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Insight Molecular Diagnostics, Inc. (IMDX)

Q4 2025 Earnings Call

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MANAGEMENT DISCUSSION SECTION

Gabrielle Woody

Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

Welcome everyone, and thank you for joining us to discuss Insight Molecular Diagnostics' Fourth 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.

Thanks, Gabby, and thanks, everyone, for joining us today. We are thrilled to announce that we've submitted GraftAssureDX to the FDA for review. To recap the significance of this milestone, in January 2023, when we first

decided to go the kitted route, I mean, we pointed ourselves directly at the FDA and the EU equivalent. Now about a 0.5 million data points later, we are, to our knowledge, the first dd-cfDNA assay to be submitted to the FDA for authorization. As we work with the FDA throughout the review process, our focus as an organization is shifting to product launch and pushing commercialization. Everything we are doing as a company right now is to accelerate the adoption ramp post-authorization.

To have a successful launch, we want to see three key things strong engagement in the registry, more head-to-head data, and some early adopters using the research use only version of our technology. Right now driving engagement and utilization with our assays is the name of the game. Just like we're doing with the FDA, we need to convince clinicians across the country that GraftAssure is safe and effective for managing their patients. And to do that, we have two big tools we can bring to bear. Our GALACTIC registry and head-to-head data. Since we announced the registry in the fall, we've had 28 centers started the process to become the trial site. That's over halfway to our goal of 50, in a very short period of time.

As we're talking with the centers, we lead with two things. Firstly, that we are introducing the absolute and combination scores to our report, giving them more information to use in patient management. And secondly, that we expect to transition the study to in-house testing when appropriate. This combination of scientific and clinical interest is driving the solid engagement we are seeing. We believe that the first centers to bring GraftAssure in-house are going to be those that have been using it prior to FDA authorization. The registry program is a perfect way of both advancing the science and also building familiarity, comfort and credibility with clinicians across the country. That way, when we show up with a regulated product for the lab manager, they are getting enthusiastic support from the clinical team. The more centers that are engaged with the registry, the faster our ramp will be.

To that end, we've made targeted investments in additional head count in clinical and technical sales and medical and clinical affairs. The sales team is driving engagement, pulling in top centers while the medical and clinical affairs team is focused on driving awareness and enrollment once those sites come online. We believe that we are appropriately staffed for this phase, but we'll plan to add some additional team members as we get closer to authorization. Convincing doctors to change what they are doing isn't always the easiest thing. And while the registry does a good job of getting clinicians to engage with our clinical report, it doesn't answer probably the biggest question in their mind. How does this compare to what I've been using?

This is where head-to-head data comes in. At the most recent Cutting Edge of Transplant Meeting, a top transplant center that has been in both our pilot and FDA program got up on stage and presented preliminary data showing that they can get equivalent results to one of the national reference labs using our GraftAssure technology. This was over 140 patient samples. So we're not talking a small study and it was strong enough data that they announced their intent to use GraftAssure in their core lab.

It was amazing how fast the switch in mentality was from, how does this compare to why should I send it out if I can get equivalent results in-house? We expect more head-to-head data to come out through the year, and more and more centers are going to be asking themselves that same question. We are actively encouraging centers to run these head-to-heads. It is a key part of the work being done by our commercial and clinical teams this year. The more direct comparison data that is out there, the faster our ramp will be.

About 80% of transplant centers do their own donor recipient matching known in the industry as HLA testing, which is like GraftAssure an advanced molecular test, if we can convince them that dd-cfDNA measurement with GraftAssure is safe, effective and equivalent to better than what they've been using, there's no reason dd-cfDNA won't look like HLA testing in the future, which means we believe that in-house dd-cfDNA testing can become widespread and common.

You can see in our shareholder letter, we outline our 2026 goals and I'll touch upon them briefly here. In addition to our goal of expanding market access activities and engagement with transplant centers, we outlined five other goals for 2026 in our shareholder letter. Those include commencing GraftAssure research use only [audio gap] (00:05:35) marketing GraftAssure core and driving samples to our Tennessee lab, we want to get our clinical readouts into the hands of as many clinicians as possible, and GALACTIC is really the driving force here.

And just as a reminder, Medicare reimburses GraftAssure core at a rate of \$27.53, submitting GraftAssure for approval in the UK and EU. The UK is self-certify. So that will move quick, while the EU IVDR is a six- to nine-month lag post post-submission. Reimbursement in these markets is still an open question, but we are seeing signs of progress. That being said, I spent last week talking with our European partners and the demand is clearly there for a kitted product. And finally, pivoting our R&D teams to focus on expanding GraftAssure's utility into heart transplant testing.

In a minute, Andrea will take you through what our investments will look like throughout the year to support these activities. But before that, I want to share with you where we see the puck going and therefore where we are skating regarding transplant patient management. We believe that over the next three years, the organ transplant rejection testing market is going to shift from one that is primarily dominated by avoiding biopsies in for-cause patients to one that is more heavily focused on screening for organ rejection. In other words, shifting from rule out to rule in. Any approval of an anti-CD38 drug will accelerate this transition. Clinicians will be trying to catch organ rejection as early as possible so that kidneys experience less damage and stay in patients longer.

The conversation is going to shift from one that is NPV only and start to sound like what we are hearing in oncology, where sensitivity, limit of quantification, MRD and early stage detection are going to matter for clinical performance. We believe the data show that our assay and droplet digital PCR are uniquely suited to meet this emerging clinical demand. We get very excited about these things because we believe that it lights a path toward our assay, becoming the de facto standard dd-cfDNA testing provider to the market. But of course we must bring the kitted version of the assay to market this year and we are highly focused on that.

Andrea?

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

Thanks, Josh. Hi, everyone. Okay. So since you've known us, this company has done one highly focused thing, and that is invest in product development for a kitted kidney transplant assay. And this year, we are preparing to do two focused things. First, we intend to commercialize and begin scaling that kidney transplant assay and so accordingly, we're making controlled investments in sales and marketing to do that. And second, we intend to maintain our product development momentum by expanding GraftAssure into heart transplant testing. Last month, we completed a \$26 million offering that allows us to do these two things at the same time.

What's great about expanding into heart is that Dr. Ekke Schütz, who's on the call with us today and his team, actually designed GraftAssure to be organ agnostic from the beginning. So we get to leverage our previous investments in the technology. So what heart transplant investment looks like is sustaining our 2025 research and development investment levels rather than dropping R&D back down to the 2024 level.

Of course, our balance sheet remains an area of focus for us, we continue to be quite thoughtful about where we will incrementally invest. You can see that in Q4, research and development ticked up quite a bit, which we had told you it would. This was tied to software development, our clinical trial costs and materials costs to support our

FDA submission. Those expenses should come back down again in Q1 to a number that's between the Q3 and Q4 levels.

We know that the capital entrusted to us by shareholders deserves to be treated with the utmost care. In our February registered direct offering, we welcomed participation from Bio-Rad, who invested in our equity for the fourth time at their pro rata ownership of just under 10%. We also welcomed participation from new and existing investors. We look forward to continuing to institutionalize our cap table as we transition into a commercial business in the coming quarters.

The way we think about our spending optionality is thus. Our maintenance spending is about \$5.5 million per quarter, and our growth spending is about \$2 million per quarter. Gross spending includes the cost of clinical trials, our contract research partner, lab materials on new products research and development, and incremental sales and marketing investment. We believe that our maintenance spending is covered at about \$35 million a year in revenue, and as if we assume a software like gross margin, that would ramp over time to get to that level on GraftAssure. We believe that we have this level of revenue well within our sales pipeline.

So when we talk about being engaged with 37 transplant centers in the United States, and we have told you in prior quarters that we expect to average about a \$1 million in annual revenue per center, you can see why we believe we're starting to see a path to becoming a self-sustaining business. Of course, our new near-term sales pipeline is just a starting point. The size of the market opportunity is pretty exciting. We value the total addressable market to be over \$2 billion. That's on an annual basis. This represents our updated and more favorable pricing for Medicare, as well as the fact that MolDx has come out with coverage for screening or coverage guidance for screening. Previously testing was only for-cause, and so now we have better visibility into the reimbursement levels at a baseline level of testing for transplant patients.

So that was a lot on the big picture. Let me take off some quick housekeeping. Number one, we expect low levels of revenue on lab services this year and almost no revenue in the first quarter. Number two, we introduced non-GAAP EPS and adjusted EBITDA tables into our financials this year, which we told you last quarter that we would do now. Number three, the intangible asset write down that you see in Q4, which we back out of adjusted EBITDA is tied to writing down the intangible value of the remainder of our oncology assets. We've been talking for several years now about our focus on transplant, and so this should not come as a surprise. We do believe that our oncology assets could be quite valuable after we properly invest in and monetize them and we continue to sustain a low level of activity on them.

Okay. I know we give a lot of information to you. We think your two key takeaways today are very simple. Number one, the external validation of demand is growing. And number two, we are moving quickly to capture that opportunity. And then finally, I'll close with this. Last month, I was able to attend that presentation by a major university hospital at the Cutting Edge of Transplantation Conference and that's the one that Josh just referenced and we also talk about it in our shareholder letter. So this major hospital stood up on stage and presented head-to-head data that is favorable to our assay. And this was great because I don't actually get to hear a lot of this in the CFO seat directly from the customer. And this talk – it's basically the hospital and its researchers are saying the exact things that Josh Riggs has been saying quarter after quarter on conference calls for three years. So it's just really great to hear.

These hospitals clearly want to do their own testing and they view us as a partner that can enable their success. It was also meaningful to hear him talk about organ transplantation, giving people a second shot at life. So I encourage you to seek it out and watch it. We appreciate these scientists and physicians and their regard for what we are doing, we also appreciate your investment and your interest in us, and we appreciate our analysts who are

covering us and joined us today on the call. We seek to create value for patients, clinicians and our hospital customers, and we seek to execute to return value to shareholders.

Okay, Gabby, we can take questions and [ph] Eric (00:13:20), if you could please bring everyone up into gallery view. And we're going to have Gabby call on you guys.

QUESTION AND ANSWER SECTION

Gabrielle Woody

Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

Right. We have Thomas Flaten from Lake Street.

A

Thomas Flaten

Analyst, Lake Street Capital Markets LLC

Hey, good afternoon, guys. Appreciate you taking the questions. Hey, can you help me walk through Andrea or Josh? So if you have 37 centers in the US that are engaged – that you're engaged with, but 28 of them want to participate in the registry study. What is participation in the registry study mean from a revenue perspective? Because I'm assuming you'll be sponsoring some of that work, right, for the registry study?

Q

Joshua Riggs

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

Yeah, we will. I think what we're targeting is about a 100 patients per center. We're not going to cap it. But we did announce that we wanted to get 5,000 patients enrolled. And if you do the easy math on that across 50 centers, it's about 100 patients. And we expect to test each of those patients about 10 times over the course of the study. This is kind of in line with what we've seen in terms of total testing per patient in other registries that have been performed in the space. And this is for clinical purposes, so you have the billable opportunity. They'll use the percentage as the guiding value there and then get access to our absolute quantification and combo score alongside that.

A

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

And just to piggyback on what Josh just said, Thomas. The goal with the registry is that it's self-funding, but not that it itself is a profit center. The goal there is that those registry participants will eventually convert to in-house testing, and that's where the profitability lies.

A

Thomas Flaten

Analyst, Lake Street Capital Markets LLC

Right. Understood. And then can you remind us please of your agreement with Bio-Rad and when the commercial rights would need to be agreed by or around what time that should – we should expect that to occur? Sorry, that was bad English.

Q

Joshua Riggs

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

No, no worries. So the explicit language in the agreement is a 90-day right of first negotiation post-authorization. And so that's, basically as soon as the FDA gives us the stamp of approval, there's a 90-day window where we

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have to negotiate with Bio-Rad in good faith on the IVD rights. I think that I would expect that those conversations wouldn't wait for that moment, it will be – we're already in active conversations with Bio-Rad on many topics, and this is definitely at the top of the list.

Thomas Flaten

Analyst, Lake Street Capital Markets LLC

Q

Got it. I'll jump back in the queue. Thank you.

Joshua Riggs

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

A

Thank you, Tom. Gabby, you're on mute. I think you were calling on Mike Matson.

Gabrielle Woody

Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

A

Mike Matson from Needham. Thanks, Josh.

Mike Matson

Analyst, Needham & Co. LLC

Q

Yeah. Thanks. So I guess first, just now that you're starting to work toward the heart application or indication, can you maybe talk about what the next steps there are in that process? And then I guess just from a higher level, I know, I guess heart's always been kind of the plan, but can you maybe talk about why heart versus liver because my understanding, there's a lot more liver transplants than heart transplants.

Joshua Riggs

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

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Yeah. I'll take the second part of that question first, and I'm going to hand it over to Dr. Schütz to talk about the heart study. The demand in heart is much stronger for a test, where liver is regenerative. It can kind of heal itself. And there's many options for those patients. If you start rejecting a heart, there's a very high risk of death. And so the testing demand there is just higher. I think it's 25% to 30% of total testing that's done in the United States right now is for heart transplant patients.

And so we feel like that's the best next place for us to go. I think there's interesting work to do in liver and kind of prove out some use cases there. But I think there's going to be some longer term research for us. But Ekke, if you want to talk a little bit about our approach in heart and sort of the 510(k) pathway that you see available to us and what we need to do this year. And you're on mute just before you get started.

Ekkehard Schütz

Chief Science Officer, Insight Molecular Diagnostics, Inc.

A

I am on mute. No, I'm not. So I think this entire heart project has two big tiers. The first tier is we are going to provide data that we are generating in the near future. We are right now in touch with, I think, four or five heart transplant centers in the US for a smaller study, perhaps around 50 people, patients, so that we can provide for CMS approval. Of course, we want to get paid for it, right. So that's one very important step for us. So that's something that more or less was there. And the start point was whenever we submit to the FDA, so actually we start on Monday. So that's going to happen next.

And then in parallel, we are going to submit to the FDA. It's going to be easier, because here we have a clear predicate device. So it's not going to be a de novo, it's a 510(k) and that's more or less how we are going to do it. We can use the same samples that we are using for the CMS reimbursement submission for the FDA as well. So that's the entire plan. And if we are – that's what we think it's going to happen. If you can really get all these samples in, in the next, let's say, four months, we should be able to get everything done during this year.

Mike Matson

Analyst, Needham & Co. LLC

Okay, great. And then...

Q

Joshua Riggs

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

And Mike, just a quick follow up on that, just as a note for the 510(k) pathway is a 90-day review period instead of 150-day review period.

A

Ekkehard Schütz

Chief Science Officer, Insight Molecular Diagnostics, Inc.

Yeah.

A

Joshua Riggs

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

So it goes much faster. All you're really doing is showing that you're equivalent to the device that's there before or that you're substantially equivalent and that would be the AlloMap assay that's already gone through the gene expression profiling test.

A

Mike Matson

Analyst, Needham & Co. LLC

Okay. And then the shift in the patient – shift towards patient management that you described in the press release as you mentioned on the call. I guess, how does that benefit Insight specifically? And is it just that your test is better suited to that type of use? Or does it somehow increase the number of tests that get done per patient or is it both of those things?

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Joshua Riggs

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

Yeah, I would say the data that we've generated in our randomized interventional study showing that we can pick up rejection 10 to 11 months ahead of standard-of-care protocol is important here, because the drugs that are being studied are the first that have shown effectiveness for antibody mediated rejection. And I think the effect is going to be largely like what happened when KEYTRUDA was launched into oncology, where you were basically hitting patients with [ph] chemo and a prayer (00:20:41), all of a sudden you had something that was really effective for a solid chunk of that population. And that's what's going to happen here.

A

I mean assuming one of these drugs gets approved in the United States that's daratumumab or felzartamab for this indication, all of a sudden you have a drug that stops AMR and [indiscernible] (00:21:01) want to catch it as quickly as you can. So yeah, I think screening is going to be much more important in the future. And then, when we talk about MRD, you see all the wonderful work that's being done in oncology where you're using kind of really accurate change management or change between time points as a diagnostic tool. And I think that's where the

absolute quantification that we have really starts to shine, particularly with the droplet digital PCR, it's just exquisitely sensitive and quantitative.

And so when you want to measure time point to time point change, that technology really shines there. And so we're already seeing preliminary data that's coming out of these research studies that shows that you can do that and is useful for managing patients. So, I think it's a rising tide. I think it raises demand for all the dd-cfDNA technology. I'm personally a homer for the Insight Molecular version of that technology that's out there. But I think it's good for all of us. And I think it's better for patients long-term, because we're going to see kidneys last longer.

And so that means that more patients are going to come off of the waiting list because instead of retransplanting patients, you're actually going to put that kidney into a new patient. So I think we'll start to see a growing rate of transplantation in the United States for new patients on the back of this. So all things are good. It's a massive tailwind for the industry.

Mike Matson

Analyst, Needham & Co. LLC

Q

Okay, got it. And then just a question for Andrea on the – there was commentary in the press release about the cash burn kind of sequencing. So it sounds like it's higher in first half. Is that timing of spending or is it the revenue level or is it both?

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

Both. Yeah, you'll see our spending ticked up in Q4 on a GAAP basis, but the cash didn't match that. So we do have some payments sitting in payables that need to go out in the first half, so tied to the Q4 spend. So that's timing. And then we are baking in some levels of revenue in the back half of the year that offsets the cash burn. So averaging, we told you last year we were averaging about \$6 million a quarter. We're now up to \$7.5 million, but it's over \$8 million in the first half and then we're going to come back down, hopefully closer to \$6 million in the back half.

Mike Matson

Analyst, Needham & Co. LLC

Q

And is that – I mean should we see that kind of reflected in the OpEx in terms of the quarterly OpEx or is the quarterly OpEx going to be flatter and this is more of a timing issue from cash flow perspective?

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

It's driven more by gross profit and payments, working capital changes than OpEx. OpEx you should model in as continuing to grow with the exception of research and development. Research and development for the full year will not be what it was in 2025. It will come down a bit. We had some sustained higher expenses in Q3 and Q4. It will come down a little bit...

Mike Matson

Analyst, Needham & Co. LLC

Q

[ph] Okay (00:23:51).

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

...but the other ones you should expect will continue to grow sales and marketing and G&A. G&A, we're trying to keep mostly flat. So, that's where you can really keep things, everybody has to do more. Sales and marketing is where we're making intentional investments and research and development, we are continuing to sustain, but it will come down because we won't have all of those. We had just a lot of costs associated with the clinical trial in the back half of the year, which we won't have again.

Mike Matson

Analyst, Needham & Co. LLC

Q

Okay, great. Thank you.

Gabrielle Woody

Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

A

Thank you. We have next is Ben Mee from Stephens.

Ben Mee

Analyst, Stephens, Inc.

Q

Hey, guys. Good afternoon. This is Ben on for Mason Carrico. Could you walk us through what needs to be done from a billing and coding standpoint once you obtain authorization, will each hospital have to establish their own code if running the test onsite or could you just walk us through what that looks like?

Joshua Riggs

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

A

Yeah, there are two scenarios here, Ben. There's inside of MoIDx and then there's outside of MoIDx. And so MoIDx is the government contractor that kind of covers what is it, 29 states, 28 states, somewhere in there.

Ekkehard Schütz

Chief Science Officer, Insight Molecular Diagnostics, Inc.

A

28 states. 28 states.

Joshua Riggs

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

A

Yeah. And so with that, we are submitting for a Z code specifically for the regulated version of our test. And so that's a unique identifier for the test itself. And we're doing a bridging study between our lab test and the lab version of the test and then the kitted version of the test. And we'll submit that data to MoIDx. This is all happening now. We've already submitted for the new Z code. And so the expectation is that we will bridge the reimbursement over to that new code.

And then when somebody inside of MoIDx like, [ph] Vanderbilt (00:25:42), that's down the street from us here in Nashville, if they were to bring the technology up, they would use that Z code. And so they would have sort of immediate access to the reimbursement there. Outside of MoIDx, it is going to be a MAC by MAC process, where each MAC will have its own set of rules on getting things covered. And I think that's where partnering with these institutions across the country and enlisting them to help us support that conversation, it's kind of a [ph] full force multiplier (00:26:12) for us going forward.

Ben Mee

Analyst, Stephens, Inc.

Q

Okay. Got it. Super helpful there. Thank you for that. Among the centers that are engaging with GraftAssure today now, could you update us on some of the internal validation studies that you're maybe seeing take place across these different centers, whether that'd be just any general feedback you have to offer from these centers, what they like, don't like?

Joshua Riggs

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

A

Yeah, I think the best place to direct you, Ben, is the presentation that was given at Seattle. I think there's a link to that looking at Andrea to see if that's been posted on the web somewhere. I know there's a recording of it. But I think it gives you a really good look into how a large transplant center views bringing this technology in-house. And they – once they show that they can get equivalent results, then they get to reap all the benefits of having it in-house, which is the faster turnaround time, the ability to sort of ask their own research questions, build protocols and then obviously be able to bill and capture that revenue opportunity that they're missing out on.

Ben Mee

Analyst, Stephens, Inc.

Q

Great. Thanks for taking the questions today.

Joshua Riggs

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

A

Sure.

Gabrielle Woody

Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

A

Thank you. Any additional questions? All right. That is all, Josh.

Joshua Riggs

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

All right. Well, guys, I appreciate you guys making the call and talking with us today. Thank you for the thoughtful questions. Obviously, we are very excited to be at the next step of our journey and pushing through the FDA, getting ready for launch later this year. I think when we get back together here in the next six weeks or so, when we report out Q1 and we hope to have some nice updates for you guys and more progress to share on centers that are engaging with us. And we'll keep our fingers crossed. So talk to you guys soon.

Gabrielle Woody

Senior Executive Assistant, Insight Molecular Diagnostics, Inc.

All right.

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

Everyone.

Joshua Riggs

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

All right. We clear? Cool.

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