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Market Intelligence

OncoCyte Corporation NasdaqCM:OCX

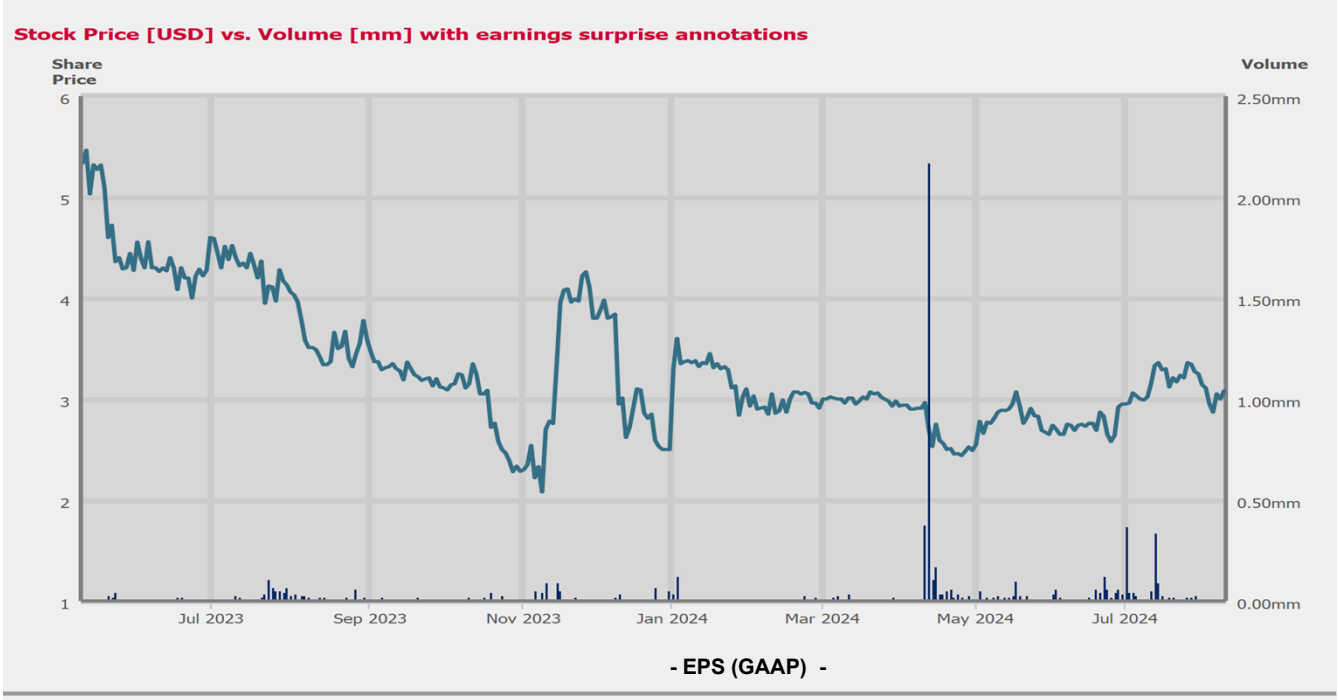
FQ2 2024 Earnings Call Transcripts

Thursday, August 8, 2024 9:00 PM GMT

S&P Global Market Intelligence Estimates

	-FQ1 2024-			-FQ2 2024-	-FY 2024-	-FY 2025-
	CONSENSUS	ACTUAL	SURPRISE	CONSENSUS	CONSENSUS	CONSENSUS
EPS (GAAP)	(0.67)	NA	NA	(0.55)	(2.93)	NA
Revenue (mm)	0.35	NA	NA	0.31	1.30	NA

Currency: USD
Consensus as of Jul-22-2024 11:55 AM GMT



- EPS (GAAP) -

	CONSENSUS	ACTUAL	SURPRISE
FQ2 2023	(1.24)	(1.07)	NM
FQ3 2023	(1.01)	(0.81)	NM
FQ4 2023	(0.99)	(2.07)	NM
FQ1 2024	(0.67)	(1.13)	NM

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EXECUTIVES

Andrea Susan James
Chief Financial Officer

Ekkehard Schütz

Joshua Riggs
President, CEO & Director

ANALYSTS

Joseph Scott Conway
Needham & Company, LLC, Research Division

Vidyun Bais
BTIG, LLC, Research Division

ATTENDEES

Jeff Ramson
ProActive Capital Resources Group, LLC

Presentation

Operator

Thank you for standing by. My name is Rochelle, and I will be your conference operator today. At this time, I would like to welcome everyone to the OncoCyte Second Quarter 2024 Earnings Conference Call. [Operator Instructions] I would now like to turn the call over to Jeff Ramson from PCG Advisory. Please go ahead.

Jeff Ramson
ProActive Capital Resources Group, LLC

Thank you, Rochelle, and thank you to everyone for joining us for today's conference call to discuss OncoCyte's second quarter 2024 financial results and recent operating highlights. If you've not seen today's shareholder letter, please visit investors.oncocyte.com to read it. Today's prepared remarks build upon the information already shared in this robust letter.

Before turning the call over to OncoCyte President and CEO, Josh Riggs, I'd like to go over our safe harbor statement. 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 Forms 10-K and 10-Q, which identify risks that may cause future actual results or events to differ materially. OncoCyte expressly disclaims any intent or obligation to update these forward-looking statements, except as otherwise may be required under applicable law.

I'd now like to turn the call over to Josh Riggs.

Joshua Riggs
President, CEO & Director

Thanks, Jeff. Welcome, and thank you for tuning in. We have on the call with us today our Chief Science Officer, Dr. Ekke Schütz; as well as Chief Financial Officer, Andrea James.

It's great to be able to announce the successful commercial launch of GraftAssure with our initial beta customers. We had confidence going into launch, but you never really know until your product is out in the field, and the feedback that we're getting is exceeding our expectations.

As we started our pivot last year, we said we were going to do 3 things: to keep our cash burn low, produce a product and welcome a channel strategic partner. And we've done all 3, and we are thrilled with the partnership and investment from Bio-Rad. Those 3 pillars set us up beautifully to meet the commitment made earlier this year to launch our GraftAssure research product in Q2, which we are happy to say that we met.

Going forward, we expect to maintain a capital-light business model, focus on site adoption in the U.S. and Germany, and deliver an IVD product to the market. Success in all 3 sets us up to disrupt the transplant testing market and deliver exceptional margins.

Our Head of Commercial and I have been out in the field talking with customers and exploring more partnerships. It's just like a flower that keeps opening up, the more we engage with the market, the more it's responding. We believe that over the next few years, our research product will double or triple the amount of research done using donor-derived cell-free DNA. This biomarker has been clinically accepted and is nearly standard of care and yet you don't see an explosive growth in research. And we believe this is reflective of how the central lab model, which we aim to disrupt, has not been able to fully support the research community and all the questions that they want to ask.

We know that there are a lot of these questions that are going unanswered today. Putting a research tool out there in the field and giving research institutions around the world access to it meets a real market need. And one of our early adopters is studying pediatric transplant patients. And sadly, there's a paucity of research in this space, and seeing one of our first centers jump in feels really good.

Empowering research not only serves the market more broadly, but it also creates new opportunities for OncoCyte, including in pharmaceutical research use. You can see the early innings of that with the Phase II clinical trial by HI-Bio, which used our VitaGraft kidney assay to monitor for responses to their anti-CD38 therapy, the results of which were published in the New England Journal of Medicine.

Since then, a second publication has shown the ability to monitor for response to a second anti-CD38 therapy for antibody-mediated rejection. In this case series study, patients were given daratumumab off-label to treat antibody-mediated rejection, and VitaGraft Kidney was able to identify that the drug was working with a simple blood test.

In addition to these publications, you may have seen in the shareholder letter that in the second quarter, we signed an agreement to be the provider of dd-cfDNA testing for a Phase II trial in AMR with a European biotechnology company. We think that this speaks to our growing market leadership and research partner of choice.

Before I go on, there's an important real world human element here to consider regarding the partnership with pharma. Many kidney transplant recipients experience antibody-mediated rejection. And when that happens, historically, there are not a lot of options for doctors or the patient. They may lose the organ and go back on dialysis or even eventually die, and it's a serious problem. And we're humbled by the opportunity to support pharmaceutical companies as they study ways to solve that problem and turn an organ rejection from a potential death sentence into a manageable condition. Of course, detecting antibody-mediated rejection very early, which data has shown that our technology can do, will be very important to solving this problem once drugs are available that can treat the disease.

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 have long been out in front with the clinical data that we are generating. We're excited, as you saw in the shareholder letter, that for the first time on July 11, researchers outside of OncoCyte began using our commercial research technology, GraftAssure. And it's a major effort for labs like this to bring up the workflow. It's a significant investment of time and resources, and they don't take it lightly. They are signing up because they believe in what we are building.

We believe that these labs are exhausted by the send-out only model, and they want to work with us in building an IVD technology. They want an IVD test so that they can detect transplant rejection quickly and easily on site, and they want to be able to run that test alongside [indiscernible] routine tests. They, like us, believe in the power of democratized access to technology.

In our launch program, they start with some sample product to get comfortable using the assay before switching over to revenue-producing product. As we pointed out in the shareholder letter, we are about 6 weeks into the commercial launch of GraftAssure, and we have transplant centers that represent nearly 25% of the U.S. transplant volume in our funnel and roughly the same percentage in Germany, our 2 key launch markets. This is exceptional and much faster than we would have expected with an RUO product.

The market enthusiasm for GraftAssure has given us the confidence to make some incremental investments in the back half of the year to support commercial launch and the FDA submission process for the IVD product. These investments include FDA compliance software engineering necessary to generate a test result, consumables to support the FDA submission as well as an inventory build to bring customer sites up. We aim to hold our cash burn in Q3 and Q4 relatively in line with what you saw in Q2.

Our product development team expects to deliver a completed data package to the FDA by summer next year. And depending on how quickly the FDA is processing submissions at that time, the earliest we could expect a positive coverage decision is in late Q4. We enjoy bench strength to support us in the IVD process, which is why I have invited Ekke to the call. He is here to help address any questions you might have today on the details of the FDA approval process.

It's going to be a lot of fun in the next couple of years. We have a lot to execute, but we are dedicated to democratizing access to novel molecular diagnostic testing, improving patient outcomes and creating substantial shareholder value along the way.

Now I'd like to introduce a newcomer to our earnings call. We welcomed Andrea James to OncoCyte in June, and she has hit the ground running. Some of you may know Andrea from Tesla or Axon. I'm thrilled to work with Andrea, and we are already benefiting so much from our insights, particularly when it comes to building and preparing for explosive growth. She is delivering decisive analytical leadership and heterodox thinking to our team, and I'm delighted by the partnership.

I've asked you to tell you why she came to OncoCyte. I think it was a great achievement for us to be able to attract her. And I think she sees in OncoCyte what we think the world will see over time. And as some of you know, Andrea has a history of being ahead of the curve. Andrea?

Andrea Susan James
Chief Financial Officer

Thank you, Josh. Hi, everyone. It's great to be here. And some of you may know me from Axon or Tesla or the sell side before that. As Josh said, I joined OncoCyte to help build and scale the company. There were 4 primary factors that drew me to OncoCyte: mission, timing, strategy and team.

First, the mission here is attractive, and it reminds me of what we had at Axon, which is to save lives. You'll notice in the new investor presentation we published today that we synthesized our mission very succinctly as follows: to democratize access to novel molecular diagnostic testing to improve patient outcomes.

We have an opportunity to do a lot of good with our technology and to do it quite soon, which brings me to timing. Where we are in our commercialization journey was very attractive to me. When I started talking with the company this spring, I learned that OncoCyte was just on the cusp of commercializing a product with more than a decade of history of development behind it. My background is in tech and finance. I don't have a background in health care, and I wasn't interested in going to a company where it would take 10 years to bring a product to market. So thank you to those of you on the call who have worked for 10 years on this product.

In addition to timing, I found the strategy to be highly compelling. I'm very much attractive to the strategy of selling diagnostic tests at software-like gross margins via a business model that is disruptive to the industry. We have the potential to be an asset-light, high-margin company that can scale quickly and eventually become quite large. The analyst and the investor in me has always appreciated businesses like that, and my guess is that many of you do, too.

Third, I was drawn to the quality of the team. We enjoy having world-renowned scientists in this company, including our Chief Science Officer, Dr. Ekke Schütz, who is on the line today. These scientists have extensive experience developing cell-free DNA products, developing immuno-oncology products and with obtaining regulatory approval to sell diagnostic test kits. This world-class expertise has created IP that we expect will support compelling margins.

Josh Riggs, who is sitting here beside me in Irvine, California, is a deep subject matter expert. He exhibits a clear ability to make important decisions with a high degree of clarity. The company's pivot over the past few years has not been easy, and I admire the combination of smarts, integrity and grit. It also helps to be a CFO stepping into a culture that already enjoys strong financial discipline. Of course, it was born of necessity, but I knew that this could be a great partnership. That muscle of fiscal discipline will remain strong, and it will support future operating leverage.

Okay. So the strategy makes sense and the team punches above their weight. Now the question is, how will this strategy play out? I saw 3 things that point to a company that is potentially in the early innings of success.

First, we have great indications of product market fit. The interest we are already gaining with GraftAssure is pretty exciting. What's amazing is that research centers are proactively reaching out to OncoCyte to get access to the transplant diagnostic even without forward sales reach from us, and wouldn't it be great if we can invest more in that sales muscle and go faster.

Second, the strategic investment and partnership with Bio-Rad really, really is a big deal. This company's channel partner is also its second largest investor. And third, the scientific validation has many proof points, the most recent of which appeared in the May 2024 publication of the New England Journal of Medicine. It was clear to me that OncoCyte is focusing on a scalable, high-margin product that fills a clear need and is selling it into prebuilt channels. This adds up to the potential to be a big winner.

Now to be clear, I also came in with eyes wide open. While I knew some of the investors in the company and I was aware of their strong support, and while I was impressed with the management team and the Board, it is also true that we are a tiny company, our trading volume is still small, and we have a weak balance sheet. All of this was solvable.

What was also clear to me from my prior background is that investors will provide money to companies with certain characteristics. These characteristics include: the ability to move fast and capture opportunities, the ability to manage risks and retire them and a compelling value proposition in the customer market, and this is where we are.

The opportunity over the next 2 to 3 years is very large. In the near term, we have the opportunity to capture market share by selling a known biomarker test into the transplant diagnostic market. We also have a compelling opportunity over the 5- to 10-year period, which is the period I've always focused on with companies such as Tesla or Axon. Over that timeframe, it is not unreasonable that we could become a $1 billion company. That potential is why I am here.

We have a compelling story to tell, and I'm eager to help tell it as well as guide it. As far as telling that story, you can see that with this earnings report, we are introducing a shareholder letter. We are also publishing a new investor deck that explains why we are investing in molecular diagnostic testing and specifically in developing test kits versus developing an in-house clinical lab model.

In these materials, we presented a graphic that is intended for you to understand why we are so excited about our beta customers that we are bringing up online as we speak. In the graphic, we show a projected revenue build that assumes we get FDA approval to sell an IVD product in late 2025 and assumes that the customer transplant center eventually switches from sending out their clinical tests to managing their patient populations in-house.

Now there's a reason why we do a forward-looking statement disclaimer on all projections, and that is because there are no guarantees. But we also felt that it was important to share our view of what we are building from where we sit today. You can count on us to be transparent on our growth journey. And that includes transparency not only about the opportunities, but also about the risks.

As for the numbers we reported in the quarter, they're in the shareholder letter, and you don't need me to read off of tables for you. The one thing I would highlight is that our April fund raise was very successful. We had participation from new and existing investors, including our first corporate partner, Bio-Rad, and it was done at market with no warrant coverage and no discounts. This speaks to the fact that we have a real market opportunity to go after, and that others in the capital markets are starting to see that opportunity.

I'd also highlight that with the preferred stock redemptions in April, we now enjoy a streamlined capital structure with just common stock and no debt or preferred stock, which hopefully excites you as much as it does me as we hit an inflection point. We truly value our partnership and relationship with the investment community, including our analysts and shareholders, so thank you for joining today, and we look forward to welcoming more investors over time as we grow.

The opportunity set that we face is exciting. Day by day, our pass-through revenue is steadily being derisked. Once we are capturing that revenue, we think you'll be pleased with the leverage in the business model itself, which is both high gross margin and capital light.

Okay. So now we welcome your questions. Go ahead, Jeff. Do we have any questions in the queue?

Jeff Ramson
ProActive Capital Resources Group, LLC
We do. Rochelle, can you allow the verbal questions?

Question and Answer

Operator

Certainly. [Operator Instructions] Your first question is from Mike Matson with Needham.

Joseph Scott Conway
Needham & Company, LLC, Research Division

This is Joseph on for Mike. But just a quick question on VitaGraft, start it out. I saw in the press release that you talked about increasing throughput at the CLIA lab. Just kind of want to get an understanding of where this test stands. I assume volume hasn't set up. Maybe you could dissect that a little bit. Maybe this prep work, what are you kind of aiming for, for volume for this test? And then obviously, liver is still under review at CMS. So if you could give an update there, that would be helpful.

Joshua Riggs
President, CEO & Director

Yes. Thanks for the question. I think what we've done is expanded our capacity in the lab in Nashville. So we're talking about an investment that we're making into that lab infrastructure. It's primarily to support the extra work that's coming at us for the FDA program. So that's just about the amount of samples and the amount of data that we need to generate to support the FDA submission. And so that's really more of a capital spend to support that effort.

We've largely pulled back on most of our commercial efforts towards the LDT service product and put all of that energy into working on the site placements where we just kind of had an overwhelming response and you needed to pivot our commercial team more towards activating sites for the RUO product.

Joseph Scott Conway
Needham & Company, LLC, Research Division

Okay. Yes, that makes sense. So I guess maybe just to ask another question on that. As we look at the chart, I guess, you provided for the beta path, in terms of just material revenue before that inflection point, I guess, estimated inflection point around second half 2026, is there anything that we should start baking into our estimates? Or is the next really material driver IVD VitaGraft for Kidney?

Joshua Riggs
President, CEO & Director

Yes. With the low burn, every dollar of revenue feels material to us. But with the RUO product, I mean, it's going to be modest revenue. And it's hard for us to gauge that because this is a new product for the industry. They haven't had anything like this. So we could be pleasantly surprised by the orders, but I think we're going to keep those expectations modest for now until we get confidence that it's going to be much above. I think we do a good job in that graphic kind of highlighting that there's a relatively slow burn of revenue per site for the RUO product. And then as you pointed out, it really kicks up once we have an IVD product out there.

Joseph Scott Conway
Needham & Company, LLC, Research Division

Okay. And then maybe just final question, just as we look forward to these next couple of years. In terms of site adoption and cash burn, just kind of wondering how you're level setting that. If you're more looking at just finding the strategic centers and planting relationships there, or if it's going to be a slow buildup of customers there over time?

Joshua Riggs
President, CEO & Director

Thanks. I would say 1 advantage that we have in transplant is an exceptional concentration at the top. So transplant is a relatively complicated surgery, and so it tends to aggregate at the higher-end academic centers that's both here in the U.S. and Europe and around the world.

And so any 1 of these top 100 centers feels meaningful to us because the top 100 here in the United States do 80% of the transplant volume are better. And so I guess, if I'm going to answer your question, I think when we get to 10 to 15 to 20 sites, we will have picked up a very meaningful percentage of that local market opportunity, and I think that's what we're excited about. So when we look at our funnel today, I mean, 25% of the U.S. transplant volume is represented there. I mean all of these guys feel strategic to us.

Operator

Your next question comes from the line of Mark Massaro with BTIG.

Vidyun Bais
BTIG, LLC, Research Division

This is Vivian on for Mark. So as it relates to FDA approval, could you just remind us of any interim milestones, what publications and studies you're expecting to leverage to get there? I think in the press release, the Q-Sub was mentioned. And then I believe FDA clearance in late '25 sort of represents your bull case, but just can you give us a range of the timing of that?

Joshua Riggs
President, CEO & Director

Sure. I'll take some of the timing question, and then I'll ask Ekke to talk about the milestones that he has in front of him. We -- I think we're -- I guess we're very hopeful that the FDA will move quickly, and we don't really control that process. But we're going to give ourselves the best chance we have to get through by the end of '25. That may drift into early part of '26 just depending on how quickly the FDA is processing things at that time.

But Ekke, if you could just talk a little bit about the key milestones that you have in front of us, the Q-Sub and then what you guys are doing from a product development point of view and where you hope to be kind of going into next year.

Ekkehard Schütz

All right. Thank you. So our Q-Sub is planned like in 6 to 8 weeks from now. We are right now putting all the material together. I would say we are 50% there. We are going to start, I would say, the revision process next week. So we are all going into that and divide it by all the needs.

And it's a pretty formalized process, where you are just presenting your intended use, you're presenting the method or the assay, and you are presenting what kinds of studies like analytical validation, clinical validation you're planning. And then you ask the FDA a question, are you fine with that? Is our analytical validation according to what you are looking for? Is our clinical validation according to what you are looking for?

And then we hope to get good answers. We had made actually pretty good experience with the FDA when we did our BPD submission last year. They are very cooperative. And so they are really trying to work with you and not against you, which I really appreciated.

So bottom line, there are some time to tell us, okay, this is -- okay, this might be for us. This is all that detail something where we want to have a modification, which at the end of the day helps us for the design and planning of our IVD endeavor.

That said, also this IVD route is a very, very formalized way of putting documents and data together. It starts with Phase 1, which is a design selling and inputs. So you are completely put together how your design should look like. And all the input in there like, okay, what are we going to achieve? What is our target? And that's something we want to get finalized by in, actually, 6 weeks from now.

So we want to have that phase done in 6 weeks. And from there, you are getting into the second phase, which is development and design output. So from there, you are developing everything like work packages, what you want to do, how you want to do that, which study and so forth. And then the design output means you are controlling that what you have put into your design document really can be achieved. So that's the second so-called phase gate.

And then the third phase is verification and validation. That's where we are going to do an analytical validation and particular validation with the, at that point, locked in final product. And this, we have planned to get accomplished by Q4 '25/Q1 '26. So that's the entire plan. It's a lot of writing documents and just show the FDA that you are -- have thought about everything that needed to be thought about and that you are not just getting some data randomly put together by chance. The entire idea behind that is [indiscernible] so-called design control. Everything needs to be set from the very beginning, and then you are just working along what you have planned.

Joshua Riggs
President, CEO & Director

Thank you, Ekke. Can I just want to make 1 comment on -- I apologize. But just 1 quick comment. Yes. One thing that we've been pleasantly surprised with is kind of the warm reception to the IVD program we felt from the community. One of the questions we're

asking these sites as we're bringing them up and we're moving them through the funnel is, hey, are you interested in participating in the IVD program? And it's just kind of been overwhelmingly positive.

I think these centers want to help us get the samples together. They want to help us with the reproducibility studies. And so it's really feeling like a community effort here to push the IVD process along. So I think we're overwhelmed by the positive support that we're getting from the community. And I think we're -- there's just a general excitement that they're going to have access to this technology and they get to help make it happen.

Operator

There are no further questions from the line at this time. I'd like to ask Jeff to see if we have any questions from the webcast.

Jeff Ramson
ProActive Capital Resources Group, LLC

Yes, we do have a few, actually. Josh, Andrea, how do you calculate the $1 billion transplant testing market opportunity? And how does OncoCyte plan to capture its $1 billion market opportunity?

Joshua Riggs
President, CEO & Director

I mean it's a good question. We put this out, I think, in our investor deck. We've got an estimate of somewhere around 3 million to 3.5 million testing opportunities globally. And that number, obviously, multiplying that by a mix of our RUO product and our IVD product, where we expect to be IVD in the U.S. and Europe and then probably stay RUO Rest of World. That market is growing, at least according to current estimates, about 9% a year. So we see that the $1 billion is a relatively conservative estimate of what the market opportunity is. We're not going to move that up until we have a chance to do more price discovery. And this is just something that's hard to do until you actually have the IVD product out there and know what you're going to get reimbursed. So we're erring on the side of being conservative there.

From a market capture point of view, I think we talked about this a good bit, but it's democratization, right? It's giving people access and it's meeting the demand where it is, which right now, the demand is at the local center, and they don't have access to a technology that works for them today.

Andrea Susan James
Chief Financial Officer

DO you want to add just a little bit about that $1 billion total addressable market is based on the current clinical indications?

Joshua Riggs
President, CEO & Director

Yes. I mean, I think the most exciting thing for us that's come out of the past 2 or 3 months is the work that's being done on like the anti-CD38 drugs, where they're really meeting an unmet clinical need from a pharma point of view. And that just opens up kind of just these significant monitoring opportunities, so therapeutic efficacy monitoring, like is the drug working, and then also recurrence monitoring. And we're seeing a lot of this in oncology right now, and there's just an enormous amount of value creation that's happening in the oncology space just kind of like on that therapeutic efficacy and recurrence monitoring. And we're starting to see that emerge here in transplant.

And so we're -- we've got our fingers crossed that these trials will continue to be successful so that patients have an option instead of just losing their organ. And I think that creates -- that's an incredible tailwind for us because we're out in front there. And so I would say that easily expands the market opportunity that's in front of us.

Ekkehard Schütz

If I may, I would just add to what Josh was [sustained] to make it really clear. What the new situation that we have created is. I recall a Board meeting like perhaps 8 months ago, where we were talking how much would you use the test in a high-risk population. And most of the people are saying, "Why should I? We don't have any therapy. Why do I want to know?" And this has dramatically changed.

Now we have the first working therapy for chronic active antibody-mediated rejection, and it's not only something where we can show our test is perfect monitoring. It's also a huge, huge relief for patients who are suffering. Because earlier than that, there was no therapeutic option and the organ would ultimately be lost, and now we have a therapeutic option.

And our contribution is really to show that people are going into this disease earlier than we can do it with standard of care. And...

Jeff Ramson
ProActive Capital Resources Group, LLC

I have 1 other question, Josh. How does OncoCyte envision building recurring revenue streams when most diagnostics currently are performed episodically?

Joshua Riggs
President, CEO & Director

Yes. I would say the transplant is inherently a recurring revenue opportunity because these patients are living with their organs, hopefully, for 10, 12, 15 years or better. And unfortunately, though, there's a high rate of rejection. And so there's just inherently a number of touch points over the life of the patient.

We're -- the physician just needs a noninvasive way or a minimally invasive way to check on that organ. We, along with the other players in the space, are kind of meeting that need. And so I think it's just inherent to the product and the industry that we're in.

Jeff Ramson
ProActive Capital Resources Group, LLC

Got it. Okay. Great. There's no more questions. Rochelle?

Operator

Currently, we don't have any questions from the line. [Operator Instructions]

Andrea Susan James
Chief Financial Officer

Thanks, Rochelle. And Jeff, I guess we'll give it maybe like 5 seconds here for a pause, and then maybe Josh will close this out.

Joshua Riggs
President, CEO & Director

Okay. Guys, thanks everybody for joining us today. I mean we're obviously excited about where we're at as a company. It feels great to be out in the field with a product, engaging with the research community and just feeling a groundswell of support. So we look forward to updating you guys on our product and capturing these sites across the United States and across Europe. I think we'll have some very exciting things to announce here in the future, and thanks for playing along.

Operator
Ladies and gentlemen, that concludes today's call. Thank you all for joining. You may now disconnect.