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Insight Molecular Diagnostics, Inc. (OCX)

Q2 2025 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Gabrielle Woody
Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

All right, everyone. Welcome and thank you for joining us to discuss Insight Molecular Diagnostics Second Quarter 2025 results. If you have not seen today's shareholder letter, please visit Insight Molecular Diagnostics Investor Relations page at investors.imdxinc.com. 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 go over our Safe Harbor. The company will make projections and forward-looking statements regarding future events. Any statements that are not historical facts are forward-looking statements. These statements are made pursuant to and within the meaning of the Safe Harbor provision of the Private Securities Litigation Reform Act of 1995. We encourage you to review the company's SEC filings, including the company's most recent Form 10-K and subsequent Forms 10-Q, which identify risks and uncertainties that may cause future actual results or events to differ materially. Please note that the forward-looking statements made during today's call speak only to the date they are made, and 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.

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Thanks, Gabby. Welcome, everyone. Thanks for taking the time today. I spent much of last week at the World Transplant Congress, meeting with leaders from top transplant centers from both here in the US and in the EU. In the future, these sites will be our customers, representing the earliest adopters of our IVD product. Today, they are our partners.

We are working together, bringing transplant centers something they are missing, the ability to manage their patients locally and get paid for it, and run their own research studies, build guidelines and explore new clinical utilities. Our transplant partners are energized and motivated to see us be successful with our FDA program, and that energy is starting to spread. Just in the last week, we've had more centers raise their hands to see if they can support the clinical trial. We are working with them to get them up and onboard as quickly as possible.

Today, I'm going to talk about our progress with the FDA product, GraftAssureDx, what we are doing to prepare for commercialization and where we are headed next as a company. To recap our key areas of focus for 2025, first was finalizing our clinical assay and trial design; the second was getting through our clinical trial to submit a data package to the FDA by the end of the year; and third, spring-loading back half 2026 revenue through our land-and-expand strategy with transplant centers.

On the first area, we talked earlier in the year about assay and workflow design improvements. I'm pleased to note that those have been completed and transferred to manufacturing, with the first kits shipping out to our beta sites in June. The changes make it possible to get both the relative and absolute quantification of dd-cfDNA at the same time on the same run. This simplifies the workflow for our future customers, making it easier to adopt and offer some improvement in turnaround time. Early feedback is positive, and multiple centers are taking it through the validation process.

As far as the clinical trial, we've had our first center site initiation visit last week, with the next two coming over the next two weeks. It feels really good to be making progress with the clinical trial, which is a key component of our FDA submission. We believe that we are still on track to submit to the FDA by the end of this year, which is the same timeline that we communicated in March and again in May. Like with any FDA program, there are several work streams that must come together, and from what we can see, we are on pace. So, we continue to target FDA approval in 2026.

On July 30, we had our third FDA meeting and walked away feeling great about our program. These meetings with our FDA review team are productive and provide clear guidance on what's expected from our study. From the first meeting back in December to now, the questions and comments have gotten much more precise and the path forward much more clear. Our team at iMDx have been through many FDA reviews, and what we see in front of us looks like a yellow brick road. We just have to stay on the path. Additionally, we have not felt any loss of continuity with our FDA review team even amid some of the macro changes in Washington, D.C.

Continuing on, to focus on 2026 revenue, recall that our strategy was to land leading transplant hospitals with our research-use-only or RUO kitted assay. Now, a year into landing, the benefits are threefold. First, we familiarized labs in key markets with our assay. Second, they've begun generating internal research and studies, and we're hoping to see the first couple of those publications out this year. And third, they provided us with valuable field-tested feedback on how to improve the assay, and those improvements are now in the field and going to the FDA.

I can say we've gotten exactly what we needed and then some out of our beta site program. The expand part of our strategy will be selling the diagnostic kits to these labs after we achieve expected FDA authorization. As of today, we are shifting into pre-commercial mode, as we get ready for a meaningful launch about a year from now. We believe that we are on track to have 20 sites trained on our GraftAssure workflow by the end of this year.

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We now have 10 sites running our RUO assay, and they are in the US, Germany, UK, Switzerland, Austria and Southeast Asia. In addition to those 10, you can see that there are 5 major US hospitals listed on our public ClinicalTrials.gov listing. Only one of those five sites is already counted among the 10 running our research-use-only assays. So, adding those two buckets, you can see that there are a total of 14 transplant centers that are already becoming familiar with our assay, either through deploying the research-use-only kits or through supporting our clinical trial.

In such a highly concentrated market, this represents great progress. From a market standpoint, the recent guidance from MolDX around surveillance testing has been incredibly helpful. The growing acceptance of surveillance in the clinical setting, moving away from strictly for-cost testing makes the revenue opportunity clearer for potential IVD customers. The draft guidance aligns with how we have sized the market, supporting our view of a substantial and growing opportunity for our kitted assay.

Now, I want to raise the curtain slightly on an exciting differentiator that is emerging about our assay, and please bear with me a second as I get a bit technical. So, one of the challenges with using dd-cfDNA for surveillance has been the low positive predictive value or PPV of either fractional or absolute quantification on their own. In lay terms, this means that high rates of false positives lead to many unnecessary biopsies. Most dd-cfDNA tests have a PPV around 50%, which is basically a coin flip, meaning if you are using it to rule in patients for biopsy, about half of those biopsies are going to come back normal. That's not great.

When you consider that dd-cfDNA adoption has largely been driven by the desire to avoid unnecessary biopsies, it leaves a lot to be desired. To put it simply, there are patients who are getting biopsied do not need to be due to dd-cfDNA's PPV problem. We think we have an elegant solution to this problem, and this is why we are so excited by the data shown at the WTC, World Transplant Congress, last week. Alongside our research partners at Charité in Germany, we were able to show a positive predictive value of close to 80% by combining our two scores together algorithmically.

So, recall earlier that I told you that our optimized assays allow clinicians to get both the relative and absolute quantification of dd-cfDNA at the same time on the same run. It's these values that we're combining into an algorithm to eliminate many false positives as a step in solving the PPV problem. We are optimistic that this represents the next generation of dd-cfDNA assays. Should it validate in our FDA program, it might prove to be a significant hurdle for companies seeking to do a follow-on 510(k), as they would have to show substantial equivalencies. The data is expected to be submitted for publication here in the near future.

Given that we are more than halfway through 2025 and we believe about a year away from a very exciting GraftAssureDx launch, we wanted to shed some light on what comes next. This is just the beginning. We're not stopping at kidney. We plan to immediately expand into additional solid organ transplant indications, building a multi-indication portfolio that we believe can unlock substantial clinical and commercial value. We see heart transplant as the most logical next indication.

We're already engaged with the number one heart transplant center in the US, which gives us confidence in our ability to execute. Dr. Anthony Langone is leading efforts here, and as soon as we complete enrollment in kidney, we expect to begin enrollment in heart, followed quickly by lung. So, the takeaway today is that we are making solid progress, and we see a clear path to product launch and potential meaningful clinical differentiation, followed quickly by meaningful revenue. And we're committed to investing in this product pipeline to deliver continuous growth and long-term value.

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Now, I'm going to turn it over to our CFO, Andrea James.

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

Thanks, Gabby and Josh. Hello, everyone. Before I briefly give financial highlights, I want to warmly invite our analysts and investors to our Key Opinion Leader Webinar scheduled for Friday, August 15, and that will feature Vanderbilt University's Dr. Langone, who's leading the efforts for our ongoing clinical trial, as Josh mentioned. The link to register for that is in our shareholder letter. We're thrilled to have Dr. Langone joining us to talk about our GraftAssureDx clinical trial and the benefits of in-house donor-derived cell-free DNA testing, since he is the national principal investigator for our clinical trial and he is very well regarded in this space.

Some of you on this call today have already registered. So, thank you. We chose this timing for this upcoming Friday due to Dr. Langone's very busy schedule. But I know that just after market close on a Friday afternoon in [ph] mid-August (00:22:13) for many of you is not your preference. So, we totally get it. And of course, if you cannot attend, there will be a replay available at investors.imdxinc.com.

Okay. So far in 2025, we've announced progress with our multi-center clinical trial, commercial expansion of sales of our GraftAssureIQ research-use-only test kits, and we've announced favorable data that further solidify our global credibility in the transplant community. Our top priority is unchanged, bringing our first clinical molecular diagnostic test kit to market, so that we may begin to capture value in the estimated $1 billion total addressable market for transplant rejection testing.

Quickly touching upon our results, we had said last quarter that we expected our Q2 pharma services revenue to come in under $500,000, and it did so at $494,000. You'll notice this quarter that we renamed this revenue category to laboratory services. This better reflects what we're doing, which is mainly sequencing and proficiency testing for customers. We're very pleased that our gross margins on this work came in at nearly 68% in the quarter.

Also in the second quarter, we sold a very small number of first generation GraftAssureIQ kits, about $24,000 worth, and as we shared in our letter, we began shipping the second generation kits to customers in June. These initial second gen RUO kits do not carry revenue, as our customers need free samples to validate in their labs. We expect those customers to begin ordering after validation, which should drive a small amount of revenue later this year.

We're pretty excited about the workflow improvements in these second generation kits. Josh had talked about this, and I wanted to double hit the point here. This innovation benefits not only the RUO product, but also the future clinical kitted product. It's an elegant solution that expands our market lead in ease of use. And we do have our Chief Science Officer, Dr. Ekke Schütz, on the call with us today if you'd like to ask more about that.

On to operating expenses. Including the impact of non-cash charges, operating expenses were roughly flat over the first quarter. Our R&D spending reflects additional investment in FDA-compliant software development for GraftAssureDx. As expected, we are also incurring increased consulting fees tied to our regulatory submission and increased laboratory and site setup costs related to our clinical trial. We're also investing more in commercial activity as we prepare for meaningful revenue ramp next year.

We concluded the second quarter with $26 million in cash, and that includes restricted cash, which we're beginning to access as we wind down our Irvine lease. Our cash used in operating activities in the second quarter was $6.3 million, plus about $350,000 in CapEx. This is right in line with our previous communication, which was

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that our quarterly cash burn of about $6 million would start to increase in Q2 and Q3 slightly as we invest in our FDA program.

Okay. So, looking ahead for the third quarter revenue, we expect to bill less than $300,000 in laboratory services. And as a reminder, and I've said this the last couple of quarters, these services can be lumpy and they're largely unrelated to our core strategic objective of selling global kitted product. Also, so far in the third quarter, we have not invoiced for any of these laboratory services.

Turning to cash management, as we noted last quarter, the biggest needle-mover is our clinical trial, and the instruments that we're purchasing at a discount support that trial at our partner sites. FDA-compliant software development is also a near-term incremental expense. We continue to target an average of about $6 million per quarter in cash burn until our commercial launch next year, although we said it'd be higher than that in Q3 before coming back down again in Q4.

Okay. And with that, Gabby, we are ready for questions. I can see a few of you guys have your hands up. Let's give [ph] Eric (00:26:02) a chance to bring everyone up into gallery view.

QUESTION AND ANSWER SECTION

Gabrielle Woody
Senior Executive Assistant, Insight Molecular Diagnostics, Inc.
A

Thank you, Andrea. We have questions. Let's – Mark Massaro from BTIG.

Mark Anthony Massaro
Analyst, BTIG LLC
Q

Hey. Great. Thanks for taking the questions, guys. Congrats on the progress. I wanted to start with the clinical trial. It looks like you guys are on track, and I just wanted to maybe double click on – I think you talked about approval as early as mid-2026. I think I have this, but just making sure I'm tracking that you think as early as six-month approval timeline, assuming you submit, call it, Q4. The six months would be the earliest. I'm just wondering if you could potentially bracket what you think the other side of the earliest would be. Is that 12 months or how are you thinking about timelines?

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

Yeah. I would say the guidance from the agency itself is five months of review time. So, we've budgeted six to seven on our side, which puts us right there at the end of Q2 next year to early Q3. What the outside of that could be, it's tough to tell right now. I think we've spent as much time as we can with the FDA, kind of reviewing where their concerns are, and I think they've been very forthright about what we need to address in the study. And I think Dr. Schütz and his team have a really good plan to address those kind of head on. So, there's always unknowns, but I think we feel confident that we can address what they've put in front of us so far.

Mark Anthony Massaro
Analyst, BTIG LLC
Q

Okay. Thank you for that. I wanted to follow with a question about the recent proposed draft LCD by Palmetto. And I'm just curious – I know you've recently spoke with the FDA and I know that the FDA is looking for safety and

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efficacy. I'm just curious if there was any potential discussion about perhaps coordination among the government between the FDA and CMS. But – so, that's the first part. The second part is, I guess, Josh, how are you thinking about the proposal draft and potentially putting some limits on utilization? And I want to square that with what do you think the appropriate level of utilization would be in kidney? And I'm just curious how you're thinking about the repeat test opportunity.

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

No, it's a great question. And so, I'll take them in reverse and go with how we think about the LCD, and then I'll answer the question on the FDA. I think it's – it always kind of rubs you a little bit the wrong way when decisions are being taken out of the hands of physicians. And so, I think our instinct is to support physicians on whatever schedule they think is appropriate for their patients. I think as we get the testing into the hands of centers and they're able to do their own research and build their own protocols, I think we're hopeful, along with the rest of the industry, that there's movement in the out-years to support more testing.

I think adding better positive predictive value, so you're having less false positives and so less unnecessary biopsies, helps in that story, because I think if you're enrolling a bunch of patients or sort of biopsying patients that don't need it, that's – runs counter to the argument that we should be testing more frequently. But in general, I'm on the side of the docs on this one, and I think we should help them build whatever data they need to support the protocol that's right for their institution. Trying to keep myself out of the direct crosshairs of MolDX with that answer.

But the FDA – we started our conversation with the FDA well back, I think, in 2024 as an LDT going in and having a conversation with them that way. And they directed us towards the path we're on. We haven't had any conversation with them that directly ties the work that they're doing to CMS. So, I don't know that I have any guidance to share with you on that. I think we're hopeful that we get to bring that test out, put it into our LDT lab and bridge the FDA and the CMS in that way. But we have nothing that says they're going to do that from a policy point of view.

Mark Anthony Massaro
Analyst, BTIG LLC
Q

Okay. Understood. I'll keep it to two questions. Thanks.

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

Okay. Thanks, Mark.

Gabrielle Woody
Senior Executive Assistant, Insight Molecular Diagnostics, Inc.
A

Thanks, Mark. Mason Carrico from Stephens.

Mason Carrico
Analyst, Stephens, Inc.
Q

Hey, guys.

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

A

Hey, Mason.

Mason Carrico
Analyst, Stephens, Inc.

Q

Thanks for taking the questions here. I guess to start off higher level, on the IOTA program, since that program went live, have you ever – have you seen any signs of margin – excuse me, marginal organs getting used more frequently? It'd be great to get some insight into what you're hearing from pilot sites as well as, I guess, centers more broadly.

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

A

Yeah. I would say – I think we expected there to be a lot of negative feedback when we were at WTC, and then we heard the opposite of that. I think folks are actually encouraged by the program and the utilization. So, I'd say early innings are generally positive from who we've spoken with. But my reach there is pretty limited. So, I couldn't say that it's a broad response.

Mason Carrico
Analyst, Stephens, Inc.

Q

Okay. And I think last quarter, you guys had called out five key questions for the Q-Sub Meeting that you wanted to ask to get more comfort around the trial. I mean, would you be willing to share some color on what those topics were? And looking ahead, what variables could materially change the current trial or your timeline assumptions there?

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

A

Yeah. No. Thanks, Mason. I think the biggest one that we had is one that all kind of blood companies face that are looking at cfDNA, which is around the blood tube and how do you manage that. And I think Guardant set a path there that was very successful. There have been others as well. I think Roche has done this in the past. And I think we've resolved that in a way that we're comfortable with and we believe the FDA is comfortable with. So, I think that was the biggest one that we had.

Outside of that, I think there was just some clarity around what orthogonal testing would be acceptable, what orthogonal testing methods would be acceptable. And I think we've – I think we were relying on the old standby of Sanger sequencing to get us through on most of those questions. So, I think we feel pretty good that we've answered those questions at this point.

Mason Carrico
Analyst, Stephens, Inc.

Q

Got it. Okay. And then, last one for me here. You guys called out at least six potential areas of expansion...

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

A

Yes.

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Mason Carrico
Analyst, Stephens, Inc.

Q

...for your kitted assays in the release. Could you just talk about how you're planning on prioritizing investments required to support those indications versus further commercial investments or data evidence investments in the kidney product post-approval?

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

A

Yeah. Great question. Thank you. So, we grouped them into two categories. One is on tissue and the other is on therapeutics. So, tissue are the ones that we've enumerated earlier. Heart is one. Lung is another. And then, I think the third would be liver. I think liver is a little bit of a longer road. Heart is pretty straightforward, at least from a technical point of view. We've published on it in the past, have a pretty good idea of what needs to be accomplished there. So, I would say an investment at a smaller scale than what we've done with kidney, where we had to create the product and get it through. I think now it's more just data generation. So, that feels lighter weight.

I can't have a number on it for you today, but it is definitely lighter than the program we're currently running. I'd say the same answer for lung, unless Ekke raises his hand and tells me that I'm completely off-base. Liver feels like a much longer study. We need to prove out the reduction in immunosuppression or sort of like the de-escalation of therapy piece, and that feels like longitudinal monitoring and tracking, which is a much heavier burden from a clinical trial standpoint.

On the therapeutics, I think we're going to be pulled through either by our research partners or by pharma itself on this one, because they're looking for tools that can monitor for therapeutic efficacy in trial and then also monitor for recurrence for patients that are on trial or post-therapy. We're in a couple of studies that are ongoing right now , one with – a follow-on on trastuzumab from The New England Journal, and then a second one is a registry study that's running in Central Europe for daratumumab, which is Johnson & Johnson's drug that's being used off-label. And so, I think those are kind of pulling us forward there, but we're not running any drug studies on our own. So, I think that one, we're really at the mercy of what's being done external.

Mason Carrico
Analyst, Stephens, Inc.

Q

Got it. I'll keep it at that. Thank you.

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

A

Thank you, Mason.

Gabrielle Woody
Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

A

Thanks, Mason. Up next, we have Thomas Flaten from Lake Street.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Q

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Hey, guys. Appreciate you taking the questions. Josh, just on the clinical study, I know ClinicalTrials.gov tends to lag, but it says only two sites are enrolling right now. And I'm just trying to do the math on the submission by year-end. There's only 4.5 months left.

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

Yeah.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC
Q

Realistically, how many more sites can you bring onboard in the study that are going to have an instrument, get trained and actually put patients into the study? Like can you just walk us through some of the math there?

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

Yeah. I think you'll expect to see two more come live that aren't announced right now, one in Europe and another here in the US, just because of the maturity of those conversations. The others are going to lag. And as far as the enrollment piece, when we look across the centers collectively, there's about 200 – 200-some-odd biopsies happening on a monthly basis. And if you look at the listing on ClinicalTrials.gov, we only need about 125 to fully power the study. So, I think we feel confident that we can rapidly enroll. It's more just getting those sites up and active.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC
Q

Got it.

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

Josh, [indiscernible] (00:36:29) talk about the fact that the clinical trial is templated. And so, there's not a lot of extra stuff that happens after the blood draw, not a ton.

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

Yeah. No, it is pretty simple to process. I think once a center has its batch together, you're talking less than a week of run time for them to process the samples, because you can get six samples through on a QX600 in a single run, and that run takes you about four hours to process. So, a single center can run through their samples rather quickly, I think. So, that's giving us confidence that we're still on pace.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC
Q

Got it. And then, you've – you mentioned some improvements to the RUO kits. Is it safe to assume that all those improvements are folded into the product that will ultimately be FDA-approved? And if so, could you give us kind of a 50,000-foot around what exactly those improvements were?

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

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Yeah. I'd like to let Ekke chime in on this point, because he – this was a labor of love for him and his team for a brief four-month sprint as we were trying to get all of the improvements into the assay. So, maybe, Ekke, you can talk just a little bit about how we improved from Gen 1 to Gen 2 of the assay. And you're on mute there, brother.

Ekkehard Schütz
Chief Science Officer, Insight Molecular Diagnostics, Inc.
A

Can you hear me?

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

Yes, sir.

Ekkehard Schütz
Chief Science Officer, Insight Molecular Diagnostics, Inc.
A

All right. So, if we are looking back at the first version that we had, it was more or less still requiring two different workflows. One workflow was for the percentage and the other workflow was for the copies per milliliter. And Josh just talked a little bit of what we could show at WTC, why we really want to have the copy per milliliter. And so, the feedback from the first customers was, yeah, it's really nice, but still we need to do two workflows. So, we took a deep breath and said, okay, how are we combining this, so that we only have one workflow, and that's actually, if you wish, what we have done and validated from every aspect. So, now, we have consolidated our assay into one single and very simple workflow that actually only requires [ph] factory two pipetting steps (00:39:02).

And then, the customer is going to see his results, which from the, I think, market acceptance alone is going to be a huge step forward. I think it's not only a very precise and – assay with an unprecedented lower limit of quantification, which is in particular, and Josh mentioned that, needed for heart transplant, which have a pretty much lower donor-derived cell-free DNA than what we usually see in kidney. So, I think this entire combination together make this assay really an assay that, I think, our customers will love.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC
Q

Excellent. Thanks for taking the questions.

Ekkehard Schütz
Chief Science Officer, Insight Molecular Diagnostics, Inc.
A

You're welcome.

Gabrielle Woody
Senior Executive Assistant, Insight Molecular Diagnostics, Inc.
A

Thanks, Thomas. Up next, we have Mike Matson from Needham.

Mike Matson
Analyst, Needham & Co. LLC
Q

Hi. Yeah. Thanks – thanks for taking my questions. So, I guess just on this Medicare reimbursement, I know that you announced the $2,753. I know it's for the Lab Developed Test version of GraftAssureCore.

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

A

Yes.

Mike Matson
Analyst, Needham & Co. LLC

Q

But the letter kind of implies that that will somehow factor into the amount that's ultimately paid for to your customers for GraftAssureDx. So, can you maybe just talk about how that process works in terms of deciding how much they'll get paid? Would it be similar or could it be lower? And when do you expect that to be known?

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

A

Yeah. Mike, the assumption that we're working off of is that when we bring the FDA product to our CLIA lab and we update our filing with MolDX to say that this is now an FDA-cleared product, that will make it really easy for centers that are inside of the MolDX jurisdiction to bridge to that reimbursement. And so, we're not expecting to see [ph] lost (00:41:11) for them on the ability to bill at that same rate.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay, got it. And then, just once you get the approval and launch GraftAssureDx for kidney, I guess, first, how quickly do you expect the transplant centers to sort of shift over to the test?

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

A

Yes.

Mike Matson
Analyst, Needham & Co. LLC

Q

In other words, I guess what I'm wondering is, do you expect it to be more of a – kind of a blanket transition where they move over 100% or is it really going to kind of be physician by physician, where you have to kind of go in and...

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

A

Yeah.

Mike Matson
Analyst, Needham & Co. LLC

Q

...convince each individual physician that they need to be using your tests?

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

A

I would say if it were that easy, I would love it. But it's certainly not. And I think Andrea put out a nice model in our shareholder letter last summer. We do expect there to be a ramp. You're going to have early converts within a health system, and then as they build confidence in the test, as they run their comparative studies, I expect fully

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that – these centers are going to run head-to-head with us and their preferred send-out test to make sure that they've validated it themselves. And once they've done that and they have confidence – and we showed in a publication earlier this year that we match up really well with the competitive technology – that the opportunity to manage those patients locally is going to continue to pull testing in. So, maybe a year after launch, they've converted somewhat fully, but it's definitely not going to be on day one.

Mike Matson
Analyst, Needham & Co. LLC

Q

Great. Got it. Thanks.

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

A

Yeah. Thanks, Mike.

Gabrielle Woody
Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

A

Thanks, Mike. Up next, we have Yuan Zhi from B. Riley Securities.

Yuan Zhi
Analyst, B. Riley Securities, Inc.

Q

Thank you for taking our questions. Probably you are going to touch on this at your KOL Seminar for the WTC 2025 presentation on this combined method for ddPCR. Can you elaborate on what it meant that only the combined models were able to distinguish all forms of rejection from normal samples? Is there any specific rejection pathology that the individual models test better than the other?

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

A

Yeah. I'd like to turn that one over to Dr. Schütz to elaborate on. And you're on mute there, brother, too.

Ekkehard Schütz
Chief Science Officer, Insight Molecular Diagnostics, Inc.

A

Okay. So, let me start with the first part. I think we have seen a couple of publications now that – and then there's kind of a little bit of a paradigm shift that cell-free DNA is really highly specific for rejections and not for all kinds of graft damage. I think that's one outcome that we show again – has been shown by – in two other publications. So, that's also going to change the utility a little bit, because now we can say, okay, if I have something that's going on in a graft on a, let's say, clinical suspicion, you can really distinguish is it a rejection or not.

The second part of the question is almost philosophical. I mean, if you are looking at the different [ph] band for lesions (00:44:47), it is pretty clear that the microvascular inflammation is a major driver of cell-free DNA, but it's not the only driver. But that makes it immediately clear why most of the rejections are pretty well seen. And we also understand right now – and that's also something we can show again – that the level of cell-free DNA clearly increases with the severity of the rejection. And that's in particularly seen in TCMR – TCMR Grade 1, which is right now even debated whether it needs to be treated or not. It is a 1A and you might know in heart the Grade 1 rejections are not treated anymore since I think five years now.

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But as soon as the rejection starts really to enter Grade 2 or even more so Grade 3, we are having a really high increase of cell-free DNA – donor-derived cell-free DNA. And so, that's the current, I would say, consensus in the literature, I mean, whether it's from us, whether it's from other groups. I think I – we presented it quite the way that everybody is thinking about cell-free – donor-derived cell-free DNA right now.

Yuan Zhi
Analyst, B. Riley Securities, Inc.

Q

Yeah. Got it. And then, since the mechanism of action for your organ rejection detection is similar among kidney, heart and lung, is it possible to run a basket trial and get a label for organ agnostics with this combined method?

Ekkehard Schütz
Chief Science Officer, Insight Molecular Diagnostics, Inc.

A

That's a good question. I mean, the major point I've already said, we have a pretty much different, let's call it, normal values for a completely healthy organ. Kidney, heart and lung, if you are only using the three because they are representing the majority of organs where cell-free DNA is used right now, have completely different normal values. So, it's around 1.5 for kidney, perhaps a little bit more than 1.5 for lung. It's 1.25 for heart. So, that also makes it a little bit hard to combine all this into one model.

I think what's going to be possible is to have a model for each and every organ. I think that's most probably how I think it, being the one who has developed the model. And I think, at the end of the day, we will have a model for each and every of the major organs, and I'm very convinced that such a model will clearly be beneficial for all our patients in each and every organ. It's not only related to kidney. It's really a biological concept that we have more or less used to build the model up.

And what we have seen in kidney and I – and we're looking at a large number of patients here. We had over 100 rejections. We had over – way over 200 normal cases and other pathologies. So, it's a very robust study in terms of the numbers. And so, I'm pretty much convinced that it's going to be very similar for heart. We have some indications from one of our competitors who have published something around that. So, I think over the next year or so, the diagnostic will go into this direction, combining copies with percentage, because it's now shown in so many publication that that's beneficial compared to a percentage alone. And I think we have a great potential here.

Yuan Zhi
Analyst, B. Riley Securities, Inc.

Q

Yeah. Got it. Thank you.

Ekkehard Schütz
Chief Science Officer, Insight Molecular Diagnostics, Inc.

A

Yes.

Gabrielle Woody
Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

A

Thanks, Yuan. Does anyone have any follow-up questions? Well, that sounds like that. Josh, can you please close us out?

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Joshua Riggs

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

Yeah. I just want to say thanks everybody for showing up today. We're excited to be finally in the trial phase and getting the proof out there. So, thanks for playing along with us. We're excited and really looking forward to the next 10 to 12 weeks of just being really deep into the FDA process, generating the data and preparing for submission later on this year. So, just thank you and talk to you guys soon. Bye, everybody.

Ekkehard Schütz

Chief Science Officer, Insight Molecular Diagnostics, Inc.

Bye-bye.

Joshua Riggs

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

All right.

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