

**Novavax, Inc.**

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H5N1 Phase I/IIa Clinical  
Trial Result Call  
Event Type ▲

Aug. 26, 2008

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**MANAGEMENT DISCUSSION SECTION**

Operator: Good morning, ladies and gentlemen, and welcome to the Novavax Pandemic Influenza Vaccine Phase I and II Results Conference Call. My name is Amy and I will be your coordinator for today. At this time, all participants are in a listen-only mode. We will be facilitating a question-and-answer session towards the end of today's conference. [Operator Instructions].

I will now turn the conference over to Novavax.

**Company Representative**

Good morning. On today's call will be Dr. Rahul Singhvi, President and Chief Executive Officer; John Lambert, Chairman of Novavax Board; Len Stigliano, Chief Financial Officer; and Dr. Penny Heaton, Chief Medical Officer, as well as Ray Hage, Senior VP of Commercial Operations; and Jim Robinson, VP of Technical and Quality Operations, who will be also available for questions on the line later on.

We remind you that during this call, management will make forward-looking statements within the meaning of the Private Securities Litigation Reform Act, which involves risks and uncertainties inherent in our business. Actual results may differ materially from our expectations and you should consider all of the cautionary statements made in our SEC filings and in this morning's press release, including risks related to product development, clinical trials and results from clinical trials and the Company's ability to obtain adequate financing. For a complete statement of these risks, please look to the Novavax website. The conference call will be available for replay after the conclusion of the call.

Dr. Singhvi, please proceed with the call.

**Rahul Singhvi, Sc.D., M.B.A., President and Chief Executive Officer**

Good morning, and welcome to the Novavax conference call for discussion of the first clinical immunogenicity results from Stage B of our Phase I/IIa pandemic influenza vaccine dose ranging study. These results are strong and very competitive and they compare well with any vaccine against pandemic flu, whether licensed or in development. These results support continued development of our pandemic flu vaccine and, in tandem, our seasonal influenza vaccine.

Today is an important day in the history of Novavax and I am delighted to report these clinical trial results from a vaccine that is based on our proprietary common and virus like-particle, or VLP technology. Recall that a VLP is a decoy of the actual virus. It looks like the virus in that it has the same shape and size of the virus and it contains the same surface proteins of the virus, but it lacks the genetic material that is required for replication. So it is not a virus, but in general, the body view it is a virus and responds as if it has been exposed to live influenza virus.

As you might already know, the overwhelming majority of licensed flu vaccines contain only hemagglutinin or HA. The Novavax VLP vaccine is different and unique. Our VLP is made up of not only the viral surface protein HA, but it contains another surface protein, neuraminidase, or NA, and a core protein, matrix M1. We believe that including all three key proteins and presenting them as the influenza virus presents itself in nature offers potential key immunological advantages. The antibody to the HA component blocks the virus from entering a cell; the antibody to the NA prevents spread down the respiratory track; and the M1 response kills the cells that are already infected. We believe that this unique design forms a basis of a potentially more effective vaccine and the clinical results today are evidence of that.

I will give some opening comments about the results and their implications, and then hand over the call to Dr. Penny Heaton, who will be discussing the clinical objectives and the initial immunogenicity trial results from this trial. I will then wrap up with some summary comments before opening the call up for questions and answers.

So let me begin by again stating that I'm very encouraged by the results from this pandemic influenza trial that we announced in our press release earlier today. At a high level, we observed the following: our recombinant VLP vaccine candidate against the Indonesia strain of the H5N1 virus was well tolerated among the individuals in this study and immunogenic at all three doses tested without the help of an adjuvant. We saw a clear clinical signal to support continued development of this novel vaccine to achieve regulatory approval. We now have further supporting evidence that our recombinant VLP approach, coupled with our manufacturing platform, can be used to produce strain match vaccine in time to potentially interrupt and/or halt a pandemic. This feature maybe especially important for countries that are particularly vulnerable and do not have in-border vaccine production capability. Our partnership with GE Healthcare highlights our commitment to offering sustainable, in-border pandemic preparedness solution to these countries. These pandemic VLP vaccine results today provides strong supporting evidence where the technology should perform well, particularly for our seasonal influenza vaccine candidate and perhaps for other vaccines based on our technology.

The accomplishment announced today is an important milestone for Novavax. Last December, we shared results from the first stage of this clinical study. In this first stage, the results showed that the vaccine was immunogenic and well tolerated among the 70 enrolled subjects. At that time we discussed that we were taking steps to optimize the vaccines prior to the initiation of the second stage of the study. Today's results are from that second stage and Dr. Penny Heaton will shortly describe these results in detail. Let me congratulate the Novavax team that has worked so hard to get us here. I am proud of this team and I'm honored to be part of it.

Now I would like to turn the call over to Dr. Heaton, who will discuss today's pandemic flu vaccine trial results.

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**Penny M. Heaton, M.D., Vice President, Development and Chief Medical Officer**

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Thank you, Rahul, and good morning, everyone. First, please let me just take a moment to send a word of thanks to our investigators, the study personnel, our colleagues from the CRO that assisted us with the study, our Data and Safety Monitoring Board members, and the team here at Novavax for their conduct of our study.

I'm going to begin this morning with a brief review of the objectives of the study, followed by an overview of the immunogenicity results, and then I'll close with some additional comments regarding these results from our pandemic influenza vaccine clinical trial.

The objectives of this Phase I/IIa clinical trial of our Indonesia strain H5N1 pandemic influenza vaccine were three fold. First, we assess the safety of the H5N1 VLP vaccine; second, we assess the immunogenicity of the vaccine; and finally, we are going to select at least one dose for further evaluation in a Phase IIb clinical trial.

This study was designed in two stages, which we refer to as Stage A and Stage B. We shared the results from the 70 subjects enrolled in Stage A last December, and in the press release this morning, we shared the results from the second stage of the study, in which we evaluated the safety and immunogenicity of the vaccine at three different doses as compared with placebo. The 160 subjects enrolled in Stage B were to receive two injections of vaccine, spaced approximately four weeks apart at one of three doses: either 15 micrograms, 45 micrograms or 90 micrograms or

placebo. Subjects were followed for all adverse events through 28 days after the second dose and they are continuing to be followed for serious adverse events for six months after the second dose. This follow-up will be completed in the fourth quarter.

The results of the study analyses are very encouraging. With respect to safety, as we reported for the first stage, the vaccine was well tolerated among the participants in the study. The clinical team is still blinded to the safety data for the second stage of the study until all of the safety follow-up has been completed. However, an external, independent Data and Safety Monitoring Board reviewed the safety data at several points in the study and they recommend that the study continued including expanding the dosage range up to 90 micrograms; and as I stated, we will receive the full, unblended, safety data late in the fourth quarter of this year.

Now on to immunogenicity. This candidate vaccine, which does not contain an adjuvant, induced robust neutralizing antibody responses among the subjects in the study. Neutralizing antibody generated in response to the vaccine is antibody that blocks the growth of the virus and it ultimately results in the virus's death. 72% of subjects who received the 15 microgram dose, 73% of subjects who received the 45 microgram dose, and 94% of subjects who received the 90 microgram dose developed neutralizing antibody titers of 1 to 20 or greater, which is a fourfold rise in titer.

Now, titer is a measure of antibody concentration and a fourfold rise in titer, or an antibody response that's four times higher than it was before receiving the vaccine, is clinically important, because it's generally reflective of an immune response that's considered to be protective against disease. Now in addition to this, we saw a dose response based upon the mean antibody concentrations observed in each dose group, and the vaccinated subjects were negative for antibody against the H5N1 Indonesia strain at baseline as were the placebo recipients.

So in summary, as Rahul has noted, the results are strong. They're very competitive, they compare favorably with that of other pandemic vaccines, be they adjuvanted or unadjuvanted, and they certainly support continued development of our vaccine.

Now, you may be wondering what additional clinical studies will be required to support regulatory licensure of our pandemic vaccine. Well, as we've stated, we will proceed forward with further clinical development when we have the support of a partner. With that being said, the studies that will be needed to confirm – the studies that will be needed will be studies to confirm the safety and immunogenicity of the selected dose and also to confirm the consistency of the manufacturing process.

Now normally, efficacy studies, or studies to show that the vaccine actually prevents avian influenza disease in humans, would be conducted as part of a Phase III program. However, this is not possible with this pandemic vaccine because there aren't enough cases of avian influenza in the world to conduct an efficacy study at this time.

Now I'd like to talk about the selection of the final dose for the later phase studies. Selection of that dose will depend on several factors, including safety data, additional immunogenicity data, manufacturing considerations, regulatory requirements and policy considerations. Before we select the final dose, we will evaluate additional data that will be coming in, including the safety data as I mentioned earlier, and additional immunogenicity measures, such as the final HAI responses, the total HA and NA antibody levels, and cell-mediated immune responses. Similar to what has been seen with other avian influenza vaccines that have been introduced, there is a gap between the neutralizing antibody and HAI responses. And as has been done with development of these other vaccines, we are also working to optimize the HAI assay for Indonesia strain vaccine. Please recall that this is one of the first avian influenza vaccines based on the Indonesia strain, so we will certainly be sharing these additional data when they are available.

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Now at this time, I want to reiterate how Novavax's influenza VLP is different from most influenza vaccines that you've recently heard about. As Rahul shared with you, a VLP is a decoy. It looks like the virus in that it's the same shape; it contains the surface proteins, but lacks the genetic material required for replication. It isn't a virus, but in general the body responds as if it's been exposed to a live influenza virus.

The Novavax VLP contains the virus surface proteins HA, NA, and a core protein M1, and that's different from most influenza vaccines because they contain just HA with little or no NA and no M1. We believe that including all three of these key proteins and presenting them as they looked in the wild-type or circulating virus offers key immunologic advantages. First of all, the HA protein in Novavax's VLPs can be matched to the wild-type virus, in other words matched exactly to the virus that's causing flu illness in humans. This may be an advantage over flu vaccines produced using eggs, because that process may result in alterations in the HA. And as is indicated earlier, that HA is critical because it induces antibody that neutralizes or blocks the growth of the virus, which ultimately results in the virus's death.

The NA in Novavax's VLPs play an important role as well. The NA induces antibodies that decrease cell-to-cell transmission of the virus. In other words, it can prevent spread of the influenza virus down the respiratory tract, potentially preventing pneumonia and other severe complications and reducing the severity of disease. In addition, the cell-mediated immune responses to M1 should lead to destruction of cells already infected. So in short, the antibodies to the HA and NA, and the responses to the M1 should block the virus, stop it from spreading, and kill cells that are already infected.

So in summary, I am very encouraged by these results and I believe that they strongly support moving forward with further development of our H5N1 pandemic flu vaccine and offer us an opportunity to uniquely help address a potential influenza pandemic. And finally, we believe that these data also demonstrate that our VLP technology is solid and it's a good foundation for additional vaccine programs, including our seasonal influenza vaccine program. We expect to begin a Phase IIa dose ranging trial of our seasonal vaccine in the third quarter of this year, and we look forward to sharing the results of that study with you by year's end. In addition, we are also pursuing opportunities to publish and present these data at key scientific meetings and in peer review journals, so stay tuned for the rest of the results.

Now, I'd like to turn the call back to Rahul.

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**Rahul Singhvi, Sc.D., M.B.A., President and Chief Executive Officer**

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Thank you, Penny. So as Penny stated, we are very encouraged by these results from our pandemic vaccine trial, and they reinforce our conviction that the VLP platform technology has broad implications for our vaccine platform and specific applicability for our pandemic and seasonal influenza vaccines.

The highlights from today's results can be summarized as follows. First, these results confirm that a recombinant VLP vaccine candidate, without the help of an adjuvant, creates a strong immune response against a difficult target, the Indonesia H5N1 influenza strain. These results compare well with any vaccine against pandemic flu, whether licensed or in development, with or without adjuvant. In addition, these results should translate into lower vaccine development risk for our seasonal influenza vaccine program, which will begin clinical studies later this year.

Second, our VLP, combined with our innovative manufacturing approach, can lead to a vaccine that is an exact genetic match to the circulating virus. This can be accomplished within 10 to 12 weeks of identification of the pandemic influenza strain, or roughly half the time that current providers can accomplish. This capability is ideal for an early response in the event of a pandemic outbreak.

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Third, we have a tremendous opportunity to continue to optimize our unique manufacturing approach, which we believe can deliver competitive operating costs, significant lower capital cost for our manufacturing facility, and with much higher yields than conventional egg or mammalian subculture processes.

Finally, in collaboration with GE Healthcare, we have a unique commercialization strategy for our pandemic influenza vaccine. Many countries do not have in-border vaccine production capabilities. In the event of a pandemic, these countries may not have access to vaccines, putting their populations at risk. Novavax has the opportunity and ability to offer an effective, fast, affordable and sustainable solution to these countries to protect their people from a pandemic.

That completes our prepared comments and we would now be happy to open the conference for questions from our participants.

## QUESTION AND ANSWER SECTION

Operator: [Operator Instructions]. Our first question comes from Ken Trobvich [RBC Capital Markets].

<Q – Kenneth Trobvich>: Morning.

<A – Rahul Singhvi>: Good morning, Ken.

<Q – Kenneth Trobvich>: Sorry, the phone wasn't working there, I apologize. I had the mute on earlier. Just wanted to follow up. I guess I wanted to get a sense from you as to your reaction between – reaction to the differences in response between doses. I'm just trying to get a sense, not only for the results of this study, but also sort of looking back to the optimization efforts that you carried out between sort of Stage A and Stage B, and how that played out.

<A – Rahul Singhvi>: Let me have Penny answer that one.

<A – Penny Heaton>: Hi; how are you this morning? So, obviously we're excited about the results of the study and the robust immune responses that we saw at all three of the doses. And we did see a dose response. And the significance of that is that it indicates that it ties our vaccine and the activity of our vaccine to the biological response that we're measuring. That's very important for any study of any vaccine. So if you look at the, just the individual antibody concentrations for each of the dosage groups, the dose response is very clear. We are not including all the data – haven't included all the data in this teleconference because, obviously, we want to have data that we will be presenting at a scientific meeting this fall, so we didn't include those exact numbers, but there's a very clear dose response. And then, the data we presented is the percentage of subjects who achieved that fourfold rise in titer, which is the clinically important titer.

As far as how these responses compared to our previous responses before we optimized the vaccine manufacturing process, they compare very favorably. I don't know, Ken, if you recall, but with the 15-microgram arm, we had nine out of 12 subjects that had a titer of 1 to 10, but we had zero subjects that had a titer of greater than or equal to 1 to 20. And with the optimized process in the new vaccine batches, we had 72% at that 15-microgram arm that had a titer of at least 1 to 20 or greater. So that's very remarkable, quite remarkable.

And then for the 45-microgram arm, it went from 63% to 73%. And then as you know at the 90-microgram arm, we had 94% that achieved that clinically important titer. We saw a lower bound on the confidence interval of 80 and an upper bound of 99, so very robust responses, particularly given that we did this without an adjuvant.

<Q – Kenneth Trobvich>: And just as it relates to the HAI, I know you mentioned there's work still ongoing in that area, is that an area that you think that the science is evolving and it's so early that it's just not clear what those actual immunogenetic response levels are going to be, or do you feel as though the standards there are established and it just has to be refined strain by strain?

<A – Penny Heaton>: I think it's the latter, that it's been clear from the history of the avian flu vaccines that they've had to refine the HAI assays for the different strains. You may recall when the avian influenza cases of the Hong Kong strain emerged in the late 90s, and then again when the Vietnam strain emerged that initially, when they had patients that they knew had culture confirmed disease, is they had very high neutralizing antibody titers upon recovery, but the HAI titers were often either low or even nondetectable. So, that's what sent the experts at WHO and CDC to the lab to actually refine these HAI assays to better reflect the immune response. And they had to do that for Hong Kong and Vietnam, and we're kind of blazing the trail here for the Indonesia strain, but we are working with experts around the world, literally, to optimize this vaccine.

<Q – Kenneth Trobvich>: Okay, and then you mentioned in the earlier comments the sort of potential for Phase IIb, and certainly there's a slide here that talks about a potential for collaboration partner. Can you give us an update as to what would be necessary for you folks to actually make that step to progress to Phase IIb, in terms of either funding or partnership?

<A – Rahul Singhvi>: Right, so we are in, as I think we've publicly stated even before, that we are in discussions with a number of governments around the world, as well as the U.S. government and several companies, and as those discussions prolong and then we do have a deal with them, then we will proceed with further development of this vaccine. I should also mention that all the work that we're doing in the seasonal influenza program will also count towards the safety database of our pandemic vaccine.

<Q – Kenneth Trobvich>: Sure. I guess maybe I just want to clarify it. When you talk about the foreign government contract, you wouldn't necessarily have to have a collaboration partner specifically at your site to develop the vaccine itself to move forward. In other words, if you receive manufacturing contracts or licenses from foreign governments, you could use those funds, then, to develop or fund the Phase IIb on your own.

<A – Rahul Singhvi>: Absolutely correct.

<Q – Kenneth Trobvich>: Okay; thank you.

Operator: Our next question comes from Vernon Bernardino [Rodman and Renshaw].

<Q – Vernon Bernardino>: Hi; thanks for taking my question, and congratulations on the strong results.

<A – Rahul Singhvi>: Hi, Vernon; how are you?

<Q – Vernon Bernardino>: Good. Just, you've touched on it a little bit; just wondering if you'd go a little more into how you would select the dose, for example, for the pandemic flu vaccine if you were to go into a Phase IIb. In particular, what are the factors you would need to consider? You mentioned manufacturing, but the 90-microgram doses at 94% and then 45 is at 73%. What other considerations there as far as going into dose selection and how does it apply to the seasonal program?

<A – Penny Heaton>: Hi; this is Penny again.

<Q – Vernon Bernardino>: Okay.

<A – Penny Heaton>: With regard to selecting a dose, there are, as you know, many factors that we have to consider. Certainly the manufacturing considerations as far as yields and cost of goods have to be considered, regulatory requirements, but of course, most importantly are the clinical results. Safety is certainly the most important consideration from the clinical perspective and, as I shared with you earlier, our Data and Safety Monitoring Board have not expressed any concerns about the safety of the vaccines. So I think with regard to safety we anticipate that any one of the doses will be acceptable.

With regard to immunogenicity, this is going to be a tough decision, because the vaccine is robustly immunogenic at all three doses evaluated, and from an individual perspective you may want that 94% protection, but on the other hand, with respect to -- from a public health perspective, if you're trying to interrupt or halt a pandemic, vaccines with lower efficacy such as in the 70 percentile range may very well be effective at doing just that. And it obviously, if you have a lower dose, then that greatly increases your capacity and your ability to provide a lot more vaccine doses around the

world. So we're going to be talking with experts, policy makers, et cetera, in selecting this final dose, and it's not as straightforward as it may appear.

Now having said that, we do have additional immunogenicity data that's going to be coming in, including the HAI results, the total – we're looking at total antibody levels to the HA and NA and cell-mediated immune responses, so that may point us in one direction or the other, but I think we're kind of, delightedly, in the position of having probably more than one choice of dose that could be the right dose.

**<Q – Vernon Bernardino>**: Well, as develop – I'm sorry.

**<A – Penny Heaton>**: I'm sorry, I want to relate this seasonal. Actually, the doses for seasonal and pandemic are very – we anticipate them to be very, very different, or potentially very different, because the doses for seasonal are typically much lower because those are human strains and so they are much more immunogenic than the avian strains. So, we anticipate that the doses in seasonal will be lower than those for pandemic. For example, in some of our pre-clinic work in animal studies that have yet to be published, we got 100% of ferrets had the protective antibody titer with the seasonal strains at just a 15 microgram dose. So, we will be looking at lower doses for the seasonal strains than for the pandemic strain.

**<Q – Vernon Bernardino>**: Will development of the HIA assay need to go forward to a certain level before any dose consideration needs to be finalized?

**<A – Penny Heaton>**: Certainly the HAI, as well as the other immunogenicity results that we're waiting on will – that will all be considered when selecting that final dose. We know that FDA and other regulatory agencies certainly take into consideration the HAI assay results. They also look at the micro-unit results and your animal studies as well, and look at all of it in combination. Certainly, as we move forward in selecting this dose, we will be discussing our dose selection and getting feedback from FDA and other regulatory agencies about that.

**<Q – Vernon Bernardino>**: And one last question if I may, this may be a question for Rahul. Given the flu seasons coming up, what stage are the discussions as well as visits for the manufacturing facility by a foreign government at? And was there a chance that they might evaluate, for example in a pilot program, a vaccine though it not be approved in the U.S., in their own country and to position for next year?

**<A – Rahul Singhvi>**: Right. So let me understand the question. Did you ask me when the foreign governments will be able to come and see our facility?

**<Q – Vernon Bernardino>**: Yes.

**<A – Rahul Singhvi>**: Yeah, okay. So, as we've stated our facility is fully constructed. We are, at the moment, are fitting it out with equipment and by the end of this year we should have all the equipment operational. We will welcome anybody to come and see our facility now, even, and so I think as our discussions with the foreign governments proceed and if they express a desire to come and view our facility, they will be welcome to come any time. So that's the answer the first question. Second question was again, what was that?

**<Q – Vernon Bernardino>**: That's basically the question. And one last question, if I may. You had mentioned presenting data in the fall, which conference, if you are prepared, to take?

**<A – Penny Heaton>**: We're going to be putting these data together in an abstract for a late-breaker presentation, and obviously we don't know if that's going to be accepted, so, I can't really tell you what conference, but stay tuned. We'll let you know, and just make sure you look at the

programs, the late-breaker programs, for the major scientific conferences coming up this fall in the U.S.

<Q – Vernon Bernardino>: Okay; great. Thanks for taking my questions.

<A – Rahul Singhvi>: Thanks, Vernon.

Operator: Our next question comes from Kevin DeGeeter [Oppenheimer].

<Q – Kevin DeGeeter>: Hey, good afternoon, guys.

<A – Rahul Singhvi>: Hi, Kevin.

<Q – Kevin DeGeeter>: Congratulations on the results. Most of my questions have been answered. Maybe just one side question. Would some of the VLP vaccines – there's been reports of a little higher than average or typical pain associated with injection. Any sense on the level of discomfort, and this would be compared to your expectations for the VLP base vaccine?

<A – Penny Heaton>: Sure. Of course we are still blinded to the results from the 160 subjects that were in the dose ranging trial. So the only data I have to share with you right now are the initial 70 subjects that we studied in stage A, 20 of whom got either 15 micrograms or placebo, and then the other 50 got 45 micrograms or placebo. There were reports of pain at the injection site. There was no statistically significant difference in the vaccine as compared with placebo groups, and the vast majority of the pain was reported as mild. We are watching this because we are aware of this in, with other VLP vaccines, but the data we have right now are reassuring. We'll continue to monitor it. That was a very small sample, and we'll have those final data in the fourth quarter of this year.

<Q – Kevin DeGeeter>: Okay; terrific. That's really encouraging. And maybe one more final follow-up, if I may, on this question of dose. Any clear sense that for the seasonal study to be kicked off later this year in the elderly, based on the data here, where we may be on dose, and specifically are you gaining any level of comfort that perhaps we'd be looking at one dose, or more likely two doses of a Novavax vaccine?

<A – Penny Heaton>: Yeah; exactly. So, the studies we're doing this fall, we're doing dose ranging in healthy adults 18 to 49 years, and we're also doing dose ranging in elderly subjects greater than 65 years of age. And we are actually looking at a range of doses in both of those populations. One thing I want to remind everybody is that it's just a single injection, first of all. It's not like the pandemic vaccine where you have to give two shots, it's a single injection, and then we'll be looking at three different doses. We're actually going to go down on the dose in the healthy adults and then look at a little bit of a higher dose above the 15 micrograms in the elderly.

<Q – Kevin DeGeeter>: Terrific. That's really helpful. Thanks a lot guys.

Operator: Our next question comes from James Rubin. Mr. Rubin your line is open. It looks like he did disconnect, and I'm showing no further questions at this time.

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#### Rahul Singhvi, Sc.D., M.B.A., President and Chief Executive Officer

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Great. So, if there are no further questions, I'd like to thank all of the participants in this call and we really appreciate your support and we look forward to having further updates in the future. Thank you again.

Operator: Thank you for your participation in today's conference. This concludes the presentation. You may now disconnect. Good day.

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