VIAVID
communications simplified.

Beyond Air, Inc.

Introducing the Role of Nitric Oxide in Autism Spectrum Disorder

June 15, 2023

CORPORATE PARTICIPANTS

Edward Barger, *Head of Investor Relations*

Steve Lisi, *Chief Executive Officer and Chairman*

Jeff Myers, *Chief Medical Officer*

CONFERENCE CALL PARTICIPANTS

Marie Thibault, *BTIG*

Matthew Kaplan, *Ladenburg Thalmann*

PRESENTATION

Operator

Greetings and welcome to Beyond Air Introducing the Role of Nitric Oxide in Autism Spectrum Disorder. (Operator Instructions)

As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host, Ed Barger, Head of Investor Relations. Thank you, you may begin.

Edward Barger

Thank you, Operator.

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 subject 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 SEC, including without limitation, the Company's most recent Form 10-K and the 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 the live broadcast, Thursday, June 15, 2023. Beyond Air undertakes no obligation to revise or update any statements to reflect events or circumstances after the date of this call.

Joining me today on the call are Steve Lisi, Chairman and Chief Executive Officer, and Doctor Jeff Myers, Chief Medical Officer. We'll begin with a presentation and prepared remarks before moving over to Q&A. With that, I'll turn the call over to our CEO. Steve?

Steve Lisi

Thanks, Ed.

Thank you everyone for joining us as we Introduce the Role of Nitric Oxide in Autism. We are very excited to share the data generated to date. We believe the path to move into human clinical studies is very clear, given where we are today.

Our deal with Hebrew University in Israel is for exclusive global commercial rights for several compounds that partially inhibit neuronal nitric oxide synthase or nNOS. Autism may be the first of several indications as we learn more about the critical role nNOS plays in the human body.

Specific to autism, the preclinical data provide evidence that nNOS overactivity is a culprit, and we will describe this in more specificity in later slides.

I would like to emphasize that Beyond Air is a world leader in NO research, and that brings us to our pipeline. As you can see, we are exploring the benefits of using nitric oxide to improve patients' lives and those suffering from persistent pulmonary hypertension of the newborn, postoperative right ventricular failure after cardiac surgery, bronchiolitis, pneumonia, chronic refractory persistent bacterial lung infections, solid tumors, and now autism. We are dedicated to saving and improving lives by harnessing the power of nitric oxide.

This is a win-win deal with Hebrew University. As development progresses, Beyond Air will pay milestones for certain clinical, regulatory, and commercial achievements. In addition, a low single digit royalty on net sales will be paid. These economics may extend to other neurological indications as well.

Several papers have been published on the topic of the role of nNOS in autism, which has led up to the most recent publication, "The NO Answer for Autism Spectrum Disorder," published in *Advanced Science* last month. Publication received enormous praise and is truly revolutionary.

The world owes this ground-breaking research to the dedication of Doctor Haitham Amal. I would like to publicly congratulate Doctor Amal and his team on reaching this point and providing us with the opportunity to potentially change the way we approach treating autism. The entire Beyond Air team and I look forward to continuing to support Doctor Amal as we move towards human studies.

The numbers are daunting, as one in 36 in the U.S. are estimated to be on the autism spectrum. Globally, this number is one in 100. The economic burden is expected to be in excess of $450 billion by 2025 in the United States alone. With continued hard work and dedication, we believe this research can provide hope in this fight.

Now I'd like to turn the call over to the Chief Medical Officer of Beyond Air, Jeff Myers, to discuss NO and autism in more detail. Jeff?

Jeff Myers

Thank you, Steve. As you've noted, Beyond Air has experience with nitric oxide across a large number of therapeutic areas and indications. We have extensively explored nitric oxide generator from the eNOS isoform, with persistent pulmonary hypertension of the newborn, and the iNOS isoform across a number of hypoxic infectious diseases.

It's a natural extension for Beyond Air to partner with Doctor Amal in defining nNOS targeted therapies, specifically for autism spectrum disorder. His work with nNOS inhibition in ASD models has demonstrated reversal of the molecular, synaptic, and behavioral ASD-associated phenotypes, which we will discuss in detail.

While perhaps not intuitive for more common clinical applications such as pulmonary hypertension, the well-established understanding of nitric oxide's function as a neurotransmitter makes it unsurprising to discover its involvement in neurologic disorders such as ASD. In fact, nitrosative stress, marked by high levels of nitric oxide and nitrogen dioxide, has been implicated in other neurologic diseases such as Alzheimer disease. Doctor Amal's laboratory has demonstrated that nitrosative stress as a result of nNOS overactivity, and importantly overproduction of nitric oxide, is present in low-functioning ASD patients.

I'm now going to review some of the data using the nNOS inhibitor 7NI in autism spectrum models.

Two different ASD mouse models, SHANK3 and CASPR2, were utilized. Both are associated with ASD behaviors and are defined by overproduction of nitric oxide. As you can see from the diagram, in the middle panel, there is also an abnormality in dendritic spines. These are protrusions from dendrites, which form the functional contact with neighboring axons of other neurons. The third panel shows down-regulation of nitric oxide to more normal levels, normalization of the dendritic spines produced, and a reversal of the ASD behaviors.

We briefly touched on the concept of nitrosative stress. Nitrotyrosine is one of the reactive nitrogen species and is associated with cell damage and inflammation. The top images show the large increase in nitrosamine, demonstrated by Western blot in both the cortex, and corpus striatum of the mouse brains in the middle bar, and the return to normal levels in treated mice. The bottom figures show increased nitrosamine levels represented by the relatively bright immunofluorescent middle image, and the return to normal wild type in the third image.

We also discussed synaptogenesis and the production of abnormal dendritic spines in ASD mouse models. The top images nicely demonstrate the decreased density of dendritic spines in M1 SHANK3 mice (inaudible) restoration to normal after 7NI administration. Enlarged bottom figures show the severely impaired production of the synaptogenesis biomarker synaptophysin, shown as red in the figure. This is restored after 7NI administration and subsequent normalizing of nitric oxide levels.

This slide shows abnormal social behaviors in the ASD mouse models and subsequent improvement with 7NI administration and normalized nitric oxide production. Number one demonstrates the concept of novelty-seeking. Mice with an ASD phenotype will interact less with the novel object, as demonstrated by the middle bars, and the interaction difference between familiar and novel objects are restored with 7NI. We can see the same abnormal ASD-associated social behaviors in the other two graphs. 7NI restored both the willingness to interact with stranger mice in number two, and the time spent exploring the open arms of the maze in number three, demonstrating improved social behavior and decreased anxiety, respectively.

Finally, and critically, when we examine normal non-ASD-type behavior such as motor activity in the ASD mouse models, 7NI did not alter these behaviors. This indicates an absence of off-target effects and no associated impact on normal non-ASD behavior with neuronal NO synthase inhibition.

In summary, in well-established mouse models of autism spectrum disorder, inhibition of the overactive nNOS and increased nitric oxide production with 7NI, the first molecular, synaptic, and behavioral ASD-associated phenotypes, without evidence of off-target effects.

Note that the NLGN3 mutation was tested after the manuscript was submitted, but the data are consistent with the two models discussed here.

Also note that we are progressing with a compound that has a superior toxicity and delivery profile when compared to 7NI.

Steve Lisi

Thanks, Jeff.

Just a little reminder of the Beyond Air patent portfolio. We have over 70 patents worldwide, with some expiring as far out as 2040. Our autism patent was filed just over one year ago and is one of dozens of pending patent applications at Beyond Air.

To wrap things up, I would like to reiterate that we are the nitric oxide company. Our expertise complements Doctor Amal's work. We will continue to assess the best path forward, but today we believe that our in-house capabilities can take this program through at least Phase 1 clinical studies. (Inaudible) the cost to us, including payments to Hebrew University, is approximately $4 million over the next 30 months. This includes a first in human study, which we expect will be complete in 2025.

With that, I would like to open the call to your questions. Operator?

Operator

Thank you. (Operator Instructions)

Our first question comes from the line of Marie Thibault with BTIG. Please proceed with your question.

Marie Thibault

Hi, yes, thank you for taking the questions and congrats on this interesting development. Certainly, very unique.

Wanted to hear a little bit about what the competitive landscape would look like for the autism spectrum disorder. Certainly, we know that it's a very common condition. Want to think about, if this is a successful therapy or shows signs of success, what you'd be competing against directly. You mentioned here at the end a patent around this application, can you tell us a little bit more about the intellectual property around it?

Steve Lisi

Thanks, Marie. Appreciate the question.

As for competition, there's really not much going on in autism spectrum disorder where you're treating the underlying condition itself and reversing the behavioral deficits caused by the condition. We're not aware of anybody who's in advanced stages, and obviously we're not in humans yet. I think it's a little premature to see what the competitive environment will be in human studies, but at this point there's really nothing going on with respect to reversing the condition. I think most things that are being used are just treating some of the symptoms, and mostly they're antischizophrenic drugs and such.

With respect to the IP, we haven't had patent issued yet, but we haven't named our backup compound to 7NI, but 7NI itself has been around a long time. I think that what we're using it for and how it's being used and how it will be delivered, I think these are the things that the intellectual property will be focused on. There won't be a composition of matter patent per se since this molecule has been in existence in the past.

Marie Thibault

Okay, that's really helpful, Steve, thank you. If I could ask my follow-up here, you mentioned incremental costs of about $4 million. Is that inclusive of any additional R&D hiring you might need to do, given the novel approach here? Saw that you signed a debt financing today, congrats on that. Any more details on sort of top priorities for some of that capital, very nice to see. Thanks for taking the questions.

Steve Lisi

Thanks. Top priority for that capital is to really support the Phase 2 of our commercial launch that we jumped into last month. That's where most of that capital will be deployed. Marie, can you state the first part of your question again? I'm sorry.

Marie Thibault

It was the $4 million incremental costs on this autism. Is that inclusive of any R&D hiring or anything additional I understand certainly around the licensing, some of that is included, but anything additional in terms of OpEx spend.

Steve Lisi

That spend is really for costs that are outside of our Company. We already have people who are doing preclinical and clinical work in statistics, pharmacology et cetera, all of the typical areas that you would have in a company of our size that has done extensive preclinical work and clinical work as well. As you know we've done multiple pilot studies with our programs. Again, going through Phase 1 is not something where I think we need to add people to our team to do anything with the autism program. This will be spend outside of what we already have on our team.

Marie Thibault

Got it, thank you. Good luck.

Steve Lisi

Thank you.

Operator

Our next question comes from the line of Matt Kaplan with Ladenburg Thalmann. Please proceed with your question.

Matthew Kaplan

Hi Steve. Congrats on the in-licensing. Can you talk a little bit about how you envision the nNOS inhibitors that you're developing to be utilized in autism? As you described, it's a spectrum? Which patients will you target initially, do you think this will have utility?

Steve Lisi

It's a little early to say that Matt. I would think that we're looking more in the more moderate to severe patients on the spectrum. I think that's probably where the target will be. Not to say that it can't, you know, we're not really sure where it will end up, if it'll be more severe or in the more moderate area, we're not sure yet. We have to get into humans before we can really pinpoint that. Mice are mice, they're not people, but we certainly—if you read the paper that Doctor Amal published, and his team, there is some work that he did to indicate that what we've seen in mice should be consistent in humans. Again, where we fall in the spectrum in terms of where the target patient population would be, I think we need to wait a little bit before we can really pinpoint that.

Matthew Kaplan

Okay. Fair enough. Then just along that same vein, how early do you think you would need to treat patients to have an effect, in terms of the—as they progress their …

Steve Lisi

Good question, internally we talk about if there's a 25-year-old or 35-year-old or what have you, would we have any effect, or are we only going to be able to have this reversal effect in younger patients. We're not sure. It's something we're going to have to again explore when we get into humans. There's nothing that tells us, in the preclinical work that's been done, that we're limited. Again, we're going to figure that out once we get into humans. At this point, I think the sky's the limit, until we learn more in human studies.

Matthew Kaplan

Okay. Then, in terms of the pathway to the IND, you mention that 7NI, the next compounds, where are you in identifying those compounds, and pathway to an IND, into the clinic.

Steve Lisi

That's why we're announcing this now. The backup molecule to move forward into humans has been identified, tested, and we feel very comfortable with the profile of this. At this point I think, as you know, Matt, there's got to be some CMC work done so we can satisfy FDA requirements. We'll do a little bit more work on the delivery, the needle that'll be used and the frequency of administration. Our goal is to be once a week. I think we're close to that goal already, but we'll be doing a lot of that work over the next 12 months, to make sure that we've got all our ducks in a row before we head off to FDA and ask them to move into humans. There is a little bit more work to do, but I think it's just blocking and tackling at this point, not necessarily a risk of whether we get there or not, just how quickly we can do it.

Matthew Kaplan

Okay. I guess last question on these compounds. What other indications do you think they would have potential utility in?

Steve Lisi

That's a theoretical question, and Jeff Myers, our Chief Medical Officer, Jeff, are you on the line?

We're having a little bit of trouble getting Jeff on the line from where he is in the world. I'll give him a second, see if he jumps on; if not, then we'll talk about—there's possibilities, Matt. If you look at Doctor Amal's work, he's published other papers on different indications. He's done some work in Alzheimer's, he's done some work in neuroblastoma. These are things he's working on, I think autism is the furthest along, so to speak, but he's certainly exploring other areas. I don't know if it'll ever work out in those other indications, but I have a lot of confidence in Doctor Amal, he's relentless worker and super duper smart, and he's very well connected with other experts around the world in this field. If there's something else that these nNOS inhibitors are going to work in, I'm sure he's going to find it.

Again, if you look at some of his work, you'll see that he has explored a few other areas. Again, I think autism is the focus at this point, I don't want to get too far ahead of ourselves on other indications, I think autism is the focus right now, but certainly there's potential for other neurological conditions.

Jeff Myers

Hi Steve, sorry, technical issues there. This is Jeff Myers. There is a history of nitric oxide in a number of neurologic conditions, going all the way back, it's been indicated or implicated in Alzheimer for a long, long time. I think there's probably a spectrum of neurologic diseases that might be affected by this, and I think to your point, I think you said it well. Doctor Amal is the guy to figure out if this is replicatable in something besides autism spectrum disorder, and my guess is it probably is.

Matthew Kaplan

All right, great. Thanks for the added color.

Operator

(Operator Instructions) There are no further questions in the queue, I'd like to hand the call back to management for closing remarks.

Steve Lisi

Thanks Operator. Thank you everyone for joining us today, much appreciated, and we look forward to giving you more updates on this program as it progresses. Thank you.

Operator

Ladies and gentlemen, this does conclude today's teleconference. Thank you for your participation, you may disconnect your lines at this time, and have a wonderful day.