

FINAL TRANSCRIPT

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GTCB - Q1 2009 GTC Biotherapeutics, Inc. Earnings Conference Call

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CORPORATE PARTICIPANTS

Geoff Cox

GTC Biotherapeutics, Inc. - Chairman & CEO

Jack Green

GTC Biotherapeutics, Inc. - CFO

CONFERENCE CALL PARTICIPANTS

Doug Rogers

Sonora Investment Management - Analyst

PRESENTATION

Operator

Good day ladies and gentlemen and welcome to the first quarter 2009 GTC Biotherapeutics Inc. earnings conference call. My name is Shaquana and I will be your coordinator for today. At this time, all participants are in a listen-only mode. We will facilitate a question-and-answer session towards the end of this conference. (Operator Instructions)

I would 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.

Geoff Cox - GTC Biotherapeutics, Inc. - Chairman & CEO

Thank you very much and good morning, everyone. Welcome to the conference call and webcast to discuss the first quarter 2009 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 Chief Financial Officer and Tom Newberry, our Vice President of Corporate Communications. Our results for the first quarter 2009 were released earlier this morning. I hope you have had the opportunity to review this release prior to our call. After some introductory comments, I will ask Jack Green to provide a summary of our financial results and expectations and I will then open the call to questions.

First, let me remind you as usual 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." Due to the risks inherent in our business, which are 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, good morning, everyone, again. Thank you for joining us for our quarterly earnings call.

In our last earnings call at the end of February, I spoke about the FDA approval of ATryn, our recombinant form of human Antithrombin. That was of course a very special and important moment for us. And today, I'm very pleased to tell you that just last week, our partners, Lundbeck Inc. announced that ATryn is now commercially available in the United States. Again, this is a very special moment for us, ATryn representing the first and so far only transgenically derived therapeutic protein to become commercially available in the United States or anywhere in the world.

Ovation Pharmaceuticals based in Deerfield, Illinois, was acquired by Lundbeck A/S of Denmark in February. In preparation for this launch, Lundbeck has hired a 16 person hospital sales force to sell ATryn together with their other hospital products. Distributor contracts have already been put in place and sales training has been completed and orders have already been received for ATryn. Following the very successful panel meeting in January, and FDA approval in February, GTC received a total

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of \$4 million in milestones from Lundbeck in the quarter. Subsequently, we also delivered ATryn product to Lundbeck, ready for commercial sale and we've received a further \$1 million from Lundbeck for this product in the second quarter.

The first indication for which ATryn has been approved is for the treatment of hereditary deficient patients undergoing surgery or childbirth. Together with Lundbeck, our plan is to continue the development of ATryn in acquired deficiency indications and here in the US, our initial focus will be on heparin resistance which occurs in approximately 15% of patients undergoing coronary artery bypass graft surgery or CABG surgery. This is an area of development in which we have significant prior clinical experience. We are developing our plans for ATryn in this indication and I look forward to updating you on our interaction with the FDA. Hereditary deficiency is a modest indication although there are between 60,000 and 150,000 people in the US who have this genetic disorder. However, ATryn is currently approved for the treatment of patients undergoing surgery or childbirth and is therefore an acute treatment for a chronic disease. We were very pleased and honored to learn this week that the National Organization for Rare Diseases is recognizing GTC for the groundbreaking development of ATryn for patients who are suffering from hereditary antithrombin deficiency.

We believe heparin resistance is a larger market, potentially \$100 million to \$150 million. There are approximately 250,000 CABG surgeries carried out in the United States each year. The plan to seek extension of the label indication for ATryn in this acquired deficiency indication is a very logical and important step in the commercialization of ATryn and building towards the full potential opportunity and value of this product.

Over the years, we believe the US market has been significantly underserved by the only plasma-derived product commercially available in the United States. In Europe and Japan, where a number of plasma-derived antithrombin markets are available, significant markets, well in excess of \$100 million in each territory have been established despite limited clinical data. With the data from our hereditary deficiency study which represents the most robust data ever collected in this indication, together with the extension of the development of ATryn in the larger acquired deficiency indications, we believe the opportunity exists to develop a major market for ATryn in the United States. Remember, we already have the production capacity established in our herd to serve both current and prospective markets.

Let me briefly comment on the situation in Europe. We strongly believe in the opportunity for ATryn in Europe. And we look forward to establishing a new committed partner to commercialized and further develop ATryn in all of the countries of the European Union. We're in the process of regaining ownership of and responsibility for the market authorization in Europe which will enable us to apply for broadening the hereditary deficiency label to include the childbirth indication which we had hoped would have been achieved last year. Reacquiring the MAA is also an essential precursor to our new partnering arrangement. In addition, we're engaged in arbitration proceedings to resolve some outstanding contractual issues regarding our former partnership in Europe and it is unlikely that these matters will be resolved before the fourth quarter of this year.

The disseminated intravascular coagulation indication or DIC which our former partner in Europe had been responsible for remains an area of significant clinical and commercial interest for ATryn and we look forward to the opportunity to pursue this indication with a new partner. We also plan to move ahead with some mission for marketing approval in the hereditary deficiency indication in Canada in the near future. And discussions are in progress with a number of potential partners to market ATryn in Canada, Japan and other territories. All in all, this is a very exciting time for us as we move forward to maximize the opportunity for our first commercial product on a worldwide basis.

Let me now move to some of our other programs. Our next program priority is the Factor VIIa program being developed in conjunction with our partner LFB. As I informed you during my last call, we have now developed both rabbits and goats which express Factor VIIa in significant and commercially viable quantities. A decision regarding which production animal will be chosen for this product will be made during the next six months. However, our projections indicate a very attractive commercial opportunity whichever production animal is chosen.

Remember, recombinant Factor VIIa is a very highly priced product at the moment. NovoSeven, the only recombinant Factor VIIa in the market today represents a market of approximately \$1.3 billion from just over one kilo of product. We believe that

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this is a great example of how our production technology can support the development and commercialization of products at competitive pricing while it's maintaining attractive margins. Our time line for Factor VIIa indicates pre-clinical development through the remainder of this year with an IND being submitted to the FDA in the first quarter of 2010. We believe the data from the Phase I study we're planning could provide data in the second half of 2010.

Our Factor IX program is also making good progress and it is scheduled approximately six months behind the Factor VIIa program. This product is being developed in transgenic pigs which already produce Factor IX and is planning to compete with Wyeth's recombinant product BeneFIX which today sells approximately \$600 million annually worldwide. These programs represent our priorities at present. Our other programs in GTC's product pipeline including alpha-1 antitrypsin and the CD137 monoclonal antibody have established their production animals and will be further developed as additional partnering and financial resources are obtained.

Our monoclonal antibody development programs are also making good progress. The CD20 monoclonal antibody program which is being developed under the GTC/LFB joint venture is progressing well. LFB has already entered the clinic with a rat cell derived product in a chronic lymphocytic leukemia indication and the binding affinity characteristics of this molecule appear very attractive in comparison with Rituxan. The same CD20 molecule expressed in our transgenic goats also appears to have attractive ADCC or antibody-dependent cell-cytotoxicity, as a result of the naturally low fucose expression in the goat mammary gland.

The transgenic program is more suited to producing the large volumes required to address the larger potential indications for this product. This is becoming a very interesting program and opportunity. It should be noted this is not an identical molecule to Rituxan and may lay outside future follow-on biologics or FOB legislation but the indications which this product is targeting today currently represent the potential market in excess of \$5 billion.

Which brings me to the other key strategic opportunity for GTC, that of follow-on biologics. Much is being written and discussed about this issue and although the details of the legislation in Congress remain a work in progress, there appears to be strong support for legislation to be passed this year. We have initiated the development of production animals for two of our potential monoclonal antibody follow-on biologics at this time. Again, we believe the ability of our production technology to support the production of monoclonal antibodies in large volumes and at competitive pricing is very attractive and this opportunity represents an important value driver for the future. We plan to seek partnerships to support the further development and commercialization of these FOBs and discussions are already in progress with a number of interested parties.

Similarly, we're engaged in a number of discussions with potential partners for our recombinant and plasma protein projects. This remains an important strategic objective for GTC, support the development and commercialization of these products, particularly through these difficult periods in the capital markets. During the quarter, we entered into an R&D external partnering agreement with JCOM of South Korea to explore the use of our transgenic production technology for the production of insulin for the Asian market. We remain interested in entering into external partnerships such as this example where there is a clear commitment to the use of our transgenic technology.

Now, let me come to my final point before handing it over to Jack Green. It is obvious that the capital markets remain challenging for our entire sector in the biotechnology industry. I want our investors to know we've been very active in the process of insuring GTC's financial future. I look forward to being able to update you in that respect in the near future. In the meantime, we continue to operate the Company in a very prudent and financially constrained manner. Our operating focus is on those programs which have the opportunity to achieve significant value-driving milestones over the coming months, particularly ATryn and the hemophilic factors.

Now, let me hand it over to Jack Green.

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Jack Green - GTC Biotherapeutics, Inc. - CFO

Thank you, Geoff.

Our revenues for the first quarter of 2009 were approximately \$200,000 compared with \$3.5 million in the first quarter of 2008. It is important to note that in the first quarter of 2009, we received approximately \$4.7 million in milestone payments including \$4 million from Lundbeck on the ATryn program that was not recognized as revenue, under the revenue recognition rules of US generally accepted accounting principles, These payments were recorded as deferred revenue on the balance sheet and will be recognized as revenue in future periods.

In particular, we now have approximately \$9 million of deferred revenue on the balance sheet from milestone payments received from Lundbeck, \$4 million from Q1 2009 and \$5 million from Q4 2008 that will be recognized as revenue over the life of the contract. The decrease in the year to year comparison reflects completion in late 2008 of our external programs with Merrimack for MMO93 and with PharmAthene for production and purification services for its Protexia product. As we've stated in the past, the amount of our quarterly revenues is affected by the nature and timing of services provided to our partners in these development programs.

For the quarter, total cost of revenue and operating expenses were \$9.7 million, compared with \$11.7 in the first quarter of 2008, a 17% decrease year to year. The year to year decrease was driven primarily by a \$900,000 reduction in cost of revenue and a \$900,000 reduction in research and development expenses. The cost of revenue decrease reflects the completion of activities in the external programs with Merrimack and PharmAthene. Research and development expenses were approximately \$6.8 million in the first quarter of 2009, compared with \$7.7 million in the first quarter of 2008, a reduction of \$900,000. The decrease in expense year to year reflects \$1.8 million lower ATryn expenses primarily related to manufacturing and a \$400,000 reduction in expense incurred in our joint development programs with LFB. These reductions were partially offset by a \$1.1 million increase in expenses in our follow-on biologics program, primarily an allocation of internal resources.

SG&A expenses were \$2.5 million for the first quarter, a decrease of \$200,000 or 17% from the prior year quarter, reflecting lower legal and patent costs. The year to year increase in other net expense of \$783,000 reflects \$500,000 in interest expense on the convertible debt with LFB, lower interest income on short-term investments and a \$165,000 DAT tax refund received in the first quarter of 2008. The net loss for the first quarter of 2009 was \$10.4 million or \$0.10 per share, compared with a loss of \$8.2 million, also \$0.10 per share in the first quarter of 2008.

The first share results were affected by an increase in the weighted average number of shares outstanding from 83.2 million shares in the first quarter of 2008 to 104.1 million shares in the first quarter of 2009. The increases in the weighted average shares outstanding primarily reflect the issuance of shares of common stock in a registered direct offering in February of 2008 and the conversion of the majority of LFB's convertible preferred stock into common in March of 2008. We had approximately 104 million common shares outstanding as of March 29, 2009.

We ended the quarter with approximately \$6.8 million of cash and marketable securities on the balance sheet, a \$4.9 million decrease compared to \$11.6 million at December 28, 2008. The cash balance excludes the \$4 million of cash we were required to put into escrow to secure our term loan with GE Capital that was done in connection with the LFB convertible debt financing we completed this summer. Consistent with our prior guidance, we project a net cash use for the remainder of 2009 to be in the range of \$13 million to \$17 million including projected receipts from new or expanded partnering arrangements. Based on our cash balance at the beginning of the quarter, as well as potential cash receipts from existing programs, and temporary deferral of certain vendor payments, we believe we have the ability to continue operations to the end of the second quarter of 2009. We're in discussion -- in discussions with new and existing investors to secure additional funding and we anticipate entering into a transaction in the second quarter.

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Finally, I'm pleased to say that just yesterday, we received notice from the NASDAQ listing qualifications staff that GTC has regained compliance with the \$35 million minimum market value rule for listing our stock on the NASDAQ Capital Market. Geoff, back to you.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

Thank you, Jack. Now, I would like to turn the call over to any questions which those on the call may wish to ask.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) You have a question from the line of [Doug Rogers with Sonora Investment Management.] Please proceed.

Doug Rogers - *Sonora Investment Management - Analyst*

Good morning, gentlemen.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

Good morning, Doug.

Doug Rogers - *Sonora Investment Management - Analyst*

Just wondered is it possible for you to outline a rough time line on the hereditary deficiency -- not hereditary deficiency indication -- the heparin existence.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

Heparin resistance?

Doug Rogers - *Sonora Investment Management - Analyst*

Yes.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

Sure. Well, I think that we would have -- I know what our plan is. Our plan is to find a way of being able to progress this forward with the FDA, at the earliest opportunity. Certainly, we have expectations that we will initiate meetings with the FDA in the very near future. And of course, we've done a lot of work in heparin resistance indication in the past.

And so, if is certainly an area which we feel that we can progress quite rapidly to a situation where we could achieve an approval for heparin resistance indication. We need to understand from the FDA what clinical work we need to do to be able to support that and we need to go and discuss with the FDA those particular plans. So, I think with that, say, for the very near future, and I think that we hope to be able to give you a more precise update during our next calls, Doug.

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Doug Rogers - *Sonora Investment Management - Analyst*

Got it. Thanks. Second question, I don't recall if you disclosed what the potential royalties of PharmAthene might be.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

From PharmAthene?

Doug Rogers - *Sonora Investment Management - Analyst*

Yes.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

I don't think we have, no. So, that, I think is a -- remains a confidential disclosure between PharmAthene and ourselves.

Doug Rogers - *Sonora Investment Management - Analyst*

Okay.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

This is for the Protexia product, is that correct?

Doug Rogers - *Sonora Investment Management - Analyst*

Yes.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

I don't think we've disclosed that in the public domain.

Doug Rogers - *Sonora Investment Management - Analyst*

Okay. Just crossed my mind. I thought I would ask. That's all I've got.

Geoff Cox - *GTC Biotherapeutics, Inc. - Chairman & CEO*

Just put it in context. That's a -- from what I remember, I believe that is a -- that is a modest single digit type of royalty arrangement.

Doug Rogers - *Sonora Investment Management - Analyst*

Right. Okay. Thanks so much. That's all I've got right now. Thanks though.

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Geoff Cox - GTC Biotherapeutics, Inc. - Chairman & CEO

Thank you, Doug. Thank you for your questions.

Operator

(Operator Instructions) At this time, there are no further questions. I would now like to turn the call back over to Dr. Cox for closing remarks.

Geoff Cox - GTC Biotherapeutics, Inc. - Chairman & CEO

Thank you very much indeed and thank you everyone for joining us this morning. As you can tell, from the progress the Company has made over the last 12 months which has been a very exciting time for us culminating in the approval and then the launch of ATryn here in the United States. And as we look forward, you can also see that we continue to make very good operating progress.

And we have important milestones and advancements over the next 12 months both with ATryn and heparin resistance indication I was just discussing with Doug and also in the hemophiliac factors as we move those toward clinical development stage and I look forward to updating you on our progress during our future calls.

So, thank you very much, indeed, everyone, once again. And have a good day.

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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