



Transcript of GTC Biotherapeutics, Inc. (GTCB) Q2 2009 Earnings Conference Call July 31, 2009

Vcall

601 Moorefield Park Dr.
Richmond, VA 23236

Phone: 888-301-5399
Fax: 804-327-7554

info@vcall.com
www.vcall.com
www.investor.calendar.c

Participants

Dr. Geoffrey Cox, Chairman & CEO
Jack Green, Chief Financial Officer
Tom Newbury, Vice President of Corporate Communications & Government Relations

Presentation

Operator

Greetings and welcome to the Q2 2009 GTC Biotherapeutics Inc. Earnings Conference Call. At this time all participants are in a listen only mode. Later we will conduct a brief question and answer session and instructions will be given at that time. If anyone should require operator assistance during the conference, please press *0 on your telephone keypad. As a reminder this conference is being recorded.

It is now my pleasure to introduce your host, Dr. Geoffrey Cox, Chairman & CEO of GTC Biotherapeutics Inc. Thank you Doctor you may begin.

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 second quarter 2009 financial and operating results for GTC Biotherapeutics, Inc., NASDAQ ticker symbol GTCB. I'm Geoffrey Cox and I'm Chairman and Chief Executive Officer of GTC Biotherapeutics, Inc and with today are Jack Green our Chief Financial Officer and Tom Newberry our Vice President of Corporate Communications and Government Relations.

Our results for second quarter 2009 were released earlier this morning and I hope you've 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 then open the meeting for 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 10K filed with the SEC, entitled "Important Risk Factors Regarding Forward Looking Statements". As you know due to the risks inherent in our business, which is described in detail in item 1A of our 10K and subsequent 10Q's, our actual results may differ materially from our current expectations.



The second quarter has been one of good progress in transitioning GTC in two areas. We have addressed the short term cash needs in our growth with the support of our strategic partner LFB Biotechnology, a transaction that I am pleased to report was just approved by shareholder vote yesterday morning. We are able to pursue our focus growth strategy while continuing to control our expenses. And our partner for ATryn® in the US, Lundbeck Inc., has very successfully begun the sales process for the approved hereditary deficiency indication, and we look forward to continuing to support this transition into commercialization.

Having set this stage let me take some time to outline where we have come from and where we are going. We're required by both the European and the US authorities to develop ATryn for the hereditary deficiency indication before developing larger market acquired antithrombin deficiency uses. We developed the most robust data set ever established for any antithrombin product in treating hereditary deficient patients undergoing surgical or child birth procedures. In February we obtained FDA approval for ATryn in this indication, as well as approval for the first ever submission for a genetically engineered animal. Very few companies of any size have achieved approvals on the first review, much less approvals on two separate regulatory submissions supporting an innovative product and technology. The new knowledge we established on the dosing and treatment of the underserved hereditary antithrombin deficient population was recently presented to the International Society of Thrombosis and Hemostasis conference in Boston. The strong clinical background for ATryn is being utilized by Lundbeck in their marketing efforts with key opinion leaders and the medical community.

Lundbeck established their distributors and sales force earlier this year. I'm pleased to report that Lundbeck has made a strong start for commercialization of ATryn in the US, and this bodes well for the continued commercialization of this product. We will have a better understanding of Lundbeck's sales projections as we progress throughout the year. Lundbeck's commitment and initial results in the launch of ATryn further strengthens our conviction that ATryn will grow to become a significant product. An instrumental initiative in bringing this to reality is the development of the heparin resistance indication of the United States with Lundbeck. As you may recall, heparin resistance describes a condition which patients undergoing cardio pulmonary bypass procedures do not respond appropriately to the heparin that is used to prevent clotting in the bypass pump. The use of supplemental antithrombin is intended to allow the Heparin to remain active throughout the procedure. We believe that this indication represents a potential \$150–\$200 million market opportunity. Our discussions with the FDA on how to develop this indication for regulatory review are in progress, and we expect to have a detailed plan for the required timeline later this year.

The second area for which we have successfully executed this quarter was in addressing our near term cash situation. I thank all investors for completing the vote yesterday that enables us to close on the financing with LFB. We are now completing the convertible preferred stock financing which will provide us an additional \$8.3 million in finance, sorry in funding, and LFB has a 6 month option to increase this funding by 6.4 million. This funding together with our already committed and planned partnering proceeds as well as the potential additional 6.4 million from LFB would take

Vcall

601 Moorefield Park Dr.
Richmond, VA 23236

Phone: 888-301-5399
Fax: 804-327-7554

info@vcall.com
www.vcall.com
www.investorcalendar.com



us through several key events, including establishing the plan with the FDA for the further expansion of our ATryn program in heparin resistance which I just outlined as well as initiating clinical studies of Recombinant Human Coagulation Factor VIIa in clinical studies early next year.

Remember the current recombinant products dominate the hemophilia markets and Factor VIIa has been used to treat acquired bleeding conditions. However, these products are extremely expensive, this high cost dramatically alters the use of these products away from the intended prophylactic maintenance therapy towards use as an acute rescue treatment after bleeding has already occurred and created longer health problems for the patient. For instance, NovoSeven®, the current marketed Recombinant Factor VIIa product with \$1.3 billion worth of sales is priced at over \$1000/mg. The manufacturers of these products are developing next generation longer half-life forms, in part to strategically address the end of patent life. It seems unlikely that these second generation products are being developed to lower the pricing of treatments and address the fundamental cost problem facing this patient population. In addition for Recombinant Factor VIIa it is not clear that a longer acting product will be clinically beneficial in acquired bleeding states, particularly in acquired bleeding states where more rapid clearance of the treatment may be helpful.

Our approach with the Factor VIIa program is to develop a follow-on form that is as close to the original form as possible. We intend to offer significant price savings in the treatment costs with our product compared to the current situation, while still being able to achieve attractive pharmaceutical level margins. The clinical development and commercialization approach that is implemented may be beneficially influenced by the emerging legislation and resulting regulatory guidance on follow-on biologics, which is currently embedded in the health care reform proposals. Importantly, our technology will be able to perform to these objectives even if we must follow the same pattern as the studies performed for the originated product.

I believe that advancing these programs will give us important first mover status in developing clinical and regulatory strategies for approving complex glycosylated protein follow-on biologics. This experience can then be applied to the Monoclonal Antibody follow-on biologic portfolio we are working to develop with partners. We anticipate submitting an IND by the end of the first quarter of 2010 to begin clinical studies for our joint venture Recombinant Factor VIIa program. The Factor IX program is currently scheduled to be introduced into the clinic about 9-12 months after Factor VIIa. After Jack has reviewed the financial results I will take some time to describe some of the progress in our other programs and partnering opportunities. So let me now pass this over to Jack.

Jack Green – GTC Biotherapeutics – Chief Financial Officer

Thank you, Geoff. Our revenues for the second quarter of 2009 were approximately \$700,000 compared with \$9.1 million in the second quarter of 2008. For the first six months of 2009 revenues were approximately \$900,000 compared with \$12.7 million in first half of 2008. It is important to note that in the first quarter of 2009 we received approximately \$5.7 million in milestone payments including \$4.9 million from Lundbeck on the ATryn program that were not recognized as revenue under the revenue recognition rules of US generally accepted accounting principals. These

Vcall

601 Moorefield Park Dr.
Richmond, VA 23236

Phone: 888-301-5399
Fax: 804-327-7554

info@vcall.com
www.vcall.com
www.investorcalendar.com



payments were recorded as deferred revenue on the balance sheet and will be recognized as revenue for future periods.

The decrease in the year to year comparison reflects completion in late 2008 of our external programs with Merrimack and PharmAthene as well as revenue recognized in the first half of 2008 from the sale of ATryn product to our former European partner LEO Pharma. In future quarters we expect shipments of ATryn to Lundbeck in the US to generate product revenue although it will vary from quarter to quarter. For the quarter, total cost of revenue and operating expenses were \$10.3 million compared with \$11 million in the second quarter of 2008, a 6% decrease year to year. For the year to date, total cost of revenue and operating expenses were \$20.1 million compared with \$22.7 million in the second quarter of 2008, a 12% decrease year to year. The year to date decrease was driven primarily by a \$6.3 million reduction in cost of revenue partially offset by a \$3.4 million increase in net research and development expenses.

The cost of revenue decrease reflects the completion of activities in the external programs with Merrimack and PharmAthene as well as the cost of goods for the ATryn products sold to LEO in the first 6 months of 2008. Research and development expenses were approximately \$6.8 million in the second quarter of 2009 compared with \$2.7 million in the second quarter of 2008, an increase of \$4.1 million. For the year to date, research and development expenses were \$13.8 million compared with \$10.4 million in the first half of 2008. The \$3.4 million increase in year to date expense reflects the impact of \$3 million of funding received in the second quarter of 2008 from LFB, they fully funded GTC's expenses for the joint development programs; Factor VIIa, Factor IX, Alpha-1 antitrypsin and CD20 Monoclonal Antibody, which did not recur in 2009, as well as a \$2.1 million increase in expense on our follow-on biologics program reflecting primarily in allocation of internal resources. These increases were partially offset by a \$1.8 reduction in ATryn expenses primarily related to lower US regulatory expense.

SG&A expenses were \$3.1 million for the second quarter, an increase of 400,000 or 17% from the prior year quarter. For the year to date SG&A expenses were \$5.6 million, an increase of 4.7%, reflecting higher legal costs associated with the arbitration proceedings with LEO. The year to year increase in other expense of \$1.5 million reflects the interest expense on the convertible debt that was issued to LFB in December 2008. Net loss for the second quarter of 2009 was \$10.8 million or \$1.03 per share compared with a net loss of \$2.2 million or \$0.22 per share in the second quarter of 2008. For the year to date the net loss was \$21.1 million or \$2.03 per share compared with \$10.4 million or \$1.12 per share in the first half of 2008. Per share results for the 2008 periods were restated for the impact of the 1 for 10 reverse stock split enacted by the GTC Board of Directors on May 26th 2009 which had been previously approved by GTC shareholders.

Yesterday morning, at a special shareholders meeting, our shareholders approved the closing of the convertible preferred financing with LFB. This financing is providing \$12.3 million of cash to GTC, 4 million of which had already been received on signing in June in the form of a convertible bridge loan. This bridge loan converts automatically into the convertible preferred financing at the closing.

Vcall

601 Moorefield Park Dr.
Richmond, VA 23236

Phone: 888-301-5399
Fax: 804-327-7554

info@vcall.com
www.vcall.com
www.investorcalendar.com



In the financing, we issued \$25.5 million of convertible preferred stock with a 10% coupon and a 5 year redemption if not previously converted. \$12.8 million of gross proceeds are to be placed in escrow to fund the dividends; including a make-whole obligation to pay the escrow proceeds to LFB should LFB convert its position within one year. If LFB does not convert within one year, the balance of the escrow will be paid to GTC.

47% of the stock is convertible at a fixed price of \$2.63 per share, with the balance convertible at \$2.23.68 per share. LFB also has an option to invest a further \$12.75 million under the same terms for a period of 6 months from closing which will provide an additional \$6.4 million of net cash to GTC.

We ended the quarter with approximately \$4.7 million of cash and marketable securities on the balance sheet. A \$6.9 million decrease compared to \$11.6 million at December 28th 2008. The cash balance includes the \$4 million of cash proceeds received in June from the convertible bridge loan from LFB. We project a net cash use for the second half of 2009 to be in the range of \$7 -11 million including projected receipts from new or expanding partnering arrangements. Based on our cash balance at the end of the second quarter as well as proceeds from the convertible preferred financing and potential cash receipts from existing partnering arrangements we believe we have the ability to continue operations into the fourth quarter of 2009. We are working to complete partnering arrangements under discussion and will continue to assess other opportunities. Back to you Geoff.

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

Thanks Jack. The proposed health care reform bill now in congress may have a direct impact of the timing of both our hemophilia programs as well as our initiative for follow-on biologic monoclonal antibodies. As you may be aware from the coverage of events in Washington, provisions to enable follow-on biologics or FOBs, known as bio-similars in Europe, have been included in the overall legislation to change the healthcare system in the United States. Most of the recent legislative activity regarding FOBs is focused on resolving the issue known as data exclusivity. Data exclusivity is a concept to help protect the investment an innovator has made in the original clinical studies by ensuring that no one else can rely on that data for a follow-on submission for a period of time after the original FDA approval, independent of the underlying patent life for the product.

Data exclusivity would only have an impact on the timeline to develop a follow-on biologic in the emerging legislation if the period for it is longer than the remaining patent protection for a given product. There has been much debate on the period of data exclusivity ranging from no data exclusivity proposed by the Federal Trade Commission to the BIO industry group position of 14 years. From this discussion proposed legislation in the House sponsored by Representative Henry Waxman specifies 5 years and legislation proposed by Senators Kennedy and Enzi is moving forward with 12 years of data exclusivity. The targeted products we are currently discussing with potential follow-on partners will not be impacted by the Senate's proposed 12 years of data exclusivity. We believe that what is important is that FOB legislation is enacted promptly.

Vcall

601 Moorefield Park Dr.
Richmond, VA 23236

Phone: 888-301-5399
Fax: 804-327-7554

info@vcall.com
www.vcall.com
www.investorcalendar.com



Earlier this year we also announced a partnership to work with AgResearch in New Zealand to establish follow-on programs in New Zealand where the patents in Europe expire before those in the United States. This would enable these products to enter the European market sooner than if the protein was produced at our farm in Massachusetts. AgResearch is pursuing the specific approvals for our program that are necessary from the New Zealand government. Underlying our FOB program is our unique advantage in being independent of what is known as the Cabilly patents held by Genentech. The Cabilly patents govern the intellectual property for expressing monoclonal antibodies in traditional cell culture systems. Licenses to Genentech's patents are a significant source of revenue for them and expense to others. Our monoclonal antibody program will enjoy the cost advantage of our production technology as well as avoiding the Cabilly license fees.

We have also added an external partner product, a service contract with JCOM of South Korea to support their interest in developing Recombinant Human Insulin products for Asia. As with any of our externally partnered programs, the timing of activities and associated revenues will be driven by JCOM's needs. We continue to work with PharmAthene on their Protexia® program while PharmAthene continues the development of this product with the Department of Defense. We have recently acquired worldwide rights to Recombinant Human Alpha Fetoprotein from Merrimack Pharmaceuticals. We had originally developed notes expressing this protein under a contract to Merrimack. Merrimack had performed clinical studies for AFP in rheumatoid arthritis and established a significant safety database. We believe that the focus of clinical development for AFP should be in the treatment for myasthenia gravis and multiple sclerosis, where strong pre-clinical evidence exists for efficacy and the currently approved treatments have significant safety concerns. We plan to seek partnering arrangements to support the development of AFP and we have already received expressions of interest in funding the development of AFP in the myasthenia gravis and multiple sclerosis indications.

The general economic conditions have been very challenging for the entire biotechnology industry. We have been fortunate to work with a strong, committed, strategic partner in LFB. We are in a good position to take advantage of the emerging opportunities in a general economic recovery as well as those in health care reform. The strengths we are leveraging to grow into these opportunities are the success of our product programs, the partnering relationships we've already established with Lundbeck and LFB and continuing developments of new partnering relationships that add to our pipeline, capabilities and resources. We remain committed to building GTC into a significant company. Our historic first approval of a transgenically produced drug, our strong patent position demonstrated expertise in this technology, control of costs and establishment of the low risk/high potential product portfolio, and track record of successful product development is leading to our objective of cash self-sufficiency over the next 2-4 years. I look forward to updating you on our progress as we move into the second half of 2009 with the expanded commercialization of ATryn and our Factor VIIa program transitioning into clinical studies. Thank you for listening to our prepared remarks and will now ask the operator to open the call to question.

Vcall

601 Moorefield Park Dr.
Richmond, VA 23236

Phone: 888-301-5399
Fax: 804-327-7554

info@vcall.com
www.vcall.com
www.investorcalendar.com



Operator

Thank you Doctor. Ladies and gentlemen at this time we will be conducting a question and answer session. If you would like to ask a question please press *1 on your telephone keypad at this time. A confirmation tone will indicate your line is in the question queue. You may press *2 if you would like to remove your question from the queue and for participants using speaker equipment it may be necessary to pick up your handset before pressing the * keys. Once again to ask a question please press *1, one moment please while we poll for questions.

As a reminder ladies and gentlemen if you'd like to ask a question you may do so by pressing *1 on your telephone keypad at this time and we will poll just one moment more for any questions.

Thank you ladies and gentlemen our first question comes from the line of Stephen Turner with Due Diligences, please proceed with your question.

<Q>: Yes I was interested in your cash position, there is obviously concern that your cash position has been shrinking radically since you lost a large revenue source from your product placement last year, or production I should say, and I was wondering how you plan on addressing this?

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

Well thank you very much indeed for your question and clearly what we have experienced is really what many other companies in the biotechnologies sector and the economy generally have found that the capital markets have been very difficult over recent months. So I think it's not something which is unique to GTC and I think in that respect we are I think quite blessed that we had a strategic investor in terms of LFB who is very committed to the company and the products and the production model which we are developing here at GTC, to invest in the company and that's obviously been, has been a very important part of our financial situation through to the current moment.

The model which we are developing, of course, is based on developing a number of products most of which are known chemical entities but which we can leverage our production capabilities to be able to produce these products and to create markets significantly in excess of the ones which exist today for those products and so our expectation and intention is to continue to seek partnering arrangements for those products. We already have some of those programmes partnered with LFB from a European perspective but also we obviously have a very good relationship with Lundbeck here in the United States and we have been very happy with the way in which the initial launch of ATryn has gone and we certainly are looking to partner our other programs as we move forward and that will be an important way in which we can help bring finance into the company through milestones and obviously being able to develop and sell product to those particular partners as we move forward. We also usually envisage with those types of partnering arrangements that partners will support the financial costs of the further clinical developments of these products. So this is the model which we are planning to continue, we continue to be extremely cautious and careful about our expenses at this juncture and I think we feel that we have come through a very difficult period, we feel we are now well set for being able

Vcall

601 Moorefield Park Dr.
Richmond, VA 23236

Phone: 888-301-5399
Fax: 804-327-7554

info@vcall.com
www.vcall.com
www.investorcalendar.com



to move forward and we certainly intend to do that. We look forward to telling you about some of our partnering arrangements as we proceed through the rest of this year.

<Q:> As a follow-up question is there any possibility that, to conserve cash, that any of the members of the board and president are willing to take a price, I'm sorry a salary cut? As many companies have done.

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

That, we have already, in fact deferred bonus payments which were due to us in 2008 for the, all those people who were entitled to bonus arrangements, those have already been deferred until the financial circumstances of the company improves. So, we have already taken some of those approaches and we've also been, also involved in some salary reductions as part of, across the board in the whole of the company in order to be able to manage this cash situation. So that's something we've already taken care of.

<Q:> Okay, thank you

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

Okay

Operator

Ladies and gentleman we have no further questions at this time and I'd like to turn the call back to management.

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

Thank you very much indeed everyone for joining us this morning, in this review of our Q2 results, we look forward to talking to you again at the end of the third quarter. In the meantime have a wonderful summer on the beach. Take care and have a wonderful day today.

Vcall

601 Moorefield Park Dr.
Richmond, VA 23236

Phone: 888-301-5399
Fax: 804-327-7554

info@vcall.com
www.vcall.com
www.investorcalendar.com