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OncoCyte Corp. (OCX)

Q4 2024 Earnings Call

CORPORATE PARTICIPANTS

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MANAGEMENT DISCUSSION SECTION

[Abrupt Start]

Unverified Participant

...Investor Relations page at investors.oncocyte.com. Today's prepared remarks build upon the information already shared in this robust letter.

Joining us today are Oncocyte President and CEO, Josh Riggs; Chief Science Officer, Ekke Schütz; and CFO, Andrea James. We also have our analysts with us as panelists. After our prepared remarks, our analysts may ask questions. Attendees may also type questions into the Q&A.

Before turning the call over to Josh Riggs, I'd like to go over our Safe Harbor. The company will make projections and forward-looking statements regarding future events. Any statements that are not historical facts are forward-looking statements. These statements are made pursuant to and within the meaning of the Safe Harbor provision of the Private Securities Litigation Reform Act of 1995. We encourage you to review the company's SEC filings, including the company's most recent Form 10-K and subsequent Forms 10-Q, which identify risks and uncertainties that may cause future actual results or events to differ materially. Please note that the forward-looking statements made during today's call speak only to the date they are made, and Oncocyte undertakes no obligation to update them.

And with that, I would like to now turn the call over to Josh Riggs.

Joshua Riggs

President, Chief Executive Officer & Director, OncoCyte Corp.

Thanks, [ph] Gabby (00:01:35). Hello, everyone. Thanks for joining. We've gotten a lot done since our update in November. It's great to be closer than ever to having our clinical assay on market. While we detail our 2024 highlights in the shareholder letter, I'll just briefly recap them here.

We launched GraftAssure, which is our research-use-only kidney transplant test with some of the leading transplant centers in the world proving that we can design, develop and ship a lab test in kit form. Having that kit in the field since last July has been tremendously valuable to our IVD product development. The labs running GraftAssure at some of the largest and most scientifically advanced transplant centers in the world. Feedback from those centers has led to improvements in user experience and assay design. We are locking in those improvements as we speak, which we believe will better position us from a competitive standpoint.

We've been fortunate to be able to lean on our CSO, Dr. Ekke Schütz. He has a solid track record of innovative science and publications, coupled with extensive experience in transplant assay development. Combining that with a group of eager early adopters, who see this as the future of transplant management, we find ourselves in a really good place heading into our US and European regulatory submissions. Our partner-first approach has brought together an amazing group of clinician researchers.

As far as new data in the past year, we continue to advance the science in both oncology and transplant. This includes a groundbreaking and favorable publication in The New England Journal of Medicine. That study used our assay to monitor response to felzartamab for patients at risk for kidney transplant rejection. This study led to Breakthrough designation for the drug from the FDA. Importantly, we believe this signals TAM expansion in the future as these drugs come to market and doctors need a tool to monitor for the drug working and disease recurrence.

In another example of TAM expansion, we published data showing that our assay can detect organ rejection in transplant patients 11 months ahead of standard protocols in certain high-risk populations. Then, within weeks of that publication, we achieved Medicare claims expansion to monitor these high-risk patients.

Combined, these new indications can expand the total addressable market up to 20%. Add to that the potential increased use of more marginal organs with the rollout of [indiscernible] (00:04:10) this summer and we expect meaningful market expansion over the next five years. Also in 2024, we attracted a key strategic partner in Bio-Rad Laboratories, which makes us look and feel like a multibillion dollar company as we go in to sign new transplant centers and get them up and running. I'm also happy to note that Bio-Rad participated in all three of our equity funding rounds over the last year, and we are grateful for their investment and partnership.

In the year, we also strengthened our team, welcoming Andrea as CFO and Dr. Paul Billings as Consulting Chief Medical Officer. They both have hit the ground running with Andrea helping to grow our capital markets awareness and build for scale and Dr. Billings providing strategic direction and connecting us to future potential strategic partners.

Towards the end of the year, we had our first pre-submission meeting with the FDA to prep for our final submission later this year. Meeting was very positive, they were engaged and thoughtful. While many of the folks in our team have been through the FDA process several times, this was a first for our company. It was a big step pushing us ever closer to having a regulated product on market. We walked away confident and feeling good about the package we are putting together.

Now, I'd be remiss if I didn't touch upon some of the macro uncertainties around the federal government, which could affect our timeline and which we are monitoring. The FDA office that will be reviewing our assay is the FDA's Center for Devices and Radiological Health, CDRH. In late February, the Department of Government Efficiency cut staff from CDRH. Then few days later, reversed its decision and those folks were hired back. We were pleased to see that reversal. We believe that one advantage our industry has amidst the DOGE cuts is that the private sector helps to fund the FDA's device review process. Specifically, CDRH is partially funded by medical device manufacturers through fees that fall under the Medical Device User Fee Amendments or MDUFA. And so, because the private sector is involved in the funding of the review process, from a federal budget standpoint, we hope CDRH will not be majorly affected. That said, we are watching the back and forth the same as you are.

The net takeaway today is that we are excited about 2025 about finalizing our assay design, launching and concluding our clinical trial and submitting our data package to the FDA. Our projected timeline for having an approved product on market is mid-2026. In the interim, you can look forward to exciting updates about our clinical trial partners, including a KOL call this spring with our national principal investigator and updates about our strengthening commercial pipeline with key institutions progressing through stages of signing and then assay validation.

Taking a step back, every once in a while, we get a chance to be reminded why we all choose to do this work. One of the potential unfortunate side effects of the immunosuppression given to transplant patients is that it makes it much more likely that a patient will develop cancer. And I've heard from many of our collaborators that they would like to study immunosuppression tapering in their patient populations, so that they can minimize such potential negative effects of immunosuppressive therapy.

Then at a conference in the fall, I had the opportunity to listen to a patient advocate talk about their stage 4 cancer, one that they'd got because they'd been on immunosuppress for a very long time. And I tell you that the need for more research and better guidelines, it really hit home. Couple that with the work that some of our partner centers are planning for pediatric patients and it feels like we are a small part of something special.

Putting our RUO test kit out there means transplant centers are finally free to do the research that matters to them. And we are proud to be a partner in that. We are reiterating our commitment today to have 20 transplant centers signed up by the end of 2025, which we believe will translate to roughly $20 million in future annual recurring revenue, once we've achieved the appropriate regulatory approvals. In fact, we are already about halfway to that goal and expect to have several more centers sign on in the coming months. And of course, we believe that that is just the beginning of several years of rapid growth in our transplant business.

From research through to the clinic, our GraftAssure family of products are designed to be easy to deploy and easy to adopt. We're in a good place as a company and we're going to have the opportunity to do something really cool. Next year, assuming regulatory clearance, the transplant testing market changes as local testing becomes a realistic option. You shouldn't have to send patient samples across the country or halfway around the world to get the answers you need. If you're a transplant doc, it shouldn't matter where you are in the world. With our kitted product, you'll have access to the diagnostic tool that you need to manage your transplant patients in real time. Most of our target institutions can already do their own HLA testing. So, we see dd-cfDNA as just the next logical step, one with strong reimbursement and margins here in the US.

Some of you on the call are new to us and we appreciate your support and funding our company. The product cycles and upfront investment are often higher in healthcare than they are in many other markets. And yet, we

believe that the bulk of the time and investment are behind us. We believe that our momentum will only build over the course of the next two years.

Now, I'm going to hand the call over to Andrea to take us through our numbers. Andrea?

Andrea James

Chief Financial Officer, OncoCyte Corp.

Thank you, Josh. Hello, everyone. It's great to be providing this update today and to be doing so over Zoom. And thank you to [ph] Gabby (00:10:10) for helping to moderate. And I also want to thank the investment community for joining us, especially as we do our first Zoom earnings call.

Okay. So, at the conclusion of our shareholder letter, you can find our financial tables. I do want to highlight a few things. First, you'll see that in Q4, we reported pharma services revenue of $1.5 million with a gross margin of 40%. We're pleased about this, and it exceeded our expectations. Our team in Nashville did an excellent job utilizing their expertise and our lab capacity to generate this revenue at the end of the year. It's a testament to the team and their ability to achieve the on-time delivery of clear, scientifically sound and accurate datasets to our pharma services clients.

The way we think about our pharma services business is that it provides non-dilutive capital, but it's not a core pillar of our long-term molecular diagnostics revenue strategy. It allows us to monetize our Nashville lab by performing studies and testing instruments for paying customers. And we're especially grateful to our R&D team for balancing these services, while remaining focused on our primary goal which is developing our kitted assay.

Our solid execution in pharma services also holds strategic value. It helps us to deepen our relationships with potential future strategic partners. These customers are actually counting on our lab to deliver data that supports their own FDA submissions. And these customers are coming away impressed about the capabilities of our team and gaining confidence regarding potential future development projects.

We do expect to see some continued revenue from pharma services in the first half of 2025. At this time, we expect that revenue for the entire first half to come in at less than what we realized in Q4. That said, our clients are pleased with our work and sometimes ask us to perform more and we're happy to oblige. The takeaway is that pharma services revenue will naturally vary as we balance it with our strategic priorities. The priority for our sales team this year is to raise awareness of our transplant assay and to support transplant centers, which we expect to become future recurring revenue customers. Also, in the coming months, we will need our Nashville lab employees to prioritize supporting our own FDA submission package, which is strategically more relevant to our long-term success.

Turning to expense management and cash flow. In the fourth quarter, our outgoing cash flow was $5.6 million, and this was favorable to our targeted spend of $6 million. This includes quarterly operating cash expenses, as well as CapEx or purchases of property and equipment. Recall that last year, I had told you on my first earnings call with Oncocyte that I had enjoyed stepping into a company that is so focused on operational efficiency. That discipline allowed us to finish the year with $10 million in cash. And then in February, so just last month, we successfully raised an additional $29 million. This most recent fundraise was fantastic for us. It was a simple and clean transaction with straight common stock, with no incentive warrants, nor discounts. Our five largest shareholders led the funding round. That included Bio-Rad, which made its third equity investment in Oncocyte and also pledged to provide non-dilutive support for the clinical trial and with our pilot site program. Bio-Rad's support should help us to mitigate the level of expense increase this year, and we're appreciative of that.

Everyone at the company has worked incredibly hard to get to this point, which is the point where our top shareholders were confident enough to invest the equity capital required to fully fund the development of our clinical kitted assay. Looking at 2025 and beyond, we are excited about the potential future value of our business and we aim to continue executing to systematically retire risk and to reduce the time distance to meaningful revenue. Every step we take toward finalizing our assay, toward launching and conducting our clinical trial and toward expanding relationships with major transplant centers, brings us meaningfully closer to building a scalable, high-margin and recurring revenue business.

We also remain committed to disciplined cash management. In 2025, we continue to target about $6 million per quarter in cash burn and that ensures us a financial runway of well over a year. The timing of that spend may vary, however, and at this time, we expect Q2 and Q3 to be our heaviest cash expense quarters of the year. Q2 is the quarter in which we pay out the company bonuses, and we also expect to have some incremental sales and marketing expense in the middle of the year as we welcome new pilot sites for GraftAssure, as well as start to incur clinical trial expenses.

We are deeply grateful for the team's hard work and dedication, and we're grateful for the investor support as we advance our mission to democratize access to molecular diagnostic testing and improve patient outcomes.

And with that, [ph] Gabby (00:15:05), let's start taking questions.

QUESTION AND ANSWER SECTION

A

All right. We will take our first question from Mark Massaro from BTIG.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Hey, guys. Thank you for taking the questions. So, I wanted to ask about the regulatory pathway. I think in the pre-sub, the FDA indicated you can use the de novo pathway and likely not the 510(k) pathway. Obviously, you've given us the timeframes, but can you just give us a sense for – my guess is approximately six months or so. But how should we think about the timing from submitting to getting approved? And can you walk us through the advantages of having a de-novo versus a 510(k)?

Andrea James
Chief Financial Officer, OncoCyte Corp.

A

You're on mute, Josh.

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

We're learning here. So, thanks for the question, Mark. I think we're budgeting seven months. That's kind of the guidance for the de novo pathway. There's no real advantage for us going de novo versus 510(k). I think 510(k) is if there is a predicate device very clearly established, there isn't one for donor-derived cell-free DNA. So, I think we were put on this path because we were the first ones gone through.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Yeah. That makes sense. Can you give us a sense for the number of centers – I know you've talked about the goal is to get to 20 signed up by 2025. You said you're about halfway there now. I maybe just want to get a little more specificity around the number of sites that will be required for the FDA package. And if you can share maybe the number of patients that the FDA is asking you to enroll?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

Yeah. I can take that and then I'll maybe ask Ekke to give just a little bit of color on the size of the trial. We're expecting at a minimum three sites is what's required just to do the reproducibility work. I expect that we will double that here in the US just with the way the study is designed, and then we'll have a couple of centers in Europe as well to support our IVDR submission. But maybe Ekke, you can comment on the size of the study that we're running here. You're on mute there, too, brother. We're going to get this right at some point.

Ekkehard Schütz
Chief Science Officer, OncoCyte Corp.

A

Yeah. Yeah. Yeah. Yeah, so the – actually, one part of the pre-sub was, is that the FDA made our lives easier for the clinical trial because they only wanted to really see one part which is pretty much defined. So, how good is your assay in detecting rejection? So, that took quite a bigger [ph] path (00:18:15) than we have thought we needed to do out. And for exactly that question, we need about roughly 150 samples, biopsy [ph] matched (00:18:25) samples that would give us this answer with high enough statistical power. And so, that's why we are not really need 20 centers. We can actually really, as Josh just told you, get away with a limited number of centers that are doing higher numbers of biopsies. And also, we can use 20% of these samples coming from outside of the US and that's where Germany and perhaps also Austria will supply samples for us.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Okay. Maybe one last one from me and I understand that obviously, we're living in some uncertain times with funding and staffing of federal agencies. But I wanted to just ask about the timing. I think if I have it right, I think on the last call, you talked about a plan to submit to the FDA in mid-2025. And now, I think you're giving us that guidance by the end of this year. So, if I have that right, I think that's about a two-quarter push. How much of that is related to perhaps conservatism versus – events that are outside of your control with FDA versus maybe things on the ground with the clinical trial enrollment of the study?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

No, thanks. It's a good question. I think we're very confident that 6 centers can enroll 150 patients rather quickly. That doesn't seem to be a very large lift from our point of view and from our clinical research partner's point of view. I think there is a lot of uncertainty in D.C. right now that we're trying to understand. And so, I think we're just being as cautious as we can there, not knowing what that environment's going to be like.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Got it. All right, cool. I will hop back in the queue and let some others ask.

A

Thank you, Mark. We'll take our next set of questions from Mike Matson from Needham.

Mike Matson
Analyst, Needham & Co. LLC

Q

Yeah, thanks. Thanks for taking my questions. I guess first, just wanted to ask about the centers that have started using the trial of GraftAssure kits. Have they worked through those? Have you seen any actually starting to purchase kits and if not, when do you expect that to happen? And can we see any sort of material revenue before you get the FDA clearance or is it really going to come after the clearance?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

Yeah. I'll take those in kind of reverse order there. So, I think we're not projecting any material revenue from the RUO product this year. I think we're very cautiously optimistic that that will get adopted in rest of world markets. But I think the big revenue opportunity for us is regulated product in both the United States and in Europe, so going through FDA and IVDR. We haven't shown any revenue in Q4 for the RUO product. I'd say we are taking advantage of some of the feedback that we've gotten from our beta sites and we're adopting that into our product. And so, I think once that one gets out, that will be more likely generate revenue for us probably towards the second half of this year.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Got it. And then just the shareholder letter does mention that Bio-Rad may provide some clinical support – I am sorry, support for clinical trial and commercialization. So, is that something where you've kind of established like a dollar amount or is that yet to be negotiated? And can you just talk about the [ph] amount of the (00:22:23) timing there and what exactly they're going to do beyond kind of the investments they've already made in the company?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

Yeah, I mean, as you can imagine, there are a lot of instruments and a lot of consumables involved with this type of trial. And I think that's where we'll get the support. I think that we can't be terribly specific about the number there, but we do expect that it's going to offset a significant portion of that spend this year.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Got it. Thank you.

A

Thank you, Mike. And we'll take our next set of questions from Mason Carrico from Stephens.

Mason Carrico
Analyst, Stephens, Inc.

Q

Hey, thanks. Could you talk about what your clinical evidence priorities will be following FDA approval? I mean, what evidence do you need to see to drive broader utilization once you've moved past the regulatory hurdle and ultimately, how do you see centers balancing the economic benefits of your assay versus the clinical evidence that backs the LDTs today?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

No, it's a good question. And I would say when we show our data side by side, the negative predictive value, positive predictive value, I think we compare favorably to any test that's on market. I believe we're the only company that's published randomized interventional data, I think we're the only company in The New England Journal of Medicine last year. So, I feel really good about the work that Ekke and his team have done, proving that the assay is clinically useful and robust.

Obviously, we're going through the FDA on kidney right now, which is the 85% of the market or so. I expect that it will bring that to our own LDT lab and we will update our submission to MolDX with the regulated product. And that'll bring all of these claims over to it. So, like the de novo DSA screening application that we got covered this year, I think that helps. It certainly helps in MolDX where we're based. Beyond that, I think we would invest in heart and then liver, lung kind of second, third, fourth, if you will, in terms of priority. But we're 100% focused on making sure that the centers are going to be able to come up and manage their kidney transplant patients on day one.

Mason Carrico
Analyst, Stephens, Inc.

Q

Got it. Thank you. And how should we think about early utilization dynamics, specifically assuming these centers take on the reimbursement risk with a kitted product, how do you plan on driving utilization ahead of broader commercial coverage?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

Yeah. I'm going to break that in two parts. So, we believe that inside of MolDX, we will have an opportunity to bridge the reimbursement from our service lab to the kitted product. And so, that helps a portion of the market, not all of it. And so, I think you'll see faster adoption there than you will outside of that jurisdiction where we'll need to go kind of [ph] MAC by MAC (00:25:45) to work on reimbursement.

As far as adoption within centers, I don't expect that these guys are going to flip 100% of their volume on day one. Nobody does that. And I think, Andrea, back in our shareholder letter in the summer last year, put out a nice model that shows kind of cautious adoption at first as centers, for the first two quarters or so of bringing it in-house, learn how it works, learn how to integrate it with their systems and their approach to patient management, and then it increases from there. And so, I think we expect the largest increase in revenue to start happening in 2027 as our day-one sites really figure out how to integrate this into their care management protocols.

Just to make sure, did I answer your question there, Mason?

Mason Carrico
Analyst, Stephens, Inc.

Q

Yeah, you did. And if I could ask one more here.

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

Sure.

Mason Carrico
Analyst, Stephens, Inc.

Q

And just on the workflow side of it, how easy does your offering integrate into the existing workflow? What level of incremental education is required there, have the existing LDT providers done a lot of the heavy lifting for you?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

Man, I'd tell you, this is my favorite thing that happened over the past six or seven months is the feedback that we got from our sites. And Ekke and his team have done such a wonderful job streamlining the workflow here. It's two pipetting steps and you're done. It's about as easy as a workflow as you could possibly put into a molecular lab, if you know how to extract DNA and put it into a master mix, run preamp and then put it on to a workflow, you're done. Basically, if you're doing HLA today, you can do this, no problem. And I think 75% to 80% of the top transplant centers in the United States are already doing HLA in-house. So, this is very easy add for them.

Mason Carrico
Analyst, Stephens, Inc.

Q

Got it. Thank you, guys.

A

Does anyone have any follow-up questions?

Andrea James
Chief Financial Officer, OncoCyte Corp.

A

I just wanted to address some of the timeline questions.

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

I'm sorry, I saw Mike pop up. I want to make sure that he didn't have a question.

Andrea James
Chief Financial Officer, OncoCyte Corp.

A

Oh, yeah. Mike do you have – go ahead.

Mike Matson
Analyst, Needham & Co. LLC

Q

Yeah. Actually, I do have one more. So, I'm just curious – I mean, I don't know if you're willing to talk about this on public call, but if you've gained things out in terms of like the competition, these lab based competitors, how do you think they're going to kind of respond? Once you're in the marketplace with a clear test and – do you think there's anything they can do to kind of throw some hurdles in your way that you need to plan for?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

A

I think they will point to the hundreds of thousands of patient samples that they've run and say that they've been in the market serving patients for five to seven years, and that's going to have some stickiness. And I think that's where we will have to show that we can generate the same answer for those patients with – a quality level that is useful for the clinical environment. I think that's what the FDA study does. I think it proves that point. But we'll have some convincing to do when we get to the market and it will be center by center and they'll have convincing to do internally. But I think at the end of the day, the data is what matters. And we're going to encourage people to run the side-by-sides, run head-to-heads, do what you need to do to get comfortable. We're confident that at the end of the day, you're going to trust what we're putting out there.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. Got it. Thank you.

Andrea James
Chief Financial Officer, OncoCyte Corp.

A

Yeah. I just want to just address the timeline question just a little bit [indiscernible] (00:29:47) perspective, we're still on sort of the rough timelines we have given – that we gave I want to say like last August, November. So, we're still generally within those rough timelines. But yes, we've certainly communicated just a little bit about watching the FDA back and forth. Okay.

A

Thank you, Andrea. Do we have any follow-up questions? Well, Josh, that sounds like it. Can you please call this out?

Joshua Riggs
President, Chief Executive Officer & Director, OncoCyte Corp.

Yeah, I mean, thanks, everybody. Thanks for joining this experiment. Actually, this is kind of fun getting to see faces well, while we do this call instead of just talking into a black hole. Obviously, we're pumped up. We're excited. I think 2025 is going to be a very interesting, very fun year for us. And I think we have partnering opportunities, we have more data coming out that we're excited about and we look forward to sharing that with you guys as it comes available. Just appreciate the support and look forward to updating everybody on our progress in about six or eight weeks or so, when we get on our Q1 call. Thank you.

Unverified Participant

Well, thanks, everybody. All right. Bye.

Ekkehard Schütz
Chief Science Officer, OncoCyte Corp.

Thank you.