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ADDXF.PK - Full Year 2009 ADDEX PHARMACEUTICALS LTD Earnings Conference Call

Event Date/Time: Feb. 23. 2010 / 3:00PM GMT



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PRESENTATION

Operator

Good morning, good afternoon. I'm Christina, the Chorus Call operator for this conference. Welcome to the Addex Pharmaceuticals full year 2009 financial results conference call. Please note that for the duration of the presentation, all participants will be in listen only mode and the conference is being recorded. After the presentation, there will be an opportunity to ask questions.

(Operator Instructions)

This call must not be recorded for publication or broadcast. At this time, I would like to turn the conference over to Mr. Chris Maggos, Head of Investor Relations and Communications. Please go ahead, sir.

Chris Maggos - *Addex Pharmaceuticals - Head - IR and Communications*

Thanks very much. Today, Vincent Mutel, the CEO, will give an introduction. Tim Dyer, our CFO, will then take you through the financial results, and Vincent Mutel will take you through an update of the pipeline. Vincent?

Vincent Mutel - *Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO*

Thank you, Chris. I will review selected programs later in the call, but first let me address the event that occurred at the end of 2009. As you can imagine, we were very surprised and highly disappointed at the end of 2009 to have to terminate our lead product, ADX10059, after liver toxicity was identified following long term administration in humans.

Since then, we have been able to determine that the issue is specific to ADX10059's chemical structure, which is not shared by any other molecule in our pipeline, including ADX48621. Some people have asked whether this problem may have something to do with the allosteric modulator characteristics of the molecule. And I would like to assure them that this cannot be the case.

As it is a complex issue, I will not spend time on that. But instead I encourage those listening to speak with experts in chemistry and toxicology, as I believe the answer should be very clear to those with the appropriate expertise.



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If we move to the first slide, this first slide is to remind all of you that Addex has successfully developed and is currently exploiting a proprietary allosteric modulator discovery and development platform. Addex continues to leverage its leadership position in the industrialization of the discovery and development of these molecules to build a sustainable pharmaceutical business.

We believe our allosteric modulator discovery and development capabilities make Addex one of the most promising young pharmaceutical companies in the world. Products issuing from our platform represent multiple innovative and truly exciting shots on goal. In short, despite the recent setback, we feel that it is not so much a question of whether or not Addex will succeed, but rather a question of when.

On the following slide, you see the pipeline of the Company. And as many of you know, capitalizing on our un-partnered clinical and preclinical assets is our priority for 2010 and beyond. We hope to demonstrate the intrinsic value of our products and technology by out-licensing the most advanced products of our pipeline, ADX48621, ADX71943 and ADX68692. Each of these products is innovative and unique, offering medical breakthroughs in areas of high unmet medical need.

In addition, we have a large number of highly innovative early stage programs which are attracting the attention of the pharmaceutical industry. Our productive proprietary discovery engine remains a core asset, which will provide a steady stream of exciting novel drug candidates but also partnerships generating near-term revenues.

As Tim will tell you in a few minutes, we are fortunate to have about two years of operating cash. As a result, although we must move fast, we are able to proceed without sacrificing the discovery engine that we believe is the heart of Addex.

Finally, let me remind you that our technology has been and remains validated by our partnerships with Merck & Co. and Johnson & Johnson, and that the potential of return from our partnerships is intact. As one can see, we are potentially eligible for up to about \$1 billion in milestones plus royalties from our two partnership with Merck and the one with J&J.

ADX71149, the mGluR2 positive allosteric modulator, partnered with J&J, entered phase I development in 2009, and we are looking forward to seeing further development in 2010. Our mGluR5 PAM program is in the capable hands of our partner Merck, and they are moving both the lead product, ADX63365, and its backup molecule toward the clinic with diligence.

Last but not least, our mGluR4 collaboration with Merck already reached two preclinical milestones last year. And, as a result, at the end of 2009 Merck made a new commitment of \$1.8 million to cover research costs at Addex, in addition to the original terms of our partnership, which was first signed in late 2007 (Company corrected after the conference call).

So both the immediate and long term perspectives allow us to devise with confidence our recovery. We are working to reward our shareholders in a fast and sustainable manner. And with this, I'd like to hand over the call to Tim Dyer, who will walk through -- you through our 2009 financial results. Tim?

Tim Dyer - Addex Pharmaceuticals - Co-Founder, CFO

Thanks, Vincent, and good afternoon, ladies and gentlemen. Before going through the details of the 2009 financial results, let me give you some highlights. So we're pleased to be able to report cash burn at the low end of our guidance of CHF42.9 million and a strong cash balance of CHF76.6 million at the end of the year.

2010 revenues came in at CHF4.5 million and our operating loss for 2010 was CHF42.7 million. We've put a number of cost control strategies in place and, as a result, our cash burn guidance for 2010 is CHF30 million to CHF35 million.

So now for the details, starting with the balance sheet. In 2009 our cash and cash equivalents position decreased by CHF42.9 million to CHF76.6 million. The net cash outflow is driven primarily by the cost of operations and, to a lesser extent, capital investment made during the period.



Other current assets have decreased by 41% due mainly to lower amounts of withholding tax reclaimable and accrued interest income at 2009 yearend compared to 2008. Other current assets relate primarily to recoverable taxes and prepayments.

Our property plant and equipment position net of accumulated depreciation increased by a modest 6.5% to CHF9.7 million. Investment in property plant and equipment during 2009 amounted to CHF3.3 million compared to CHF6.1 million in 2008. This amount was partly related to equipment and refurbishment costs of the research facilities at both Plan-les-Quates and a little bit in Archamps in France.

Payables and accruals amounted to CHF10.2 million at the yearend 2009 compared to CHF11.5 million at the end of 2008. The decrease of CHF1.3 million is primarily due to reduced amounts payable or accrued under ongoing preclinical and clinical studies.

Deferred income amounted to CHF700,000 at yearend 2009 compared to CHF1.9 million at the end of 2008. 2009 deferred income relates to a technology access fee and research funding received from Merck & Co. under the mGluR4 positive allosteric modulator collaboration, which was entered into on November 30, 2007, and extended on November 30, 2009. I'll be covering the income recognition of this agreement later in the presentation.

Other noncurrent liabilities relate to accrued pension costs, which result from the IFRS19 retirement benefit obligation calculation. At the 2008 yearend, this represented a small deferred cost which were recorded in other noncurrent assets. Shareholders equity has moved in line with the reduction in the cash balance, as you can see on the slide.

Moving on to the statement of income, revenues amounted to CHF4.5 million in 2009 compared to the CHF26.9 million in 2008. The significant decrease of CHF22.4 million is mainly due to the CHF24.8 million upfront fee we received from Merck & Co. under the mGluR5 positive allosteric modulator out-license agreement, which we signed in January 2008. This upfront fee was recognized in full in January 2008, as we have no continuing involvement in the program.

In 2009, revenues included CHF2.6 million from Merck & Co. under the mGluR4 PAM collaboration. This amount relates to the second research milestone, which was achieved in July, and a technology access fee and a small amount of research funding. The remaining amount of revenues relate mainly to the CHF1.5 million from J&J, which was received on the entry into phase I of ADX71149, which is the lead compound in our mGluR2 positive allosteric modulator collaboration.

Moving on to R&D expenses, these have slightly decreased to CHF40 million in 2009 compared to CHF44.2 million in 2008. This 10% decrease reflects the measures taken to control costs associated with our discovery and development capabilities. G&A expenses remain stable at CHF7.6 million in both 2009 and 2008, which again reflects the decision to limit growth in 2009 after significant growth that we saw in 2008.

The net finance income amounted to CHF0.4 million in 2009 compared to CHF2.8 million in 2008, an 87% decrease, which is primarily due to lower interest rates and, to some extent but to a lesser extent, on the lower average cash balance.

The net loss increased significantly to CHF42.7 million in 2009 compared to CHF22.1 million in 2008, mainly due to the significant decrease in the revenues, while expenditures slightly decreased. Basic and diluted loss per share also increased accordingly, CHF7.44 per share in 2009 compared to CHF3.85 in 2008. It's important to note that the magnitude of the net loss is significantly influenced by the timing and the financial terms of the new licensing agreements and timing of milestones under existing agreements.

The next slide is an analysis of the headcount development. I'd like to point out that in line with our decision to limit growth in 2009, we had net new hires of nine R&D staff in 2009, which represents a 6.5% increase in total headcount. Of the total headcount of 144 at the end of the year, 118 are in R&D and 26 are in G&A, which includes business development, HR, finance, IR and other support functions related to running discovery laboratory facilities.



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Moving on to the analysis of the cash flows. So, the purpose of this slide is to reconcile cash and cash equivalents over the reporting period. So we started the year with CHF119.5 million of cash. We used CHF42.3 million in operations and we invested CHF4.2 million in CapEx.

This was compensated by CHF2.9 million of cash inflows from Merck and from J&J under the licensing agreements, also CHF0.4 million of interest income and forex gains and a small amount related to the issue of shares under the Addex share option plan. This resulted in CHF76.6 million at the end of 2009.

So, based on current expectations, which include the preparation of 48621 phase IIb development, which is scheduled to start in quarter four 2010, and the advancing of our current discovery and preclinical portfolio, we expect 2009 full year cash burn to be in the range of CHF30 million to CHF35 million.

Now, moving on to the accounting treatment of the deal related revenues, firstly, under the agreement with J&J we received a milestone payment of CHF1.5 million for the entry of 71149 in phase I testing. This occurred in July. This was -- sorry. This was achieved in June and due to the fact that we have no continuing involvement in the development, the full amount was recognized in June.

Secondly, under our mGluR4 PAM collaboration agreement with Merck, we achieved a second research milestone of \$500,000 in July 2009 due to our active research efforts. As part of this collaboration, we are required to recognize this milestone over the period of the continuing involvement, which is type of achievement was July through until the end of the original research term of November 2009.

We also received a technology access fee of \$250,000 which is being recognized over the extended research period, which is December 2009 through till November 2010. The extension of the research phase of this collaboration, which was announced in December of last year, provides for \$1.8 million of research funding. This amount is being received quarterly in advance and is being all recognized on a straight line basis from December 2009 through to November 2010.

And moving on to the next slide, we have an update on the share information. So at the end of the year 2009, the total number of outstanding common shares is 5,871,243 and conditional capital is CHF2,922,496, compared to 5,862,492 shares and CHF1,993,746 at December 31, 2008. This small increase of 8,750 shares is due to the exercise of share options by employees under the Addex share option plan, which occurred during the year. The yearend 2009 free float is 99% and market capitalization today is around CHF71 million. And now I will hand over to Vincent, who will review our product pipeline.

Vincent Mutel - *Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO*

Thank you, Tim. So, as I said before, our expectation for cash flow is foreseen through the potential out-licensing of our most advanced product and as well from the milestone payment that we are expecting to come from the partnered molecules.

So, I'd like to focus first on our un-partnered programs and give you a flavor of what is our perception of the value of the products that we have currently in development, beginning with our most advance asset, ADX48621. As you know, this compound is an mGluR5 negative allosteric modulator that comes from a different chemical series than the product we discontinued in 2009. It has a different metabolic profile and is not expected to have the same issue that we have seen with ADX10059.

We are developing ADX48621 for Parkinson's disease levodopa induced dyskinesia. This mechanism of action, the mGluR5 inhibition, is clinically validated for PD-LID, thanks to the work done by Novartis with their product, AFQ056, which is now in phase IIb testing. ADX48621 has completed three Phase I trials in 110 healthy volunteers, including older subjects, and achieved satisfactory pharmacokinetic, safety and tolerability with single and repeated dose administration.



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Addex disclosed that ADX48621 showed strong efficacy in the MPTP model of Parkinson disease levodopa induced dyskinesia. Furthermore, ADX48621 appears to be highly differentiated from other products in development for PD-LID by the fact that it displayed efficacy on both components of dyskinesia, chorea, which is the trembling, and dystonia -- this is particularly interesting -- painful cramping. No other product in development or on the market has been reported to have efficacy on dystonia so far. And a phase IIb study of ADX48621 is scheduled to begin during fourth quarter of 2010.

As you may know, PD-LID also is a commercially exciting indication where there is an important and growing unmet medical need that commands premium pricing. Although we are looking to partner ADX48621, we will retain co-development and co-marketing rights in some territories. This would allow Addex to establish control over our own revenue stream through product sales as early as 2016, providing the basis for a substantial and sustainable business.

Now turning to ADX71943, it's a GABA-B positive allosteric modulator in late preclinical development, which is scheduled to start phase I testing in fourth quarter of 2010. And this is a compound which we are actively looking to out-license. While efficacy of 71943 was similar in preclinical model of pain, which is on the next slide, compared to the marketed GABA-B agonist, baclofen, ADX71943 demonstrated markedly better tolerability in the same models.

As a result, it has potentially a wider range of indications, including osteoarthritis pain and other types of nociceptive pain. Again, like ADX48621, this product has a first-in-class potential in a very large and growing market where existing drugs have important limitations. ADX71943 is the only GABA-B positive allosteric modulator available on the market for out-licensing, to our knowledge. And we have great expectations for the business development activity we have with this compound.

Then the next molecule is ADX68692, which is an orally active, follicle stimulating hormone negative allosteric modulator that has potential for the treatment of endometriosis and benign prostatic hyperplasia. Preclinical studies have demonstrated the ability of ADX68692 to reduce estradiol levels in females and testosterone production and prostate weight in vivo in males. As these indications fall outside of our three core areas of therapeutic focus, which are CNS, metabolic disorders and inflammation, we look forward to out-licensing ADX68692.

Now I will turn to our partnered programs, starting with the collaboration we have with Ortho-McNeil. As I mention earlier, in June 2009 our partner, Ortho-McNeil-Janssen, a J&J subsidiary, initiated a Phase I trial with ADX71149, an mGluR2 positive allosteric modulator in development for the treatment of schizophrenia. And J&J is responsible for funding and performing all future development and commercialization of ADX71149. We have already received and are eligible for milestone and royalties with the development of this compound, which should move fast now to further steps of development.

Regarding 63369 -- rather 63365, sorry, as you know, this compound, our mGluR5 positive allosteric modulator, is in late preclinical studies and is being developed and is fully funded by our partner Merck & Co. ADX63365 is being evaluated by -- as a potential treatment for schizophrenia. It is a very differentiated mechanism of action, in particular showing activity or potential activity in positive symptoms, negative symptoms, but also cognitive impairment.

Finally, we are very pleased when in late 2009 Merck extended our mGluR4 positive allosteric modulator Parkinson disease research agreement for an additional year. I think many of you missed the fact that Merck agreed to cover research costs at Addex, committing to pay \$1.8 million over and above the original terms of the deal signed in late 2007. The Merck decision followed the achievement of the first two preclinical milestones, showing that the collaboration has yielded orally available mGluR4 positive allosteric modulator with efficacy in an animal model of Parkinson disease.

Let me take this opportunity to remind you that we have a co-marketing option as well on this mGluR4 positive allosteric modulator deal. And as a result, Addex is well positioned to build a franchise in Parkinson's and other neurological disorders.

Last but not least, turning to our pipeline, I'd like to draw your attention to some of the projects in discovery. These early stage projects, like the GLP-1 positive allosteric modulator program or the TNF receptor 1 or IL-1 negative allosteric modulator



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programs, may provide some exciting preclinical data later in this year. This, in turn, could catalyze early -- new early stage partnering activity at Addex.

We look forward to advancing these scientifically and commercially exciting programs and unlocking their value for our shareholders. We are planning an exciting R&D Day quite soon and hope to communicate the date of this event in the near future. And with this conclusion, I would like to open the call for your question.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions)

The first question is from Mrs. Philippa Gardner, Jefferies International. Please go ahead, madam.

Philippa Gardner - Jefferies International - Analyst

Oh, hello there, Vincent. I have a question just on the sort of the partnering discussions that you're having. And you mentioned that you're keen to partner your most advanced products and you mentioned three of them. I'm just wondering, out of those three products, where are you -- where is the most excitement coming from in terms of potential partners? Which is the one where you're having the most discussions about? And I guess sort of with that in mind, are you willing to say which of these you might partner first and sort of what the timelines for that might be? Thank you.

Vincent Mutel - Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO

Yes, thanks. Very good question about the out-licensing. I have to say that we have very strong discussions for the two most advance molecules, so 48621 and 71943. I think coming from the results we have and coming also from the interest, I think the differentiation of these molecules is so clear and so large that there is no difficulty to find interested parties.

Now, to tell you which one is going to be the first, well, that is a bit difficult. I hope both together. I don't know. We see less traction for the molecule for the BPH and which is quite normal because it's a more restrained number of potential partners. It's also a market which is a bit more difficult. And the differentiation of the molecule we have because of the data we have which are quite partial, is probably not large enough. But I see the two first ones very positively.

Philippa Gardner - Jefferies International - Analyst

And can I just ask a follow-up to that? I mean in terms of when you're thinking about who your ideal partners are, would you prefer to partner the molecules with different partners or having the same partner for a number of programs within your pipeline? Is that an option or would you prefer to kind of go with a number of different partners so that you're not sort of tied up with one partner -- ?

Vincent Mutel - Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO

No, we are having all type of possibilities currently. We are having discussion for the two compounds with the same partner. We also have different discussions with different partners for only one of the two compounds. I mean we have all the geometries.

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I should say that for me it doesn't matter very much. These compounds are advanced in our development. It's the time to find a good partner to move them forward because of the nature of these indications, because of the way we want to speed up now the development and make sure that the compounds are going to go even faster, in particular due to their differentiation. So, no, I don't think we are particularly having a problem to have multiple partner for the two compounds. But it might be that we will find at the end the same partner for both.

Philippa Gardner - *Jefferies International - Analyst*

Okay, perfect. Thank you.

Operator

Next question, Mr. Robin Davison, from Edison Investment Research. Please go ahead.

Robin Davison - *Edison Investment Research - Analyst*

Right. Hello there. First of all, I just wondered if you could give any sort of guidance on the likely R&D expenditure in 2011. I mean obviously you've given cash guidance for 2010, but it really will be next year when you've got the 48621 phase II study that there's going to be a significant cost. Presumably it will increase. That was the first question.

I also wondered if there were any exceptional costs regarding the 10059 trials -- are you sort of closing those out, that fall into this year, the 2010 year. And thirdly, I just wonder whether there was an intention to study the 71943 in urinary incontinence and GERD, which I think has previously been indicated as well.

Tim Dyer - *Addex Pharmaceuticals - Co-Founder, CFO*

Okay, so I'll take the first two parts of that question and then I'll hand over to Vincent for the urinary incontinence question. So we're not giving -- there's too many variables, so we're not actually giving guidance for 2011. What I can say is that the majority of 48621 costs do fall into 2011. We had significant 59 costs in 2009. And our cash -- our clinical cash burn is significantly reduced during 2010.

Now, regarding the specific question on 59, we do have some -- in fact, it's more a question of having cost savings because the migraine trial was terminated early, rather than there actually being additional costs. So, in fact, there are less costs which were expected in 2010 than prior to the termination regarding 59. I'll hand over to Vincent.

Vincent Mutel - *Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO*

Yes. Well, regarding the urinary incontinence and GERD, essentially the development we have and the results we obtained with the pain indication and all the aspects which are associated with the risk benefit in this indication is leading us more now to prioritize this one. Now, for sure, a drug of this kind can be developed for GERD -- because it's a powerful mechanism of action with the GABA-B -- and urinary incontinence. But we are not going to invest in any of these indications in the preclinical or in the clinical development. We believe that it is much more efficient, and in term of cost as well, much better to use the funds we have to be able to demonstrate a clear differentiation of the molecule in, for instance, osteoarthritis, osteoarthritic pain, which is quite valuable and high unmet medical need for the industry. And this is what we are currently going to do.



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Robin Davison - Edison Investment Research - Analyst

Right. But the phase I study will be in healthy volunteers?

Vincent Mutel - Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO

For sure. I mean, you know this is -- it's always easy in this type of indication and at this stage of development to do pharmacodynamic studies in man, even in phase I.

Robin Davison - Edison Investment Research - Analyst

Right. Can I ask if you can give an indication of the size in terms of numbers of patients of the 48621 phase IIb study that you're envisaging?

Vincent Mutel - Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO

Yes, we are contemplating 140 patient. It's -- the protocol is being finalized. I don't want to go too much to the detail because my Chief Medical Officer will otherwise be very upset. So at the time being, we want to do a phase IIb. We want to conduct something which is significant in term of size. And particularly we don't have a lot of choices as well in terms of the way to move forward because PD-LID is not an indication per se, so you have to develop more or less a trial for Parkinson disease itself.

And so in this regard, the size of the trial and the way we are going to move is highly condition by the indication itself. So it's around 150, 200 patient. It's a long term dosing, so at least 12 weeks dosing, and so on and so forth. I cannot give you more color than that because we are having a lot of finalization with all the investigator about the protocol.

We want to also look at a number of parameter which are very important for the differentiation of this product, in particular the dystonia and so on and so forth. That is why for the time being it's a bit too early to give more details.

Robin Davison - Edison Investment Research - Analyst

Right. I also wanted -- I mean to what extent is that trial start dependent on a possible licensing or partnership deal for that product? I mean would you still start it if you didn't have a deal, for example?

Vincent Mutel - Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO

The (inaudible - microphone inaccessible) drug in development is conditioned by our ambition to have it on the market by the right time. So for the time being I cannot give you any idea of deal or not deal. What I can tell you is that if we want to be on time, we have to initiate the activity that we are currently initiating. As you can believe, there's a lot of things to do to prepare a phase IIb program. And we have to do it. And by the way, the partner we will have or we may have are going to be very sensitive to that as well. It's part of the -- it's certainly part of the equation to have the possibility to start as soon as possible.

Robin Davison - Edison Investment Research - Analyst

Right. Okay, thank you very much.

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Operator

(Operator Instructions)

We have a question from Mr. Mike Aitkenhead, Piper Jaffray. Please go ahead, sir.

Mike Aitkenhead - Piper Jaffray - Analyst

Good afternoon, and thanks for taking my question. It really is just a follow-up to Robin's question about the 621 study. Based on your current cash runway, which is two years of cash left, do you believe that you'd be in a position to continue that study and deliver at least some data readout from it? I'm just trying to reconcile your cash window with what is the expected duration of a 140-patient trial would be.

Tim Dyer - Addex Pharmaceuticals - Co-Founder, CFO

Yes. Our calculations are that we would be able to read that study out before we ran out of cash.

Mike Aitkenhead - Piper Jaffray - Analyst

Brilliant. Thanks.

Operator

(Operator Instructions)

[At the moment] there are no more questions at this time.

Chris Maggos - Addex Pharmaceuticals - Head - IR and Communications

Thanks very much, Vincent, do you want to --

Vincent Mutel - Addex Pharmaceuticals - Vice-Chairman, Co-Founder, CEO

Thank you all for your attendance and for the time. And it was, I think, very important for us to stress again the belief, the strong belief we have in our productivity and the work which have been doing. I think we have deliver regularly on milestones, this company has achieved regularly with time all along the years and we have been developing something which is outstanding. The value is there. We have to clearly show it to the world and give the return to our shareholders. This is what the Company is currently focused on and I hope we will be able to come as soon as possible with the excellent news that, yes, indeed, we are back on track.

Chris Maggos - Addex Pharmaceuticals - Head - IR and Communications

Thanks very much. Have a good day, everybody.

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Operator

Ladies and gentlemen, the conference is now over. Thank you for choosing the Chorus Call facility and thank you for participating in the conference. You may now disconnect your lines. Goodbye.

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