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Beyond Air, Inc.

First Quarter 2024 Earnings Call

August 10, 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

Les Sulewski, *Truist Securities*

Marie Thibault, *BTIG*

Scott Henry, *ROTH Capital*

Jason Bednar, *Piper Sandler*

Matt Kaplan, *Ladenburg Thalmann*

Yale Jen, *Laidlaw and Company*

PRESENTATION

Operator

Good afternoon, and welcome, everyone, to the Beyond Air Financial Results Call for the Fiscal Quarter ended June 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 first 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, August 10, 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.

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

Steve Lisi

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

Since it's only been about six weeks from the last time we spoke, we'll keep the prepared remarks short today. LungFit PH continues to be well received in the market and we have begun Phase 2 of the commercial launch. We are very happy to report that we have now in excess of $1 million in contracted annual revenue, though only a small portion of these revenues are recognized in the June quarter. We continue to match our momentum in the marketplace with the thoughtful expansion of our commercial team. Our Chief Commercial Officer will discuss this further in a few minutes. We provided a thorough review of our pipeline during the last call. Everything continues to be on track.

Before turning the call over to Duncan, I'll reiterate a few near-term catalysts and highlights. By the end of the calendar year, we expect to submit a PMA supplement to FDA for the LungFit PH cardiac label expansion, receive CE Mark in the EU, and present data from Beyond Cancer's first in-human trial. Additionally, following agreement with FDA, we will be conducting a pilot study in viral community-acquired pneumonia in the United States this winter.

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

Thanks, Steve, and good afternoon to our investors.

As Steve mentioned, we have eclipsed the million-dollar mark for signed annual contracts. We're very pleased with the momentum our team is building as we progress with Phase 2 of our launch. The overall feedback from hospitals regarding LungFit PH continues to be extremely positive, and we would again like to thank all the hospitals and clinical staff that have partnered with us and committed to using our device.

Our plan is to build out our field team based on the opportunities developed over the past year and the growing interest in LungFit PH as we broaden our reach. These additions will be carefully targeted and designed to ensure a strong and sustainable foundation for growth. We also expect to add to the team, pending the anticipated cardiac label expansion, which we expect to significantly expand our reach in the hospital. We have planned for a thoughtful and measured increase in the size of our team through to the approval of our next-generation LungFit PH, which is anticipated in calendar year 2025.

In closing, we are confident that LungFit PH is the best-in-class nitric oxide technology available today, and we continue to be excited by the support we have received from hospitals throughout the U.S. I'm looking forward to providing updates on progress in the upcoming quarters.

With that, I will turn the call over to Doug Larson, our Chief Financial Officer, to provide an overview of our financial results for the fiscal quarter ended June 30, 2023. Doug?

Douglas Larson

Thanks, Duncan, and good afternoon, everyone.

Our financial results for the fiscal quarter ended June 30, 2023 are as follows. Revenue for the fiscal quarter was $0.1 million, as compared with zero for the fiscal quarter ended June 30, 2022.

Research and development expenses for the fiscal quarter ended June 30, 2023 were $4.7 million, compared with $3.2 million for the fiscal quarter ended June 30, 2022. The $1.5 million increase was due to an increase in headcount and incremental research, mainly in cancer and autism.

SG&A expenses for the fiscal quarter were $10.9 million, compared with $8.2 million for the fiscal quarter ended June 30, 2022. Almost all of the $2.7 million increase was due to salaries, as additional headcount is needed to scale operations in the field and in the back office.

Other income and expense for the fiscal quarter showed a $0.8 million gain compared with a $0.2 million loss for the fiscal quarter ended June 30, 2022. The gain this year was mainly driven by the remeasurement of warrants and derivatives associated with our long-term debt.

For the fiscal quarter ended June 30, 2023, the Company recorded a net loss of $15.1 million, of which $14.1 million, or $0.45 per share, was attributable to the shareholders of Beyond Air, Inc., compared with a net loss of $10.9 million, or $0.37 a share, for the fiscal quarter ended June 30, 2022.

Net cash used by the Company, excluding one-time expenses, was $10.6 million during the fiscal quarter. We forecast our average quarterly cash burn to be approximately $10 million per quarter as we move through fiscal 2024.

In June 2023, up to $40 million in debt financing was provided to the Company by Avenue Capital, of which $17.5 million in gross funds were drawn in the quarter. As of June 30, 2023, the Company had cash, cash equivalents and marketable securities of $57 million.

With that, I will hand the call back to Steve.

Steve Lisi

Thanks, Doug. We will now take any questions you may have.

Operator

(Operator Instructions)

Our first question comes from Les Sulewski from Truist Securities. Please go ahead, Les.

Les Sulewski

Hi, good afternoon. Thanks for taking my questions, and congrats on the progress, guys. Just to confirm, the $1 million is now the annual base? Can you quantify the market opportunity out there that's remaining over the remaining of this year? Do you have a sense of how many hospitals are out there near end of contracts with a competing product that are marked in your book for an opportunity to convert? I have a follow-up.

Steve Lisi

Thanks, Les. Appreciate it. Yes, I guess the $1 million is the base, but that would not be starting at the beginning of this fiscal year, so it wouldn't be a start from April 1. It would be a start from this quarter when we obviously sign the contracts to get us above that level. I just want to be clear on that.

Yes, look, I don't think that we're going to really reveal how many hospitals we're speaking to right now and what it looks like for the rest of the fiscal year in terms of opportunities for us. I don't think we want to share that information, but I do think that we will be in a position when we report our next quarter in November to give you some guidance on that and probably some guidance for our anticipated revenues for the full year.

Les Sulewski

Got it. I understand. Then on the cardiac label expansion opportunity, what size is that potential to TAM? Is that essentially you calculated into your figures that you initially rolled out, or is there more to the story here? Just walk us through the high-level overview of what you think of the cardiac label expansion. Thank you.

Steve Lisi

Okay. Cardiac surgeries, nitric oxide use there, it's the biggest of all the, I guess, subcategories for use of nitric oxide in the hospital would be cardiac surgeries. I think it's very important to get this label expansion. It will help us have access into an area that's exclusively now off-label. That's an area where we don't market and we don't detail. That's certainly going to open things up in a good way, I would think.

Les Sulewski

Great. Thank you.

Operator

Our next question comes from Marie Thibault from BTIG. Please go ahead, Marie.

Marie Thibault

Hi, good afternoon. Thank you for taking the questions. Now that we have revenue, I want to try to understand how many contracts were signed, how many hospitals now have LungFit PH? Any details on contract value and length of some of these contracts, just any additional detail you can offer at this time would be really helpful.

Steve Lisi

Sure, Marie, probably not too much. But most of the contracts are annual contracts. Sometimes they renew for two years, another year or three years. But we haven't said; I don't think there's too many contracts beyond three years out there. But there might be a few, not for us but perhaps for others. Again, we're not really discussing the number of hospitals we have, there are multiple hospitals. There's plenty for us to get plenty of feedback from our customers that they're very happy with our service and with the product. But we're not going to give an exact number. I apologize for that. Not really sure how much really more we want to say; it is a competitive environment. We're kind of keeping things close to the vest, if you can understand that. There are other people listening.

Marie Thibault

Of course, okay. Maybe I can ask about gross margins. It's not surprising, of course, that they're negative to start this early in the launch. But how do you think about that flipping positive? What's the right level to think about for gross margins and those COGS in the first year of expansion? Thanks for taking the questions.

Douglas Larson

Hi, this is Doug, I can I can jump in with that one. No, in the next couple of quarters, at least, that gross margin is going to turn positive. The drivers behind that are actually the devices that we're producing, we're starting to depreciate them. There's some costs there for devices that aren't actually deployed yet. Then setting up our supply chain infrastructure so that we can expand across the U.S. or wherever we have an opportunity. Those are basically the fixed costs, if you will, that are going to be absorbed very quickly as we expand. Again, my expectation is that either next quarter, or the following quarter, will be in positive territory.

Marie Thibault

Thank you for that.

Operator

Our next question comes from Scott Henry from ROTH Capital. Please go ahead, Scott.

Scott Henry

Thank you, and good afternoon. A couple of questions. First, with regards to selling expenses, what would you estimate the quarterly selling expenses are today and where would they be at peak? Just trying to get a sense of how much it costs to market, pay all the reps how we should think about that number?

Steve Lisi

Scott, there is an industry standard for a fully loaded rep. I'm sure you know that, you've been modeling this for a long time. We're certainly on the low end of things. We just started our second phase where we're starting to bring more people in and hire them. From a pure headcount, we're probably around 15 people or so on the commercial side and growing, and that number is probably going to get up, well north of 50, probably close to 70, 75 people at peak. That peak will probably be two to three years from now depending on how quickly we bring people in. It's not going to be a very rapid expansion.

But I would say to use that industry average is a good number, because not all those people that I've mentioned in those numbers will be reps, but when we get out to peak, the vast majority will be reps. Right now, it's a much lower ratio for reps to others, because we really need our clinical specialists, the respiratory therapists are the ones that are out there training in the hospitals that are working with us. We need to train in the beginning. It's very important to have the customer service level very high, and the reps will be expanded later.

Scott Henry

Okay, great. That's helpful. Then the $57 million of cash, how much of that is in Beyond Cancer? Just so I get a sense of the net cash you have.

Steve Lisi

About 30% or so. About a third, maybe.

Scott Henry

Okay. Thank you. Then when we think about this burn of $10 million a quarter, and at the same time you'll be expanding sales, would it be safe to say this is a low point and by low point I mean this is the—where the burn is going to max out? You probably, as you add sales, you'll also be bringing in gross profit. Should we think about this being the maximum burn, decreasing maybe not this year, but soon thereafter?

Steve Lisi

Yes, and no, Scott. It does depend on what we do with our pipeline. If we move into a pivotal study in calendar ’25, whether that be for pneumonia and/or NTM, we're going to spend, so that's going to cost money. But obviously, it'd be for very good reason. We've done four pneumonia studies that have worked. We’re entering our fifth pneumonia study in a few months. We would expect the number five to look just like the first four in terms of overall efficacy and safety profile. With that kind of confidence going into a pivotal study, we're going to spend money on it. We don't know how big it will be yet, we're still waiting to get this last study done and speak with the FDA. But I can't say that those costs wouldn't force us to spend more money than $10 million in one quarter. I just don't know. But if we're not running pivotal studies, then yes, you're right.

Scott Henry

Okay. That leads into a bigger picture question for you and the Board from the standpoint of, is there any concern that you might cast too wide a net? A lot of these programs are great. But it's the working capital problem a new business often faces that if you stretch yourself too thin, there can be financial distress. How do you balance that? I know you have a pretty good balance sheet right now. But you’ve got a lot of good ideas that you're chasing right now.

Steve Lisi

Yes, Scott, we're not chasing them all, that's for sure, for that reason. We're not chasing COPD at the moment. NTM is not until ‘25. We're not stretching. We're almost three years away from an NTM study starting, and COPD is going to be based on available funds, where we'd love to do it, we'd love to do it in three months. But we can't. This launch is the most important thing. The other programs like cancer is funded. We haven't entered into the real expensive part of cancer yet. We haven't gotten into Phase 2 human studies, which is where the big money will be spent. That's another ‘25 occurrence, most likely. The autism program, there's not much being spent at the moment on that. It's still obviously in preclinical stage

with our partner in Israel. Again, that expense probably won't kick in. Heavy expenses won't kick in till '26 or '27 calendar.

Can we accelerate these things? Sure. If we have more cash or sales come in and we have a good gross profit, then yes, we can. But right now, we're being very prudent in terms of which programs we're working on and how quickly we're pushing them. Right now, pneumonia is full steam ahead. Cancer and autism are moving, but the other programs are not moving right now. Just because, you're right, we don't have the balance sheet to do everything that we want to do. It's not everything we want to do. It's everything that the data tells us to do. Our NTM data are very strong. Pneumonia, very strong. With NTM and pneumonia being as strong as they are, it begs the question why we're not doing a COPD study.

But again, the answer is we're not funded do that study. We're just going to bide our time, make sure that this launch is successful, or more successful; it's already been successful. We'll see how that works out. But yes, we're being very prudent with our cash. Doug doesn't like spending money. He's a very good CFO. He beats up everybody. So…

Scott Henry

Okay, great. Thank you for the color on that. I'll jump back into the queue. Thank you for taking the questions.

Operator

Our next question comes from Jason Bednar from Piper Sandler. Please go ahead, Jason.

Jason Bednar

Hey, good afternoon, thanks for taking the questions, and congrats on reaching that $1 million milestone. Maybe if I could start on the contracting so far, and where we're going in the future. Totally understand, Steve, there's only so much you might be able to share. But can you speak to whether the contract sizes are what you expect them to be so far? Is there any difference in overall contract size you'd expect as maybe you move further down the road with Phase 2 of your commercial plans? Just anything you can share there.

Steve Lisi

I think that they're fairly in line with what we thought in terms of overall size. There's a mix, right? The volume at hospitals is a huge range in the U.S. You have hospitals doing 1,000 hours, 500 hours, 2,000 hours; you have hospitals doing 50,000-plus hours of nitric oxide a year. It varies all over the place. I think it's in line with what we had expected. I would say the same thing about the pricing, pretty much what we expected as well. Right now, we're not really seeing anything that's outside of the parameters that we had entering into the market.

Jason Bednar

All right. That's great to hear. Then I'd be curious, just maybe on the competitive response from some of your closest peers. Just thinking, given where you're at and where you maybe hope to be in a year or two, I think having some perspective today would be enlightening. Just how are you seeing them behave as they start to lose contracts to you? Are they getting more aggressive in follow up contracting efforts? Are they holding the line on where they're pricing? Again, just curious how the success you're starting to have in contracting is influencing their behavior at all.

Steve Lisi

They've been aggressive from day one. I don't think it's changed. I think they're nervous. They're worried. That's how they're acting, it's how they're behaving. I might do the same thing if I were in their shoes. I don't think that there's anything that they're doing that, again, is surprising to us. I would expect some of the things they're doing to be done. I might not do everything they're doing. But certainly some of the things they're doing if I were in their shoes, I would do. But it's a competitive environment, there's no doubt about it. You would expect all the players to do everything they can to either keep customers or take customers from a competitor.

Duncan, you're on the line. If you have anything else to add to that, you're a little closer than I am.

Duncan Fatkin

Jason, appreciate the question. I think that there's a couple of things I would say. Firstly, a lot of the competitor activity was apparent to us before we even started to get contracts. A lot of the work that was done was to block us from even getting in there in the first place. I think that what we've done is we've broken through in various locations. Actually, once people get exposure and do evaluations, etc., then things start to build. The way that these things work is they then start to see that another hospital in their area is using the device, and they get more confident. The neighboring hospitals start to get involved.

The other thing that happens is that the initial contracting is easier with individual hospitals, there's not that many of those nowadays. The larger groups and small networks take a little bit longer. We're starting to get to those now. We're getting to that phase where a lot of those contracts are running out, which wasn't the case at the beginning of our launch. It's a much better environment for us. In other words, our competitors have thrown a lot of ammunition at us already to stop us from getting in. The response once we're in isn't that different. We're feeling much more positive about where we are as we get through that process.

Jason Bednar

All right. Perfect. Thank you. Maybe one just quick clarifying question to finish it off. I think it seems like there's no change on the CE Mark, timing or expected timing on receiving that. I think that originally in the last quarter you had said September, October timeframe. Does that still hold? I know you're saying by the end of the calendar year, but should we still expect to hear within the next couple months?

Steve Lisi

I would love to announce it on our next quarter. That would be my goal. This is out of our control. We are moving as quickly as we can. But again, this is a regulatory matter and sometimes, it just takes a little longer than you expect. I hope to announce it on our next quarter. That's my goal. It will be second week in November, roughly. I expect to announce it there. If not, I'll let you know where I stand then. But yes, the guidance, we just give our guidance based on—Ed here told me, Steve, we've got to be consistent with guidance, this half that half, instead of saying a month. I'm going to go with Ed, and we'll say by the end of the year, but hope to say November.

Jason Bednar

All right. Very helpful. Appreciate it. Thanks, guys.

Operator

Our next question comes from Matt Kaplan from Ladenburg Thalmann. Please go ahead, Matt.

Matt Kaplan

Hey, guys. Thanks a lot for taking the questions. Now that you're in the phase of signing contracts, can you—maybe what would be helpful, can you tell us little bit about the mechanics of signing a contract? Is there a demo period, a test drive period and then potential conversion to contract or how does that work?

Steve Lisi

Yes, in the beginning, Matt, it was always a demo and then there's an evaluation. I think that the evaluation is not that important for every hospital anymore now that we're out there and there's experience and people chat to each other. It's a small world, the RT world, there's lots of little conferences, they're all meeting each other and talking about what's going on. I think that, going forward, we may not need to do an evaluation at every potential customer. Eventually, we won't be doing evaluations at all. I would say that probably sometime in calendar '24, we won't be doing evaluations any longer. It'll just be what we call bench testing and then we go into a contract.

We're over that initial phase where everybody was evaluating to the point where some are still evaluating and some aren't, and eventually, when it gets to the point where there's just no more evaluations because there's so much experience with our product and so much comfort and confidence in us as a Company being able to support the hospitals, that there will be no more need for that evaluation.

Matt Kaplan

Okay. Then, now that you're in the second phase of the launch, what do you see as the bottleneck in signing new contracts?

Steve Lisi

I'm going to let Duncan go on that one. But I would say I don't think there's one specific bottleneck, there's not one thing that stops you from getting a contract. I think it's hospital specific, they all have different things that are important to them. Sometimes it hits our sweet spot and other times it doesn't. I don't think it's so simple to say that every hospital has the same opinion or viewpoint or needs. I don't think there's one bottleneck.

I know, Duncan, you might want to follow up there.

Duncan Fatkin

Oh, no, it's good question, Matt. I think that contracting during the first 12 months was definitely the area we had to spend most time navigating because a lot of hospitals (inaudible) are a part of those systems, as I described just now. The way they do that and the bureaucracy associated with that definitely was initially our biggest challenge. I do think of it like dominoes, once you start knocking over some of those hurdles, then a lot of the others become freer. Then there are individual hospital situations, changing from one hospital, one device to another involves an investment in training, etc. Depending on where they are in their particular supply chain process, they might have other priorities within the hospital that mean that they're not willing to focus on our particular category at the time, which is kind of related to contracting but also related to the hospital's individual priorities.

From a clinical point of view, we're not getting push back clinically; it's really more on the contracting side where we have to navigate that. That's really where most of our work is evolving and improving.

Matt Kaplan

Okay. That's helpful. Then the average number of devices per hospital and the expectation for the average revenue per device, how should we think about that?

Steve Lisi

I'm not going to tell you how to think about that, Matt, because then everybody else would know. But it's pretty wide in terms of how many hours per year per system a hospital uses, it's a pretty big range, different hospitals have different needs, like I've said. It's a very difficult question to answer. I don't want any of our competitors to know how we think about that and how we view it because it's very important in how we approach things. I wish I could give you those answers. But I can't. I mean, I can, but I won't.

Matt Kaplan

Yes, fair enough. Just last question, as you're getting close to the CE Mark, what's your partnering strategy ex-U.S. or do you plan to go it alone outside of the U.S?

Steve Lisi

We are not going it alone outside the U.S., that's for sure. It's enough to build up a commercial team in the U.S. That's all we can handle for the moment. We will partner ex-U.S. and our goal is to get the best royalty rate we can on net sales, and that's what we'll do. Hopefully we'll be able to talk more about that in the near future.

Matt Kaplan

Okay. Great. Well, congrats on the progress, Steve. Thank you.

Steve Lisi

Thanks, Matt.

Operator

Our next question comes from Yale Jen from Laidlaw and Company. Please go ahead, Yale.

Yale Jen

Good afternoon, and thanks for taking the questions, and congrats on your first commercial sale. My first question is, in terms of the $59,000 revenue of this quarter, what's the accounting principle behind it? How has that been recognized? How should we think about going forward in terms of does the same principle apply?

Douglas Larson

Sure. This is Doug, thanks for the question, Yale. The best way to think about it is, for the most part, we're signing annual contracts. Most of the contracts, from a revenue recognition perspective, it's a little more complicated than I'm going to make it but if you think about it ratably over the life of the contract, that's pretty safe. We do have to do some testing every quarter to see if we're within the range of use of the machines and things like that. But for the most part, annual contract ratably over the 12 months is how we're going to recognize that revenue.

Yale Jen

Okay, great. That's very helpful. The question to just follow up on the previous one, which is regarding getting labor on the cardiovascular side. Question is (inaudible) has been used in real world off label, presumably can also get reimbursed for a long time. What could be additional benefits if you guys get a label for your system?

Steve Lisi

Well, yes, the main benefits, obviously, are our ability to directly market to cardiac surgeons, as well as potential for reimbursement, there's no doubt. But you know, Yale, it takes time to get a specific code. We wouldn't have a direct code, day one. There might be miscellaneous codes of some sort, but a direct code would take several years, as you know. Was there any—is there anything else you were looking for besides those? Those are the two main benefits.

Yale Jen

Okay. But so, does that the—just want to confirm that currently the use in the cardiovascular surgery suite also get reimbursed or not necessarily get reimbursed?

Steve Lisi

No, it is off label use. I can't speak for what the hospitals do, but it is 100% off label. I think that reimbursement is difficult.

Yale Jen

Okay, great. Maybe the last question here is in terms of your VCAP trials that you intend to start this winter. Could you give us a little bit more color regarding the study design, and including (inaudible) and others? As well, how this one should be considered as a Phase 2, maybe Phase 3, how should we categorize that? Thanks.

Steve Lisi

Yes. I would look at the design of our study that we had in Israel for pneumonia. It's going to be very similar to that study. This will not be a registration study. We're a device, Yale, not a drug. It's no Phase 1, 2, 3; it's pilot, pivotal. This will be another pilot study, FDA has requested that. After this study, the next one would be a pivotal or registration study. This study, then one more, and we would hope to get approval from that.

Yale Jen

Maybe just to refresh our memory that in terms of the end point, what was end point they are pursuing and any other colors on the study?

Steve Lisi

Yes. Obviously, it will be safety is the primary which is not a pivotal study so that's easy. But on the efficacy endpoints, in the study in Israel, it was an oxygen specific endpoint. It was a time to oxygen cessation for these patients in and out of the hospital. You could look for an endpoint similar to that, something along the lines of either how long they're on oxygen or whatever time period we pick, how many hours they didn't need oxygen. But something along those lines will be related to oxygen.

Again, when we did the infants in pneumonia, there were no comorbidities. It was easy to look at hospital discharge or being fit for hospital discharge. Those endpoints are not relevant with adult pneumonia as they have multiple comorbidities. There could be several other reasons besides the viral infection that caused the hospitalization for them to stay beyond the resolution of the pneumonia episode. We need to measure something else. There will be some other endpoints besides action related, but I think that is the one that we'll be looking at closely.

Yale Jen

Maybe I'll squeeze in one more, which is that does that end point could be considered as approvable endpoint from FDA, (inaudible) have you spoke with the agency in terms of this issue?

Steve Lisi

This won't be a registration study. I can't say that the endpoints we have in this study as secondaries would be considered the endpoint to be used in a registration study. But you could guess that my team and I are not looking at this for no reason; we're looking at this because this is what we believe would be something similar to what would be in the pivotal study. But there's no way for me to guarantee that there's an endpoint in my current study that would be mimicked for my pivotal. Hopefully, it's close to it. But we would still have to sit with FDA to agree upon what the exact primary endpoint would be in that study. We haven't agreed to that yet. That's pretty standard. But I think what we have is our secondary endpoint on the efficacy side is going to give us the answers we need to get an agreement with FDA on a primary endpoint. I'm pretty confident that we're going to have something that will work.

Yale Jen

Okay. Great. That's very helpful. Again, congrats on the first sale.

Steve Lisi

Thanks so much, Yale.

Operator

At this time, there are no further questions. I'd like to turn the turn the call back over to Steve to close out the call.

Steve Lisi

Thanks, everybody. Appreciate your time. Look forward to talking to you in three months.

Operator

This concludes today's conference call. Thank you for attending.