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Beyond Air, Inc.

Third Quarter Fiscal Year 2023 Earnings Call

February 9, 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

Matthew L. Kaplan, *Ladenburg Thalmann*

Greg Fraser, *Truist Securities*

Yale Jen, Ph.D., *Laidlaw & Company*

Suraj Kalia, *Oppenheimer & Company*

PRESENTATION

Operator

Good afternoon, and welcome, everyone, to the Beyond Air Financial Results Call for the Third Fiscal Quarter ended December 31, 2022.

Now I would like to turn the conference 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 third quarter of Fiscal Year 2023 operational highlights and financial results. A copy of this press release can be found on our website under the News and Events section.

Before we begin, I'd 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 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 the live broadcast, February 9, 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. Good afternoon to everyone joining us.

Today, I'll be providing an update across our portfolio, including Beyond Cancer, This will be followed by an overview of our financial results for the quarter by our Chief Financial Officer Doug Larson, and then as usual we will open the call up for questions.

Before discussing our pipeline and financials, I would like to turn it over to our Chief Commercial Officer Duncan Fatkin for an update on the LungFit PH commercial launch. Duncan?

Duncan Fatkin

Thanks, Steve, and good afternoon to our investors.

During the last quarter, we have continued to make tremendous progress with the initial phase of our commercial launch of LungFit PH.

As a reminder, our go to market strategy is a multiphase 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 completed evaluations of LungFit PH at a variety of different hospitals, in line with our strategy to gain feedback on our logistics, customer service, and of course the clinical performance of the device. The feedback has been in line with our expectations. We have moved into the contracting phase with a number of hospitals as a result of their experience and awareness of our technology.

In addition, our team has demonstrated the LungFit PH system in person at over 150 hospitals, and at state and national conferences in our target regions; a tremendous achievement, given continued restrictions in hospitals as a result of the triple threat of COVID, RSV and flu during the winter period so far.

As anticipated, respiratory therapists and neonatologists are highly motivated to eliminate cylinders, and are impressed with how simple and easy the LungFit PH system is to use. Hospital administrators are reacting very positively to the flexible and transparent business models presented, and we believe in some cases they will revisit some of the restrictions placed on the use of nitric oxide due to cost and logistical challenges.

We've been able to test our logistics infrastructure, as well as our clinical and sales operation support, through our 24/7 Lungflex service.

Based on the feedback received in the first seven months since launch, we are planning to move into an accelerated phase of promotion in the spring. We will use the experience from this first phase of our launch to refine our business model, geographical focus, and clinical training, to make sure that we optimize the next phase of our launch.

As I have previously mentioned, during this second phase we will be expanding our commercial team, both field sales and clinical specialists, and building a network of reference hospitals and key opinion leaders.

We are very excited about the progress made over the last quarter, and look forward to building a coalition of hospitals supporting this amazing new technology and accelerating awareness of a new way of delivering nitric oxide across the U.S. and beyond.

With that, I'll turn the call back to Steve for the pipeline review. Steve?

Steve Lisi

Thanks, Duncan.

I will start with LungFit PH, where we have faced regulatory delays. Our quest for CE Mark is going well, but we must postpone our anticipated approval until the first half of our Fiscal Year 2024. In the U.S. we have faced similar issues of delays beyond our control, and thus we have not yet submitted our PMA supplement for cardiac label expansion, but expect to do so before the end of the first half of this calendar year. We remain confident in achieving both of these goals.

With respect to our VCAP program, we continue to work closely with FDA to agree upon the protocol for our study which we intend to start in the fourth quarter of calendar year 2023. We began this discussion over the summer, and we believe that FDA should allow this study to be conducted, given our efficacy and safety profile, in an adult pneumonia study, three bronchiolitis studies, two NTM studies, along with several other studies. These studies have resulted in excess of 5000 endo-administrations at 150 parts per million to 250 parts per million nitric oxide in over 170 patients, not to mention the squeaky-clean safety data in animals that we have mentioned many times in the past.

As a reminder, this proposed study is extremely similar in design to what we reported from our Israeli viral pneumonia study. We expect to treat patients hospitalized with pneumonia who test virus-positive for any virus, including any and all variants of SARS-CoV-2.

We have seen no SAEs related to 150 parts per million and 160 parts per million NO in three bronchiolitis studies and one adult pneumonia study. Plus we followed the infants long term, some out more than five years, and saw no long-term effects from the acute NO treatment.

Our studies and long-term data reflect our continuing ability to manage concerns of methemoglobinemia and nitrogen dioxide exposure associated with high-concentration NO treatment. We are confident that we will be able to build on these results.

Moving to 250 parts per million NO, which was delivered in our study multiple times per day, at home by patients with no medical professional present, for more than 11 weeks. You can see these data as they were presented at the 2022 Chest annual meeting by visiting our website. Just a reminder, no methemoglobinemia and no nitrogen dioxide issues were reported. We believe that these data support moving forward with a pivotal study for NTM patients, and we will move as fast as possible.

At this time, we do not see the study beginning until the second half of our Fiscal Year 2025. We look forward to working with FDA to meet or shorten this timeline.

Our pilot study in patients with underlying COPD will not be conducted this coming winter. We will look to begin this study in the fourth quarter of calendar 2024. LungFit PH and VCAP are our immediate priorities, but we'll continue to work with FDA in addressing the varied applications of NO.

Moving on to Beyond Cancer. Progress over the last 15 months, since the money raise, has been very strong. The Phase 1a human clinical study is ongoing, with our current believe that we will be releasing top line data later this calendar year. Our first publication is out, with another expected later this year. Our preclinical team is quite active, with data expected at several medical conferences this year, and we've already shown a doubling of survival in animals when we added our Uno therapy to anti-PD1 therapy, compared to anti-PD1 alone.

The team has also been expanded with the recent hiring of Gavin Choy as COO and the additions of Doctor Fred Dirbas and Doctor Mark Pegram, both world-renowned oncologists at Stanford, to our Beyond Cancer SAB.

In addition, the first patent for our technology was issued. Please visit beyondcancer.com for detail on all of these accomplishments, and stay tuned for more later this year.

I will now turn the call over to Doug Larson, our Chief Financial Officer, to provide an overview of our financial results for the fiscal quarter ended December 31, 2022. Doug?

Douglas Larson

Thanks, Steve, and good afternoon, everyone.

Our financial results for the third quarter of Fiscal Year 2023, which ended on December 31, 2022, are as follows.

On a GAAP basis, research and development expenses for the fiscal quarter ended December 31, 2022, were $5 million, compared with $2.5 million for the fiscal quarter ended December 31, 2021. This increase was driven mainly by compensation costs from scaling up operations in Beyond Cancer, as well as from increased investments in preclinical work being done across the group in our targeted therapeutic areas.

General and administrative expenses for the fiscal quarter ended December 31, 2022, increased to $8.9 million, compared with $4.9 million for the fiscal quarter ended December 31, 2021. $3 million of the increase was due to the planned structural investments in Beyond Cancer, with the remaining $1 million attributable to continued investments in people and systems necessary to support the commercial launch of LungFit PH in the U.S.

Other income and expense for the fiscal quarter ended December 31, 2022, was a $0.2 million gain, compared with a $0.5 million loss for the fiscal quarter ended December 31, 2021. The two main drivers in this year-over-year improvement were the gains we made from our investments in marketable securities, as well as favorable foreign exchange movements.

For the fiscal quarter ended December 31, 2022, the Company had a GAAP net loss of $13.8 million, of which $12.7 million or $0.43 per share was attributable to the shareholders of Beyond Air, Inc., compared with a net loss of $7.7 million or $0.29 per share for the fiscal quarter ended December 31, 2021.

Net cash used by the Company, including Beyond Cancer, was $9.3 million for the quarter ended December 31, 2022. Through the first nine months of this fiscal year, net cash burn has been $27 million.

As of December 31, 2022, the Company reported cash and cash equivalents, marketable securities, and restricted cash of $63.2 million. We still forecast that our average quarterly cash burn for fiscal 2023 to be within a range of $8 million to $10 million per quarter.

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

Steve Lisi

Thanks, Doug. Hope everyone is as pleased as I am with the execution and progress at Beyond Air. Operator, let's go to Q&A.

Operator

Our first question comes from Matt Kaplan with Ladenburg Thalmann. Please go ahead.

Matthew L. Kaplan

Hi, good afternoon, and thanks for taking the question. Just wanted to follow up on how the LungFit PH launch, initial early launch is going, Phase 1. Is there anything that you've learned about the competitive marketplace in the hospital, which is new or unexpected, which could potentially help to expedite the launch or would potentially slow it down in terms of marketplace penetration?

Steve Lisi

Thanks, Matt. I'll turn this over to Duncan to answer this question. But the one thing I'll say before that is, man, the hospitals move very slowly. I think COVID's just made things a little bit more difficult to get things through in the hospital space. Lots of new things, in terms of getting your teams into the hospital to get work done. But that's just from my bird's eye view, but I'll let Duncan comment on this further.

Duncan Fatkin

Thanks for the question, Matt. No, we're really pleased with the way it's going. Essentially, there's no change to the plan. We're executing as per our previous conversations, first six months to nine months up to a dozen hospitals, and that's all we have been doing, and we've had really excellent feedback during that period. As we've said before, we've been focusing on the logistics, the service, and from a clinical point of view things have gone as absolutely well as we could expect. We're very pleased with the feedback that we've been getting.

We've trained hundreds of respiratory therapists in a number of different hospitals, and now we're in the contracting process. As I mentioned in my remarks, I'm very impressed with the access we've got, considering the triple threat that we're all familiar with, and now we go through the contract process with these various hospitals, and the ones that we're now moving forward with in the early phase of that broader expansion. Each hospital is different. There are different stages, and they have different processes. Some of those have become more onerous, some of them haven't changed. It depends from hospital to hospital.

Nothing that we've learnt that has surprised us, and we're pleased with the progress.

Matthew L. Kaplan

All right. Then specifically, how should we think about the Phase 2 as you—moving into this accelerated phase in the spring?

Duncan Fatkin

I think that we said that the first six to nine months would be that Phase 1. We're coming to the end of that, so in the next fiscal year is when we start to ramp up. As I said, it depends on the mix of hospitals that we end up with from a contractual point of view. We can't know for sure exactly when they're all going to hit, partly for the reasons that Steve commented on and partly just the luck of the draw in terms of where they are in their contracting process. Unfortunately, we can't control that to a significant extent. As we get more scale, we'll obviously have more confidence in that.

Matthew L. Kaplan

Great. Great. Thanks for (inaudible).

Operator

Our next question comes from Greg Fraser with Truist Securities. Please go ahead.

Greg Fraser

Good afternoon, folks, thanks for taking the questions.

For the hospitals that have done an eval and decided to not move forward with contract discussions, have there been any common reasons why?

Duncan Fatkin

I think it all comes down to contracting. If they're in a phase where we've done an evaluation and they are looking at, for example, dual source, in some cases they can do that, in some cases takes a little bit longer. That's part of the reason is around contracting. The other might be to do with the scale of the hospital in terms of it might be part of a group, and that group might have, in some cases, we've done work with a hospital that was acquired by a group, and that slows things down. Typically it's around the timing of the contracting process. That's the most common. But we have been selective, and we're still working with most of those hospitals.

Steve Lisi

Greg, just to follow up on that. You're getting at the question of is there something consistently wrong that is seen with our system, that people aren't signing up with us. I think that's way off base in terms of what's actually going on. The process moves slowly. You can look back at all the conference call transcripts that we've had in the past two years, and I've said that this is a six- to nine-month process to get the ball moving. We've just completed six months at the end of December, including July and August. Launching in the summer in this industry, you know, is usually a no-no. Those were rough months, obviously.

We knew it was going to take a long time to get the ball rolling, and this is not just fill the channel with some pills and get going. This is a process that takes time, it's an education and so forth, training with the hospitals.

We haven't seen anything about our system that concerns us or concerns any of the hospitals that have seen our system and played around with it. Are there little tweaks here and there? Of course. These are things that are normal in the beginning of a launch. We'll probably be tweaking our system for the next ten years, just like our competitors have. If you look at the INOmax DSIR, go look when it was first approved, and what it looked like then and what it looks like now, and they're still coming out with new versions of their system. There's always room for improvement. But we've seen nothing with our system that stops hospitals from using our system. That has nothing to do with where we are at this moment in time.

In fact, we're pretty much right where we thought we'd be at this moment in time. Would I like it to go faster? Of course, everybody wants things to go faster. But the reality is, six to nine months is what we estimated, and it's going to take that time. It's going to take the full nine months for us to get the ball rolling in the place that we'd like to be.

I think that's what you were getting at with your question, but if it wasn't, please follow up.

Greg Fraser

Yes, no, that's what I was asking, and that's a very helpful answer, thank you.

On the contracting discussions, I believe your objective is to supply NO at a price similar to what the hospitals are already paying. Are hospitals receptive to that? Are some looking for discounts? Any color there would be helpful.

Duncan Fatkin

Again, it varies; once you've seen one hospital, you've seen one hospital, is kind of the saying. We've looked at various business models, as we've evolved and learnt, we've adjusted to what different hospitals are looking for, and it very much depends on the circumstances, the clinical setting. In some cases, we expect that the winning formula is going to be in line with current expectation, in some cases we might be actually at a premium. It just very much depends on the benefits of eliminating cylinders in that hospital and the value of the logistical hassle that we're removing.

Again, I'm not giving you a blanket answer, because it is so varied. But we certainly haven't had any general difficulty in that area. But we're going to continue to be very flexible and responsive to their needs.

Greg Fraser

Got it. That's very helpful.

Then can you just comment a bit more about the CE Mark process and what contributed to the later timing for action versus your prior expectation?

Steve Lisi

They changed things in the EU a few years ago. The new MDR, I guess they call it. That resulted in a significant decline in the number of notified bodies in Europe, plus a lot of the capacity of these remaining notified bodies was being used up by companies with products that were already on the market. A lot of these things, these products were subject to the new rules and could have been pulled off the market. There wasn't a lot of capacity.

We were in; we had a timeline with our notified body. We communicated guidance to you based on that timeline communicated to us. They just couldn't get it done. They're overworked, overwhelmed, and these

things happen. We're working with them. They're doing a good job. We don't see any reason why we won't be getting CE Mark, but we still have to work through the process with them. Things are just taking longer than expected. We went through these things with them and got timelines and thought we all could hit them. Us and them together thought they could hit these timelines. It just didn't happen.

There seems to be delays with regulatory stuff in the U.S. and Europe. I think the regulatory agencies are recovering from what happened during COVID, and what happened in Europe anyway from the change in regulations. But some companies are getting luckier than others and getting their timelines.

But it's really been nothing of concern for us in terms of we're insufficient to get approval. That's not the issue. The issue is just working through it and trying to meet the timeline. It's unfortunate, but it is what it is, and we'll just get it in a couple months. That's all we can do.

Greg Fraser

Got it. Okay, I'll ask one more and then I'll hop back in the queue. On the cardiac filing, I think you had a meeting with the FDA. Did anything come up in that meeting that was unexpected and can potentially be a hurdle to approval? Thanks so much.

Steve Lisi

Our meeting on the cardiac label expansion was pushed back by FDA, so it was scheduling conflicts. That meeting has not yet occurred, which is why we haven't submitted the PMA supplement. I really can't comment, I'm sorry.

Greg Fraser

Okay. Okay, thank you.

Operator

The next question comes from Yale Jen with Laidlaw & Company. Please go ahead.

Yale Jen, Ph.D.

Good afternoon and thanks for taking the questions and congrats on all the progress.

In terms of LungFit PH, you mentioned that in the second phase you're going to expand the sales force. Could you give us a little bit of color how that pace might be and how that size might be? Then I have a follow-up.

Steve Lisi

Yale, thanks. The pace at which we expand the commercial team is going to be dictated by what we see coming in the next six to twelve months in terms of expected contracts. Duncan is going to be building up that team, starting very soon, and we're going to be focusing on our clinical team buildup first. Those are the guys who educate and train the hospital employees. That's really the hurdle in the beginning as you get rolling, since it is relatively new for these hospitals. Then we'll focus more on the actual sales reps once we've gotten our clinical people up to the number that we need.

This will be ongoing. The expansion of the team will be ongoing, probably for the next 18 to 24 months. We don't just snap our fingers and bring everybody in, right? They'll come in waves. That's the Phase 2 of our

launch. Like I said, would get going in the next few months and last probably 18 to 24 months of us building that team.

I hope that answered the question. If it didn't, please let me know.

Yale Jen, Ph.D.

That's very helpful, appreciate that. Maybe one more question, in the FDA meetings for the LungFit PRO on VCAP, any colors of that meeting you can talk about?

Steve Lisi

We don't like to talk about what was said between us and the FDA, our communications are private with them. But again, what I will say is that we are certainly enthusiastic about getting this study started up in the fourth quarter of this calendar year. We're looking forward to it, that's for sure.

Yale Jen, Ph.D.

Okay, great. Maybe just to tuck in one more, which is that we notice that the LungFit PRO, the trials, both in the NTM as well as in COPD, has been pushed out quite a bit compared to your earlier guidance, including your recent slide deck. Was there any strategic reason you will take that move? Thanks.

Steve Lisi

COPD is not strategic. That's just, again, FDA timelines have been pushed out. We need time to set that study up properly, because even though you don't see it as a seasonal study, it really is, because we're looking for exacerbations in these patients, and seeing those exacerbations result in hospitalization. That's going to be a lot—there'll be a much more volume in the winter months than in the summer months. We don't want to do this outside of a winter season, and there's no way we can get it done in the upcoming winter based on the timelines that have been given to us by FDA. That's just the reality of where we are today.

With respect to NTM, yes, I think we said we were shooting for late '24 calendar, and I think we just made our guidance to back half of our fiscal year. It's kind of semantics, not really a delay, but we'll try to get this done as quickly as possible. I think that maybe we're being a little conservative because FDA's kind of overloaded with things a little bit and we don't want to—we'd like to give ourselves a little bit of a cushion in case there's some push out there as well, but things run smoothly maybe we can pull that back in a little bit, Yale. But we'll have to see how that goes.

This is more of a—this is not just a protocol discussion with FDA, but it's also a discussion of our final home system that's being built. We need to obviously get the device approved by them, as well as the study, whereas for pneumonia it's just about the study, not about the device.

Yale Jen, Ph.D.

Okay, great. Very helpful, appreciate it, and again congrats on all the progress.

Steve Lisi

Thanks, Yale.

Operator

Our next question comes from Suraj Kalia with Oppenheimer & Company. Please go ahead.

Suraj Kalia

Good afternoon, everyone. Two questions. Duncan, one for you and one for Steve. Let me start out with you, Duncan.

Duncan, you all have been consistent in terms of the phased launch of PH. I was wondering if I could push you a little bit in terms of quantifying the sites that have gone through evaluations and are now in the contracting phase, and specifically, when you see a site has finished evaluation, what does the typical NICU that may or may not already be contracted with (inaudible). What all have they done from an evaluation perspective, to push it to the next stage?

Steve Lisi

Hey Suraj. We're not going to comment on those numbers. But Duncan can comment on the other question.

Duncan Fatkin

From an evaluation point of view, again, it varies from hospital to hospital, depending on the protocol and the quality assurance process they have in place. In some cases, in fact, they do what they call a bench test. That requires them to go through a protocol without actually connecting it to a patient. But in a typical evaluation where they do have clinical experience, they will go through that process in a matter of somewhere between a week and three to four weeks. It's usually lined up with a period before their contract is due, and again, some hospitals begin their contracting process six to nine months, in some cases 12 months ahead, based on the protocol and the various stakeholders in a value access committee or something of that nature that they need to go through.

Unfortunately there's no "one size fits all" again. But from our perspective, it's a pretty straightforward process, because our system is so fast and simple. They just have to use our system instead of the system they're currently using as per their protocol.

I hope I've answered your question?

Suraj Kalia

Fair enough, Duncan.

Steve, one question for you, and I know you guys at this stage are somewhat averse to giving specifics on numbers. But picking up on the commentary in terms of some of the things getting delayed, the processes taking longer, maybe if I could just position it this way, Steve. Fiscal fourth quarter numbers are about $3 million in revs; Fiscal '24, if I'm looking at it correctly, is almost $40 million. Maybe you can help thread the needle here in terms of what you are seeing, in terms of the phase launch, and how would you guide us, based on what the consensus numbers are out there?

Gentlemen, thank you for taking my questions.

Steve Lisi

Thanks, Suraj. Let's be clear, those numbers are from you and the other analysts, that's consensus. We have given no guidance whatsoever, so that's just your interpretation. We're not going to be giving guidance at this point. I think I have been very clear about that. We're going to wait and see how things play out, and gather more information before doing that, and that'll probably happen when we announce our fiscal year, which obviously ends March 31. You can look forward to us discussing in more detail what kind of guidance we'd be giving at that time. I think it's still a little bit too early to discuss those things.

Operator

At this time, we are showing no further questions in the queue, and this concludes our question-and-answer session. I would now like to turn the conference over to Steve Lisi for any closing remarks.

Steve Lisi

Thank you, everyone, for joining us today. Very much appreciate the interest. Look forward to speaking to you very shortly at a couple of upcoming industry conferences. Thanks very much.

Operator

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