

Lippert Heilshorn & Associates

Moderator: Kim Golodetz
April 7, 2011
11:00 a.m. ET

Operator: Welcome to the Series 2010 Financial Results and Business Update conference call. At this time, all participants are in a listen-only mode. Following management's prepared remarks, we'll hold a Q&A session. To ask a question, please press star, followed by the number one on your touchtone phone.

If anyone has difficulty hearing the conference, please press star zero for operator assistance. As a reminder, this conference call is being recorded today, Thursday, April 7, 2011.

I would now like to turn today's conference over to Kim Golodetz. Please go ahead, ma'am.

Kim Golodetz: Thank you. This is Kim Golodetz with Lippert Heilshorn & Associates. Thank you all for participating in today's call. Joining me this morning from Spherix are Dr. Claire Kruger, chief executive officer; Robert Clayton, chief financial officer; and Dr. Robert Lodder, the company's president.

Last week, Spherix issued a press release reporting its 2010 financial reports and business highlights. If you have not received this news release or if you would like to be added to the company's distribution list, please call Lippert Heilshorn in New York at 212-838-3777 and speak with Carolyn Curran.

As we begin, I would like to caution that comments made during this conference call by management will contain forward-looking statements regarding the operations and future results of Spherix.

These forward-looking statements involve risks and uncertainties that include, without limitation, risks that product candidates may fail in the clinic or may not be successfully marketed or manufactured, that Spherix may lack financial resources to complete development of D-Tagatose, that the FDA may interpret the results of the studies differently than management's interpretation, that competing products may be more successful, that demands for new pharmaceutical products may decrease, that the biopharmaceutical industry may experience negative market trends, that the company's continuing effort to develop D-Tagatose may be unsuccessful, that its common stock could be de-listed from the NASDAQ capital market and other risks detailed in the company's filings with the Securities and Exchange Commission.

I encourage you to review these filings, including the company's forms 10-K and 10-Q, which identify specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements.

Importantly, the content of this conference call contains time-sensitive information that is accurate only as of the date of the live call, today, April 7, 2011. The company undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this call.

With that, I would like to turn the call over to Claire Kruger. Dr. Kruger?

Claire Kruger: Thank you, Kim. And my thanks to each of you for participating in this call.

Our intention today is to provide you with an update on several recent and significant accomplishments at Spherix, review our business strategy and provide a near-term roadmap for activity. Robert Clayton will also go over our 2010 financial results with you.

Let me start with a few words on our health sciences consulting business. As you are aware, this wholly-owned subsidiary accounts for almost all the revenues of the company. In 2010, those revenues were 1.4 million, largely unchanged from 2009. We performed work on behalf of 23 customers last year compared with 12 customers in the previous year.

Our scientists regularly publish and present at major trade and professional shows in conferences, and importantly, this subsidiary is responsible for overseeing the research work at our biospheric subsidiary, which is our pharmaceutical development company. We have made significant progress during this quarter, and recently in developing D-Tagatose as a treatment for mixed dyslipidemias, that of elevated triglycerides and high cholesterol and atherosclerosis.

Before I discuss this program, though, I'll turn the call over to Robert Clayton, who will review our financial results with you. Robert?

Robert Clayton: Thanks, Claire. As mentioned, our revenues for 2010 were 1.4 million, which were largely unchanged from revenues in 2009. The net loss for 2010 was 7.7 million, or 43 cents per share, compared with a net loss for 2009 up 9.1 million or 62 cents per share. The narrowing of the net loss was attributed to lower R&D expenses of 4.8 million in 2010, down from 6.3 million in 2009.

During both years, the company was conducting a phase 2 and a phase 3 clinical trial with D-Tagatose in type 2 diabetes. The overall higher R&D expenses in the prior year included the purchase of 1.4 million of D-Tagatose from the contract manufacturer for use in our trials.

As of December 31, 2010, cash and cash equivalents were 5.6 million. Subsequent to the year – subsequent to the end of the fourth quarter (inaudible) received net proceeds of 2.6 million and a fundraising consisting of 4.3 million shares of common stocks and warrants to purchase an additional 2.1 million shares at 80 cents per share.

We believe that we have sufficient cash to fund our operations for the coming year, including the completion of two animal studies of D-Tagatose in the treatment of mixed dyslipidemias in animals on a high-fat and a high-carbohydrate diet and a phase 1b human post-prandial dose response trial. Should results warrant further development of D-Tagatose, we anticipate the need to raise funds later in the year in order to further build the value of the assets.

With that, I'll turn the call back to Claire.

Claire Kruger: Thank you, Robert. For those of you who are new to Spherix, I'd like to recap our experience with D-Tagatose as a treatment for diabetes. As a reminder, D-Tagatose was originally developed as a low-calorie sweetener, and its safety in humans was established in 2001, when it received the designation as Generally Recognized Safe, or (GRAS), for use in foods at up to 15 grams per day by the U.S. Food and Drug Administration.

In October, we reported top-line results of our phase 3 double-blind placebo controlled trial with D-Tagatose in patients with type 2 diabetes. The trial involved approximately 500 patients at more than 50 sites in the United States and India. The results showed a statistically significant reduction in HbA1c levels of 0.4 percent in the intend to treat global population at 10 months and a 1.1-percent reduction in the U.S. per protocol population at 10 months, which we believe may be due to differences not only in patient compliance between the populations, but due to differences in adiposity as reflected in this study by Body Mass Index, or BMI.

The bottom line is that D-Tagatose is sufficiently effective to support continued development in diabetes. However, the cost to do so is beyond the means of Spherix. We have had a number of discussions with potential partners who could fund the additional studies required by the FDA.

In particular, we are finding interest from companies operating in Asia and the Pacific Rim, owing to the shorter approval pathway and the lower development costs for oral anti-diabetic medications outside of the United

States and the longer data exclusivity in many countries outside the United States. That said, and at this time, we can't say if or when a partnership agreement might be reached.

As we drill down into our phase 3 results and perform subgroup analyses, and as we further review the data generated from our phase 2 results, it became clear to us that D-Tagatose holds potential for use in dyslipidemia by lowering triglycerides and cholesterol, lowering body mass, and perhaps, as research continues, a treatment for atherosclerosis. Note that in our phase 2 trial, there was a statistically significant reduction in serum triglycerides in the intend-to-treat group.

Importantly, unlike other drugs, D-Tagatose lowered triglycerides without elevating low-density lipoprotein or LDL to bad cholesterol. High-density lipoprotein, or HDL, the good cholesterol, remained unchanged in contrast to many current triglyceride lowering drugs, which tend to lower HDL or raise the LDL.

The development pathway for these indications has lower hurdles in terms of study requirements for approval and less lower development costs than for diabetes. Therefore, we've chosen to fund additional research to explore these indications. In addition, treatment for high triglycerides is a large and underserved market with an estimated worldwide treatment market of \$26 billion annually. In the U.S. alone, the market for triglyceride lowering drugs exceeds \$4 billion annually.

With fully 1/3 of the population of the U.S. overweight or obese, the market for pharmaceutical products to treat the metabolic syndrome is enormous, and a host of drugs have been fraught with safety problems and denied approval by the FDA. A safe drug such as D-Tagatose, if effective, could be expected to garner very meaningful sales.

In order to guide us on the trial design and appropriate dosing for humans, in December 2010, we engaged a leading contract research organization to conduct in vitro and animal studies of D-Tagatose. To date, eight studies of

our lead drug to investigate metabolic state, mechanism of action and proof of concept in treatment of dyslipidemias such as hypertriglyceridemia have been initiated. These studies have been designed to follow a logical sequence of execution that will be used to establish an understanding of the dosage regimen and potential mechanisms of action by which D-Tagatose act so that we can design and execute a phase 2 trial with the best chance of success.

With that, I'll turn the call over to Dr. Robert Lodder to discuss the progress in the animal studies and the data that have been generated to date. He'll also discuss next steps in the clinical program.

Robert Lodder: Thank you, Claire. It is important to point out that in the analysis of our diabetes studies, serum triglycerides were directly correlated with BMI through the months the patient was taking D-Tagatose. Another study published in the literature also showed that serum triglycerides were directly correlated to HbA1c.

Patients with higher HbA1c – that is, patients who reported glucose control – also tended to have higher triglycerides. Taken together, these results suggest a role for adipocytes, fat cells, and the maintenance of glucose and triglycerides levels.

As a result of these analyses of the phase 3 clinical results, we have designed new studies in cell culture, animal models and humans to clarify the mechanism of action of D-Tagatose in modulating triglycerides in glucose in the metabolic syndrome. (Arcero) has been very active since the beginning of the year. Currently, we have eight studies initiated. These eight studies are listed below in the order of expected preliminary results being reported back to us.

First, we have one drug synthesis and formulation study under way. This study also involves the production of radiolabel drug to enable us to track it in the body. Production of the radiolabel drug is on schedule, and this drug is expected to begin to be used in cell culture and animal studies.

Second, we have a human clinical assay development program. This program is producing good preliminary results, demonstrating measurement of D-Tagatose, D-glucose and D-fructose simultaneously in spiked blood bank samples. (The assay) will be used to support (inaudible) studies and PK/PD studies as well as within clinical trials.

The third study is in genetically modified mice on a high carbohydrate diet. These mice normally begin to develop obesity before they develop high triglycerides and atherosclerosis. We expect to have treatment blood measurements soon, which will help us to understand the effect of the D-Tagatose on triglycerides as well as body mass.

Fourth, we have under way a study in wild type hamsters on a high-fat diet. These hamsters develop atherosclerotic disease on that high-fat diet. Conducting this study in a different species satisfies an important FDA regulatory requirements. Testing a high-carbohydrate diet in mice and a high-fat diet in hamsters covers an important fraction of the diet of the U.S. population suffering from metabolic syndrome.

In addition, one of our pipeline compounds, (FPX 10624258), is also being tested in combination with D-Tagatose in both the mouse and hamster models. We also have three cell culture studies in development involving liver cells, fat cells and intestinal cells, and the eighth program is a human clinical postprandial trial with D-Tagatose and control of triglycerides. This trial is like a phase 1 trial, and it's designed to test a small number of patients.

If they do not exhibit any adverse side effects and the pharmacokinetic data are roughly in line with predicted safe values, the dose is escalated, and the group of subjects is then given a higher dose. This is continued until the pre-calculated pharmacokinetic safety levels are reached or intolerable side effects start showing up, at which point the drug is said to have reached the maximum tolerated dose, or MTD.

We expect to randomize patients to this trial in the closing days of December of 2011. The study will screen people with elevated BMIs, probably between

28 and 45, and very high triglycerides levels. The details of the protocol will be dependent on what we learn from our animal studies.

Back to you, Claire.

Claire Kruger: Thank you, Rob. Before we open up the call for your questions, I just want to reiterate that, in the United States alone, more than 100 million people have elevated triglycerides, as defined as 150 milligrams a deciliter and above. About 10 percent of these are poorly served by current drug regimens. We anticipate that a study in the use of D-Tagatose in patients with high or very high triglycerides could be completed within the next six to eight months, and a triglyceride lowering effect could be observed fairly quickly.

Thus, the path to commercialization is a relatively short one compared to that of oral anti-diabetic medication, while the patent life for D-Tagatose and these new indications remains long. We expect that for the new studies mentioned earlier, it could take approximately three years to complete these studies and trials and attract a pharma partner to complete the triglyceride's development, an additional two to four years to complete all necessary studies for an (NDA) filing.

This concludes our prepared remarks. And now, operator, we're ready to take questions.

Operator: Ladies and gentlemen, if you wish to register for a question for today's question-and-answer session, you will need to press star, then the number one on your telephone keypad. If your question has been answered and you wish to withdraw your polling request, you may do so by pressing the pound key. If you are using a speakerphone, please pick up your handset before entering your request.

One moment, please, for the first question. And your first question comes from the line of Chris Lahiji with LD Micro.

Chris Lahiji: Good morning, you guys. I had a quick question on the loss for 2010. The 7.7 million, was any of that number non-cash items?

Robert Clayton: Well, there's always you know variances between accrual and cash accounting. But it's a pretty accurate reflection, I think, on the cash (inaudible) for the year.

Chris Lahiji: I see. And next question is, after the last two financings, what is the current fully diluted share count of the company?

Robert Clayton: Well, right now, it's like 25 million that's out there.

Claire Kruger: (Inaudible).

Chris Lahiji: And can you guys elaborate as to why cash burn is actually going to go down in the coming months?

Claire Kruger: Compared with the previous years?

Chris Lahiji: Yes.

Claire Kruger: Yes. Well, as you know previously we were in the midst of conducting our phase 2 and 3 clinical trials for diabetes, which are cash intensive. We are – although actively pursuing and in the middle of this development program for triglycerides that we've just described, the amount of cash required to execute those studies is far less than that needed for our phase 3 and 2 clinical trial for diabetes.

Chris Lahiji: I see. Well, thank you so much.

Claire Kruger: You're very welcome.

Operator: Once again, ladies and gentlemen, as a reminder, to register for a question, please press star, then the number one on your telephone keypad. Your next question comes from the line of (Allen Friedman), private investor.

(Allen Friedman): Yes. Is there an expectation for starting a human proof of concept trial?

Robert Lodder: Yes, that's coming up in the fall of 2011. End of summer, we'll have patients randomized.

(Allen Friedman): OK, and how long would that trial be?

Robert Lodder: Well, this is a postprandial study. So a feeding study, as we described, with ascending doses. So the trial will actually only take a couple of days to execute.

(Allen Friedman): Oh, so it's from start to finish from beginning of recruitment until getting results ...

Robert Lodder: Oh, well, recruitment takes six to eight weeks. You have to go through a database of patients to decide and identify the ones that are appropriate. Then they have to go through an (employment) consent process. And they have to pass inclusion/exclusion criteria. So that actually takes quite a bit of time. The execution in the facility for a postprandial trial of triglycerides is very short, though, because triglyceride particles don't last long, eight or nine minutes in the body, and you can actually collect a lot of data in a very short period of time.

(Allen Friedman): I see. So again, you said that would start in the fall?

Robert Lodder: Well, it's actually starting now. But the – you know it's a phased sort of development process. And randomization would be really the key trigger to the – to the starting the actual procedure in the clinic. That's expected to occur sometime late in the summer.

(Allen Friedman): Oh, I see. So in other words, you're shooting for results in the (inaudible). Is that what you're saying?

Robert Lodder: Results before the – yes, before the end of 2011 will be available.

(Allen Friedman): All right. And just – just one more question about that. I know you guys are thinking about a dose and frequency that's different from what you would give to a diabetic, and I read about your theory about how you think the Tagatose may compete with other sugars. So if that's your theory, wouldn't it have to be taken at every meal to be effective?

Robert Lodder: It's currently dosed at every meal. When phase 2 and phase 3, we've done that – we did it that way to basically maximize the effectiveness. However, we don't really have any studies, except this postprandial study, that are going to address the issue of how long it hangs around the body and remains efficacious. So that's something we are working to – this is data that we're working to get.

Claire Kruger: As we said before, we're looking at animal models to help us identify what we would need to know to look at different dosing regimens and where Tagatose is going and how it might be efficacious for this end point. So that human ...

(Allen Friedman): So it's – so it's safe to say that it's – you're thinking it might be possible that a frequency might not be necessary for every meal for efficacy? Is that the possibility?

Robert Lodder: I can tell you that no current studies are designed with three times a day administration. So there are no studies going on this year that are using that model.

(Allen Friedman): I see. And my last question is why is the annual meeting date tentative?

Robert Lodder: Tentative? Where is it listed as tentative?

Claire Kruger: Right now, it's tentatively scheduled for August.

Robert Lodder: So we've put that out in the releases?

Claire Kruger: Yes, (inaudible). And we're relatively certain it's going to be that date.

(Allen Friedman): Oh, OK. All right. Thank you very much.

Operator: As a reminder, ladies and gentlemen, to register for a question, please press star, then the number one on your telephone keypad. Again, that's star one. And there are no further questions at this time. Please proceed with your presentation or any closing remarks.

Claire Kruger: Thank you. In closing, we're very excited about the new possibilities being explored in the current drug development program. We look forward to continuing to update you on our progress. In the meantime, I wish you a good day.

Thank you.

Operator: Ladies and gentlemen, that concludes your conference call for today. We thank you for your participation and ask that you please have a great day.

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