are organizing ourselves in such a fashion to enable us to do that and to make sure that we can address

all of these opportunities in an appropriate fashion; something which the Company's actually been quite familiar with over the years in which we have developed a number of these different partnerships and worked with different companies so this is not new territory to us but, nonetheless, it's a very important point and as programs mature they obviously need more resources and more attention and we will structure ourselves organizationally to make sure that we can address each of these and give the appropriate priorities to our partners.

Sean Wu - Rodman and Renshaw - Analyst

Thank you very much for answering my questions.

Operator

Your next question comes from the line of Donald Hudson. Please proceed.

Donald Hudson Analyst

Geoff, Jack, good work. I -- it sounds like your short term plan is to be a production company and so my first question is do you see profitability there? Second question is, long term do you plan to develop some products yourself that you would sell yourself and, therefore, generate obviously much larger profits?

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

Well, clearly we are a first and foremost production company at this juncture. But obviously as we move ATryn® through to approval in the United States there is a strategy with which we're still assessing at this moment which is actually one of the things which I'm asking Rick Finnegan to try to help us to assess as to whether we commercialize ATryn® ourselves or whether we work with a partner or whether we're doing some type of co-marketing arrangement.

Certainly we do feel at some point in the future we would like to develop a commercial capability. Most companies who become significant companies have taken the opportunities to do that at some point. I think that the -- what I would not want to do though is to not have the financial resources and the capabilities to be able to exploit a large market opportunity such as we believe the United States presents to us, particularly once we get the DIC approval and we may well want the resources of a larger commercial capability to help us to do that and that may also provide some financial income to the Company in that process. So I think that's the way we see that and I think it's still an evolving story at this point in time.

With regard to profitability, that's a question which I'm asked many times and clearly that can come from a number of different directions. We're always very conscious of the fact that we do not have a right over the long term to continue to just burn cash and this Company is very focused on its responsibility to bring the Company to being cash positive and profitable at the earliest opportunity. And that's really one of the things why we believe partnering and collaborations can help us in that process because if we can defray some of the costs through the partners to help us in both clinical development and also to bring milestones and those types of cash into the Company, that can help us to bring us back to that point a little earlier.

So I'm not going to make any prediction or projection of when that will be and that will obviously be dependent on how successful and the timing of some of our -- the way we can establish these partnerships and collaborations; but it's something which is very high on our agenda to address and something with which we share your interest and the interest of all our investors to get to that point at the earliest opportunity.

Donald Hudson Analyst

Thanks, Geoff.

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

You're very welcome. Thank you.

Operator

(OPERATOR INSTRUCTIONS) And there are no further questions at this time. I'd like to turn the call over to Dr. Geoffrey Cox for closing remarks.

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

Well, thank you very much indeed everyone for joining us for this review of our financial results for this first quarter of 2007. We expect to be able to discuss our second quarter 2007 results in August, the date yet to be arranged. But let me, also, as a reminder tell you that our annual meeting is on May the 23rd and so we look forward to speaking to you again, anyway, in August on our next call and update you on the progress that we're making. The Company is at a very exciting moment and I look forward to these calls and look forward to talking to you all. Thank you for joining us today. Goodbye.

Operator

Thank you for your participation in today's conference. This concludes the presentation. You may now disconnect and have a good day.

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