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Beyond Air, Inc. (XAIR)

Q2 2023 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon and welcome to the Beyond Air Second Quarter 2023 Earnings Call. All participants will be in a listen-only mode. [Operator Instructions] After today's presentation, there will be an opportunity to ask questions. [Operator Instructions] Please note that this event is being recorded today.

I would now like to turn the conference over to Ed Barger. Please go ahead, sir.

Edward J. Barger

Head-Investor Relations, Beyond Air, Inc.

Thank you operator. Good afternoon everyone and thank you for joining us. Today, after market close, we issued a press release announcing the second quarter of fiscal year 2023 operational highlights and financial results. A copy of this press release can be found on the Investor Relations page of our website.

Before we begin, I would like to remind everyone that we will be making comments and various remarks about future expectations, plans and prospects, which constitute forward-looking statements for the purposes of the Safe Harbor provisions under the Private Securities Litigation Reform Act of 1995. Beyond Air cautions that these forward-looking statements are subjects to risks and uncertainties that could cause actual results to differ materially from those indicated.

We encourage everyone to review the company's filings with the Securities and Exchange Commission, including, without limitation, the company's most recent Form 10-K and Form 10-Q, which identify specific factors that may cause actual results or events to differ materially from those described in the forward-looking statements. Additionally, this conference call is being recorded and will be available for audio rebroadcast on our website, www.beyondair.net.

Furthermore, the content of this conference call contains time sensitive information that is accurate only as of the date of this broadcast, November 8, 2022. Beyond Air undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this call.

Joining me on today's call are Steve Lisi, Chairman and Chief Executive Officer; Duncan Fatkin, Chief Commercial Officer; and Douglas Larson, Chief Financial Officer.

With that, I would turn the call over to Steve Lisi. Steve?

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Thanks, Ed, and good afternoon to everyone joining us. I'd like to take a moment to welcome Ed Barger to the Beyond Air team. Ed is our new Head of Investor Relations, and we're very fortunate to have someone with edge experience, which includes some time on Wall Street and the last eight years on the investor relations teams at Teva and Organon.

Turning to our review of the business, on today's call, I'll begin by providing an update across our portfolio, including Beyond Cancer before turning it over to our Chief Commercial Officer, Duncan Fatkin, for an update on the LungFit PH commercial launch. This will be followed by an overview of our financial results for the quarter by our Chief Financial Officer, Douglas Larson, and then we will open the call up for questions.

Let me start by stating that we continue to successfully execute our strategy across our pipeline, which is a testament to the quality of our team and our LungFit therapeutic platform of nitric oxide generators targeting pulmonary diseases. Leading the way is our commercial program for LungFit PH that received FDA approval in late June. As a reminder, this is our first commercial product and we believe it has the potential to revolutionize the treatment of persistent pulmonary hypertension of the newborn or PPHN and cardiac surgeries around the world.

The sales and marketing teams have been working hard over the past few months implementing the initial phase of the commercial launch. I am very pleased with their progress thus far. Perhaps most important is that the feedback from hospitals remains very positive. As we look ahead, the team is on track with the commercial timeline we have in place and we anticipate being able to progress to Phase 2 of our launch in the second quarter of calendar year 2023. We also anticipate launching internationally through a partner next year given our current expectation of receiving CE Mark in Europe by the end of 2022. We will provide more information on our global strategy as these matters unfold.

Turning now to our development pipeline, which has delivered several data announcements at recent scientific conferences. We're excited to present favorable safety, tolerability and efficacy data from the LungFit GO at-home study of patients with severe treatment refractory nontuberculous mycobacteria or NTM lung disease during a rapid oral session at the CHEST annual meeting last month. These data show that high concentration inhaled nitric oxide was well-tolerated following a total of 2,492 inhalations self-administered at home with no treatment-related discontinuations reported and an overall high treatment compliance rate, above 90%.

Respiratory function and physical function were maintained during treatment end to 12-week follow-up period. Key efficacy endpoints of quality of life and bacterial load reduction showed strong results with improvements seen in the majority of quality of life domains and a statistical reduction in bacterial load four months after NO treatment began or one month after cessation of NO therapy. It is important to note that according to the FDA's

most recent guidance for an NTM pivotal study, a patient reported outcome or quality of life questionnaire is the required primary endpoint with bacterial load as a secondary endpoint.

In addition to further supporting the development of intermittent high dose NO for the treatment of NTM, this study breaks new ground by successfully showing the ability of our at-home NO generator-based system to be used safely and consistently by this patient population in a real-world setting. We believe there is an enormous home market opportunity for the LungFit GO in treating NTM as well as other respiratory conditions, if approved. To expand the landscape for both LungFit PRO and GO, we are currently planning to initiate a pilot study in late 2023 that will evaluate the LungFit GO treating severe exacerbations due to lung infections in COPD patients. This, of course, is pending discussions with FDA.

Moving on to our viral lung infection program, which uses the LungFit PRO system at 150 parts per million NO to treat viral community-acquired pneumonia or what we call VCAP in adults and bronchiolitis in children under two years of age. Last month, we presented positive incremental data from the completed LungFit PRO pilot study of high concentration inhaled NO in VCAP, including COVID-19 in a poster presentation at Infectious Disease Week 2022.

These data show that NO treatment with the LungFit PRO was well-tolerated overall with no treatment-related serious adverse events and improved efficacy on multiple parameters compared to standard supportive treatment. Our next milestone for this indication will be discussion with the FDA over the next few months on a US trial design with the intention of starting such a study in the fourth quarter of calendar year 2023. As a reminder, under this program, we've already conducted a total of four studies with NO concentrations of 150 parts per million or more in hospitalized subjects suffering from viral respiratory infections. All of these studies have shown a strong safety profile with consistently positive results on efficacy. Considering these data, we believe [indiscernible] (00:07:58) NO delivery with LungFit PRO can be a powerful tool against any type of pneumonia, especially COVID-19. And we remain dedicated to bringing this important therapy to market as soon as possible.

And to conclude our highlights for the pipeline, we like to remind everyone that we have now completed an adult pneumonia study, three bronchiolitis studies, two NTM studies along with several other studies to give us in excess of 5,000 NO administrations at 150 parts per million to 250 parts per million to over 170 patients with an excellent safety profile.

Moving to our private affiliate Beyond Cancer. In late August, we announced that the first patient was treated in the Phase 1 clinical trial to evaluate the maximum tolerated dose, safety and efficacy of our UNO therapy or ultra-high concentration nitric oxide for patients with cutaneous solid tumors in the refractory setting. We are excited to announce that we've already seen evidence of an immune response at the low dose of 25,000 parts per million nitric oxide.

While still early, this is extremely encouraging. We anticipate announcing initial data from the study in the first half of 2023. Beyond Cancer will present pre-clinical in vivo data at the SITC Conference this Thursday, which will show that the combination of UNO therapy with anti-PD1 achieved higher tumor regression rates and prolonged survival in CT26 tumor-bearing mice compared with anti-PD1 alone. Based on this study, we believe there is a strong possibility that high concentration NO assists the immune system in overcoming anti-PD1 resistance.

As a result, we believe the combination of high concentration NO and immune checkpoint inhibitors such as anti-PD1 could be a potential breakthrough therapy with important clinical implications. I encourage everyone to review the full dataset on Thursday.

One last point to make on Beyond Cancer is that we very recently received a notice of allowance from the US Patent Office for our first patent, an important milestone.

Now it is with great pleasure that I hand the call over to Duncan Fatkin, the Chief Commercial Officer of Beyond Air, to speak about the first few months of US commercial launch for the FDA approved LungFit PH. Duncan?

Duncan Fatkin

Chief Commercial Officer, Beyond Air, Inc.

Thanks, Steve, and good afternoon to our investors. The past few months have been extremely productive for the Beyond Air team as we kicked off the initial phase of our commercial launch of LungFit PH. During this time, we have been busy implementing and executing against our go-to-market strategy, which includes a multi-phased commercial approach. The initial phase represents a measured release of LungFit PH to a select group of hospitals that have Level 3 or Level 4 NICUs and staff experienced with inhaled nitric oxide.

I am very pleased to report that our team has already conducted dozens of demonstrations of the LungFit PH system to the staff at these hospitals and trained well over 100 respiratory therapists from which the feedback continues to be overwhelmingly positive. As anticipated, the hospitals we visited so far are highly motivated to eliminate cylinders. In addition, the most common feedback we get when we demonstrate or run a training session is that the system is simple and easy to use, offering the potential to eliminate steps in the previous setup and allow respiratory teams to focus more on patient care, which is especially important as demands on their time have increased dramatically since the onset of COVID. Our goal with the initial limited and highly controlled release is to make sure that everything runs smoothly. Over the first six to nine months, our team is working closely with hospital staff to ensure that Beyond Air has optimized our logistics, customer service and product performance. We expect these initial hospitals will have a sufficient volume of hours per month to provide a rigorous test for LungFit PH and the Beyond Air team.

We are also attending local and national respiratory conferences to raise awareness of LungFit PH and set ourselves up for success during this period. In fact, we're in New Orleans this week for AARC, the premier conference for respiratory therapists, which is the perfect opportunity for us to give key decision makers from hospitals throughout the US some hands-on experience with our LungFit PH system. We encourage all of you to attend from tomorrow through Friday if you have the opportunity.

We will use the learnings from the first phase of our launch to ensure that we are ready to significantly broaden our sales effort in the spring of 2023. During the second phase, we will be expanding our commercial team, both field sales and clinical specialists and capitalizing on the leads generated during the demonstrations completed throughout our controlled launch period. This is a very exciting time for our team, as we start our commercialization journey in the US.

Also, as Steve mentioned earlier, we remain on-track to submit our supplemental PMA to FDA for an expanded cardiac label before the end of 2022. In addition, we anticipate the CE Mark for LungFit PH will be granted around the end of 2022.

I'm very encouraged with the speed of which we have mobilized our field team, the access we've been granted in these first few months since approval and the very positive response to our LungFit PH system. I look forward to sharing more of our progress early in 2023.

I will now turn the call over to Douglas Larson, our Chief Financial Officer, to provide an overview of our financial results for the fiscal quarter ended September 30, 2022.

Douglas Larson

Chief Financial Officer, Beyond Air, Inc.

Thanks, Duncan, and good afternoon to our investors. Our financial results for the second quarter of our fiscal year 2023, which ended on September 30, 2022, are as follows. On a GAAP basis, research and development expenses for fiscal quarter ended September 30, 2022, were $4.5 million, compared with $2.8 million for the fiscal quarter ended September 30, 2021. This increase is almost exclusively due to investments in Beyond Cancer and Project UNO.

On a GAAP basis, general and administrative expenses for the fiscal quarter ended September 30, 2022, increased to $8 million, compared with $3.4 million for the fiscal quarter ended September 30, 2021. This is mostly attributable to the planned staffing and scaling up of Beyond Cancer in both the US and Israel as well as continued investments necessary to support the commercial launch of LungFit PH in the US.

Other income and expense for the fiscal quarter ended September 30, 2022, was a loss of $0.2 million compared with a loss of $2.5 million for the fiscal quarter ended September 30, 2021. If you recall, in the prior year, we recorded a $2.4 million contingent liability related to a lawsuit in our second quarter.

For the fiscal quarter ended September 30, 2022, the company had a GAAP net loss of $12.8 million of which $12 million or $0.40 per share was attributable to the shareholders of Beyond Air, Inc. compared with a net loss of $8.7 million or $0.36 per share for the fiscal quarter ended September 30, 2021. Net cash used by the company or cash burn, including Beyond Cancer, was $10.4 million during the quarter ended September 30, 2022, which includes a $2.5 million payment to Circassia in accordance with our settlement agreement. During the first half of the fiscal year, total cash burn has been $17.9 million.

I would like to point out that you will see a shift of $32.6 million from cash to marketable securities in this quarter. Since we are now a commercial company, we have started looking for ways to optimize our future cash inflows. This is just the first step in that direction. As of September 30, 2022, the company reported cash and cash equivalents, marketable securities and restricted cash of $72.5 million. We still forecast that our average quarterly cash burn for fiscal 2023 to be within a range of $8 million to $10 million and expect that we will start recording revenue in our fourth fiscal quarter. As such, we believe our current cash and cash equivalents are sufficient to fund operations well beyond the next 12 months, including through the initial commercial launch phase of LungFit PH in the US.

And with that, I'll hand the call back to Steve.

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Thanks, Doug. Operator, let's go to the Q&A.

QUESTION AND ANSWER SECTION

Operator: We will now begin the question-and-answer session. [Operator Instructions] And our first question here will come from Suraj Kalia with Oppenheimer. Please go ahead.

Suraj Kalia
Analyst, Oppenheimer & Co., Inc.

Q

Good afternoon everyone. Steve, can you hear me all right?

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Yes, I can. Thanks, Suraj.

Suraj Kalia
Analyst, Oppenheimer & Co., Inc.

Q

Perfect. Hey everyone, congrats on the progress. So Steve or Duncan, in terms of your original plan, commercial plan for targeting certain NICUs, I'd love to get – maybe you could quantify for us how many initial sites are under evaluation? How is the process flowing through? You all are obviously seeing something that in fiscal Q4 some of these will get converted into revenues. Maybe if you can just quantify and put some guideposts around this effort would be great.

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Hey, Suraj. So, Steve here. So, everything's going pretty much as we expected it to go. Feedback is very good, as Duncan stated in the prepared remarks. And yeah, we're in the process of going through demonstrations and evaluations that lead to commercial contracts. And this is a lead time in hospitals that takes several months as you know. So, we're not going to put any parameters on numbers of hospitals or quantifying anything that we think is going to happen at this time. So, we'll leave that for future calls to discuss those in more detail.

Suraj Kalia
Analyst, Oppenheimer & Co., Inc.

Q

Okay. And Steve, the international partnership for LungFit PH, I presume you all are in relatively advanced stages of discussion with some potential partner?

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Well, we're definitely talking to partners. I'm not going to discuss at what stage we're at, but we're certainly talking to people. And again that's going to be really hinging – hinged upon the CE Mark, when it comes. So hopefully it comes in a timely manner. But again, those things are out of our control.

Suraj Kalia
Analyst, Oppenheimer & Co., Inc.

Q

Got it. And finally, Steve, from my side, or maybe even Duncan can jump in. Would love to get your perspective on INOMAX EVOLVE, just given the form factor is changing, the mobility part, the automated set up, the 1-pound

cylinder. I'd love to get your thoughts as Mallinckrodt looks to get – submit the 510(k) and at least all indications are by next year they should be on the market with EVOLVE and I'd love to get your perspective as you see it today. Gentlemen, thank you for taking my questions.

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Thank you, Suraj.

Duncan Fatkin
Chief Commercial Officer, Beyond Air, Inc.

A

Thanks, Suraj, for the question. I'll take that. This is Duncan. So obviously I will focus on LungFit PH. I can't reveal specific details about the direction that Mallinckrodt are going in, but obviously we're aware of their plans for next generation design. Our focus is to implement our Phase 1 strategy, which won't be affected by the launch of any other system because there's so many opportunities for us. What I will say is that we continue to reinforce the unique features of our 3-in-1 design and the fact that we use room air to generate nitric oxide, which has been reinforced probably even more significantly than I would have expected. There's definitely a desire to get rid of cylinders, whatever the size of those cylinders and I think that momentum will continue and actually accelerates. So, we don't see any significant impact from that in the – certainly in the short to medium term and we'll see a major assessment as and when new products enter the market.

Suraj Kalia
Analyst, Oppenheimer & Co., Inc.

Q

Thank you.

Operator: Our next question here will come from Matt Kaplan with Ladenburg Thalmann. Please go ahead.

Matt L. Kaplan
Analyst, Ladenburg Thalmann & Co., Inc.

Q

Hi. Thanks for taking the questions and congrats on the progress. Just wanted to zero in on the launch, and maybe some of the comments that Duncan made in his prepared remarks. I guess you mentioned that you trained over 100 respiratory therapists so far. Can you give us a sense in terms of the typical number of respiratory therapists you would expect to train at each hospital to operate your system?

Duncan Fatkin
Chief Commercial Officer, Beyond Air, Inc.

A

Yeah. So, I think that it depends, because each hospital has a different approach to what constitutes an evaluation. So, some will have a very small group, and they'll be very focused on a particular team, some will widen that. So, as Steve mentioned, we don't want to share specific information about the number of hospitals, but it's clearly a number of hospitals. And so depends on the length of the trial and the number of patients that they want to treat to get the data that they need to progress. So, it varies, and presumably, as we get more and more experience, those numbers will increase, because the whole of the hospital will routinely need to be trained.

Matt L. Kaplan
Analyst, Ladenburg Thalmann & Co., Inc.

Q

Okay. And the feedback from the respiratory therapists and, I guess, beyond the respiratory therapists, others in the hospitals, what has that been like so far?

Duncan Fatkin
Chief Commercial Officer, Beyond Air, Inc.
A

I think that there's a great deal of excitement. This is clearly a big innovation step for them. There's an adjustment because they're used to dealing with cylinders, so they have to change that protocol as appropriate. But what's most common is it's very easy to train the respiratory therapists. They find it very simple to use and very quick to set up. There's no surprises beyond that. And the rest of the time we've used to test our logistics and customer service and so far, so good.

Matt L. Kaplan
Analyst, Ladenburg Thalmann & Co., Inc.
Q

Okay. Great. And just shifting to the pipeline a little bit. Maybe, Steve, can you give us some color in terms of the feedback and the reception that you had at the recent CHEST meeting to the data – the LungFit GO data that you presented for NTM patients?

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.
A

Sure, Matt. So, at the CHEST meeting, the reception was very good. There were several people there we were chatting with after the data were presented. All positive people are excited. Obviously, they want to see a large number of patients treated. And certainly it begs – well, the data out there beg the question of how long do you treat for? Is 12 weeks enough? Can you continue the maintenance therapy for longer period of time? So, was all positive, in my opinion.

So, we'll be discussing with FDA in the first half of next year what that path forward is. For NTM, I think, right now, as it stands, everything's positive, pointing in the right directions. And, as you know, the – what FDA wants to see as a primary endpoint is a patient reported outcome, which would be a quality of life questionnaire, which is what we showed strong data on in these results as well as they certainly want to see impact on bacterial load and we showed a nice reduction. As I mentioned in my prepared remarks, there was a time point where it was significant. So this is what we wanted to see. It's a 15-patient study, a small study, and we saw very positive results and good trends.

So while we're moving forward, we're very excited about the key opinion leaders that are interested in helping us. But again this is a process that will take a little bit of time. We just closed the study in August officially. That would be last patient, last follow up. And then, of course, as you know, [indiscernible] (00:26:18) the data, closing the database, locking it and then, of course, analyzing everything, preparing for FDA. So this is a process that'll take a little bit of time. I wish we could go faster, but it's not really possible, so excitement around it. And we're going to have a little bit of a lull in terms of preparation for the next study in the US, but we should get that up and running in 2024.

Matt L. Kaplan
Analyst, Ladenburg Thalmann & Co., Inc.
Q

Okay. That sounds great. And then last question in terms of LungFit PRO, your planned bio-community acquired pneumonia study in the US, could that be a pivotal study or what are your thoughts there?

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.
A

I think it could be. Yeah. I mean, we'll have to see what FDA agrees to in terms of the overall design of the study and the size of the study. So when we have that information, we'll obviously share it. And we'll make our own

determinations, you and I and everyone else, as to whether it's a large enough study and powered as such to be a pivotal, but we believe it will be.

Matt L. Kaplan
Analyst, Ladenburg Thalmann & Co., Inc.

Q

Okay. Thanks.

Operator: [Operator Instructions] Our next question here will come from Greg Fraser with Truist. Please go ahead.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Great. Good afternoon, folks. Thanks for taking the questions. I want to ask about the cardiac surgery application. Curious if you could talk about kind of the regulatory path and your confidence and success and what the potential hurdles are?

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

A

I'll give it a shot, Greg. So, the path is to go to FDA and explain to them that this is a standard of care. For these cardiac surgery patients when they need nitric oxide, as you know, there's a challenge in the cath lab for patients who may be in need of nitric and during that challenge test, you'll know if they need it or not go along with their surgical procedure. This is done in hospitals across the US, obviously around the world. It's approved everywhere in the world and always available except the United States or maybe the major countries. I don't know about some of the smaller countries, but let's just say in most countries outside the US, it's approved.

So, we'll have to see what FDA requires for this approval. We do feel good about what – the package that we've put together. And I really, honestly, I couldn't tell you what the exact hurdles are, because that's going to be revealed when we discuss this with FDA shortly. So, until we have that discussion, I really don't know exactly what those hurdles are. So, we're having a discussion with FDA prior to submitting the actual application. So, that discussion will take place obviously between now and the end of the year, and we hope for a very quick turnaround post that conversation and we would submit our actual PMA supplement. So, that's, kind of, where we stand. Was there another part for the question? I'm sorry if I missed it.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

No, no, you covered it. Thank you. But related to that, if you can't secure a label expansion or if it takes – let's say it takes some time and requires some additional work, do you expect hospitals to use LungFit PH off-label like they do with the cylinder systems?

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Well, I can't speak for the hospitals. I – it's obvious to everyone that nitric oxide is used off-label today for the competing products that have been out there for longer than we have obviously. It's obvious it's used not just for cardiac surgeries, but also in acute respiratory distress syndrome, which is most related to COVID recently. It's certainly used there. I can't speak to whether they'll use the LungFit in that capacity. It's not something that we promote or we look for. However, there's no reason why our system can't be used in the same vein that other

systems are used in. Again, the major difference is the source of NO, ours being ambient air, the others being cylinders filled with NO or perhaps another competitor has a cartridge that creates NO in a chemical process at bedside.

So, again, the NO that's delivered to the patient is the same NO from the cylinders as it is from our generator. So, I would think that you would see use of all the systems in the same manner. But again, that's going to be up to the hospitals and the physicians. It's not for us to decide. It's for us to just go out there and present our system, what it does, train the respiratory therapists in the neonatal intensive care unit and what happens beyond that is really not up to us.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Got it. Okay. And I just wanted to ask about on Beyond Cancer. I thought you'd mentioned seeing an immune response at the low dose. Were you referring to the first patient that was dosed in the Phase 1 study?

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

A

So I didn't say how many patients it was. I just said it was in the low dose. So what these trials, they're [ph] 3 by 3 (00:31:48) designs. So you usually do a minimum of three patients at each dosing level. So I didn't say whether this was one, two or three patients. I didn't say that at all. It certainly was only at the low concentration. And we – I'm not saying if we have or haven't seen it at a higher concentration yet. I'm just commenting on the fact that based on what we've seen to date, the patient or patients that have been treated at 25,000 parts per million, we have seen an immune response.

Gregory D. Fraser
Analyst, Truist Securities, Inc.

Q

Got it. Okay. Thank you very much.

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Okay.

Operator: With no remaining questions, this will conclude our question-and-answer session. I'd like to turn the conference back over to Steve Lisi for any closing remarks.

Steven A. Lisi
Chairman & Chief Executive Officer, Beyond Air, Inc.

Great. Thanks everyone for joining us today. And I hope to see a few of you down in New Orleans tomorrow and Thursday and Friday at the AARC meeting where we'll be demonstrating the LungFit PH at this largest conference for respiratory therapists and nitric oxide of the year. Thank you.

Operator: The conference has now concluded. Thank you for attending today's presentation. You may now disconnect your lines.