S&P Global
Market Intelligence

OncoCyte Corporation

NasdaqCM:OCX

Earnings Call

Tuesday, November 12, 2024 10:00 PM GMT

Call Participants

EXECUTIVES

Andrea Susan James
Chief Financial Officer

Ekkehard Schutz
Chief Science Officer

Joshua Riggs
President, CEO & Director

ANALYSTS

Benjamin Henry Mee
Stephens Inc., Research Division

Joseph Scott Conway
Needham & Company, LLC, Research Division

Vidyun Bais
BTIG, LLC, Research Division

ATTENDEES

Julie Silber

Presentation

Operator

Thank you for standing by. My name is Kayla, and I will be your conference operator today. At this time, I'd like to welcome everyone to the Oncocyte Third Quarter 2024 Earnings Conference Call. [Operator Instructions]

I would now like to turn the call over to Julie Silber, Senior Managing Director of PCG Advisory. You may begin.

Julie Silber

Thank you, Kayla, and thank you to everyone for joining us for today's conference call to discuss Oncocyte's third quarter 2024 financial results and recent operating highlights. If you have not seen today's shareholder letter, please visit Oncocyte's Investor Relations page at investors.oncocyte.com to read it. Today's prepared remarks build upon the information that was already shared in this robust letter.

On today's call is Oncocyte's President and CEO, Josh Riggs; Chief Science Officer, Ekke Schutz; and CFO, Andrea James.

Before turning the call over to Josh, 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 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-Q, which identifies the risks and uncertainties that may cause future actual results or events to differ materially from those expressed or implied in the forward-looking statements. 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 to reflect subsequent events or circumstances, except as otherwise required under applicable law.

Finally, we will conclude today's call with a Q&A session, with questions from our analysts, as well as written questions that we have received from our investor community.

And with that, I would now like to turn the call over to you, Josh. Josh, you may begin.

Joshua Riggs
President, CEO & Director

Thanks, Julie. Welcome everyone and thanks for tuning in. The transplant market is changing, and Oncocyte is a leading force in that change. Transplant centers around the world are realizing that they do not have to accept the limitations of the current molecular testing model. In Q3, we worked with our beta sites to bring up our tests and we're able to celebrate our technology being run on 3 continents. We signed up leading transplant centers in our key markets, built upon our market leadership and clinical data generation, and took the first major steps in our FDA program. Milestone after milestone, promise after promise, we continue to deliver. 1.5 ago, we told the market that it was time to democratize transplant testing and today, we are closer than ever to making that goal a global reality. The positive response from the transplant community tells us that we are on the right path, and that we can count on their support to make our IVD product a reality, because at the end of the day local care can mean better care for patients.

Making dd-cfDNA testing broadly accessible means more research can be done, new questions will be answered, and progress will start to accelerate in the clinic. Transplant centers are tired of being left out of this important piece in the patient care value chain. They want to manage their patients locally and we believe that they should be able to participate in the economic value they create. Oncocyte is committed to enabling both. Fast, easy-to-use tests with strong revenue potential are a no-brainer for most transplant centers across U.S. This is the future they want and the ones they'll get. It feels gratifying to be able to report such great progress every quarter. We are retiring risk on our path to meaningful revenue. Demand for our GraftAssure RUO kit test is exceeding our expectations in Europe. And in the

U.S., we believe, we are carving out potential meaningful market share, while also staying on pace with our FDA program. We are moving quickly and that's a testament to the team's dedication and hard work, our shareholder support, and the market enthusiasm for what we're building.

Shortly after launching GraftAssure, we signed a top 5 transplant center here in the United States and a top 5 transplant center in Germany. In the long run, democratization of transplant testing is inevitable. What we are seeing here is just the first sign of the beginning. Just think, basically every other biomarker needed to manage a transplant patient can be measured locally, except for dd-cfDNA. And there's no good reason that dd-cfDNA should be any different. Transplant is a highly concentrated market and the top of our sales funnel skews towards the largest of the 100 transplant centers that matter the most in our space. We are actively talking to more than 30 sites that do high organ transplant volumes. We believe we are on track to meet or exceed our site placement goal of having 20 sites signed by the end of next year. We believe each of these sites can eventually average about $1 million per year in high-margin recurring clinical test kit revenue. So it's not hard to do the times 1 math, on how we think revenue will build once we achieve FDA clearance for our kits to be used in clinical decision making. And, of course, that's just the starting point. We expect that the value proposition and regulatory clearance will drive accelerated adoption in both the U.S. and the EU.

We've engaged with the FDA and we'll have our first meeting with them in early December to go through our validation plan. We have a team of experienced hands that have put many products and devices through the agency. And I have every confidence that we will find an efficient path to success. In recent weeks, I've spent a fair amount of time meeting face-to-face with many stakeholders in our industry, including customers and research partners, and companies in our space, who are interested in strategically partnering. I've traveled to meet with customers and partners, not only in the U.S., but also in Europe. We are leaning into the long-standing relationships we already have while we build and explore new potential commercial and strategic relationships. It seems like every stone we lift up, we're finding someone who is frustrated with the current industry practice and is looking to us for a better way.

Our customers are telling us that our product is both easy-to-use and fast, and we believe that, that sets us apart. If you can extract DNA, then most likely you can run our tests. And for centers that want same-day turnaround time, our digital PCR-based assay offers an advantage over NGS solutions. We believe we are pursuing a form of the classic technological disruption strategy of introducing products that fundamentally change the nature of competition in a given market.

On the strategic side, we believe our IP gives us a seat at the table in the broader molecular diagnostic space, which will allow us to have productive conversations with strategic players, both on the product side, such as the instrument makers, as well as with clinical service labs. And our IP has value, not only in transplant, which currently gets most of our strategic focus and sales investment, but also in oncology. We believe we can continue to drive growth even after transplant is up and humming for us.

I do want to highlight favorable data out of Milan related to one of our oncology products. DetermaIO, an immune classifier, continues to outperform standard of care biomarkers and assays. A peer-reviewed study published in Clinical Cancer Research in September validated DetermaIO's utility to identify breast cancer patients most likely to benefit from atezolizumab. The takeaway for investors is threefold. Firstly, this study gets us 1 step closer to reimbursement for DetermaIO and we plan to add this to our data submission at CMS. Secondly, the data supports our ongoing DetermaIO partnering conversations. We believe we have identified partners who want market access to this technology on a global basis. And finally, it validates our R&D pipeline and shows our continuing progress in targeting a multibillion dollar addressable market in oncology diagnostics.

Even though we are a small company and we are still largely pre-revenue in transplant, we sit upon an established body of science and more than 10 years of research in the field. We believe we have long been out in front with the clinical data that we are generating and have a strong pipeline to power new opportunities and growth well into the future.

I'll hand it over to Andrea.

Andrea Susan James

Chief Financial Officer

Thank you, Josh. Hi, everyone. You'll notice in the shareholder letter that, we highlighted 2 areas of focus to derisk our path to meaningful revenue. Those 2 areas are: One, signing new customers who should turn on nicely for us after we get FDA clearance for our kits; and 2, preparing that FDA submission, so we can achieve clearance and those customers can start buying our kits to manage their patients. In the meantime, while Josh and the rest of the senior leadership team focus on serving customers and advancing the science in our industry, my team and I are focused on capital allocation. And this includes tightly controlling expenses, as well as ensuring access to capital to give us enough runway to get us to where we are self-sustaining. Last month, we raised $10.2 million in gross proceeds in a private placement. We were thrilled to welcome support from existing investors, including our strategic partner Bio-Rad. We also welcome support from new investors. We raised this capital at the market with no discount to the closing price and we raised it in a tough environment.

I believe that we were able to accomplish this because investors can see the opportunity for us to generate healthy returns on their behalf. We expect that growth capital allows us to keep executing on new customer agreements and keep pursuing FDA clearance. That capital also provides runway for us to continue actively pursuing additional strategic partners. We're growing increasingly excited about the long-term.

Josh has stated for several quarters that molecular diagnostic testing, particularly in transplant, is moving away from a centralized lab solution and toward a kitted solution. We believe that this disruption is going to happen and that Oncocyte can be a key driver of this trend for 3 reasons. First, our researchers have had a seat at the table since the beginning scientifically in establishing the donor-derived cell-free DNA biomarker. We are now simply seeking a commercial seat at the table, which is no easy feat, but we believe that the science is behind us and the science is the hardest part.

Second, our digital PCR assay is a differentiator because it's easier to use and gives a faster result. We believe that the existence of a digital PCR kitted transplant test with reimbursement enables our customer labs to participate in the economic value chain of transplant diagnostic testing. Remember, we are aiming to design test kits to enable centers to perform the tests themselves and generate revenue for themselves. This increases the sustainability of care at the local level. It can also better serve patients with fast results.

And third, we are small and nimble and we can adapt quickly. We have relatively low operating expenses and we strive to keep our cash burn low, so we can stay flexible.

Finally, we are focused on ensuring we have the right people and processes in place to prepare for future scale. Last week, we gathered as a senior leadership team at our Nashville Innovation Center. Our goal was to prepare for our upcoming growth and think strategically about our long-term objectives. We came out of those planning sessions energized to keep executing and keep building. We're looking forward to delivering upon our mission to democratize access to molecular diagnostic testing, as well as creating shareholder value along the way.
Okay. Julie, do we have any questions in the queue?

Question and Answer

Julie Silber

Yes, we do. We have our first question from our analyst, Mike Matson from Needham. I'm assuming we can put you on speaker.

Joseph Scott Conway
Needham & Company, LLC, Research Division

This is Joseph on for Mike. Yes, can you guys hear me?

Joshua Riggs
President, CEO & Director

Yes.

Joseph Scott Conway
Needham & Company, LLC, Research Division

Okay. Maybe just starting off with the first one. If you guys can maybe discuss the role that Bio-Rad is playing here over the next year and change, I guess, before a potential FDA approval? Are you seeing assistance from them in opening up dialogue with these transplant centers or maybe individual physicians? So, I guess, is there any assistance marketing the RUO product? Or do you think their role will be more robust?

Joshua Riggs
President, CEO & Director

Yes, I think it's a great question. And I answer it in 2 parts. I think we've got really nice experience here in the U.S. and really, really good support over in Germany. We were over there about a month ago and we got to sit down with their Head of Central Europe and the commercial team. And they're absolutely excited to support us and they've been opening doors left and right for us in Central Europe. They have really strong relationships as you might imagine, as a research, at least on the research side of their company with labs all across the countries that we're targeting. And so, that relationship has been very helpful for us. It gives us a feeling of being a heck of a lot bigger than we are. So when we go and set up a site, they also have, the Bio-Rad reps standing right there alongside, our team. And so, it feels like there's a really nice handoff in that relationship, and it gives the labs a lot of comfort. And I'd say in the U.S., they've certainly opened doors where we don't have reach today. And so, it's been fruitful for us, I would say. And it gives us a lot more credibility than when we're standing at a transplant conference and most recently over at ASHI, Bio-Rad was there with us. They had -- their life science team was in the booth with us, giving confidence to folks that when they're talking to us, they're going to get the backing of $9 billion company. And so, yes, 100% we've felt that support.

Joseph Scott Conway
Needham & Company, LLC, Research Division

Okay. Yes. That's great to hear and very helpful. And then, I guess, just -- it's early days and what have you, but maybe just on the reception of the workflow for GraftAssure that you have introduced to the physicians thus far in this first phase. Are you seeing a lot of your reps or Bio-Rad reps dedicating a lot of time to teach how to run GraftAssure? Or would you say that the teaching process has been a little bit more intuitive given the type of PCR-based assay?

Joshua Riggs
President, CEO & Director

No. I think it's an insightful question. Most folks that are trained on molecular are trained on PCR technology. And so, a lot of people just come with that kind of skill set to a molecular lab. So that, I would say, the workflow is not foreign to most people. It is -- there is -- there are nuances to the Bio-Rad

platform that we have to train on. But I would say in general, it takes us about a week to 2 weeks to get folks up and going and comfortable with the technology to where they're generating their own data. And the way we've been working with our first group is, they're sending data to us on a daily basis and we're going through it with them, making sure that they're comfortable. We're learning about our assay and how it performs in the field. But we haven't experienced any meaningful challenges in just sort of the pure technology itself. It seems to be fairly easy to adopt and get set up and run.

Joseph Scott Conway
Needham & Company, LLC, Research Division

Okay. Perfect. And maybe just one more, if that's all right. Could you maybe just discuss the value that the VitaGraft adds, especially to high-risk transplant patients? And just kind of understanding where some of the clinical volume can come from. Do you expect that VitaGraft will be used among a subset of patients, maybe the high-risk individuals that kind of need that test result in a much more expedited manner? Or do you think by the time that these hospitals are trialed GraftAssure that they would be more apt to transition to VitaGraft more broadly or to a broader patient set?

Joshua Riggs
President, CEO & Director

Yes. I'm going to separate the question into 2 parts. So the GraftAssure assay is our RUO product. And so, that's not really useful for the clinical population. But once we get to the IVD product, which we expect to call VitaGraft+, yes, there's probably a handful of patients that need immediate testing. And then the majority of the patients who -- there's some little blip on the clinical radar that the doctor wants to investigate. I would say that the transplant center will be heavily incentivized economically to capture and run as much testing as they can in-house. And I think that will be the primary driver of the switch from send out to in-house testing. But, yes, we really -- like, the market hasn't experienced same-day turnaround time on testing. And so, we don't know all of the use cases that could be there. I don't know if that answers your question, but I would expect that if I had an opportunity to build into the thousands for a test that I would want to do that as often as I could when it's clinically needed.

Joseph Scott Conway
Needham & Company, LLC, Research Division

Okay. Yes. I think that makes perfect sense. I think common sense and the test will be helpful there. But since it's novel, it's more of a wait and see. That's all very helpful.

Julie Silber

The next set of questions I'm assuming comes from our analyst, Mason Carrico from Stephens Inc.

Benjamin Henry Mee
Stephens Inc., Research Division

This is Ben on for Mason today. You guys have talked about transplant centers reaching out to you proactively to get access to the RUO product without direct sales outreach from your end. Could you sort of provide an update on how that's playing out? And then are there any specific use cases or research initiatives that you think are a better product fit for yours versus maybe competing offerings?

Joshua Riggs
President, CEO & Director

Oh gosh, I love the question. So the first thing I'll say is, we got outreach from a pediatric unit, not based here in the U.S. And they were working with their patients and they were sending blood, all the way across the ocean to some labs in California trying to get an answer and it was taking them a month to get a result back. And so, when we went over there and set up, they had their entire team there, they had the adult team in the room and they had the Bio-Rad rep standing there and we all worked together for about 1.5 weeks on getting them comfortable with the technology and showing that they could do this in-house. And as of today, they're up and running and they're figuring out how to take care of their patient population locally and being able to manage those patients, those children right there. And I think

that's for us a huge win that we know that we're empowering people that didn't have the access that they needed to this type of testing.

Beyond that, I think, we've been publishing over the past couple of months in anti-CD38 drugs. So these are drugs that are supporting patients or helping patients with antibody-mediated rejection. And so far, I mean, we are way out in front of the rest of the world here on publishing data that says that donor-derived cell-free DNA is useful. We're also anticipating publication that shows that we're able to pick up antibody-mediated rejection 10 months ahead using the absolute quantification that's native to our technology. And so, I think there are very clear use cases that we're developing that are sort of on the kind of the cutting edge of what's possible with donor-derived cell-free DNA. Whether it's only doable with our technology or other technologies will catch up, I can't really say today. But I do believe that we are opening new markets with the science that we're doing.

Benjamin Henry Mee
Stephens Inc., Research Division

Great. Really appreciate the backdrop there. Just a quick follow-up on the RUO product there. When you're in discussions with the transplant centers, can you speak to who are the decision makers in terms of whether that product is getting adopted? And then really just if you could share any of the common pushbacks that you may hear for why this product may not be the best fit for them and how you go about addressing that pushback?

Joshua Riggs
President, CEO & Director

Sure. I'd say, you're going to need buy in from someone on the transplant side of the house. So if you think about you have a lab manager and then you have a transplant center manager, you really need both of them together to get to, yes on this. And so, we're looking for the transplant surgeons or nephrologists, who are research-minded, who have questions that they've been wanting to ask, but haven't been able to because of the current structure and the availability of testing. And then they go talk to the lab manager and say, ''Hey, we should really consider bringing this technology in-house. We have this, that, or the other study that we would really like to run on our patients.'' And then that's what really kicks off the process. And so, it's really it's a 2-part sale there.

The hurdle that we have is -- I mean, it's one that's kind of painfully obvious when you're trying to sell a box into a lab is that, this is the first piece of content that's coming out on the QX600 for the transplant lab. And so, you you're trying to work through adoption of a new instrument into a lab that has 1 piece of content. And so, the value proposition has to be pretty strong to make that sale happen. I think so far we've felt a little bit of that pushback, but I think the demand to have access to technology so far has been winning the day.

Julie Silber

The next question comes from Mark Massaro from BTIG.

Vidyun Bais
BTIG, LLC, Research Division

This is actually Vivian on for Mark. So I understand that you're meeting with the FDA shortly. I guess, what -- could you just provide some clarity on what's your supporting FDA pivotal study? And additionally, do you plan on doing any concordance studies to on-market transplant tests? I think I heard you talk about identifying AMR with 10 months of lead time over other tests. So maybe just some more discussion on when you would expect that publication?

Joshua Riggs
President, CEO & Director

Yes, great. So, I've got the -- what's going on with the publication relative to AMR detection, and then the conversation with the FDA. So I'll take the FDA one first and then I'll go to the AMR question. I think it was about 1.5 months, 2 months ago, we submitted our validation plan into the FDA. And basically,

we're looking at a Class II device here. So we're not looking at PMA. So that means that we're on track for clearance, not approval. And so, it's not a binary decision point.

And I think we're doing a relatively simple study here. We're looking at biopsy as the gold standard and doing a blood draw matched to biopsy and showing in the data how good of a job we do in identifying graft damage in the blood. And that seems to be a fairly straightforward study design. We've got a lot of confidence that it will provide the data that we need to give the FDA confidence that we have a reliable assay, which at the end of the day is kind of the most important piece. We're only going in kidney to start off. I expect that once we have success there that we would do follow on submissions in the major transplant types like heart or lung or liver. But right now, we're focusing on the biggest piece of the market, which is clearly the kidney patient population.

And with that -- I just want to make sure before I go on, did that answer all your questions around kind of the FDA program?

Vidyun Bais
BTIG, LLC, Research Division

Yes, that was perfect.

Joshua Riggs
President, CEO & Director

Okay, great. And then, so the data that's going to publish is the data we presented back at ESOT, I believe this was last year and so the European Society of Transplantation, we showed in an interventional study, and this is kind of important. We -- these patients were randomized and then they were ruled in for biopsy based off of our assay. And this is the first time anybody has run an interventional study using donor-derived cell-free DNA to decide when to do a biopsy. Normally, this test is used to rule out, right, because you're trying to avoid biopsies that aren't necessary. And in this scenario, we're saying these patients need a biopsy because it's highly likely that they have antibody-mediated rejection. And so, that's the study that's going to come out.

We're excited about it because I think it dovetails really well with the data that we've been publishing on the anti-CD38 drugs, felzartamab and daratumumab. And so, this is the drug that's now owned by Biogen and then J&J's drug. And so, that becomes important, like, if you have a drug that can actually treat [Technical Difficulty] antibody-mediated rejection, it's important to catch it as early as possible, because the time loss here is graft loss. And so, there's going to be a lot of push to catch AMR as early as possible, so that you can get these patients on treatment as soon as possible to avoid significant damage to the kidney and eventual graft loss or death or they're going to have to go back on dialysis. There's like a whole lot of bad outcomes that could be avoided if you can catch the AMR earlier. And we've got, what I believe is the best data out there. Certainly, the only interventional data that's out there showing that you can catch it early enough to actually have an impact with these drugs.

Vidyun Bais
BTIG, LLC, Research Division

That was perfect. Josh, and then, maybe just a follow-up on the U.S. sales funnel. I think you called out that this is 25% of transplant volumes. Just how long do you think that's going to take to convert that to revenue after securing FDA approval? And just what steps you've taken to prepare for launch there?

Joshua Riggs
President, CEO & Director

Yes. Let me take a second to think on that one. So, Andrea put together a really nice chart in our last shareholder letter, where we put out some thinking on what adoption could look like inside a major transplant center. And we don't expect that physicians are overnight going to just jump in and use our technology on 100% of the time on 100% of their patients. There's going to be some kind of lead-in period. We're assuming about a 6-month or 2-quarter lead-in from the point of time when they've adopted the IVD product to where you'll see a meaningful switch from sending out primarily to doing

things in-house. I think that may happen faster in the centers where they're already comfortable with our technology and that's where I think our pilot sites matter a lot. But I think for the new adopters, the ones that are adopting very close to the time when we have FDA clearance are sort of like immediately after, there's going to be a lead-in period. But I wouldn't expect it to last much longer than 6 to 9 months as they're kind of exploring how to work that in. And then after that the argument to send out gets rather tenuous, just because you'll be able to do it yourself. It's a heck of a lot easier to send a tube of blood down the hall than it is to send it across the country.

Operator

[Operator Instructions] And Julie, I'll turn the call back to you for the pre-submitted question.

Julie Silber

Sure. We have 1 question that came in via e-mail and the question is, can you explain why people wouldn't just use the NGS tests that are already out there?

Joshua Riggs
President, CEO & Director

Yes. I love this question, and I think, Ekke is probably a really good person to answer this one for us. So, yes. So, Ekke, if you can take the question on why wouldn't you just run the NGS test?

Ekkehard Schutz
Chief Science Officer

Yes. Thank you for the question. I really like it. So, we have developed the -- our test on digital PCR for good reasons. And I start with the fact that digital PCR is way faster than what you ever can do with sequencing that right now with the current technology that is out there is taking up to like 24, 30 hours before you can even have a result. And that really limit all these NGS technology to situations where the doctor doesn't need an immediate answer. So for all indications where the doctor wants to know what am I going to do, the NGS tests are not really feasible. So that was actually the reason why we went into that direction and we started developing the test.

The second reason is that, if you're looking at NGS, the sequencing alone comprises a high cost factor. So what labs need to do is to wait until they have enough samples together that they can put on one run of the NGS machine. So that's actually almost the same thing because it's all about timing. So you can just run 1 sample that is very urgent in your lab based on NGS. Our test is different. It doesn't matter whether you're running 1 sample or 10 sample. The percent of costs are actually the same. So it's all really patient-driven. If you need a fast result or a critical situation in the patient, NGS does not serve you. So that's the major reason why we were going into the direction of a PCR technology where you can easily get the results within 1 working day.

Joshua Riggs
President, CEO & Director

Thank you for that, Ekke. And I think that, that nails it, because I think most centers are going to struggle with the idea that they have to batch to get their costs down because there's always going to be a couple of cases a week where you're going to want a quick answer. And that's just not a great place for NGS technology to serve.

All right. Do we have anything else in the question queue there, Julie?

Julie Silber

No more questions from where I can see.

Joshua Riggs
President, CEO & Director

All right. Well, I appreciate everybody that tuned in and listened to us today. We look forward to continuing to update you guys on the progress that we're making as a company. We're having a lot of fun out here right now working with the transplant surgeons and researchers around the world. It feels really good. And so, thanks to everybody who has been supporting us, and we look forward to updating you all in the future.

Operator
And this concludes today's conference call. You may now disconnect.