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# Beyond Air, Inc.

## Second Quarter Fiscal Year 2024 Earnings Call

## November 13, 2023

## CORPORATE PARTICIPANTS

**Edward Barger,** *Head of Investor Relations*

**Steve Lisi,** *Chairman and Chief Executive Officer*

**Duncan Fatkin,** *Chief Commercial Officer*

**Douglas Larson,** *Chief Financial Officer*

## CONFERENCE CALL PARTICIPANTS

**Jeremy Jacoby,** *Truist Securities*

**Marie Thibault,** *BTIG*

**John,** *Piper Sandler*

**Matt Kaplan,** *Ladenburg Thalmann*

## PRESENTATION

**Operator**

Good afternoon, and welcome, everyone, to the Beyond Air Financial Results Call for the Fiscal Quarter ended September 30, 2023.

(Operator Instructions)

Now, I would like to turn the call over to Edward Barger, Head of Investor Relations at Beyond Air. Please go ahead.

**Edward Barger**

Thank you, Operator. Good afternoon, everyone, and thank you for joining us.

Today after market close, we issued a press release announcing the fiscal second quarter 2024 operational highlights and financial results. A copy of this press release can be found on our website, www.beyondair.net under the News & Events section.

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 Form 10-Q, which identifies 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, November 13, 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; Duncan Fatkin, Chief Commercial Officer; and Douglas Larson, Chief Financial Officer.

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

**Steve Lisi**

Thanks, Ed, and good afternoon to everyone joining us today.

I'll start today's call by highlighting the revenue guidance we announced earlier today in our quarterly press release. For the fiscal year ending March 31, 2025, we anticipate $12 million to $16 million in revenues. The impetus for providing guidance at this time is threefold. First is the great work done by our commercial and supply chain teams to provide hospitals with confidence in LungFit PH and our support for users of the system. Second, the Vizient contract we announced in October. Third, the FDA approval of an update to our software which was granted in September. Our entire fleet of systems will be updated by the end of January with production of new machines ramping up significantly as well to meet anticipated demand.

Looking outside of the U.S., in September, we announced the partnership with Getz Healthcare for commercialization of LungFit PH in the Asia Pacific region, excluding Japan. We look forward to triggering a milestone payment once CE Mark is received, which is expected to occur early next year. We are very pleased to have the endorsement of a company with the reputation of Getz.

Another recent milestone achievement under the LungFit PH program is the PMA submission for the expansion of our label to include cardiac surgery. Our clinical and regulatory team is to be commended for putting together a strong submission, and we look forward to a positive impact on our revenues beginning in the back half of fiscal 2025.

Moving on to our other programs, at the SITC conference last week in San Diego, Beyond Cancer presented topline data from the Phase 1A first-in-human trial. In this study, five patients, all of whom had failed an average of six prior treatment regimens, each received one five-minute intratumoral administration of 25,000 parts per million nitric oxide. The treatment was safe and well-tolerated. Additionally, an immunostimulatory effect was clearly evident over the 21-day observation period with upregulation of key biomarkers such as cytotoxic T-cells, T central memory cells, M1 macrophages and dendritic cells, while downregulation of T regulatory cells and mononuclear myeloid-derived suppressor cells were shown.

I would like to emphasize that the effect on these immune biomarkers is very similar to what we have seen in animal studies. Our animal studies presented and published over the last three years have consistently shown efficacy with monotherapy UNO as well as in combination with multiple checkpoint inhibitors with respect to tumor regression and survival in multiple tumor models.

Also, during the quarter, Beyond Cancer presented positive preclinical data at the EORTC International Conference on molecular targets and cancer therapeutics, demonstrating a statistically significant survival benefit in mice treated with UNO plus anti-PD-1 versus anti-PD-1 alone. This was a pooled analysis of multiple studies done with 50,000 or 100,000 parts per million nitric oxide for a single administration of five minutes or 10 minutes.

Additionally, Beyond Cancer's second manuscript was published in the cells journal in an article titled *Intratumoral Administration of High-Concentration Nitric Oxide and Anti-mPD-1 Treatment Improves Tumor Regression Rates and Survival in CT26 Tumor-Bearing Mice*. We're very excited by the data and progress of the UNO program and look forward to sharing the data from our completed Phase 1A study in 2024.

Our cancer team will also be initiating a Phase 1B study in 2024 as well as approaching the FDA and other regulatory authorities about a Phase 2 program that is expected to begin before year end 2025. I encourage all of you to visit the Beyond Cancer website to get better educated on this potential transformational therapy for those suffering from solid tumors.

Our viral community acquired pneumonia or VCAP study is underway. As a reminder, this randomized double blind placebo controlled pilot study will treat hospitalized patients with 150 parts per million nitric oxide intermittently for up to seven days. Keep in mind, we have already completed four studies treating viral pneumonia, which have consistently demonstrated both safety and efficacy. Due to viral pneumonia following seasonal patterns of activity, this is a seasonal study running through the fall and winter months. As a result, we expect to announce top line data by the middle of calendar year 2024. Viral pneumonia is a significant unmet medical need with over 300,000 hospitalizations annually in the United States and more than 15 million worldwide.

Let me conclude my opening remarks by touching on our newest program to treat autism that is on track to have human data in 2025. Recall that this is in partnership with The Hebrew University of Jerusalem, which continues to produce exciting preclinical data. In September, we announced the publication of new data showing a therapeutic effect for at least 10 days after a single injection of an extended release formulation. Just like the daily injection, the data show reversal of behavioral phenotypes associated with autism, and we look forward to additional data from the university.

Now, we'll turn the call over to our Chief Commercial Officer, Duncan Fatkin, for a closer look at the LungFit PH commercial launch. Duncan?

**Duncan Fatkin**

Thanks, Steve, and good afternoon to our investors.

As Steve mentioned, we have given revenue guidance for LungFit PH for fiscal 2025. Since we last spoke in August, we have more than doubled the number of hospitals using LungFit PH.

Another metric I would like to share with you is the shipment of NO2 filters to our customers. In fiscal Q1, our first quarter with customers, we shipped approximately 450 filters. During the quarter that we're reporting today, which ended September 30, that number eclipsed 1,300, and in October alone, we shipped over 900 filters to our customers. We expect to continue this acceleration given the recent approval of our software upgrade for LungFit PH by the FDA.

Based on hospital feedback, we sought and gained FDA approval for software updates that address some minor limitations on device usage. We expect these updates to further increase the separation in value between LungFit PH and our competitors in the marketplace. I can make that statement with confidence given our recent experience at the American Academy of Respiratory Care that took place a week ago.

Another event that gives us confidence in accelerating our growth in the market at this stage is our Innovative Technology Contract Award from Vizient, the nation's largest provider-driven healthcare performance improvement company. This recognition represents a seal of approval for our revolutionary technology from the largest group purchasing organization in the U.S., representing more than $100 billion in annual purchasing volume. This achievement validates the positive customer experience and feedback that we have been reporting for some time. We are very excited by this opportunity to expand our reach through the Vizient customer network. I would like to emphasize that an Innovative Technology Contract signifies to Vizient members that the LungFit PH has unique qualities that may enhance clinical care, patient safety, healthcare worker safety, and business operations.

As mentioned previously, we are building out a field team based on the opportunities developed over the past year and the growing interest in LungFit PH as we broaden our reach. Over the next 12 months, as our revenues build, we expect to continue increasing our sales team across the majority of the continental United States to capitalize on the opportunities afforded by the Vizient contract, the updated LungFit PH system, and the anticipated approval of a label expansion for cardiac surgery.

Now I'll turn it over to Doug.

**Douglas Larson**

Thanks, Duncan, and good afternoon, everyone.

Our financial results for the fiscal quarter ended September 30, 2023 are as follows. Revenue for the fiscal quarter was $0.24 million as compared with zero for the fiscal quarter ended September 30, 2022. Research and development expenses for the fiscal quarter were $7.1 million compared with $4.5 million for the fiscal quarter ended September 30, 2022. The additional $2.7 million was due primarily to an increase in stock-based compensation, salaries and development costs associated with the pipeline.

SG&A expenses for the fiscal quarter were $10.2 million compared with $8 million for the fiscal quarter ended September 30, 2022. The $2.2 million increase was mainly due to stock-based compensation, professional fees and salaries. Other income and expense for the fiscal quarter showed a $0.1 million gain compared with a $0.2 million loss for the fiscal quarter ended September 30, 2022. There's a lot of moving parts, but essentially interest income roughly offsets interest expense and the gain we saw from the remeasurement of warrants and derivatives associated with our long-term debt was only partially offset by true ups to our non-product related litigations.

The fiscal quarter ended September 30, 2023, the Company recorded a net loss of $17.4 million of which $16.2 million or $0.51 per share was attributable to the shareholders of Beyond Air, Inc. compared with a net loss of $12 million or $0.40 a share for the fiscal quarter ended September 30, 2022.

Net cash used in the quarter ended September 30, 2023 was $16.5 million, including $6.4 million in one-time payments, which had previously been disclosed and accrued. Aside from these one-timers, cash burned in the quarter was $10.1 million, which is in line with our guidance of approximately $10 million per quarter. As of September 30, 2023, the Company had cash, restricted cash, cash equivalents and marketable securities of $43.9 million.

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

**Steve Lisi**

Thanks, Doug.

We will now take any questions you may have.

**Operator**

Thank you.

(Operator Instructions)

The first question we have is from Jeremy Jacoby of Truist Securities. Please go ahead.

**Jeremy Jacoby**

Hi, thanks for taking our questions. Can you just give us your puts and takes on how you got to this guidance range and then what's causing the delay in the CE Mark approval? Thanks.

**Steve Lisi**

Delay in the CE mark approval is not in our control. We're not saying it's not coming by the end of December. We just think it's more likely it'll come after that. Again, this is not in our control.

With respect to what's driving the guidance, it was pretty straightforward. We got a software upgrade from FDA for our system, which had been waiting for quite some time. This gives us the ability to be compliant with lots of different devices out there that nitric oxide systems go on, ventilators obviously being the main system. This is important as well as some other tweaks to our system to optimize performance.

Obviously, we have visibility into hospitals that are waiting for this upgrade. We have visibility into hospitals that are on Vizient as our GPO that we're now a part of, and again, the feedback we get from existing customers and potentially new customers is very encouraging for us with respect to our ability to deliver on the service side, which is critically important in this market. Hope that answers your question. We feel highly confident in that range.

**Jeremy Jacoby**

Thank you.

**Operator**

The next question we have is from Marie Thibault of BTIG. Please go ahead.

**Marie Thibault**

Hi, good afternoon. Thank you for taking the questions. Maybe I can try to understand a little bit more about the ramp. Thanks for that great detail on filters shipped. Are the filters when they're shipped, are they typically, is there a big stocking bolus and then folks are reordering as needed? What's the dynamic, how to think about that ramp you gave us, the October number, which is very impressive, but I don't want to make the mistake of prorating that over the entire quarter if that's not the appropriate approach. Then anything to cite in terms of pricing along these contracts? Are you seeing a wide range? Are things staying stable with what you'd expected?

**Steve Lisi**

Thanks, Marie. I think that the pricing is pretty much as expected. It's within the ranges and it's not all one price for everyone, obviously, but it's within the range of what we've expected over the past year plus. That's not going to change in our opinion. The market is stabilized in the range that we expected.

Yes, the filter stocking is, if you look at it on a monthly basis, it can be chunky. There's no doubt, but some hospitals will want to deliver every month. Some will look every quarter and, there's obviously interim there. If they do a monthly and they're running out, they'll call us sooner. Same thing on the quarterly basis. I don't know how to guide you with respect to the October number. Obviously, these things will move depending on how we get more contracts coming on with hospitals. Just really put that out there to show you that there is this upward trend, obviously, in usage and in number of customers that we have.

**Marie Thibault**

Yes, it's helpful for sure. Okay. Then my follow up, glad to have the fiscal '25 guidance. Some of those drivers like Vizient, like the new software approval, they seem like they could start to help the adoption earlier ahead of fiscal '25. Help us think about maybe time points for that. Are there times when folks start to look at the list of vendors on their GPO, GPO list, that sort of thing? How to think about one of these drivers could start to hit?

**Steve Lisi**

Yes, thanks for that and these things take time. The Vizient GPO came a middle of October. It takes three to six months on average to contract with a hospital roughly. That's a timeframe you need to see the improvements come as well as the software upgrade to our system or class three medical device. This doesn't just happen overnight, which is why you heard in the prepared remarks that we'll have things pretty much up to specs for all of our existing systems, the market plus ramping up new systems that'll happen. It's happening now, but it'll take a few months and we'll be completed with that process in January. Yes, if you think about it that way, you're looking at things happening towards the Jan, Feb, March timeframe, when you're going to see the major impact from these events.

**Marie Thibault**

Okay. It's very helpful. Thanks for taking the questions.

**Steve Lisi**

Yes.

**Operator**

The next question we have is from Joseph Downing of Piper Sandler. Please go ahead.

**John**

Hey, this is John for Jason. Appreciate the question. Yes. Curious how your conversations are going with hospitals in the current environment, are you seeing any lengthening of decision cycles or just slower contracting processes in general? Then just a quick follow up, anything else to note on how hospitals might be behaving differently right now in terms of forming new partnerships or embracing technology.

**Steve Lisi**

Okay. Yes. I don't think the hospitals are going any slower than what is normal for them. Post pandemic, things are a little bit slower post the pandemic and we're still in that mode. Things don't bounce back as fast in the world of the hospitals nor in the supply chain world. Things aren't back to what they were prior. That's why it's—you're looking out three months to six months to get things done with a hospital. I don't think that's really changed in the past year or so and it's probably not going to change going forward. There was another part to your question. I'm sorry.

**John**

Yes. In terms of how hospitals might be behaving differently in terms of forming your partnerships or just embracing new technology.

**Steve Lisi**

Yes, I think look, the embracing new technology part it's normal for these things to take time. Again, we had to prove ourselves to the hospitals that we can support them. These are lifesaving technologies. You can't not be able to support the hospital in a crisis situation where they have an overload of need and they may need another machine or two or more filters or more kits or so forth. They had to be sure that we could support them and provide them in those critical time periods and obviously, we've proven that over the last year plus and that's a major part of why we've given out guidance at this point.

The adoption curve is based on a number of things and one of them is confidence in us. The other one obviously is optimization of our system to work across all—be compatible with all ventilators across the offerings from the event companies. These are two obviously critical things and then of course the GPO contract. This is just the timing that we're on. These things took time to get through and now we feel that that's complete and what we need and we can move forward.

Again, I don't think the first six to nine months that we were out was something that was ever conveyed as us taking significant market share. That was really the time period to learn and to get the hospitals comfortable with us, and here we are in this period after that where we think we'll be taking share and we're happy to show you guys that we'll be taking share. We've certainly hit milestones with respect to our optimization of our system and getting the comfort of the hospitals. That's just where we are today. I don't think the adoption curve was going to be any different than what we saw. Maybe it could have been a little faster with a few things falling in our favor but it's just where we are.

**John**

Appreciate that, Steve. Then just piggybacking off of your comments there about gaining share, are you seeing any pickup in interest or great interactions with potential customers as a result of competitive struggles across the landscape?

**Steve Lisi**

Absolutely, 100%. Our system, we had this big Respiratory Conference in Nashville last week and it's clear if anybody was there. I'm sure there weren't too many people on this call that were there but it's clear we have the best system out there overall and there are some struggles from our competitors and it's certainly coming our way. There's no doubt that there's increased interest in our system, increased interest in doing business with us. We wouldn't have put that guidance out there. This is a very, very careful decision that we made to put that guidance out.

**John**

Great. Thanks, Steve. Appreciate it.

**Operator**

The next question we have is from Matt Kaplan of Ladenburg Thalmann. Please go ahead.

**Matt Kaplan**

Hey, guys. Thanks for taking the question. Just wanted to get a little bit more, perhaps some granularity with respect to when we should start to see an inflection with respect to the impact that the new software and the GPO contract should have to have—should start to have on revenues and is that something we're starting to see, the momentum you're seeing in October in terms of the filters. When does that translate in terms of increase in revenues?

**Steve Lisi**

Thanks, Matt. Like I said, this is about three to six months to feel the impact of these events, which took place in September and October. You're really looking in the Jan, Feb, March timeframe when you're going to see us, in our opinion, picking up significant contracts and volume picking up. I wish it were sooner. I wish I could tell you December is going to be a bang up month, but this is just the time that it takes. Things don't move that quickly.

I do think there'll be progress in the December quarter over the September quarter, we just reported, but I wouldn't expect it to be massive magnitudes because this is a three to six month process. That would put us in the Jan, Feb, March timeframe for us putting up numbers that that would give you comfort and confidence that we're going to do what we say we're going to do.

**Matt Kaplan**

Okay. No, that's helpful. Do you think the increases in revenue would be chunky and as you get additional GPOs and additional contracts, or how should we think about that ramp?

**Steve Lisi**

Oh, yes, it's going to be chunky, Matt. I can't predict when certain contracts coming up. One month could be, three new hospitals and they're small. The next one could be one hospital that's five times those three combined. These are just timing issues with respect to when contracts are up and, that's something that is obviously beyond our control. It may not be as smooth as you would like to model, but we've taken that into account and that's why we're putting the guidance after fiscal '25, and March 31, 2025 and that's why we're doing it this way, because it's very difficult to predict on a monthly or quarterly basis.

We'll get better clarity as we go forward. I hope to give better clarity, either in February or June, when we report our next two quarters. Hopefully we'll have a—I'll be able to give more details on how chunky it might be and when, but right now, it's very difficult.

**Matt Kaplan**

That's helpful. Thanks for giving the guidance and then one question on the pipeline. The VCAP study that you just started, what do you hope to show when you complete that study?

**Steve Lisi**

No. We've done four studies already in pneumonia, three in infants and one in adults during the pandemic. You're going to see pretty much what you saw there. You're going to see safety, which will have to be the primary endpoint in a pilot study of course, safety, tolerability and then you'll see our efficacy endpoints will be there as well. Same efficacy endpoints you saw in the other studies. We have them on our website. They've been published at medical conferences as well as journals.

You're going to see the same thing. You're going to see these patients improving faster than if they don't have nitric oxide in general. Again, this will be the fifth time we've done it. I think anybody would be shocked that you go four for four. You're probably going to go five for five. If you're going to want to take a look at our previous results, you'll know what's coming.

**Matt Kaplan**

Just a follow up on that. The goal of this study is to generate data that you can take to FDA to get clearance to a pivotal or what do you hope to show?

**Steve Lisi**

Yes, this would be the final study before we go into a registration study. That's correct. The next study will be a registration study in the United States.

**Matt Kaplan**

Oh, great. Great. Thanks, Steve.

**Steve Lisi**

Thanks, Matt.

**Operator**

There are no further questions at this time. I would like to turn the floor back over to Steve Lisi for closing comments.

**Steve Lisi**

Yes, thanks, everybody, for joining today. Internally here, we're very positive on our outlook. We wouldn't have put that guidance out there and as Matt mentioned on the last question, we're very excited about our pneumonia program. Just one last note on that, it is a seasonal condition. These studies do move quickly. With that, I will say thanks again and talk to you soon.

**Operator**

This concludes today's conference. Thank you for joining us. You may now disconnect your lines.