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Insight Molecular Diagnostics, Inc. (IMDX)

Q3 2026 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Operator: Welcome, everyone, and thank you for joining us to discuss Insight Molecular Diagnostics' Third Quarter 2026 Results. If you have not seen today's Shareholder Letter, please visit imdxinc.com for today's letter. Today's prepared remarks build upon the information already shared in this robust letter.

Joining us today are Insight Molecular Diagnostics' 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.

Before turning the call over to Josh Riggs, I'd like to review 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 Insight Molecular Diagnostics 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, Insight Molecular Diagnostics, Inc.

Thanks, Gabby. Good afternoon, everybody, and thanks for joining us. Today, I will focus on two main topics: start of US revenue from GraftAssure, and what we believe will be the final steps related to our FDA submission. We've made investment into two areas to drive pre-Dx launch revenue. Admittedly, this revenue stream has taken

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a little bit longer than we had hoped to get started, but it seems like it is finally ready to begin, namely, from the GALACTIC registry, and also the beta-site program, which I will describe in a moment.

Before I get to that, I'd like to mention our new Head of Commercial, Donnie Purto. Mr. Purto is an accomplished sales leader with more than 20 years of experience building and leading high-performing sales organizations across diagnostics, life sciences, and healthcare. During a decade at Natera, he had success in leadership roles, spanning sales, training, oncology, transplant, and women's health. He managed new product launches, as well as hundreds of millions of dollars in revenue in highly competitive markets. His experience makes him a great fit as we transition out of the development stage towards being fully commercial. We're counting on his leadership to make GraftAssure the leading product in transplant management.

On that, I'm pleased to announce we've officially started enrolling patients in our GALACTIC registry. Big congratulations to the UCLA team for being the first to enroll. They've been a foundational site for the validation of dd-cfDNA broadly, and we are glad to have them on board as we build the next generation of clinical utility. As a reminder, GALACTIC aims to show the power of having a positive predictive value north of 80%. Contrast that with current assays clocking at around 50%, which is basically just a coin flip. The expectation is that we'll see a higher on-target rate for biopsies. It looks like we're going to have five or so sites enrolling by the end of the year with more in the hopper for Q1. Enrollment in the GALACTIC study begins a mostly predictable revenue stream. And importantly, it means that the clinical community will gain experience using our GraftAssure tests.

Shifting over, for about a year-and-a-half, we've been supporting beta sites across the United States. The goal was to get centers familiar and comfortable with GraftAssure technology. We've seen a couple head to heads come out demonstrating equivalency to legacy tests, this is great for building clinical confidence. And just recently, at ASHI, one site showed a turnaround time of just 6.5 hours. That's a significant improvement over the several days it takes to get a send-out test back. Quickly, just in case anyone needs it, ASHI is an annual conference where transplant lab leaders meet to learn about new technology and best practices.

Perhaps the most exciting news coming out of that conference is how close transplant centers are to launching in-house dd-cfDNA testing services here in the United States. It's clear to us that leading labs are no longer intimidated by the idea of bringing testing in-house. A handful of hospital laboratories have completed both analytical and clinical validation and are moving on towards reimbursement. By our count, centers representing a little north of 1 in 20 US kidney transplants have indicated that they are committed to in-house testing and lining up to launch in 2027. I expect that this will be a watershed moment in the transition from centralized to local care. The support of ASHI broadly has been great. They continue to make progress on establishing proficiency guidelines, which lays the groundwork for the broad option of dd-cfDNA at HLA labs across the United States.

Shifting over to the FDA. In late July, the FDA completed the first phase of its substantive review of GraftAssureDx, and requested additional information, which is common for a de novo submission such as ours. In late September, we met with the FDA to discuss our approach to addressing the additional information request. Known as an SIR meeting, this is a de-risking step to help make sure we have good alignment on expectations. The agency has provided both verbal and written feedback to help guide our next data package. We are busy finishing up the extra homework they gave us on our way to a final submission.

We have two external processes that factor into the timing for our response. The first is an independent study to further demonstrate the accuracy and consistency of our test results. This will bolster our internally-generated data. And the second is an additional review of biopsy slides, for which we have secured two well-known expert pathologists, to establish the diagnoses against which our test results will be evaluated. We currently expect both processes to be completed before the end of the year and to submit our complete response before the January

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21st 2027 deadline that we have. The FDA has a targeted review timeline of 150 days for Class II de novo submissions. Since we received the additional information request in late July, the review clock has been paused. We estimate that approximately half of the review days remain and the clock will restart once we submit.

One additional note before I hand the call over to Andrea. We have added GraftAssure urine screening for t-cell mediated rejection into our pipeline. Missing early TCMR has been one of the biggest drawbacks of today's blood-based test. We believe that we are the first company to demonstrate the ability to detect early TCMR in urine using a donor-derived cell-free DNA test. We can see a future where docs will order both blood and urine together in the first three years to rule out both main types of rejection, ABMR and TCMR. We believe that this has the opportunity to drive significant growth in demand. This will come alongside our expansion to heart testing in transplant patients in 2027.

Now, I'll hand over to Andrea to take us through the financials.

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

Thanks, Josh. Hi, everyone. Okay, so earlier today, we published our robust Shareholder Letter and that allows me to keep my prepared remarks relatively short, that was filed as an 8-K right after the close. It took us a minute to get it up online, but hopefully you all had a chance to read it.

Regarding our third quarter performance, I want to point out simply that our operating expenses and free cash flow trended in the right direction. So, operating expenses peaked in Q4 2025, as we incurred significant expenses associated with our FDA program. And as we alluded to last quarter, we believe that cash burn had bottomed in Q2 of 2026, so the most recent quarter, behind us, and as we work through some of those payments that were associated with our Q4 GAAP expenses. That OpEx growth that you saw go through the P&L over the last several quarters was driven largely by our FDA program. And so, OpEx peaked in Q4 2025 when R&D expenses reached $5.8 million and that's [ph] above (00:09:16) $2 million above the prior quarter Q3, and it was driven by lab supplies, consulting and FDA trial site costs. So, R&D back down to $3.8 million in the third quarter, and that still includes the remaining work to advance the GraftAssureDx toward authorization.

You'll notice in the third quarter that operating expenses less the non-cash items were flat with Q3 a year ago. So you can really see those FDA program expenses winding down. And as the FDA review concludes, the R&D focus shifts from securing authorization to building out the GraftAssure platform by expanding the menu, which Josh had talked about, and the evidence base where each transplant center can do more with our technology. Our target is for future FDA programs to be sustained by the gross profit from our kidney transplant assay.

Before we go to questions, I thought I'd share what brings me excitement about our trajectory and why since becoming CFO, I have invested in the company personally, both through capital raises, as well as via open market buying. IMDx has many of the hallmarks of companies that enjoy the kind of growth that comes from disrupting a market. The concept of turning a molecular lab test into a kit is a good idea, and you need three ingredients for this idea to be successful. You need high clinical demand, meaning will doctors order the test. You need strong reimbursement, meaning can we get paid. And you need the product to be IP-protected, meaning we have a right to sell it with a sustainable, competitive advantage. IMDx has all three. For high clinical demand, donor-derived cell-free DNA tests are already ordered in the hundreds of thousands of times per year every year by clinicians. And these same clinicians who order these tests are telling us that they want to do their own testing. And matter of fact, Josh is sitting with a lot of these potential future customers right now.

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For reimbursement, we've had Medicare MolDX reimbursement since August 2023 on our Tennessee lab developed test, and FDA authorization would allow us to port this reimbursement to our customer labs. And finally, our proprietary digital PCR-based assay is IP protected, and we expect to continue to grow our patent portfolio. We believe that the total addressable market for regulated transplant testing, that's the kitted testing that we seek to sell, is $800 million in the US alone, and after kidney, our product pipeline includes expansion into other organs like heart and lung transplant testing, as well as testing modalities other than blood such – specifically urine testing. Our assay performs well out in the field, it's been tested on research-use-only mode for over two years now, and our FDA dialogue has been very rigorous as expected, but also encouraging.

Okay, Gabby, now we can take questions. And I saw some of the hands come up while I was speaking.

QUESTION AND ANSWER SECTION

Operator: [ph] Eric (00:12:03), can you put us into gallery mode, please? All right. We'll start with Alex Nowak from Lucid.

Alex Nowak
Analyst, Lucid Capital Markets LLC

Q

All right. Hey, good afternoon, everyone. Hopefully you can hear and see me. Thanks for taking the time. Appreciate it.

So, the release says – basically the release says FDA's preliminary view is that the submitted clinical data does not yet support the proposed intended use. Can you just expand on really what that means? Like, what are the FDA ultimately is pushing back here on?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Yeah, I would say, there was the size. So, we had only submitted about 75 samples. They wanted more subgroup analysis which we'll be able to do with the larger sample set that we have available to us now. And then there's the additional studies that they were asking for, one of which we referenced here, which is the additional accuracy studies that were to be performed outside. And I think that all rolls together. I think it's just kind of blanket language that says they weren't completely satisfied and they wanted to see a little bit more information from us.

Alex Nowak
Analyst, Lucid Capital Markets LLC

Q

Sure. I mean, the company has tons of samples, tons of data, tons of publications that I think you can rely upon. Do you need to go back and do a bigger, broader study based on the feedback review...

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

No...

Alex Nowak
Analyst, Lucid Capital Markets LLC

Q

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...yeah, do you really think you could put everything together that you have and get it through the FDA when you go back to them in January?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Yeah, I think we're in great shape. We've tripled the amount of sample that's available to us since we first started. And so, we're in much better shape to answer some of the more detailed questions. And unfortunately, the FDA doesn't let you point to your 10 years of history as an LDT, they want fresh samples that came out of the FDA prospective study.

Alex Nowak
Analyst, Lucid Capital Markets LLC
Q

Got it. Okay. And then maybe just one more kind of follow-up to all this. So, you respond to the FDA end of January, let's say. Walk me through the timeline a little bit. So we get half the review clock remaining. I'm thinking launch is going to be looking like a second half of 2027. What can you do really between now and then to kind of see the market, get things established at the transplant centers, get reimbursement established, et cetera?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Yeah, as far as our understanding goes, there's no mechanism to stop the clock again. And so, the – once we submit the package, we're really on this kind of like, call it, 75-day window. Does that mean that they're going to be completely done in 75 days? No. I mean – and this is – they don't have – they have the opportunity to extend beyond that. But we expect that they're going to hold close to that.

Alex Nowak
Analyst, Lucid Capital Markets LLC
Q

Okay. And then just timeline on launch, reimbursement and kind of seeding the market.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Yeah. So, the launch would happen, I'd say, right after authorization. The only difference between the RUO version of the test and the IVD version of the test is a sticker. And so, we're already manufacturing the exact same product that would go into the IVD box. Seeding the market has been happening through the beta site program, which we discussed, and then also through the FDA program. Every one of the centers that you see listed on our FDA trials.gov site has our instrument in-house. And so, all of the data was generated locally. Every one of these centers is familiar with our workflow, has been trained on it and ready to adopt.

Alex Nowak
Analyst, Lucid Capital Markets LLC
Q

Okay, all right. Well, good stuff. Thank you for the time. Appreciate it.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Thanks, Alex.

Operator: ...Alex. Mark Massaro from BTIG.

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Mark Anthony Massaro
Analyst, BTIG LLC

Q

Hey, guys. Thanks for taking my questions.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Hey, Mark.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

How's it going?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Good.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Yeah. So, I wanted to ask, was there any – have you submitted any biopsy slides in the first submission or is that something that came perhaps as a surprise to you?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Well, we tried to do just the local pathologist and the FDA really didn't like that. They said, we want to see a three-part review. So, you have a national reviewer and then you have a tiebreaker that sits on top of it. And so that's one of the long poles for us was getting all that organized, getting all the slides up into a digital database, that's all going now, so they're all being reviewed. But that was something that they clearly were not excited about in our original submission.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Okay. And then I just wanted to clarify the significance of the January 21 deadline. Maybe why is that the right date? Maybe that's day 180, perhaps.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Yeah.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

And correct me if I'm wrong. But the other thing is, in the event you need more time, just – I know you think you'll hit it, but if you did need more time, is there a process in place that would allow you more time?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

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Yeah, you just – you have to resubmit at that point. It basically kills the submission and you're starting back over, so you're restarting the 150-day clock.

Mark Anthony Massaro
Analyst, BTIG LLC
Q

Got you. And just for clarification, you're feeling pretty confident that you'll hit these two additional processes by, you said, year-end 2026.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Yeah.

Mark Anthony Massaro
Analyst, BTIG LLC
Q

So, you're giving yourself like a three week...

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Yeah, that is exactly right.

Mark Anthony Massaro
Analyst, BTIG LLC
Q

Okay. Last question for me. As we think about the market for your LDT and then recognizing that GraftAssureDx will be the core product going forward, how do we think about you selling those two in tandem? I would expect the kit would probably be exhibit A for quite some time, but how do you think about offering [indiscernible] (00:17:47)?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Yeah, I would say with the registry, those samples will come to us until we get to Phase 2. And so, as we were working with these centers, we negotiated that there would be a Phase 1 and Phase 2 in the registry. And so, Phase 2 is they start running it themselves and so [ph] where they start (00:18:06) sending samples to us, like we want to be in the kit business, we don't really want to be in the lab business, we want to be a supplier to labs. And so, I think the opportunity is to use the registry as a way to help convert sites that want to participate scientifically, and then they also want to bring it inside for clinical purposes. And so, that serves dual purpose.

Mark Anthony Massaro
Analyst, BTIG LLC
Q

Awesome. Thanks so much for the time, guys.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Sure.

Operator: Thanks, Mark. We have Mike Matson from Needham.

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Mike Matson
Analyst, Needham & Co. LLC

Q

Yeah, thanks for taking my questions. I guess, just want to ask more on the heart trial. So, just given the kind of extended timing on the de novo for kidney, and the fact that you want to kind of fund the other trials with the gross profits from kidney, does that mean that's going to get pushed out a few quarters as well?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Yeah, I would say, we had a KOL call maybe two months ago with Loyola, where they were talking about they wanted to start sending us samples [Technical Difficulty] (00:19:13) that's I think the advantage of going into heart as opposed to kidney, where in kidney, we were de novo, like we were the first one to go through the FDA, it's why we're facing so much scrutiny on the process. In heart, there is a predicate device. And so all I have to do is show that I'm not inferior to that device and that becomes a much simpler pathway, so that's 510(K) instead of de novo. So I think for us, it's not as heavy of a lift. And I think we're – we're expecting that we're going to be able to do that much more efficiently than we did with kidney. We'll get the samples in. Hope – and I'm – we don't have formal guidance on this, but we – hopefully we got the samples that we need in in the first half and that supports the submission maybe late second half next year.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay, got it. And then just on the beta site and GALACTIC registry kind of nearer term revenue opportunities, is there any way you can kind of frame that out or quantify what that could actually amount to in terms of revenue over the next few quarters until we get the kidney test launch?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

No, Thanks. I don't expect that it's going to be changing our life in a meaningful way. I think it's going to be nice-to-have revenue and it's going to – and it's going to do its job, which is introduce our clinical report into the hands of clinicians that have never seen it before. But I would say it'll be some, but not much.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay, understand. And then finally – and I understand if you can't comment on this, but you did announce a capital raise. So, just curious, why now. And any comments there? But if you're not able to respond to that, I'd understand that. Thanks.

Andrea James
Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

Yeah, thank you so much. There is a [ph] pro-sup (00:21:05) that's filed and we have to refer you to that and direct the questions to the filing. Sorry, Mike, our hands are tied there. But I will say, one of the things that we hope that people see on this call and there's a new earnings deck that's live online, it talks about our pipeline, it talks about seven centers we're validating, it talks about we have line of sight getting through the FDA and so why we're excited about 2027, and that's what the focus of the call is today.

Operator: Thank you, Mike. We have Ben Mee from Stephens.

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Ben Mee
Analyst, Stephens, Inc.

Q

Hi, good afternoon, and thanks for taking the questions. This is Ben on for Mason Carrico. Appreciated the color you guys gave, sort of where the centers stand in their validation activities. I was hoping you could expand a little bit on what that process looks like as they're moving into reimbursement, and the reimbursement question is that next step both for Medicare and any commercial payers as well?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Yeah. So, we can't – just because it's an [indiscernible] (00:22:19) product, we can't support them in that process. This is something they have to do on their own under kind of CLIA rules. And so, in that context, it looks a lot like what we went through as a CLIA lab. We had to show that there was analytical validation, we had to show that the test was clinically valid and the intended use population. And then we had to submit to MolDX for reimbursement under the LCD. And so, we would expect that anybody who's in a MolDX jurisdiction would be following exactly the same process. And there are several labs that have been successful getting reimbursement through that exact process.

Outside of MolDX, it looks a little bit different. A lab that's maybe in First Coast would have to go to their MAC to try and either get on a case by case basis or get medical policy written. One thing that we do influence with – once there is a PLA code in place for our test, that does influence what MACs that are outside of MolDX pay once they write medical policy. And so, that's supposed to go into effect. I'm looking at Andrea. I think early January would be the PLA code goes into effect?

Andrea James
Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

We hope to have a nationwide price in January of 2028. We are working on ways to bring that in and do that sooner by porting over to another reimburse test. But that is TBD, but we hope to have a nationwide code early – starting 2028.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Yeah.

Andrea James
Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

But – and just sorry, actually just to zero in on that, we just did like strategic planning for next year, Josh. A huge part of what we were focused on is going after those initial centers in the MolDX jurisdictions. There is a lot of work that we can do where there's reimbursement. So, I don't know if, Josh, you want to talk about going after those initial centers and what we're doing to kind of get ready for a launch.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

A

Sure. Yeah. I mean, that part's pretty straightforward. There's 67 centers or so that do greater than 50 kidney transplants a year inside the MolDX jurisdiction. For them, it's plug and play. Once we have an authorized product, they'll be able to – we will port over the reimbursement rate and then they can plug in the instrument and

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then basically a week later, they're off to the races. And so, we'll be focused on those labs in the initial launch phase, while we work on market expansion in the other MAcs and getting medical policy there.

Andrea James
Chief Financial Officer, Insight Molecular Diagnostics, Inc.
A

Yeah. So, it is a very highly concentrated market and there's lots of great customers we can go after while we wait for that nationwide reimbursement.

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Yeah.

Ben Mee
Analyst, Stephens, Inc.
Q

Sounds good. Thank you. Thank you for all that detail there. And then, could you just give us an update on Europe? Have you submitted the necessary applications there and just how should we think about the timing to commercialization there?

Joshua Riggs
President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.
A

Thanks. We're still looking kind of right here at the end of year or early part of January doing the IVDR submission, that will be both for kidney and for heart. And then the review time on that looks like about six months right now. Obviously, we don't control TÜV SÜD any more than we control the FDA. But that's the guidance that they're giving us, so that would put us with clearance mid-year.

We know that ESOT is working on an update to guidelines for how these tests should be used. Many of the writers and the folks that are engaged in that process are using our technology in some form or fashion. So we feel good that there's push from the clinical community in Europe. But right now, there's really no broad reimbursement. There's maybe two or three countries that have found a way to pay for it, which is really, really limiting our ability to commercialize at this time.

Andrea James
Chief Financial Officer, Insight Molecular Diagnostics, Inc.
A

ESOT is European Society for Organ Transplantation. I mean, just a quick commentary to understand the European market where you have more single payer systems. We expect the reimbursement to be lower than in the United States. But as a kitted product company, that's actually very advantageous to us because it makes it hard to operate in LDT, but more of that reimbursement will just be passed through to us, whereas in the United States, there's more of a profit motive, so the customers would buy our kit, here it is, and then they would bill at a higher rate. If there's lower reimbursement internationally, it would pass through to us. So, kit is actually how you go after the European market. So, even if you start to see reimbursement come through, don't be alarmed. If it's lower than the US, we just – it gets passed over to us for our kit.

Ben Mee
Analyst, Stephens, Inc.
Q

Got it. That makes sense. Appreciate you taking the questions today. I think I'll just keep it to two here.

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Operator: Thank you, Ben. Do we have any additional questions? All right, Josh, I'll turn back over to you.

Joshua Riggs

President, Chief Executive Officer & Director, Insight Molecular Diagnostics, Inc.

All right. Well, thank you, everybody, for attending the call. Thank you for the thoughtful questions. I think we're very excited to be sort of in the final steps here on a process that we started about three years ago. So, really looking forward to having GraftAssureDx on market here in the United States, and making it a lot easier for transplant centers to manage their patients locally. So, appreciate you guys, and thank you.

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