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**GENZYME**

**Moderator: Geoff McDonough  
Cambridge, Massachusetts USA  
August 10, 2009  
4:00 p.m. (Eastern)**

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode. After the presentation, we will conduct a question and answer session. To ask a question, please press star 1.

As a reminder, today's conference is being recorded. If you have any objections, you may disconnect at this time. I will now turn the meeting over to Ms. Kathleen Coolidge. Ms. Coolidge, you may begin.

Kathleen Coolidge: Okay, thank you very much. First of all, I want to welcome everyone to this Genzyme and National Gaucher Foundation Town Hall. We had one earlier today at 1:00 and we're very glad you could join us this afternoon.

I am in charge of US Patient Advocacy at Genzyme. And I'd like to first introduce Rhonda Buyers from the National Gaucher Foundation. Rhonda?

Rhonda Buyers: Hi, everyone. I just wanted to let you know that one of the reasons we felt it was important to do these town hall meetings was the fact that we have gotten so, so many questions and we decided that it would be a good way to have Genzyme clarify things and be able to ask.

And we've compiled the questions that everyone has sent in and we will also - we'll go through those - some of those questions and also open this up to the

floor later in the meeting to ask questions live. And I want to also thank you for joining. I know it's kind of a strange time but we tried to pick some various times and we're going to be doing more of these. And we've taken into consideration some of the thoughts and emails that have come to us.

And with that being said, I want to turn it back over to Kathleen to introduce our first person - first speaker.

Kathleen Coolidge: Okay, thank you very much, Rhonda. So we have Dr. Geoff McDonough who's going to be speaking for the rest of the hour. But before Geoff has a chance to speak, I want to introduce Tracey Quarles from our legal department for a few words.

Tracey Quarles: Thank you, Kathleen and good afternoon everyone. On this call, we'll be making forward-looking statements concerning Genzyme's business, including our production and supply expectations and timelines, including with respect to the remaining finished lots and work-in-process material, our inventory management plans, and our expectations and timelines for our new manufacturing facility and the development of GENZ-112638, including the treatment IND we submitted with the FDA.

These forward-looking statements are subject to a number of risks and uncertainties and our actual results may differ materially. For more information on those risks, please refer to our press release dated August 10, 2009 and in the Risk Factors section of our Form 10-Q for the quarter ended June 30, 2009 which was filed with the SEC today.

Also, many of you are probably aware of the recent investor class action lawsuits that were filed against the company. Please understand that we

cannot answer questions regarding those lawsuits or the allegations made in those lawsuits during this call.

Thank you again. I would now like to turn the call over to Geoff McDonough.

Geoff McDonough: Thank you, Tracey and good afternoon everybody. Please let me begin by asking you to forgive us for some of the more formal elements of this town hall format. We are of course accustomed to meeting you in person at patient meetings and in educational formats around the country and we vastly prefer that more personal way of connecting.

But of course, these are unusual times and we are trying our best to explore every possible modality to keep you well informed. So we'll work our way through this learning experience in a town hall format. But based on our call earlier today, we would anticipate the opportunity to do this many times again in the future as needed.

My name is Geoff McDonough, I'm responsible for the genetic disease business here at Genzyme. And I wanted to take the next 10 or 12 minutes to give you an update on where we are today and to cover a series of pertinent developments which were contained in the press release which Tracey just referred to earlier today.

As you know, since June - June 16th when this contamination occurred in our Allston Landing facility specifically when we detected this so-called Vesivirus in our CHO cells, our Chinese hamster ovary cells, which produce - Cerezyme and Fabrazyme. We've been working to provide you with clear, consistent and accurate information to you as well to the broader community of stakeholders about this situation to the best of our ability and information at

each step of this enormously complex situation which I think today we stand at the far end of in terms of understanding it and of course its implications.

From the outset as we've worked to understand this situation, we've been focused on the impact to you, patients and to your families, with three basic principles in mind which we've articulated along the way as follows.

First, we're working in this period of shortage to try to ensure therapy for the most vulnerable patients. Second, that we're trying to ensure equity on a global basis so that no one country is contributing disproportionately to this shortfall compared to others.

And thirdly, that we would not discern between charitable and commercial patients in the way that we think about managing the allocation of what Cerezyme is available.

The purpose of these guidelines or principles was to help us make decisions in the following three most important areas in our view; first, how to provide guidance to the treatment community on how to make it through this period of shortage. Secondly, determining how best to most safely and reliably restart production at our Allston Landing facility for Cerezyme and Fabrazyme. And thirdly, to determine how much Cerezyme is available, both in standing finished inventory as well as what we call work in process inventory.

Before I go on to describe the updates in the current situation, I do want to take a moment to describe what this term work in process inventory means. Essentially, work in process describes Cerezyme in the stages of production between the cell culture area where it is primarily produced in the cells and the downstream processing where we take that harvest material from these

cells and we progressively purify it and isolate it into the form that you see in the finished and labeled vial which is ultimately released for shipping.

The reason I'm taking some time to describe this is that the event that we detected in this circumstance in Allston Landing came at the end of a roughly 100-day harvest cycle, specifically between Day 96 and Day 99 is when we saw some of the abnormalities in the growth of these cells.

So if you consider that over a 100-day period, we were harvesting Cerezyme during that time. And if you consider that the overall time from the beginning of cell culture to the release of finished files is about 120 days, this event had the very unusual circumstance of having a very large amount of Cerezyme that was in this work in process category. Now I'll certainly say more about that but I wanted to give you some flavor for how we talk about where Cerezyme is in the process of production.

As you know, we sent you a letter on June 18th about this situation and about a week later on June 25th, we shared the initial guidance created in consultation with the Cerezyme stakeholders working group asking for a set of criteria which would allow us to identify patients, specifically those aged younger than 18, pregnant women, patients with Type 2 and Type 3 Gaucher Disease as a group that could continue their Cerezyme in an uninterrupted way during this period of shortfall and to ask for a voluntary 50% reduction in dose for Cerezyme in all other patients in consultation with their physicians.

The guidance at that time, formulated by the stakeholder's working group was based on an understanding of the work in process inventory that had acknowledged that about half of that work in process had been finished and released to the market at the time of the contamination in the plant.

At that time, we had discarded between 10% and 15% of harvest material in conjunction with this event and were working through a process for the remaining work in process inventory to understand the safety for further processing and distribution to patients.

We continued to run the Allston facility for several days after this event in order to bring this work in process to stable hold time to give ourselves time to decide how best to process that material at a later time.

Since then, we've been working on three areas. First, as I said, restarting the plant; second, on monitoring inventories around the world; and third, on assessing what portion of this work in process inventory would be usable by the end of July and making clear that the US demand or consumption was not at the level that was needed in order to continue to be able to protect the most vulnerable patients. We targeted roughly about 60% of use.

This was not for any lack of effort on your part. We know that many of you, perhaps most of you on the phone, willingly missed a dose or reduced your doses in the month of July and at the end of June in order to contribute to this process. Rather we attribute the failure to bring the level of consumption down to the appropriate or needed level in this case to the complexity of the US distribution system, where we were not able to translate these actions in the month of July to the inventory position that we needed at the end of August to insure continuous supply to the most vulnerable patients.

This led us to reconvene the stakeholder's working group at the end of July and beginning of August with the addition of the ICGG coordinators from the Gaucher Registry. At that time, the group was asked to consider very limited on-hand inventories at that time and how to define a smaller group of patients who could be protected. And at that time, the group came up with the current

guidance which you're familiar with, defining that group as pediatric patients, Type 2 and Type 3 patients and adult patients in life-threatening situations related to their Gaucher Disease.

The goal at that time was to preserve inventories for the most severe patients and to await further updates on the progress and restarting production at Allston and a determination on the work in process inventories.

Today, our press release issued earlier this afternoon gave substantial updates in both of these areas which I'd like to summarize now. First, with respect to the restart of the Allston facility, I can tell you today that we have fully and successfully sanitized and reassembled and restarted the systems and processes in the Allston facility. And at this moment, we have three out of six bioreactors operating at a commercial scale, two of those for Cerezyme and one of those for Fabrazyme. All three of those are performing as expected so far.

We expect to inoculate or set up production scale for the remaining three bioreactors by the end of August. This represents the most important step for us in assuring continuance and reliable supply of Cerezyme once we reach the end of the production cycle, which I mentioned earlier is about 120 days.

We would expect, on the basis of our progress so far, that the first commercially available and releasable vials for Cerezyme would start to enter the market at the end of November 2009 and start to approach global demand by the end of 2009 and beginning of 2010.

With respect to the work in process inventory for Cerezyme, we did make a decision as contained in the press release to discard roughly 80% or the majority of the remaining work in process inventory for Cerezyme. This

process of decision-making was enormously complex and it was related to the ability to reliably detect at a quantitative level the presence of this virus in various stages of this inventory. Not balancing patient safety because in the end, since this virus is not known to infect humans and since we are quite confident that it would not make its way into any commercial or finished or released vial.

Rather instead, we were balancing a very great need for this material among patients and families in the communities against the risk of bringing this virus back into the Allston facility which we had just decontaminated and fully cleaned and restarted.

The reason for this concern is that work in process inventory needs to go back into Allston in order to be finished and released for final distribution. So in the end, after a very complex situation - investigation, including not only consultation with our science and research groups but also with the regulatory authorities, we're left today in a situation where we have far less Cerezyme inventory on hand than we previously had thought.

So for this reason, we have moved from a shortage situation with a potential for a relatively short-term disruption of therapy to one which will now last between three and four months from today through the end of 2009. There's simply not enough Cerezyme to date to treat all those who need it and we have a series of very difficult, maybe even impossible decisions to make in terms of how to best manage and most fairly manage the supply of Cerezyme that we do have.

The current dose conservation program, as it was outlined on August 3rd, is designed to try to protect the most vulnerable patients. And other than the extension and the duration of this program, we would not expect a specific

guidance of this program to change in the face of reduced inventories. However, this plan does depend on the release of two finished lots of material which would need to be released in the next two to three weeks in order to maintain supply for the current protected populations of pediatric patients, Type 2 and Type 3 patients and the most severe adults.

The reason I bring these two finished lots up in this call is we have heard and are trying to respond to feedback from patients and healthcare providers urging us to give a sense of the absolute worst case possible. And in this spirit, it is important to note that if these two finished lots of Cerezyme are not released, then we would not have sufficient inventory to continue supply, even to the smaller, more restricted populations beyond early September.

We will know about the disposition of this material before the end of August. And of course, we'll come back with this as one of the most important updates for the community in that timeframe.

So as we focus on restarting Cerezyme production, we're also actively working on alternatives to bring to bear during this very difficult period for the community. The first and most important of these that's within our control to bring forward is the development of the oral - orally available small molecule Genzyme 112638.

As many of you may know, this small molecule for Gaucher Disease has completed its Phase 2 development and is currently enrolling two Phase 3 trials, one for patients who have not previously been treated with ERT and which will be conducted at eight US sites, many of which are open and ready to enroll this month. The second is a switch trial which will be open to patients who have been stable on Cerezyme and is today at six confirmed and

four additional sites in the United States. And those confirmed sites are - will be beginning to enroll throughout the course of August and September.

In addition to those Phase 3 trials, which will have a duration each of nine months and will have extension periods through approval, we have also submitted a protocol for treatment INDs to the FDA with six confirmed sites and six proposed additional sites which is awaiting review and approval by the FDA which we expect to hear of by the end of August.

Secondly, the stakeholder's working group has reconvened today and will continue to meet in the coming days to issue revised guidance. In light of these current updates, both with respect to individualizing those within the pediatric population as well as providing additional detail around the Cerezyme emergency access program.

Finally, we have begun reaching out and will be working with our partners in industry to help make sure that options are available and coordinated in providing access to patients as much as they can be within the constraints of our abilities to communicate together in this space.

So with that, let me close and ask, Rhonda, for you to take the floor back and we'll look forward to addressing your questions and then going to the live Q&A.

Rhonda Buyers: Okay, I'm going to ask - what we've done actually is compiled questions based on topics. And as you all can well imagine, the majority of those have had to do with supply. Geoff, you've just given us some new information which actually answers some of these questions. And what I want to - excuse me - I'm sorry - I want to just ask a few questions that perhaps weren't addressed.

One was what has been done with regard to supply and with the plant to assure that this type of situation won't happen again?

Geoff McDonough: Of course, Rhonda, that's the most important question in our minds, thinking about how to be sure that going forward from here, having cleaned the plant - as I mentioned with work in process inventory - that we don't expose the plant in the future to any additional risks.

So there's perhaps first a broad answer to your question and then a more specific answer. The broad answer is that all of the companies and suppliers who produce the raw materials that we use in helping to grow and nurture the cells that produce Cerezyme and Fabrazyme have been in close contact with us. And learning what we know about this particular virus and learning to integrate the specific tests, which we in fact created to both identify and work further in this virus within our plant to their quality systems as appropriate.

We will be integrating this testing into our own testing panel which, of course, already exists and covers many, many viruses to make sure those materials and other elements are tested throughout the process.

In addition to that, we're looking at more mechanical means of treating these components as they come into the plant to make sure that any viruses are inactivated as well as in process testing throughout the course of the plant's operations which we already do but which we'll be augmenting with these more specific measures.

And finally, we are - we'll be implementing a series of filtration steps which are specific for very, very small viruses of which this is one example. So it's a combination of making the (inaudible) this particular agent and also taking

