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Beyond Air, Inc. (XAIR)

Q4 2023 Earnings Call

CORPORATE PARTICIPANTS

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OTHER PARTICIPANTS

Marie Thibault

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Matt L. Kaplan

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MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon, and welcome, everyone, to the Beyond Air Financial Results Call for the Fiscal Year ended March 31, 2023. At this time, participants are in a listen-only mode. A question-and-answer session will follow the formal presentation.

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

Edward J. Barger

Head-Investor Relations, Beyond Air, Inc.

Thank you, operator. Good afternoon, everyone, and thank you for joining us. Today, after market close, we issued a press release announcing the fiscal fourth quarter and full year 2023 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 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, June 22, 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 on the call are Steve Lisi, Chairman and Chief Executive Officer; Duncan Fatkin, Chief Commercial Officer; and Douglas Larson, Chief Financial Officer.

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

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Thanks, Ed, and good afternoon to everyone joining us. Welcome to phase 2 of our commercial launch. This is an exciting time for us as we have visibility into what the PPHN market will look like over the next several years. With our initial limited launch completed, we are highly confident that we have gained the knowledge required to satisfy the needs of hospitals using nitric oxide.

LungFit PH has been well received in the market. We believe that our ability to support and service most hospitals has been established. Now is the time to increase the size of our commercial team and increase our market share. Our Chief Commercial Officer, Duncan Fatkin, will have more on this in a few minutes.

Outside of LungFit PH commercial operations, we have been very busy and I am proud of what the Beyond Air and Beyond Cancer teams have accomplished. LungFit PH cardiac label expansion application will be submitted before the end of this calendar year to FDA. This is later than we had hoped, but we want to be certain that the application is high quality and will satisfy FDA requirements. We also expect CE Mark in the EU for LungFit PH late next quarter.

We anticipate LungFit PRO will be used in a community-acquired viral pneumonia study in the United States this coming winter. LungFit GO is scheduled for an at-home COPD study start in 2024 and NTM in 2025. Beyond Cancer anticipates phase 1a data this fall. As announced last week, we now have another NO-related program, autism. Please refer to our announcement last week for details.

Our portfolio consists of programs where NO was approved to treat acute pulmonary hypertension in newborns, [ph] is in human studies for (04:12) hypoxemia associated with viral lung infection, chronic refractory persistent lung infection and solid tumors, and in preclinical development for autism. We can consider ourselves the preeminent NO company with the investments we have made into NO research and development. We believe that we have only scratched the surface of the impact NO plays in human health.

We recently secured debt financing of up to \$40 million from funds managed by Avenue Capital Group. We believe this additional capital strengthens our position to execute on our strategy for LungFit PH and our other programs. In addition, I believe that securing this capital from a well-known healthcare investment firm with a history of investing in nitric oxide speaks volumes about our programs and the progress we're making.

Now, I will turn the call over to our Chief Commercial Officer, Duncan Fatkin, for an update on the LungFit PH commercial launch. Duncan?

Duncan Fatkin

Chief Commercial Officer, Beyond Air, Inc.

Thanks, Steve, and good afternoon to our investors. As Steve just mentioned, we've made steady progress with our commercial launch over the past few quarters. The feedback from hospitals regarding LungFit PH continues to be extremely positive, and we would like to thank all the hospitals and clinical staff that have contributed to this first wave of clinical use.

As I mentioned on previous calls, our go-to-market strategy is a multi-phased commercial approach. The initial phase represented a measured release of LungFit PH to a select group of hospitals that use inhaled nitric oxide on a regular basis. During this first phase, we received positive feedback from a variety of different hospitals on our logistics, customer service and the clinical performance of the device. As a result, several hospitals have signed contracts for LungFit PH. These accounts set an important foundation from which the team will build upon.

In regard to our sales pipeline, we're excited by the interest in LungFit PH. As one point of reference, we have conducted more than 150 in-person demonstrations that have resulted in positive feedback and help to optimize the LungFit PH system, our service and support, supply chain, logistics and back office operations.

Based on our success to date, we moved into the second phase of our commercial program in the beginning of the current quarter. In this phase, we are expanding our commercial team, both field sales and clinical specialists, and expanding our network of reference hospitals and key opinion leaders. We expect that this will lead to market share gains over the next 10 to 12 quarters before we enter the final phase of commercialization.

In closing, we continue to be excited by the growing coalition of hospitals supporting this amazing new technology and believe the program has gathered tremendous momentum to drive future growth. We project the annual value of contract signings over the next six months to be measured in the millions. In addition, a key point to remember is that the customer base and commercial function that we're establishing will support the future launch of LungFit PRO for additional indications for the hospital, if and when approved.

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

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Thanks, Duncan. I will start with LungFit PH. I mentioned earlier that CE Mark is expected near the end of the next quarter and we expect the FDA submission for the cardiac label expansion before year-end. We continue to execute on our regulatory strategy in our interactions with the FDA and other regulatory authorities, prioritizing as needed. We are confident that both milestones will be achieved.

With respect to our VCAP program, we are preparing to conduct a study this coming winter in the United States. This study will not be a pivotal study, but a small study that we would expect to lead to a pivotal study.

As for LungFit GO, we look to initiate a pivotal study in the first half of 2025, pending discussion with the FDA for NTM. We hope to initiate a pilot study in the second half of 2024 for COPD patients released from the hospital after having been hospitalized for an exacerbation. This is an exciting time for the clinical, regulatory and engineering teams.

Before I move on to Beyond Cancer, I would just like to emphasize that, to date, we have completed multiple studies in several clinical settings where 150 parts per million to 250 parts per million nitric oxide has been

delivered to the lungs in more than 145 patients and over 4,500 individual administrations with zero serious adverse events directly attributable to nitric oxide.

In addition, strong efficacy trends were seen in multiple studies. This portfolio of clinical data, along with our preclinical data, leads us to believe that exogenous nitric oxide generated and delivered by LungFit will improve the lives of patients.

Earlier in the current quarter, we presented impressive new in vivo and in vitro data at the American Association [ph] of (09:35) Cancer Research Annual Meeting. These data suggests that ultra-high concentration NO, or UNO, is effective in treating solid tumors as a single agent and in combination with checkpoint inhibitors such as anti-PD1 and anti-CTLA4.

To be more specific, the data shown in mice were in a very aggressive triple negative breast cancer model called 4T1. An UNO therapy, in combination with both anti-PD1 and anti-CTLA4, showed improvements in survival against each checkpoint inhibitor alone. Repeated UNO therapy suggests that repeat dosing is safe and effective.

We remain very enthusiastic about our ongoing phase 1a human clinical study, which is expected to have topline data later this calendar year. I would like to emphasize that thus far the data from the human study are consistent with the preclinical animal studies with respect to immune biomarkers.

Turning to our newest program, neuronal nitric oxide synthase, or nNOS, inhibitors. I would like to thank Dr. Haitham Amal and his team at the Hebrew University in Jerusalem for working with us over the past year. We expect big things going forward. The relationship is focused on what nNOS inhibition can do in neurological disorders and, as stated in our recent announcement, is initially focusing on reversing the effects of autism spectrum disorder. Considering we just held the conference call dedicated to the announcement of this particular program last week, I suggest anyone who didn't listen to the live call, visit our website and listen to the archive of the call.

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 year ended March 31, 2023.

Douglas Larson

Chief Financial Officer, Beyond Air, Inc.

Thanks, Steve, and good afternoon, everyone. Our financial results for the fiscal year ended March 31, 2023 are as follows: Revenue for the fiscal year ended March 31, 2023 was zero as compared with zero for the fiscal year ended March 31, 2022. I'm very happy to say that this will be the last time you hear me say that revenues are zero.

On a GAAP basis, research and development expenses for the fiscal year ended March 31, 2023 were \$16.8 million compared with \$11.8 million for the fiscal year ended March 31, 2022. The main driver of the \$5 million increase was compensation costs from scaling up operations in Beyond Cancer. We also further increased staff in Beyond Air's R&D team, recognized some of the initial work with autism, and had generated costs early in the fiscal year for the final push to get approval for the LungFit for PPHN.

Selling, general and administrative expenses for the fiscal year ended March 31, 2023 increased to \$34.7 million from \$18.4 million for the fiscal year ended March 31, 2022, mainly due to \$9.2 million in structural investments in Beyond Cancer, with the remaining \$7.1 million mainly driven by the US commercial launch.

Other operating expenses for the fiscal year ended March 31, 2023 were zero compared with \$10.5 million, which were entirely related to the contingent liability for the Circassia settlement from May of 2021. As a reminder, we paid \$2.5 million to Circassia in the second fiscal quarter of 2023. We have another \$3.5 million to pay in the second fiscal quarter of 2024, with the final \$4.5 million not due until the second quarter of fiscal 2025.

Other income and expense for the fiscal year ended March 31, 2023 was a net loss of \$7.3 million compared with \$3.4 million for the fiscal year ended March 31, 2022. The \$3.9 million increase is from a non-product related legal matter that was previously partially reserved for and resolved in the fiscal fourth quarter.

For the fiscal year ended March 31, 2023, the company had a GAAP net loss of \$59.4 million, of which \$55.8 million, or \$1.86 per share, was attributable to the shareholders of Beyond Air, Inc., compared with a net loss of \$43.2 million, or \$1.68 per share, for the fiscal year ended March 31, 2022.

Net cash used by the company, including Beyond Cancer, was \$37.9 million during the fiscal year ended March 31, 2023. We forecast our average quarterly cash burn to be approximately \$10 million per quarter as we head into fiscal 2024.

As of March 31, 2023, the company had cash and cash equivalents of \$45.9 million. We believe that this amount, in addition to the \$17.5 million secured through our agreement with Avenue Capital, is sufficient to fund operations for at least the next 12 months.

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

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

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.

QUESTION AND ANSWER SECTION

Operator: Thank you. Ladies and gentlemen, at this time, we'll be conducting a question-and-answer session. [Operator Instructions] Our first question comes from the line of Marie Thibault with BTIG. Please proceed with your question.

Marie Thibault

Analyst, BTIG LLC

Q

Hi. Thank you for taking the questions this evening. Very glad to hear that we will be seeing revenue this next coming quarter. Would love to hear a little bit about how the fiscal fourth quarter went, the timing of some of these contracts that you described [ph] us (15:48) as signing, and what you can tell us about what's taken place commercially in the last couple of months here as the – as you've shifted to phase 2?

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Thanks, Marie. Appreciate that. I'm going to turn this over to Duncan, our Chief Commercial Officer, to comment on that.

Duncan Fatkin

Chief Commercial Officer, Beyond Air, Inc.

A

Thanks, Marie, for the question. So the contracts, typically, there's quite a few that start in the first quarter of – first month of a quarter. And so you get that kind of effect and so we [ph] afford (16:20) to get some of these to start a little bit earlier. But the timing of the negotiations and the way that kind of fell just pushed us a little bit further. But certainly nothing that's put us off our long-term schedule.

From a learning's point of view, we continue to get really good clinical feedback. The training has gone really well, and we've refined the way we train and go to the hospitals and we've certainly made some improvements to the software to make the system work even better than it has been.

It's certainly fair to say that we're a little bit behind where we [ph] wanted (16:52) to be. Some of the supply chain challenges from earlier in the fiscal year, it kind of flowed through, and we've taken our time to work with our team and they've done an amazing job actually to make sure we can stay close to where we need to be.

And going forward, we're focusing on expanding. And as you can see from the prepared remarks, we're going to increase the team now, because we feel like we're ready to support that expansion, something that we were a little bit more cautious about earlier on in the year.

Marie Thibault

Analyst, BTIG LLC

Q

Okay. That's really helpful, Duncan. Maybe I can ask as a follow-up. How should we think about that commercial sales force expansion? What do you think is the right number for this phase? And how quickly are those folks getting hired?

And then, as a second part of that question, for Doug maybe, if I look at the SG&A this quarter and exclude the \$9 million or so that was invested in Beyond Cancer, I'm getting to about \$25 million. Is that the right level that you would have us look at for SG&A here in this next fiscal year?

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Hey, Marie. So it's Steve. I'll take the sales force expansion. So it's an expansion to what we would believe would be our peak size. And I think we've said that number would be somewhere around 70 to 80 total people. That wouldn't just be sales reps, that would be everybody, clinical specialists and operations and marketing and so forth.

So that'll probably take us the next 18 to 24 months to bring those people on in an orderly manner, get them on, train them, deploy them and go back and bring more people on. So that's how it'll happen. We're not in any rush to bring the people on in one big fell swoop like maybe a much larger company might do. So this is a good 18- to 24-month exercise that we've begun to go from a sub-20 number and multiply that by [ph] 4 to 5x. I don't know, does (18:50) that answer your question, Marie?

Marie Thibault

Analyst, BTIG LLC

Q

That does. That does. I wonder if Doug could comment on the \$25 million in spend this quarter and what it might look like going forward.

Douglas Larson

Chief Financial Officer, Beyond Air, Inc.

A

So \$25 million is the annual number if you pull out Cancer. So that was – the \$9 million is an increase versus last year.

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Yeah.

Douglas Larson

Chief Financial Officer, Beyond Air, Inc.

A

So it's not the absolute number that we're looking at, right? We did have three months of Cancer last year. We've got [ph] 12 months (19:23) this year. Keep in mind that we are going to continue to consolidate Cancer into our numbers as well. So I don't know if you're trying to pull those numbers apart. It might be a little bit [ph] tricky. We can (19:35) maybe follow-up on that one, if that [ph] works (19:40).

Marie Thibault

Analyst, BTIG LLC

Q

Okay. Okay. Okay. Certainly. Happy to follow-up later. Thanks for taking the questions.

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Thanks, Marie.

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

Matt L. Kaplan

Analyst, Ladenburg Thalmann & Co., Inc.

Q

Hi. Thanks for taking the questions. Just staying with the LungFit PH, I guess, now that you've completed phase 1 of the launch, can you tell us a little bit more about what you accomplished in phase 1, specifically maybe some more detail around the number of contracts? And then, with that, what you – what we should look for as you now launch into the second phase of the commercial program here?

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

So, Matt, I'm going to let Duncan talk about what we've learned and what's going to help us going forward. But with respect to the number of contracts, I mean, we did state that we had multiple contracts that have been signed. I would say that the number, as we see here today, is less than 10. So we're looking at single-digit number of contracts. And going forward, obviously, we expect that number to increase quite dramatically over the next four to six quarters.

I mean, as we bring more people on and we are able to handle more volume of customers, it is going to increase significantly. And that was always the plan with our three-step process towards this launch as we've had in our slides for the past 18 months and we've been stating on every quarterly conference call that phase 1 would be where we learn and make sure everything we have is up to speed, ready to go to expand. And now we're in phase 2 where we're going to expand our team and start to take some serious market share. It's how I look at it.

But Duncan, you want to comment on what we've learned in phase 1?

Duncan Fatkin

Chief Commercial Officer, Beyond Air, Inc.

A

Yeah. And thanks for the question, Matt. So, I mean, we – our focus has been on making sure that the logistics are smooth, the clinical performance is as we'd expected, and the training and everything associated with that continues to go well, which we definitely feel good about that.

Certainly, the feedback continues to be that our system is very simple to use and it doesn't take too long to do the training. We've been refining some of our programs because in the simplicity and ease, sometimes actually a lot of the clinicians using the device don't spend as much time as we'd like them to. And so, we kind of do some remedial work. And so, we refine our program.

We certainly also understood better the profile of the hospitals that we need to go to, to make sure that we pick the ideal locations and the ideal partners, which is why we took our time to go to a variety of different types of hospitals. So from our perspective, that probably [ph] are (22:34) the main learnings, nothing that has been shocking to us, and definitely some optimization that we've done with the device. So we're pleased with what we've learned and now we can really start to expand with, I'll call it, much more confidence.

Matt L. Kaplan

Analyst, Ladenburg Thalmann & Co., Inc.

Q

Okay. And I guess with that, how should we think about the contracts converting into the revenues over time as you add?

Douglas Larson

Chief Financial Officer, Beyond Air, Inc.

A

So, Matt, most of these contracts are going to be annual. So if we sign up [ph] \$600,000, it's going to be \$50,000 a month or \$150,000 (23:10-23:15) a quarter. So as you sign them, they start to build upon themselves, right? So that's how they're going to translate. We don't get the cash up front, we don't book the revenues up front, right? So this is an annual contract that's spread over four quarters.

So as we – we got a bunch this last quarter, we'll get a bunch the next quarter, so they'll build on each other and then the next quarter and it'll just keep piling on top. And the more we expand our team, the more people we get trained and out there, the more volume we can have. So every quarter should get better and better from the previous quarter in terms of not just the number of contracts, but the size of those contracts we're able to handle larger hospitals as well as we get bigger.

Matt L. Kaplan

Analyst, Ladenburg Thalmann & Co., Inc.

Q

Okay. And just shifting gears to Beyond Cancer. You mentioned that you're going to have a phase 1 data later this year. Can you give us some more detail in terms of how many patients and what we should be looking for in that data from Beyond Cancer later this year?

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Yeah. So I don't know exactly how many patients we'll be showing, but it's going to be, I don't know, give or take, 10 patients, maybe a few less, maybe a few more. It'll depend on the cut off. And I said in the prepared remarks that it's the immune biomarkers that – from an efficacy standpoint – as you know, Matt, this is a safety study. So we'll be looking for safety, and that's the most important thing at this stage. But we do want to understand what's happening to the immune system.

So I mentioned in the prepared remarks that – what we saw in the mice, which – we've shown several studies in mice, and you can see on the Beyond Cancer website what the immune markers have done going in the direction that we expect them to go and by arming the immune system against these tumors, we're seeing similar activity in the immune biomarkers currently in the patients that we have data on so far.

So I think that's what you want to look for, safety and these immune biomarkers to see if we're able to predict efficacy going forward. So we're pretty excited about it. I can't wait show it, but we'll have to wait until we complete a few more patients and we get the data in house and we get our statisticians to put that data together so we can share it with you.

Matt L. Kaplan

Analyst, Ladenburg Thalmann & Co., Inc.

Q

Okay. Very good. And then last question and then I'll jump back in the queue. LungFit PRO, you mentioned in your prepared remarks that the next study that you plan to launch will be a pilot study. What do you hope to learn from this pilot study prior to moving into a pivotal study with the program in the viral pneumonia setting?

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

So I think we – the purpose of this pilot study is to give comfort to FDA and to some of the sites we've spoken to that the safety is there and that they feel very comfortable treating their patients. And since this is not really a

study that we can go in the literature and see these types of endpoints that we're looking at, this study will also give us the ability to optimize our stats package for the primary endpoint that we're targeting. So I think it's twofold there. I think it's to give a little more comfort on the safety side. Not for us. We're very comfortable on the safety side, as you see from all the data that we've shown publicly. But it will help inform us on the primary endpoint and give us a little bit more confidence in sizing our study.

Matt L. Kaplan

Analyst, Ladenburg Thalmann & Co., Inc.

Okay. That's great. Thanks. Thanks, Steve.

Q

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Thanks, Matt.

A

Operator: Our next question comes from the line of Yale Jen with Laidlaw & Company. Please proceed with your question.

Yale I. Jen

Analyst, Laidlaw & Co. (UK) Ltd. (United States)

Good afternoon, and thanks for taking the questions. For the LungFit PRO – I'm sorry, LungFit PH, you mentioned that you have a number of contracts. So should we anticipate that you report that as a group later on in the next earning call, or you – should we anticipate that you will provide some update between this call and the next call in terms of [ph] what you get out there (27:52) several contracts being signed?

Q

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Thanks, Yale. Since the start fiscal year end or at the end of – almost at the end of June and we're going to report early in August, it's about six weeks difference between now and then. So I don't know how much update there will be. You would anticipate that based on the number of contracts we have in – we've signed, well, there'll probably be a few more by the – we get there August, but it's not going to be a material difference in six weeks. So – but again, we'll be making progress. I think that there should be a material difference when we report in November for sure. It's just these are very tight, our fiscal year-end and fiscal first quarter.

A

Yale I. Jen

Analyst, Laidlaw & Co. (UK) Ltd. (United States)

Understood. That's helpful. And one other thing in terms of your [indiscernible] (28:46) expecting CE Mark later this year and the question is that, beforehand, there's a discussion in terms of partnering ex-US. Any update of that front as of now?

Q

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Yeah, I mean, we're getting close to CE Mark. So the conversations are certainly progressing with ex-US partners now that we kind of see the light with CE Mark. But again, we don't have it in hand. So I think we will have it in hand in September, maybe October timeframe. So I think that our talks will heat up and we'll probably see some kind of a partnership in short order after we get the CE Mark in hand. So we're pretty comfortable with the profile

A

of the product. I think that our potential partners have seen this profile of the product. They're pretty happy with it. So things are moving along [indiscernible] (29:52)

Yale I. Jen

Analyst, Laidlaw & Co. (UK) Ltd. (United States)

Okay [indiscernible] (29:54)

Q

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

I mean, Duncan is with me as well. I don't know if he has anything else to add, but...

A

Duncan Fatkin

Chief Commercial Officer, Beyond Air, Inc.

No, I think that the timing obviously is associated with the CE Mark and there's really nothing that should slow us down. So from my point of view, there's no product issue. It's all about this timing coinciding with CE Mark availability.

A

Yale I. Jen

Analyst, Laidlaw & Co. (UK) Ltd. (United States)

Okay. Maybe just last question here, which is about the UNO in the cancer. I just want to confirm that all the studies – the study so far is in combo, in other words, is the UNO plus the checkpoint inhibitor, is that correct? Or are there any single agent studies for PK and other aspects?

Q

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Well, yeah, I mean, there's no PK obviously because it's not a systemic therapy. But yes...

A

Yale I. Jen

Analyst, Laidlaw & Co. (UK) Ltd. (United States)

Right.

Q

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

...I mean we've done multiple studies with monotherapy and even the combination studies that we reported on all had monotherapy arms as well. So there's plenty of monotherapy data. And of course, the first-in-human study is monotherapy. So I mean, you can go to the Beyond Cancer website and see all that data. It's all there. It's all out in the open and public. And I encourage you to call the CEO of Beyond Cancer and have a chat with her, and she can walk you through everything. But, yeah, there's a lot of monotherapy data, and it's obviously very positive.

A

Yale I. Jen

Analyst, Laidlaw & Co. (UK) Ltd. (United States)

Right. Right. And just talking about the human study that there's currently still – it is in the single agent [ph] path (31:32). So that's very helpful. And well, thanks a lot. I really appreciate that, and congrats on the progress and looking forward to see the figures next – not too long from now.

Q

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Thanks, Yale. Appreciate it.

Operator: [Operator Instructions] Our next question comes from the line of Suraj Kalia with Oppenheimer. Please proceed with your question.

Suraj Kalia

Analyst, Oppenheimer & Co., Inc.

Q

Steve, can you hear me all right?

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Yes. Yes, I can, Suraj.

Suraj Kalia

Analyst, Oppenheimer & Co., Inc.

Q

Perfect. Good afternoon, everyone. So couple of questions, one for Duncan and one for you, Steve. So, Duncan, let me start out with you. So appreciate some of the color you all have provided on a contract. Maybe if you could expand on it a little bit more, like, what does the contract really mean in terms of exclusivity, average revenues, utilization? Is [ph] \$600,000 (32:28) the right bogey to think about? And the sub-part of that question, Duncan, would be 150 demos for [ph] LungFit PH (32:36), consensus estimate for the next year is [ph] \$19 million (32:42) from what I see, is the right way to think about it? The bogey you need is at least, let's say, 35 to 40 sites.

Douglas Larson

Chief Financial Officer, Beyond Air, Inc.

A

Yeah, Suraj. I used [ph] \$600,000 (32:54) as an example. That's got nothing to do with anything. I could have said [ph] \$300,000. I could have said \$120,000 and said \$10,000 (32:58) a month. I mean, that was just a simple math exercise. I wouldn't read into that number at all in any way, shape or form.

And hospital contracts, of course, mean exclusivity. We have the contract with the hospital. We're the only one there. And our competitors, where they have their contracts, they're the only player with nitric oxide in those hospitals. That's the game. There's no dual supply in the nitric oxide market. You don't have two separate machines in the same hospital. It's quite unique in the medical device arena.

So – and as for size of contracts, we've said in the past that with this market, you got about 1,000 hospitals, 1,100 hospitals or so. It's a \$350 million, \$400 million market. You can do the average contract per hospital if you really want to do the math. So that's the best way to look at it. I mean, we've been pretty clear on number of hospital, size of the market. You can back into an average contract size. So please don't take the numbers I gave you in any way to mean that.

So, Duncan, did you want to comment on any of the other points?

Duncan Fatkin

Chief Commercial Officer, Beyond Air, Inc.

A

Yeah. I think that the – so, Steve obviously explained that, the dynamics, but from a sort of contractual point of view specifically, I think we said earlier, it's going to be spread over the annual monthly rate. It's going to be a [ph] twelfth (34:29) of the contracts and the contracts are going to very much depend on the size of hospitals. So unfortunately, it's kind of you've seen one hospital and you've seen one hospital. So it really depends on how they land. It's hard to predict what the average for us will be because so many variables in each specific hospital. But the good news is once you get them, it's a little bit like an annuity kind of like builds on itself and you don't have to kind of repeat until the contract is up. So as we grow, that growth will start to compound.

Suraj Kalia

Analyst, Oppenheimer & Co., Inc.

[ph] Got it. Okay (35:04).

Q

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

And Suraj, I'll comment on your consensus question, if you'd like. I don't think consensus is \$24 million or whatever you said. But yeah, I – we've given guidance as best we can in conversations with analysts about how our business works and they make their own decisions on what they're going to put in their models. So we're not going to control what you want to put into your model in any way, shape or form, but we have certainly not intimidated in any way that this is going to be a massive launch of any size, that this is more of a slow build. Every quarter, we add hospitals and we build and we build and we build. And as we build and get more people, it starts to accelerate later on.

A

Maybe four, six, eight quarters from now, you'll see a pretty big acceleration. This is what we've been saying. We are consistently saying it. So I know there's somebody out there with a number that's close to \$20 million for fiscal 2024. I don't know why anybody would consider that a rational or reasonable number based on what we've been saying prelaunch and since the launch. But again, everybody's got their own way of analyzing the market.

Suraj Kalia

Analyst, Oppenheimer & Co., Inc.

Got it. Steve, final question, I'll just bunch couple of them together. So you – in your prepared remarks, you talked about the sites, maybe I'm paraphrasing here, the knowledge gained from these sites about NO. I'd love to understand what was the incremental gap you all identified as you all get into phase 2 of commercial launch?

Q

And specifically, Steve, a broader question, or rather a high-level question, multiple programs going on, right? And we appreciate the color and the progress on all of these. How do you and your vantage point, right, sit and decide on the ROI on the commercial launch of [ph] LungFit PH (37:08) versus ASD versus other programs? Just kind of walk us through how you are thinking about it from your vantage point, what makes more sense from an ROI perspective? Gentlemen, thank you for taking my questions.

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

Sure. Thanks, Suraj. So I'll address your first question. There's no gap in our knowledge about nitric oxide when we launched this program. It was more of where a company that's putting together our own customer service, which is 24/7 logistics. No one's ever had a product like this, so it's brand new to any logistics provider. Putting together a team that hasn't been together before, highly intelligent, highly experienced nitric oxide people, [ph] well (37:56), they still need to gel as a team.

A

Our machine, while coming through FDA, is approved and working great. There are always tweaks you can make. There are always modifications to ventilators [ph] well (38:07) need to be compatible and we couldn't do that while we were going through FDA because the design is frozen and we need to work with FDA on what we've given them. You don't make changes until later when you can try to adapt and work with ventilators. I mean, this is normal. This is classic for the medical device space and especially for a PMA product.

So those are the things that we were learning and honing in on the way we contract, listening to the customer and adapting to their needs. We really couldn't talk to them till we got approved. So it's pretty standard. I don't think we did anything different than other companies would do, except maybe a massive company might have been a little faster than us because of the infrastructure, but it's pretty standard. And that's why we needed that six to nine months of that first phase where we were learning.

As for how we do our ROI, boy, there's a lot of different ways to do ROI. I mean, you can approach it many different ways. So there's a lot going on. In nitric oxide, it's an untapped part of medicine, in my opinion, and in the opinion of most, if not everyone, at Beyond Air. There's a lot going on with nitric oxide as you can see in the neuro space now with autism. This is not something, in our opinion, that takes away from the focus on the launch of the product. That is our number one focus, is our commercial launch by far.

And for Beyond Cancer, their number one focus is cancer. That's why we spun that program out into its own company because we didn't want to have – there'd be an impact on our Beyond Air activities. So that's why it was separately funded and that's why there's a whole management team and group of people there doing an amazing job.

So really, I guess autism is the new kid on the block, so to speak, that is different than what Beyond Air proper is doing with LungFit PH, LungFit PRO and LungFit GO. And this is obviously very early stage. It was a great opportunity. We love what Dr. Amal with the Hebrew University has done. It's very unique. And really, we hope that when we get into humans, it's going to bare itself out as it did in the mice. If it does, we can really make an impact and make a difference.

So this is not a very expensive program at this point. It doesn't take a lot of our people at this point. As we go forward over the next 12 to 18 months, there'll be a little bit more expense, which we talked about last week when we told everyone about this program and you can refer to that in our presentation. And it's still not that much of an incremental hit to the people on our team. Especially on the commercial side, it's got nothing to do with the commercial team at all. And the people who support the commercial team, they have nothing to do. The ones who work with autism, we have statisticians and pharmacologists and so forth, and scientists, they're not doing anything for the commercial launch. So, yeah, it's a little bit maybe extra for me, but I like to work 100 hours a week. So it's not a big deal for me. I got to fill my time somehow.

So this is a big program, but it's early stage. And perhaps in 12 to 18 months or 18 to 24 months, when we're in a human study and we're getting results, then it might take on a little bit more need and more focus, and that's when the ROI really needs to be discussed because I don't want it to take away from the other programs. But we'll see when we get there and we'll see how this program progresses.

So that's kind of how we look at it. Cancer, we realized was too big for our bridges at that time and we moved it over to have a great team run it, who – people who are cancer experts. In this situation, I don't think autism has risen to the point where we need so-called autism experts or neurological expertise.

Although I would like to point out that our new Chief Medical Officer has certainly done a lot of work in nitric oxide, actually did PhD thesis in nitric oxide way back in the day when he was younger and has done work in neurological space with respect to nitric and has done work in other neuro areas that are non-nitric related. So he brings some expertise there to help out Dr. Amal in Israel and his lab and some of the other people that we have on our team. So, again, that's kind of how we look at it. And if there's something that's going to impact our commercial launch, we just defer. We don't take it. We don't bring it in house. It's not worth it.

Suraj Kalia

Analyst, Oppenheimer & Co., Inc.

Q

Appreciate the color.

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

A

Sure.

Operator: There are no further questions in the queue. I'd like to hand the call back to Steve Lisi for closing remarks.

Steven A. Lisi

Chairman & Chief Executive Officer, Beyond Air, Inc.

I'd like to thank everybody for joining us today. Thanks for keeping track of us and we hope to give you some more good news as we go forward. 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.

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