CORPORATE PARTICIPANTS

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

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

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

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

OTHER PARTICIPANTS

Mark Anthony Massaro
Analyst, BTIG LLC

Harrison Parsons
Analyst, Stephens, Inc.

Mike Matson
Analyst, Needham & Co. LLC

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Management Discussion Section

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

Good evening everyone, and welcome everyone, and thank you for joining us to discuss Insight Molecular Diagnostics' Third 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 welcome, everybody. If you've had a chance to look at our shareholder letter, you'll have seen that our momentum is building. I'd like to talk a little bit about how we got here before shifting to how we are positioning ourselves for success in 2026. A couple of years ago we set out to change how transplant patients are managed. The idea was and is simple, transplant centers should have the tools on site to monitor their patients. Intuitively, that makes a lot of sense. Each year, hundreds of thousands of tests and hundreds of millions in payments go out for post-transplant monitoring. As of today, not one of those tests is performed at a transplant center, and not $1 of reimbursement accrues to these center's benefit.

In 2026, with the expected FDA authorization of GraftAssureDX, this is going to change. Last summer we started a pilot program that put a research version of the assay, the same design we were taking to the FDA into the hands of researchers around the world. We wanted to do three things; one, get feedback on the workflow so that we could get ideas on what needed to be improved; two, get technical data on the performance of the assay so we could have a sense of how robust our design was in the field; and three, engage with clinician researchers so we could get a look into what clinical demand might be for a regulated product. Feedback from transplant center's labs helped us optimize our test workflow from two steps down to one step.

That improves our turnaround time and ease of use, which means faster results with less labor for our customers. As you probably recall, our PCR-based technology is already much simpler and faster than sequencing-based technology used by major centralized labs. With our one step workflow, we have further increased these advantages. Just last month we published a white paper that

showed that our assay performance across multiple centers, from Singapore to Switzerland, had exceeded expectations. You can find this white paper on our website. This gives us high confidence that the assay will perform well in the very rigorous FDA process. Across the board, in the US and Europe, we are filling pent-up demand for in-house testing.

Because we are a kit-first company, we are seen as a partner in patient management, and institutions are eager to support our mission of broadening access. I should point out that, just getting through the FDA is not enough to give us the market. The expectation is that, clinicians will want to familiarize themselves with GraftAssure and compare to legacy technology before making a switch. This could look like head-to-head comparison or interacting through the registry program we recently announced. Case in point, earlier this year we saw data come out of Heidelberg, a research transplant center in Germany, where they compared the performance of our test to another commercially available RUO assay that is on market in Europe.

This data showed statistical equivalence on the relative measurement of dd-cfDNA between the two tests. It's great because the market today is largely dominated by the relative measurement method, showing that we get to the same answer with an easier to use technology reduces the barriers to adoption. Recently, we've also seen preliminary results from a 100-plus patient study at a major center here in the US that is a direct head-to-head against a leading US centralized lab test, and we and the researchers are very happy with those results. Showing that you can get equivalent to better results with on-site technology is critical to our success.

There are more of these types of studies ongoing. We expect the data will start coming out in the New Year that shows clearly that GraftAssure is reliable and that it compares well to legacy technology. The feedback we get from transplant centers, primarily in the US is that they are optimistic about being able to bring testing in-house, but fully expect that some level of head-to-head work will be needed to fully support conversion and internal adoption within their center. We welcome this activity. The more data that gets out there showing positive comparison to cumbersome legacy providers, the faster we'll see broad adoption. Alongside the generation of head-to-head data, we announced the launch of a registry program.

The goal of this program is to capture how the industry uses our alternative measurements of dd-cfDNA, namely absolute quantification, and our proprietary combination model score algorithm, while they use our currently available relative measurement for patient management. The benefits of this approach in our registry are twofold; firstly, it familiarizes clinicians with our report and tests probably making them more likely to use the technology once it's available in-house; and secondly, it generates real-world data on the utilization and performance of our alternative measures. Early data and publications suggest that these alternative methods may be superior ways of quantifying and analyzing dd-cfDNA data.

If we are successful, we should see improved biopsy yield at transplant centers that are using the combination model score because of its expected higher positive predictive value. When the CM score data first came out at the World Transplant Congress this summer, we saw an immediate spike in interest from our clinical partners. So we've been moving as quickly as possible to get the novel score into production. I expect that we'll see the first reports going out with the new CM score in first half of 2026. Early access is likely to be limited to participants in the registry. Once the peer-reviewed publication is out, we will start to make it more broadly available and begin a conversation with MolDX on any potential positive billing impact.

I'm amazed by the progress we've made in such a short time. That is attributable to our team of researchers and development scientists, clinicians and centers around the world that have embraced our partner-first approach, and a strong support from Bio-Rad, who have been with us every step of the way in our planning engagement with the FDA. And now, after almost three years of absolutely grinding on product development with a modest staff, here we are in November 2025 very close to our planned FDA submission. While the shareholder letter details our recent accomplishments in our FDA submission timeline, I'd like to add some color on our clinical trial.

You can really feel the energy at the sites right now. They're excited, they're engaged, and we love to partner with them. Tampa General was the first to bring in samples, and Vanderbilt and Cleveland Clinic were up and running shortly thereafter. These are leading transplant centers in the US, and they are genuinely committed to this effort and that makes all the difference for us. Some of you may have recognized the sentiment in the comments from Dr. Anthony Langone of Vanderbilt University on our August 15th KOL Call. He pointed out the issues with the current paradigm of send-out transplant monitoring, many of which can be resolved with in-house testing.

Now, I'm going to take a few moments to talk about what's going on at the FDA. After our planned submission in December, we start the clock on their review process, which is listed as 150 days on their website. That being said, the FDA is not accepting new submissions while the government is shut down. We have been told that our FDA reviewer team is still working through the shutdown, which is good for clearing their docket and review backlog. At the same time, the FDA has paused, answering questions from companies like ours that are preparing a new submission. It's common for companies like ours to ask the FDA questions on their preferences and what they would like to see.

We do have some outstanding questions that we ask in September, and since the government shut down on October 1st, we have not received those answers. We are staying focused on what we can control, which is completing our clinical trial and being ready to submit to the FDA by the end of the year. I want to make clear that the government shutdown does not affect our ability to drive engagement with customers. We can process tests at our Nashville CLIA lab, and pursue our registry study even while the government is closed. Looking forward to 2026, we expect to move forward with validation of both heart and lung assays in our lab. That work sets us up to submit for reimbursement for heart in 2026 and lung in 2027.

The nice part is that, for heart and lung, we can leverage all of the analytical work already done for kidney when we go to the FDA, which really streamlines the regulatory submission process. We are excited about heart next. You'll see a chart in our shareholder letter that showcases our assay versus legacy technology, regarding the threshold for rejection detection in heart transplant patients. We are in the rare event detection business, and so lower on the bar chart is better. Being able to quantify at low volumes matters

when you need to establish a trend line prior to reaching the clinical threshold. We've also made real progress on our registry study, which we announced in September. The study design is complete, the protocol is written, and we already have 10 centers, including three of the top 10 programs in the country lined up and working their way through legal.

We expect that you'll see the registry study show up on clinicaltrials.gov early next year. As we approach FDA submission, we believe the excitement around our company is building. This excitement extends to other companies with whom our products and services are symbiotic. We continue to be thrilled with our relationship with Bio-Rad, which has been mutually supportive and productive, and we continue to pursue strategic relationships that can support our increasing reach and need to scale as we go into 2026. We've been a development-only stage company for the past two to three years, and that period of time is coming to an end.

Now, we are focused on shifting into a commercial organization. We believe we are building a product that is going to be the de facto standard of care assay. We also have opportunities to grow the pie. There are developments changing the structure of the market itself. We see tailwinds when we look at the potential for reference lab adoption, anti-CD38 drug approval and dd-cfDNA guideline and adoption. We believe we are bringing to market the most precise testing for transplant rejection while broadening access to the test for patients. The margins available to us in GraftAssure, along with a highly concentrated market, represent a rare opportunity to create an exceptionally profitable business line with operating margin that should be industry leading.

Now, let me turn it over to Andrea, and then we can take questions.

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

Thank you, Josh. Hi, everyone. Thank you for joining us. And I also just want to do a quick shout out to Gabby Woody, who's MCing this call and whose Zoom decided to malfunction right before we went live. So anyway, you've got our financial tables in the shareholder letter and in the 10-Q, so I'm just going to touch upon the highlights. We finished the quarter with $20 million in cash and equivalents and no debt. Lab services revenue came in as expected, and you can model that sequentially flat in Q4. Last year, recall that we did perform some work late in Q4 that came in unexpectedly, and of course, we'd be thrilled to do that again if the work comes in. So far in the fourth quarter, we've built for about a $100,000 worth of these services.

We kept our cash burn in Q3 below our stated goal of $6 million per quarter, and we expect that $6 million to tick up a bit in Q4 due to expenses associated with our FDA submission and clinical trial. This is the same as our prior communication with one small change. The Q3 cash burn came in favorably because some expenses did shift into Q4 instead. You can see that we've invested incrementally in research and development over the course of this year as we prepared for FDA submission. We were able to absorb these expenses while still maintaining our cash burn levels at $6 million a quarter, and we achieved that by continuing to deliver gross profit by performing extra lab services work at our Nashville lab.

We're really proud of that, actually, and we expect to continue to cultivate activities like this and others that extend our cash runway. Also, it's worth noting that going into next year, we have the option to scale back select expenses as needed because much of the incremental 2025 research and development expenses are tied to consulting, software development and laboratory supplies and materials associated with our FDA program. Onto some quick housekeeping for our analysts. Historically, our company has presented its operating loss on both a GAAP and a non-GAAP basis. Starting next quarter, we will begin talking about adjusted EBITDA instead, which is essentially the same line item as non-GAAP operating loss, but it's just more intuitive phrasing for investors.

We also intend to introduce non-GAAP net income and a corresponding non-GAAP EPS. The primary reason for this is we want to give you metrics that help you to track the underlying profitability of the business that we are building. To do this, it makes sense to back out certain non-cash items such as the contingent consideration line that fluctuates from quarter-to-quarter. Contingent consideration, for those of you who are not familiar, relates to acquisition accounting. In our case, it's tied to certain earn-out arrangements related to our prior acquisitions. I want to leave you with two ideas as I close. The first is, I want to give you an easy way to think about our total addressable market or TAM and how it's growing. And then the second thing is, I want to give you a fly-on-the-wall visibility into our strategic planning meetings that we hosted all last week at our national headquarters.

So on our TAM, I'm going to throw a bunch of numbers at you, but I think you can follow this. So we publicly state that we have a greater than a $1 billion TAM, and this is for kitted transplant testing. And I want to walk you through some of the easy math on our assumptions and how to think about our growth relative to TAM expansion itself. So we assume about 150,000 transplanted organs per year in our key markets. That's US, Europe, some of Asia and Latin America. Then, we talk about total patients under management being 10 times the annual transplant volume, and that's based on estimated median graft survival rates. So the total expected patients under management is simply 10 times 150,000 or 1.5 million patients.

Next, you take the 1.5 million patients under management and you assume a number of tests per year per patient. You're going to see a lot of numbers out there floating around, but the most conservative is two per year per patient, and this number factors in higher testing volumes in earlier years post-transplant and lower testing volumes in later years for an average of two. In fact, the MolDX draft LCD, which many of our analysts are very familiar with on kidney surveillance testing, is for 4 tests in the first year of a transplant, and 2 tests per year thereafter. So you can see that assuming 4 tests per year per patient under management is a conservative and reasonable number. If you take the 1.5 million patients under management and multiply it by 2 tests per year, you get 3 million testing opportunities per year.

You multiply 3 million testing opportunities per year, times our expected ASP on our kit, and you can easily get an expected TAM of over $1 billion. That ASP is supported by the fact that our laboratory version of our kidney test is reimbursed by Medicare at $2,753 per result, and we believe we can sell our kits to hospital customers for a significant fraction of the reimbursed value. So you'll hear us [indiscernible] (00:17:40), and it's usually focused on one of those key levers that I just described. So for example, expanding into

more solid organs helps us to grow into our stated TAM. Also, some organs, such as heart, require more than 2 tests per year. Investments in market access and geography should also help us expand into our stated TAM.

But then there are some things that could grow the TAM itself, and this is what Josh was talking about when he talks about growing the pie. So remember the multiplier 2 test per year. When Josh mentions reference lab adoption, anti-CD38 drug approval, dd-cfDNA guideline adoption, we're actually talking about developments that would help the industry to increase its testing volumes will be on an average of 2 tests per year. Also, any therapies that extend the lives of patients grows the patients under management because they're living longer, and therapies that require testing to manage dosage already grow the testing opportunities per year.

And then organ transplant itself, sorry, it's so macro, but I think it's important, organ transplant itself is growing as a category. So remember, that our kitted testing strategy sits within the macro truth about the strong benefits of organ transplants. For example, kidney transplants not only dramatically improve a patient's life, but also can represent a tremendous cost savings over dialysis. And so we believe we are so well-situated with these tailwinds. And that's just in transplant. We haven't talked about oncology today. Our long-term objective after we establish our GraftAssure franchise is to also unlock whole new testing markets in cancer, which of course grows our TAM substantially.

Another thought I want to leave you with, I can see you guys putting your hands up, I love it. Another thought I want to leave you with is, we're shifting from a development stage company to an integrated commercial operation. This is obviously very exciting. Our strategic planning meetings last week were appropriately intense and pinpoint focused on driving engagement and utilization of our assay via our Nashville laboratory. This is something we can do now, even before we have achieved FDA marketing authorization for our test kits. We're also honing and streamlining our market access strategy in the US and EU, which we believe will set us up with some nice natural growth over the coming years as we achieve expanded coverage. I believe that if an investor [indiscernible] (00:19:55) could have been a fly on the wall during these meetings, you would have seen that we are a company that is playing and preparing to win.

We want to enable our customers, which are the transplant centers themselves, to participate in the testing value chain, and we want to drive better and more localized, accessible patient care. But this doesn't mean that we intend to lose our hard earned cost discipline. If you look at the market capture activities that we seek to invest in, we see customer acquisition costs that are quite favorable relative to these customers expected long-term value. This is particularly owing to the fact that we are targeting a highly concentrated market, with only about 100 transplant centers doing most transplants in the US, for example, is also owing to the fact that the life sciences industry, and particularly kitted diagnostic test usually enjoy a nice degree of customer stickiness that we believe should help us to retain our customers for many years.

Okay. Now, we can take questions. And just, IT housekeeping, [ph] Eric (00:20:54), if you could please bring everybody up into gallery of you. And we also have Gabby back on screen. Yay!

Question And Answer Section

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

A

And wonderful, Gabby appears to be frozen. So I will just start. Mark Massaro, you popped up on my screen first. Mark Massaro with BTIG. Go ahead. We'll take your question.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Hey. Thanks, Andrea. So yeah, congrats on the progress. I wanted to start with maybe a macro question just about the LCD that we're waiting for with Palmetto GBA. I think, if I heard you correctly, you're talking about the 422 kidney protocol. Is it safe to say that even if the interval is finalized as is, you expect to have that $1 billion opportunity in front of you? And then maybe, Josh, if I could just get like your latest temperature on how you think the final LCD might come in, do you see there is any opportunity for improvement from the interval? And also, do you think there's a possibility that the limits could potentially be removed?

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

A

Oh, man. Some great questions there, Mark. I think, I'll start by saying, I think we're hopeful along with the rest of the industry that the brakes get taken off here. It feels unnatural to limit access to a technology that a clinician feels they need to manage their patient. I think, we heard some of that commentary from Dr. Langone when he was speaking in the KOL Call. We're behind him 100%. He expects that if he had this technology in-house, that he'd be doing four tests a year. And so right now, he wouldn't get paid for that under the current draft of the LCD, which is unfortunate. I mean, I think, we'll support him in that process as far as negotiating with MolDX on expanding. We haven't heard anything around how that conversation is going, so I don't have any special knowledge there. But we agree with the industry that this needs to be a clinical decision.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Okay. And then, I don't think you mentioned this, but certainly the Increasing Organ Transplant Access model or IOTA, I wanted to just maybe pick your brain on that. To what extent do you think that could be helpful to utilization of transplant testing? And I'm just curious if you have any thoughts on that as a potential driver.

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

A

It's another great reason why you don't take the clinical decision out of the hand of clinicians, right as you're changing how transplant centers are being incentivized to use more at-risk organs, and then tell them, well, they can't monitor them on the scale and schedule that they need is feels counterintuitive to me. You know, we have seen some positive feedback, some negative feedback on the program itself. But in general, I think it drives demand for testing. I think, it's natural as you use more at-risk organs that you're going to want to follow those patients more closely. You should expect to see higher rates of AMR in that population. And so they may need to know if you can you bring in these next generation drugs like the felzartamab or daratumumab. So we're optimistic that it increases demand for technology and more kidneys going into patients.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Okay. And I'll just ask one more, if I can, and then leave some FDA questions for others. But I wanted to ask about GraftAssureCore LDT. Recognizing you've got the lab up and running in Nashville, maybe just walk me through how you're thinking about that as a potential source of upside? Obviously, I think that could be potentially a source of, if you will, cash preservation. So can you just give me a sense for what the strategy is on the LTD?

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

A

Thank you. And it's very closely tied to the registry for us. I mean, when we looked at the market initially, I think, one of the big reasons we went kit is that, we didn't feel like we could compete at least initially toe-to-toe with the big guys that are out there. When the opportunity to do the registry came up, it seemed like a natural fit for us and a reason to kind of spool up sort of our capabilities with the CLIA lab, and we think the process is going to be, call it, somewhere between four and six months with each site as we kind of negotiate through the various contracts. And we thought, I think we've engaged with about 10 right now. That puts us kind of end of Q1, middle of Q2 before we start to see patients coming in off of that registry.

The expectation is that, we'll be able to bill for the relative measurement of dd-cfDNA, which is what our current claim is with MolDX, while we capture the information around those other measures that we have. I'd say in general, I mean, this has been very normal for the industry. I think, we've seen very successful registries out there for our competitors. I think, we're kind of following in that vein, although with a slightly different clinical question that we're asking. So yes, it should improve the revenue profile for next year, but we're not predicting that that starts in a meaningful way in Q1 or Q2. That's kind of like just when it starts to pick up. Andrea, anything that you would add to that? I know you've been a little bit closer to the numbers on that than I have.

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

A

No. I love it. The only thing I would add is, you might be wondering, like, what changed, why are we doing this. And it really is, we press release that late breaking data at the World Transplant Congress. We do have the opportunity to look to see if there is extra clinical utility in our assay. And so that's really what changed and what's driving the strategy, its we've had new data come out in our favor.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Got it. Thanks, guys. I'll hop back in the queue.

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

A

Thanks, Mark.

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

A

I'll just keep calling on people. Harrison Parsons at Stephens. Please go ahead.

Harrison Parsons
Analyst, Stephens, Inc.

Q

Hey. Yeah. This is Harrison on for Mason. Thanks for taking the questions this afternoon. So as institutions validate GraftAssureDx head-to-head against current readout assays, what conversion curve are you expecting over the 12 to 18 months post-clearance, and what are the gating factors to go from early adopter physicians to center-wide adoption?

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

A

Yeah. I'd say, Andrea put out a curve in our shareholder letter back in, I think, August of last year, so coming out of Q2 of last year, which gives us at least a look at it. I think, what we're trying to do is influence that curve right now. I think when we get a little bit more confidence in how clinicians are feeling about the technology and what kind of engagement we're getting, I think, we'll update that curve. But right now, that should be considered our best thinking, and we can share that with you afterwards if you don't have access to it.

But I think, in general, the market is going to be very much [indiscernible] (00:28:38), which is, they've been very comfortable using technology that has helped them manage their patients for five, six, seven years now. And I think, they're going to want to see that they're getting similar to better results before they jump. I think once there's enough data out there, there's kind of a saturation point where the question comes off of the table. But certainly, in the early days, it's incumbent upon us to help generate that data and get it out there for the industry.

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

A

Yeah. And Harrison, if you look in the shareholder letter, we actually put a launch framework graphic where we talk about driving engagement in utilization with our potential future customers. We can't start talking about GraftAssureDx as a kitted test until we have FDA marketing authorization. So there's a wall there and you can't, but we can start to drive utilization of our national lab, start talking about our registry study. So when we talk about influencing the slope of that curve, these are activities that we can do now, today, and we are doing them actively today.

Harrison Parsons
Analyst, Stephens, Inc.

Q

Got it. Yeah. I think that all makes sense. And then, I guess, next, so you previously highlighted the favorable PPVE data and how this could be a differentiator for your kitted product. Could you share any broader feedback you've received from clinicians on this point?

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

A

Yeah. I think I'm happy to, and Ekke if you have any comments, I think you've been out there on the front end with some of our research partners, I'd love to hear how you think about it. But I'd say, it's broadly been very positive. I think, there is a general sense that we are applying biopsy too frequently, and that a higher positive predictive value perhaps is better suited to the screening application that the world is looking at right now. But let me hand it over to Dr. Schütz, who's been out there. He's obviously the one that created the score and been working with our research partners on it, and sort of why they're looking at it and what they're looking for.

Ekkehard Schütz

Chief Science Officer, Insight Molecular Diagnostics, Inc.

A

Thank you, Josh. Yeah. Hi, Harrison. I think, what the entire field in transplant was always missing is, it's a way of using cfDNA as a rule in test as well. Right now, it's a rule out testing so which also gets to the fact that if cfDNA is normal, you might fall free to biopsy, but it's not, then you do a biopsy. But under those where you are doing a biopsy way more than 50% now turning out to have a rejections, and that's actually the, I would say, conundrum clinicians are in. And what we are able to provide is a way of testing, that if you see, okay, this patient doesn't look normal, which means, I would not forego a biopsy, then your chance of having really a rejection is way over 50%. So it's actually really good for the patient. So you are not biopsying patients when you only have a 30% chance that the patient's even had something.

And that is still something that clinicians understand. They don't want to do a biopsy if it's not really necessary. And we have only had really a lot of positive feedback. It's really up to people, I say, that's a change in paradigm for cell free DNA. And so yeah, that's why we put it in the center of our registry as an okay, let's convince the field that this is really a huge step forward for your clinical interpretation of cell free DNA. And I think, it's going to more or less, gets into a world of its own once we can show that there's going to be a lot of clinical debates around are you using – do you want to use a test that really has no positive predictive value, or do you want to use a test where you can also make the positive decision for a biopsy with way better chance of doing it in the right situation.

Harrison Parsons

Analyst, Stephens, Inc.

Q

Andrea, I just had one more last question, and then I'll let others go. I guess, so at this point, after the government shutdown, is mid-2026 still the right timeline to think about potential regulatory approval of commercial launch, or has that timeline been pushed out at all, if any? Thanks.

Joshua Riggs

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

A

It's tough.

Ekkehard Schütz

Chief Science Officer, Insight Molecular Diagnostics, Inc.

A

Government never opens again.

Joshua Riggs

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

A

Yeah. I think, we're hopeful that the government gets funded and stays funded. Obviously, the current conversations going on in Washington only funds the government through January. I can't predict what happens if the government shuts back down. I can't predict what's going to happen to our reviewers. I would say, it helps that these reviewers are funded by industry, by and large, through ADUFA. But I can't – yes, I mean, I assume as long as everything's normal and we get through the FDA fine then yes, we're still on pace. But outside that there's things that we don't control.

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

And if I could just add, Harrison, I think the takeaway is that, we are still preparing for a mid-2026 launch, and we're not changing anything, and there's things that we can do regardless of the government shutdown, which is focused on the engagement and utilization of our assay, which we are very much going to focus on. We can drive revenue out of our Nashville lab. We don't need the government to be open to do those things. And then the other thing, and we pointed this out in the shareholder letter, but we got word that our reviewer was working. That's nice to hear that they were working even though they were not accepting new submissions.

So we're just focused on that. And the final thing I would say is, when we talked about the FDA review timeline, we did bake in some time from them to ask questions and for them to respond. So the FDA would say that the review timeline is actually shorter than the number of months we gave you because we did bake in a bit of cushion for them to ask questions, they stop the clock, we respond. And so we're still planning on the same thing we've been planning on all along. But of course, we have as much insight as you do into what's going to happen with the government.

Harrison Parsons
Analyst, Stephens, Inc.

Q

Great. Thank you.

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

A

Of course.

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

A

Thanks, Harrison.

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

A

Okay. Mike Matson, I'm going to take your question. Thank you for coming on video.

Mike Matson
Analyst, Needham & Co. LLC

Q

No problem. Thanks. So just in terms of the trial, it sounds like it's still on track for the end of the year. But I was wondering, can you give us any sort of metrics around enrollment or samples that have been collected to-date?

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

A

Yeah. I would say, gosh, I guess, everybody would say that sample enrollment is going slower than they would like. But we are enrolling samples. There are, I think, we can't actually update our clinicaltrials.gov listing right now because the government is shut down. But I think, we actually have five sites that are actively enrolling patients at this point. And so I think, medium to high confidence that we're going to have all of the samples that we need to complete the submission by year end.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay. And then, you mentioned that, in terms of, once the test is commercialized that the centers and the doctors are likely to try to do head-to-head testing, or maybe potentially use the registry. So can you maybe just explain, I guess, I'm a little confused in terms of how the registry would help them figure out? I understand head-to-head, you run both tests and kind of compare them. But the registry, how does that kind of serve that same purpose, I guess?

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

A

It's a wonderful question, and I think, it's really on the engagement and utilization front. And so, it's an opportunity for a clinician who's never used our technology before to have our report in their hands. You see how it comes out, see the data, and then use it in their patient and see how it performs in kind of a real-world setting. And so that familiarization piece that we're trying to get to also show them the new ways of measuring donor-derived cell free DNA. So to engage that kind of intellectual curiosity that they have around it. So that, I think, that's not head-to-head, that's more getting in their head, if you will, and you're getting them comfortable using our technology.

Mike Matson

Analyst, Needham & Co. LLC

Q

All right. And then, in terms of, if the doctors or the centers are doing head-to-head testing, how would that work from a reimbursement standpoint? I imagine, they can't bill for both, and then [indiscernible] (00:38:00) sort of helping them out with that, I mean, I remember that's [indiscernible] (00:38:04), but giving them a price break or free tests or something like that.

Joshua Riggs

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

A

Yeah. So no. It's a great question. And we've done this before in some of our oncology assays, and what we call is a clinical evaluation program. And so it's a specific program where we signed an agreement with them for a certain quantity of samples. And it's I think the number is 20 samples where they send 20 out to our competitors, they send 20 to us. We don't bill for those samples. We just generate report because under CMS rules, only one center is allowed to bill per patient, and so we basically just eat the cost on that to generate the data for them.

Mike Matson

Analyst, Needham & Co. LLC

Q

Okay. Got it. And then finally, just stepping back, the mid-2026 launch, what do you think are the biggest risks to that timing? Is it mainly the FDA, as you mentioned, in terms of them back and forth, they're kind of stopping the clock, or is there something else you can point to, I guess?

Joshua Riggs

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

A

Yeah. I guess, there's always unknown unknowns. I'd say, we feel like we've checked a lot of boxes kind of retiring risk over the past two-and-a-half years. Obviously, the government being in flux right now is a big one for us that can immediately impact the timeline. Outside of that, I think, I mean, it's probably the biggest risk. Andrea, if you've got some, I know we get this question a lot, and I think you generally have better answers. I'm so optimistic on all of this stuff, it's hard for me to say where it's all going to blow up. But Andrea is a much more level-headed than I am.

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

Go ahead, Ekke.

Ekkehard Schütz

Chief Science Officer, Insight Molecular Diagnostics, Inc.

A

I think, Mike, we are pretty confident with production and everything. So I think, we don't have really a big risk in-house. We are right now producing our third lot for the FDA trial, and it's working out pretty well. Just look at the results today. So I would really think our biggest risk is the FDA. If they drag it out, then there's not much we can do about it. My philosophy or strategy right now is that, whatever we can think of that the FDA might ask us, we shall be prepared to hit the answer already before they ask, so which means it's not really stopping the clock. The obvious is, they're sending out a question, they stop the clock until they have the answer. And my wish is that, when they send us a question in the morning, the answer goes out in the afternoon. So that's more or less what I'm trying to do.

Mike Matson

Analyst, Needham & Co. LLC

Q

Yeah. Okay. That makes sense. Kind of like prepping for an earnings call, you want to try to predict what the analysts are going to ask you guys. All right. Thank you.

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

A

I love that. And Mike, the other thing is, we've communicated with you guys, we had all those pre-submission meetings with the FDA. So that's great because the team has been getting feedback from the FDA. And so it's not like the first time the FDA sees our submission. They're like, what is this? There have been meetings all the time.

Mike Matson
Analyst, Needham & Co. LLC

Q

Yeah. Okay. All right. Thank you.

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

A

Thomas Flaten at Lake Street.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Q

Hey, guys. Thanks for taking the question. Just nothing too granular, Josh, but so there's 51 days or so until the end of the year and a bunch of holidays. And with five of 10 sites recruiting, are the others going to meaningfully contribute to the number of samples? Then how many days do you guys need to take that data, analyze it, compile it, get it into a format that is acceptable to FDA and squeeze it into an application, then send it off. Can you just walk us through? I know we're getting way in the weeds here, but.

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

A

Sure. Yeah. I'll take the first half of the question, and then I'll hand the second half to Dr. Schütz, who is a lot more closer to it than I am. I'd say, there are sites that won't contribute to the first phase of the submission. We are looking at this in two waves with the FDA. So the first is to get basically just over the bar, which is that 85% negative predictive value. And then there's the combo score, which is kind of the second wave of this. And that's where the other sites coming on. We're going to continue to enroll past the New Year. Andrea talks about this in the shareholder letter. I think, we have a few more points to prove with this study that will create kind of like follow-on submissions. But Ekke, maybe you kind of talk us through. I know, there's a lot of focus on the number of events as much as the number of samples that are going into the study.

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

A

Yeah. So Thomas, if we are recruiting as we think we are, we know from each and every of our sites how many biopsies they are doing per month. And from there we can more or less calculate are we on track, we are on track. And we are right now full steam writing the submission already. So we are not waiting until we have this data. This clinical data are, believe it or not, the smallest part of the entire submission. It's, if you wish, a very simple evaluation, what is the sensitivity, what is the specificity, and I can do the calculations in an hour. So what we are doing, we are really preparing the entire submission right now. And at the very last day, if you wish, we just plug in these two numbers from our clinical study and push the submit button.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Q

Yeah. It's super helpful.

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

A

Yeah. Okay.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Q

Super helpful. Andrea, I know you said your expenses are ticking up a little bit because of the study and FDA expenses, et cetera. How should we think about the first half of next year? I know we haven't gotten there yet, but do you expect the cash burn to moderate a little bit, or would you expect it to go up as you prepare for launch?

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

A

It's a great question. Right now, I would say, we're preparing to keep it flat. If we were to go faster and we want to go faster for some reason, we would communicate that to you. I would keep our expenses flat for now. And I would say flat to, I mean, I think they're going to go up a little bit. We are looking at areas where we could invest to go faster. We scrutinize every dollar. And so we haven't greenlit anything yet. But I think we'll come back at you in March, and we'll update you on how we think 2026 is going to look.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Q

Got it. I appreciate it, guys. Thank you.

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

A

Thank you.

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

A

Thank you, Thomas.

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

A

All right. Any other questions?

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

All right. Well, guys, thank you so much for making time for us today. It is fun to get to share sort of the results of all the hard work that the team has put in. I think, we're encouraged, we're excited, we've been waiting to celebrate submission for about two-and-a-half years. And it feels like we're finally about to give birth. So we're excited and looking forward to sharing this positive news when it happens. So thank you, everybody. And we'll talk soon.

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

Thank you, all.