



# **Transcript of GTC Biotherapeutics, Inc (GTCB) Q3 2009 Earnings Conference Call November 6, 2009**

## **Vcall**

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## **Participants**

Geoffrey F. Cox, Ph.D., Chairman and Chief Executive Officer  
John B. Green, Chief Financial Officer  
Thomas E. Newberry, Vice President of Corporate Communications and Government Relations

## **Presentation**

### **Operator**

Greetings and welcome to the GTC Biotherapeutics, Inc. Third Quarter Earnings Conference Call. At this time, all participants are on a listen-only mode. A brief question and answer session will follow the formal presentation. 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 and CEO for GTC Biotherapeutics, Inc. Thank you, Mr. Cox, you may begin.

### **Geoffrey F. Cox, Ph.D. – GTC Biotherapeutics, Inc – Chairman and Chief Executive Officer**

Thank you very much and good morning, everyone. Welcome to the conference call and webcast to discuss the financial results for the third quarter of 2009 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 Chief Financial Officer, and Tom Newberry, our Vice President of Corporate Communications and Government Relations.

Our results from third quarter were released earlier this morning and I hope you've had the opportunity to review this release prior to our call. I want to begin this call by providing an overview of our progress with our key programs ATryn and Factor VIIa, and our recent financing with LFB, and our organizational restructuring. Jack will then provide an overview of the financial results for the third quarter. I'll then have some further prepared remarks prior to opening the call 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 in item 1A of our 10-K and subsequent 10-Q's, our actual results may differ materially from our current expectations.

Good morning again, everyone, and thank you for joining us this morning for our quarterly earnings call.

Earlier this week, we announced very positive news regarding additional financing from our strategic partner and investor, LFB Biotechnologies. This is a further demonstration of their commitment to our production technology and products and, aligns with their strategic focus on recombinant plasma proteins and monoclonal antibody products particularly Follow on Biologics, or FOBs. As Jack will discuss in more detail later, this funding and the associated conversion of some of LFB's preferred stock both strengthens our balance sheet and helps us address the NASDAQ Capital Market's requirement for the total market value of our listed shares of common stock.

To help conserve this cash and align our organization with our key strategic ATryn and Factor VIIa programs, we are reorganizing our organization and reducing our administration cost to address these priorities, including a reduction on our headcount from 154 to 109 people. While all of our employees have made tremendous contributions to the progress and accomplishments of GTC, we have reached the point in the development of the programs that enables us to prudently manage our expense commitments by reducing our staff as we continue to navigate these uncertain and volatile markets. We thank all the 45 employees who have left us for their contributions to the company's progress and we wish them well for the future. We expect that these changes and operating expense reductions will result in a restructuring charge in our fourth quarter results and generate savings of \$5 million to \$6 million on an annualized basis.

In October, we also announced the restructuring of GTC's Board of Directors to more appropriately reflect LFB's ownership in GTC. I want to take this opportunity to recognize and thank Dr. Ken Bauer, Dr. Mary Ann Gray, Marvin Miller, and Robert Baldrige for their service on our Board and their commitment to the interest of our investors. In addition, we welcome William Heiden, Evelyne Nguyen, Dr. Jean-François Prost, and Bertrand Merot to our board.

Let me now turn to our key programs. A priority for GTC and LFB is the development of our recombinant human coagulation factor VIIa program for the treatment of hemophilia. As you may recall from previous conference calls, factor VIIa is used in the treatment of both type A and B hemophiliacs who have developed antibodies, or inhibitors, to factors VIII or IX. The only recombinant version of this protein, NovoSeven from NovoNordisk, has a \$1.3 billion annual market and is very expensive at over \$1000 per milligram. We believe that our recombinant form of this product can be produced with a low cost of goods using our technology and can achieve significant penetration in this market based on competitive pricing. We are producing a purified product at this time and planning to complete our preclinical testing program by the end of the first quarter 2010. We have a pre-IND meeting planned with the FDA for the first quarter of 2010 with the aim of initiating a Phase I clinical study in the

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second quarter 2010. Based on a full clinical development plan this indicates a potential filing for approval of this product in the 2013 timeframe. However, depending on the outcome and the interpretation of the follow-on biological or FOB legislation currently embedded in the Healthcare Reform Bill, this timeline may be reduced.

Our ATryn program, the recombinant form of human antithrombin, is also a strategic priority for GTC. The currently approved plasma derived antithrombin product in the US, Thrombate III from Talecris, has sales of about \$20 million per year. We believe that this is in no way represent the long term opportunity for ATryn in the USA. Remember that in Europe, annual sales of plasma derived antithrombin products represent approximately \$125 million. The initial approved indication for this product is in the Hereditary Deficient patients undergoing surgical and childbirth procedures which is a modest indication. The strategy for this product continues to be the further clinical development of ATryn in acquired deficiency indications such as heparin resistance and Disseminated Intravascular Coagulation, or DIC. These are potentially very significant indications and leverage ATryn's production ability to support these markets without production constraints which plasma derived products are subject to. I reported last quarter that Lundbeck launched ATryn in the U.S.A. in May for the approved treatment of hereditary antithrombin deficient patients undergoing surgical and childbirth procedures, and it appears they have made a strong start in penetrating the existing market. We would know more about sales projections and future revenue as we gain more experience with the commercialization of ATryn.

As I have stated, the next steps for ATryn are to progress the development in acquired deficiency indications. Lundbeck is interested in the further development of ATryn in the heparin resistance indication in coronary artery bypass surgery. This is a significant market, which we estimate to be about \$150 million per year. Some time ago, we conducted a number of studies in heparin resistance and our interest is to conduct a further Phase III study to support this indication. We have progressed our discussions with the FDA regarding our existing database and we plan to continue these discussions to define our protocol for the further Phase III in this indication. Our contract provides for Lundbeck to finance such a study.

Disseminated intravascular coagulation associated with severe sepsis also remains an important part of our development plans for ATryn and a very significant commercial opportunity. We look forward to establishing a new partnering arrangement and pursuing this indication once we have resolved the arbitration proceedings with our former partner in Europe, LEO Pharma.

In that respect, we recently re-acquired sole responsibility for the market authorization in the EU following our termination of our contract with LEO. We plan to file the data required to expand the European hereditary deficiency indication to include childbirth using data acquired in our study for U.S. approval.

We are in discussions with a number of potential new partners for the European development and commercialization of ATryn. However, these discussions will most likely be completed following the determination of the outcome of the arbitration proceedings in the new year.

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Recombinant alpha fetoprotein, or AFP, is a program which we acquired in the middle of this year for Merrimack Pharmaceuticals. This is a program in which we have had a long term interest and we already have a significant herd of goats which produce this protein. AFP is believed to be a modulator of the immune system and there is strong supporting evidence that it is a potential treatment of autoimmune diseases such as myasthenia gravis and multiple sclerosis. This program has attracted significant interest from a number of potential partners and we are in very encouraging negotiations to support the further development of AFP. Once we've established a partner for this program, we plan to progress AFP into a phase II clinical study in myasthenia gravis in 2010, with myasthenia gravis being a stepping stone to a significantly larger multiple sclerosis indication.

At this point, I'm going to ask Jack to provide an overview of our financial results and I will then have some further comments before opening the call to questions. Jack?

**John B. Green – GTC Biotherapeutics, Inc. – Chief Financial Officer**

Thank you, Geoff.

Our revenues for the third quarter of 2009 were approximately \$750,000 compared with \$2.9 million in the third quarter of 2008. For the year to date, our revenues were approximately \$1.6 million in 2009 compared with \$15.6 million in the first nine months 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 the U.S. Generally Accepted Accounting Principles. These payments were recorded as deferred revenue on the balance sheet and will be recognized as revenue in 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 nine months of 2008 from the sale of ATryn product to our former European partner LEO Pharma. Under our agreement with Lundbeck in the United States, we received a transfer price for the supply of ATryn to Lundbeck as well as obtaining a royalty on their sales. In future quarters, we expect shipments of ATryn to Lundbeck in the U.S. 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 \$8.8 million in the third quarter of 2008, an 18% increase year to year. For the year to date, total cost of revenue and operating expenses were \$30.3 million compared with \$31.5 million in 2008, a 4% year to year decrease. The year to year decrease was driven primarily by a \$6.8 million reduction in cost of revenue partially offset by a \$5.2 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 nine months of 2008.

Research and development expenses were approximately \$7.1 million in the third quarter of 2009 compared with \$5.3 million in the third quarter of 2008, an increase of \$1.8 million. For the year to date, research and development expenses were \$20.9

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million compared with \$15.7 million in the first nine months of 2008. The \$5.2 million increase in year to date expense reflects the impact of \$4.1 million of funding received from LFB in the first nine months of 2008 to fully fund GTC's expenses on the joint development programs factor VIIa, factor IX, alpha-1 antitrypsin and CD-20 monoclonal antibody, which did not recur in 2009. The increase also reflects a \$2.4 million increase in expense of our follow on biologics program, primarily reflecting an allocation of internal resources as well as a \$1.2 million non-cash charge for in process R&D incurred in the third quarter of 2009 in securing the rights to alpha fetoprotein from Merrimack Pharmaceuticals. These increases were partially offset by a \$3.1 million reduction in ATryn expenses primarily related to lower U.S. regulatory expense.

SG&A expenses were \$2.6 million for the third quarter, an increase of \$289,000 or 13% from the prior year quarter. For the year to date, SG&A expenses were \$8.2 million, an increase of 7%, reflecting higher legal costs associated with the arbitration proceedings with LEO.

Net other income in the third quarter and the year to date includes \$5.3 million in non-cash income which represents the change in the fair value of the derivative and option components of the July 2009 redeemable convertible preferred stock financing, which is a requirement under generally accepted accounting principles. This was partially offset by \$2.7 million of interest expense, year to date on the convertible debt that was issued to LFB in December of 2008.

The net loss for the third quarter of 2009 was \$5.1 million or \$0.48 per share compared with a net loss of \$6.1 million or \$0.59 per share in the third quarter of 2008. For the year to date, the net loss was \$26.2 million or \$2.51 per share compared with \$16.5 million or \$1.71 per share in the first nine months of 2008.

The 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 26, 2009 which had been previously approved by GTC shareholders.

### **LFB Financing**

Now, let me say a few words about the LFB financing. Earlier this week, we announced that LFB had exercised the option to purchase an additional \$12.8 million of convertible preferred stock under its Green Shoe Option, from the July 2009 financing. This provides an additional \$6.4 million of cash to GTC. LFB also converted the convertible preferred stock it acquired in the July 2009 financing into 10.6 million shares of common stock to support our market capitalization under NASDAQ's listing qualification rules. Finally, LFB also purchased \$3.6 million of common stock at the market price of \$1.07 per share, adding an additional 3.4 million common shares outstanding to further support our market value of listing shares for the NASDAQ listing requirement.

### **Cash Position**

We ended the quarter with approximately \$1.8 million of cash and marketable securities on the balance sheet, a \$9.8 million decrease compared to \$11.6 million at

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December 28, 2008. Based on our cash balance at the end of the third quarter and anticipated receipts from existing agreements, as well as the \$10 million of proceeds from the LFB financing transactions, but excluding any cash impact of new partnering arrangements currently under discussion, we believe we have the ability to continue operations to the middle of the first quarter of 2010. We are working to complete these partnering agreements and the resulting cash proceeds will extend our cash runway further into 2010. Of course, we will continue to closely control our operating expenses and to minimize our net cash use as we aim to cash flow break even within the next two to three years.

Back to you, Geoff.

**Geoffrey F. Cox, Ph.D. – GTC Biotherapeutics, Inc – Chairman and Chief Executive Officer**

Thank you, Jack.

Let me briefly make some final comments. As I stated, our focus for the present is on ATryn and Factor VIIa. However, we continue to see value in our other pipeline programs. Factor IX program which we are developing in transgenic pigs in conjunction with LFB is tracking approximately nine months behind Factor VIIa. Like the Factor VIIa program, our Factor IX program is being developed as a biosimilar. Depending on the outcome and interpretation of the proposed FOB legislation, the timeline for the clinical development program for Factor IX may be reduced.

This brings me to the subject of FOBs. We now have four programs in various stages of development of the transgenic production system; one of which is with our partner AgResearch in New Zealand. We remain committed to the development of a portfolio of FOB's and continue to be engaged in a number of partnering discussions to support further clinical development and commercialization. We very much hope that a regulatory pathway for FOBs will be clarified as part of the Healthcare Reform Bill currently battling its way through Congress.

Finally, let me summarize by saying that GTC continues to make strong operational progress on our core programs. We will continue to meet the challenges of commercializing our innovative technology and take whatever tough decisions we need to ensure our success. I thank our investors for their patience and their commitment to our common goals.

Thank you for listening to our prepared remarks and I will now ask the operator to please open the call to any questions.

**Operator**

Thank you. We will now be conducting a question and answer session. If you would like to ask a question, please press \*1 on your telephone keypad. 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. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the \* keys. One moment please while we pool for questions.

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Once again, if you would like to ask a question, please press \*1 on your telephone keypad.

Dr. Cox, there are no questions in the queue at this time.

**Geoffrey F. Cox, Ph.D. – GTC Biotherapeutics, Inc – Chairman and Chief Executive Officer**

Thank you very much. I thank everyone for joining us this morning. We look forward to talking to you again and discuss our fourth quarter results early next year. Today you've heard our story. We're continuing to make good progress. We've taken some tough decisions to make sure that we stay healthy and that we demonstrate a confidence in the future of our company. So thank you very much indeed and I look forward to speaking to you again in three months' time. Thank you.

**Operator**

This concludes today's teleconference. You may disconnect your lines at this time. Thank you for your participation.

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