10-Aug-2026

Insight Molecular Diagnostics, Inc. (IMDX)

Q2 2026 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' Second Quarter 2026 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 review our Safe Harbor. The company will make projections and forward-looking statements regarding future events. Any statements that are not historical facts are forward-looking statements. These statements are made pursuant to and within the meaning of the Safe Harbor provisions 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 Form 10-Q, which identify risks and uncertainties that may cause future actual results or events to differ materially. Please note, the forward-looking statements made during today's call speak only to the date – 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. It feels great to be coming to you today with line of sight, on expected FDA marketing authorization for GraftAssureDx. We have three brief but promising takeaways today in our Shareholder Letter. The first is that after three years of rigorous kitted product development, we believe that we are seeing the light at the end of the tunnel on having a regulated product.

Back in July, we got our additional information letter from the FDA. It's a normal part of the Class II process where they ask for some additional data and clarification on intended use as part of their review. Since submitting back in March, we've about tripled the amount of samples collected in the study and feel good about addressing all their questions and comments.

Prior to submitting our next data package, we are going to have an SIR Meeting with the FDA. This meeting is a lot like the Q-Sub process where you get direct and written feedback on your planned approach. It's an opportunity for both parties to make sure there is clear understanding on what is needed to get through to authorization, and clear up any potential misunderstandings.

Once we have the green light from them, the next steps are pretty straightforward. We package it all up, hit submit, and wait for their response. Since March, we have been pleased with the timeliness of the FDA's engagement. We continue to target receipt of FDA marketing authorization later this year, with the caveat that the timing of government agency review is not completely within our control.

The second takeaway is that we can see that the market landscape is likely improving for transplant rejection tests like GraftAssureDx. We believe that Medicare's recently expanded reimbursement guidelines for these tests even better primes GraftAssureDX for commercial success. We know our analysts are well familiar with the recent MolDX LCD, which boosts surveillance from 8 tests to 14 tests in the first three years post kidney transplant.

This higher testing frequency is potentially great for our customers. It strengthens the economic case for bringing dd-cfDNA testing in-house. The market landscape is also improving on a competitive front. We believe that we are about two years ahead with regard to kitted product development among competitors.

And third, and finally, we've seen strong head-to-head data that favorably compares our assay to other leading assays on the market, driving increased interest from potential future customers. That includes top transplant centers and reference labs here in the United States. It feels like half the country is in a three-point stance, waiting for the opportunity to bring dd-cfDNA testing in-house.

From an expense standpoint, and Andrea will take you through some of that in a minute, we believe that we are fully staffed to support material revenue growth. So far, we have invested ahead of revenue generation preparing for commercialization. Future investments will be tied to our expectation of revenue growth.

Given where we are with the FDA, which we believe is likely in the latter stages of the review process, we are looking at all areas of the organization to make sure that we are well aligned for success. I expect that we will have opportunities to strengthen commercial and operations ahead of launch, as the momentum we've built attracts more and more industry attention.

Market demand for dd-cfDNA testing stretches into the hundreds of millions annually, and we are building the team that can get us there. The investments we have made have opened many doors. Over half of the top 10 transplant centers in the United States are working with us, either through our FDA program, or through our registry. Going forward, we will be focusing on closing business, and driving a top line and margin profile that brings us to breakeven and beyond that strong profitability.

One last note before I hand the call over to Andrea. So much of our energy right now is pointed towards getting things done at the FDA, but I'd be remiss [indiscernible] (00:05:44) mention the progress we are making on the science side. The head-to-head data that has come out has been fantastic, showing clinical equivalence to leading tests that are performed at central laboratories. And we continue to demonstrate leadership in showing how dd-cfDNA can help manage patients on therapy for antibody mediated rejection. We are starting to see a future where dd-cfDNA can do much more than just rule out for biopsy. This progress on the science side supports growth in our total addressable market, which Andrea will cover.

Now, let me turn the call over to our CFO, Andrea James, to provide a review of our financial results for the first quarter – should be second quarter. Andrea.

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

Yeah. Hi. Thanks, Josh. Hi, everyone. First, as Gabby said, I hope you've had a chance to read our Shareholder Letter and if you haven't, please do go check it out. It is considerably more thorough than a typical earnings press release and accordingly it allows us to keep our prepared remarks relatively brief and allow more time for Q&A.

This is the ninth quarterly Shareholder Letter we've published since I joined the company two years ago, and we're thrilled to be updating you about our planned transition from a product development stage company into a revenue-generating profitable business.

In the second quarter, core spending came down further from its Q4 2025 peak. You see this in the GAAP OpEx figures as well as in the sequential narrowing of our adjusted EBITDA loss to $7.8 million. Our peak spend in Q4 2025 was tied to activity regarding our FDA submission. This and other working capital items drove cash burn of $10 million in the second quarter, which we expect to be the high watermark on cash burn for the foreseeable future.

We now expect to burn approximately $8 million per quarter in the second half of this year. This is above our prior expectation of roughly $6 million per quarter, primarily reflecting the timing of cost to complete the regulatory review process along with registry activities ahead of associated GraftAssureCore revenue, and investments to prepare for commercial launch of GraftAssureDx.

We continue to expect modest revenue in the second half across laboratory services, research use only kits sales and GraftAssureCore. And remember GraftAssureCore is our lab developed test. We are prudently exploring all options to extend our runway while still properly investing to meet market demand. And we will continue to enforce cost discipline across the business.

Future investments will be tied to our expectation of material revenue growth. We remain very excited about the size of the market and our disruptive approach. We believe that Medicare's higher reimbursed testing frequency is favorable to our previously stated $2 billion total addressable market for kitted, transplanted organ testing.

You can think of our TAM is growing in concentric circles, the core TAM which takes total kidney transplants per year and living kidney transplant recipients multiplied by a baseline and conservative two tests per year at our ASP approaches $2 billion. Higher surveillance testing frequency grows this beyond $2 billion. Adding in therapy monitoring, which Josh just mentioned, grows the TAM again, and then of course, expanded organ indications, grows the TAM yet again.

Remember that Dr. Ekke Schütz and his team designed the GraftAssure platform to be organ agnostic, and we've talked about how we're not stopping at kidney, but we are also investing in heart. To that end, we have a KOL call planned for August 17 to talk about heart transplant testing. It will feature Dr. Max Jacob Liebo of Loyola University Medical Center as well as our VP of Medical Affairs, Dr. Nick Ioannou; and our CEO, Josh Riggs. They will explore how in-house dd-cfDNA testing may be used for heart transplant rejection monitoring. So, stay tuned for a press release with registration details.

Okay, Gabby, we can now take questions. And, Eric, if you could please bring us up into Gallery View. That would be awesome. Thank you. Everybody's got their hands up. Yay.

QUESTION AND ANSWER SECTION

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

Thank you so much, Josh and Andrea. Let's – Mason Carrico from Stephens.

Mason Carrico
Analyst, Stephens, Inc.
Q

Hey, guys. Appreciate you taking the questions here. So, you called out the SIR meeting with the FDA. Could you just expand on that meeting a bit? What was the reason the meeting was set? What's it's focused on specifically? And did you call out a date for that meeting?

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

We did not call out a date. I'd say the, any time you get questions, there's some interpretation that's possible there on the best way to respond to them. I think, the SIR meeting is just an opportunity for us to make sure that we're 100% aligned with the FDA before we package up this additional data and hit the submit button.

Mason Carrico
Analyst, Stephens, Inc.
Q

Got it. And I guess, if authorization were to slip into, let's say, the first half of 2027, could you walk us through, I guess, the changes, I guess the levers that you can pull from an operations standpoint to extend the cash runway if need be?

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

Yeah. I mean, I'd say they're the usual ones, but I would – the investment that we're making in the registry, I think is probably the most significant lever, I think accelerating enrollment there provides a revenue offset that we don't have right now going into the second half just because of some delays in getting that started.

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

Remember that we have a test that we can run out of our national lab that's reimbursable at $2,753 per result. So, not only is it registry revenue, but we think we can attach some GraftAssureCore revenue to that along with those registry participants.

Mason Carrico
Analyst, Stephens, Inc.

Q

Got it. I'll stop there. Thanks, guys.

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

A

Thanks, Mason.

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

A

Mark Massaro from BTIG.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Hey, guys. Thank you for taking the questions. I'm curious about – and I recognize it's still early days, but I am curious about some of the research use only kit revenue you saw, I think it was $21,000 in the quarter. Can you give us a sense for what these kits were for? Was this for – actually, I'll just leave it there. I mean, can you explain why these were ordered and for what use?

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

A

Sure. It's ex-US usage right now and so there's some areas of the world that have trouble accessing testing here in the United States from where they're at. And so, they brought it and validated it for clinical purposes there. And so, that's what's driving that demand.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Okay, that's helpful. And then, what is the latest thinking around the commercial opportunity with Bio-Rad? Is there any potential expansion of that agreement? And assuming you get FDA approval, what gives you confidence in the current strategy versus potentially seeking some alternate strategies?

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

A

Yeah, Bio-Rad has been such a great partner for us throughout this process. They've supported us on sort of every phase of the FDA engagement. And we have an opportunity to negotiate with them both ahead of authorization. And then, there's a 90-day period after authorization. And I think we're encouraged by kind of the support that we feel. We got to sit down with them while we were at ADLM a week-and-a-half ago. And I think everybody kind of looks at the list of centers that we're engaged with here in the United States and in Europe, and can kind of see how that's a real opportunity, especially for instruments that maybe don't have a natural home in the central labs, or the core labs there, or even in the HLA labs.

That kind of adoption menu and placement is very attractive for platform manufacturers and the ability to build additional content. So, I'd say we're both motivated to figure out a great way to work together in the future and drive this high value molecular content closer to the patient.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Awesome. Last one for me and then I'll hop back in the queue. Obviously the final LCD for MolDX I thought was very favorable. Certainly for CareDX and Natera, I'm just curious if you've had conversations, I mean, presumably what's good for the send-out, it's probably good for the kitted, right? So can you just give us a sense for any conversations you've had about your confidence around utilization of kits on a repeat surveillance basis?

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

A

Yeah. You know it's funny, we were actually talking to MolDX the day before they put the LCD out, and we were talking to them about surveillance. And we got a lot of, well, under the current LCD, so it was a very interesting conversation to be a part of. I think what we're going to see is exactly what the [ph] Starzl group (00:15:06) described back in January, which is, these centers need to have the test in their hands, so that they can really build the protocols that make the most sense for them. And they want to work together as a group. And this is international as well, where they want to really figure out what's the optimum schedule.

It's hard for me to gauge if the centers themselves are going to follow exactly what's in the LCD, if they're going to go beyond that. I think, the medical necessity here is still being evaluated. And we're very happy to see that MolDX sees the value in an early and opt-in intervention. Particularly as we see the impact that these anti-CD38 drugs are having on patients.

We just published another paper a couple of weeks ago that shows that early intervention matters. And doctors aren't going to want to wait until you've had kind of a long development of AMR before they intervene. And so, I think the flexibility that MolDX has given clinicians here is great to actually be aggressive in the management of patients, aggressive in the management of AMR.

And I think we're building a great tool for that. And so, I think it's all good for both, I think for the labs send-out labs, and for those centers that choose to bring this in-house.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Awesome. Thank you very much.

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

A

Yeah. Thanks, Mark.

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

A

Thank you. Thomas Flaten from Lake Street.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Q

Yeah, great. Thanks for taking the questions. Josh, anything you can comment on the nature of the questions that FDA sent back to you regarding the review and approval?

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

Yeah. I think we're going to keep the exact questions confidential. But I would say we didn't see anything terribly surprising in there. I mean, the questions all felt fairly routine and addressable with the data that we have in-house.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC
Q

Got it. And then you didn't mention, I don't think in your prepared comments anything about the self-certification process or the IVDR submission. I was curious if you had an update on that.

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

Yeah, I'd like to hand that one to Dr. Schütz. I know he's working closely with his team on getting through the final audits here so that we can hit that submit button. So maybe, Ekke, you could talk just a little bit about the work that we're doing to get ready for Europe? And you're on mute there just in case before you dive in.

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

So what we had, meanwhile, was an informational meeting with our notified body where we more or less got very good guidance. And also, I think the way that the IVDR process is going to go is a little bit more flexible and easier than what we are seeing with the FDA.

So, we are still really planning to get this done in the second half of this year. And I think there is a very, very realistic chance that we can do it. We are not anticipating that we need to provide large clinical studies or anything that would really put a big burden on my team. It looks really, to my mind, way easier than when I actually initially thought.

Of course, there are going to be a couple of hurdles that we have to address. But I'm very positive about the IVDR approval process and the SaaS certification, which is IVD, which only applies to the UK, as you might think is even easier.

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

Thank you, Ekke. It certainly helps to be able to tap into the network of researchers that we have there. And the long history of publications that we have in Europe. Heidelberg has been a wonderful supporter of the regulatory process, and so we're happy to bring those samples along as well. I think we are seeing, just on the market access side in Europe, Switzerland has figured out a way to pay for some of this testing, which is great. I think they're one of the first countries to kind of be pushing this forward. We're starting to see tenders in Italy and some of the other countries, but it still feels very early days in Europe. I think that the biggest catalyst will be the approval of an anti-CD38 for routine use. I think the data is showing that there's clear clinical utility for using donor-derived cell-free DNA to manage the application of those therapeutics. And we've had kind of robust conversations with the pharma that are engaged in that, and trying to pull that forward.

So, we remain hopeful that that drive sort of market access, and demand, and reimbursement across Europe, which we see as largely the gating factor for them adopting the technology broadly.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Q

And then just one quick one. How many of the FDA study sites do you anticipate being registry sites as well? I'm trying to figure out how many the study sites will be kind of early adopters on the commercial side versus opting for the registry.

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

A

Sure. I mean, Ekke, I mean, maybe you can comment real quick. I think the overlap is about 50% of the FDA sites are coming into the registry. But I don't know if you would modify that. You're on mute there, brother.

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

A

Of course. No, I agree. I think we have a couple of candidates that I would say that are going to be 100% in, and we have half of that where we actually have no real visibility [indiscernible] (00:21:06).

Thomas Flaten
Analyst, Lake Street Capital Markets LLC

Q

Got it. Thanks, guys.

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

A

Thanks, Thomas. Mike Matson from Needham.

Mike Matson
Analyst, Needham & Co. LLC

Q

Yeah, thanks. So, just want to ask one. It was good to hear about the interest of the large reference labs in the test, but I'm wondering about the economics of selling to them versus like the transplant centers, which would probably be buying lower volumes. I'm thinking maybe these reference labs that have like kind of a volume discount, but then maybe you wouldn't have all the – you have to pay a sales commission or something. They're just putting in big orders. So...

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

A

Yeah. As you know, I love the question. And we spend a lot of time, as you might imagine, debating pricing power here at the company and we're not going to publish the list price. But I think, you give discounts based off of volume and threat of substitutes.

And right now, there aren't a ton of substitutes out there, if any. And so, I think we expect early on that we're going to have significant pricing power that may change over time. But I think Andrea has thought a lot about this...

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

A

Yeah.

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

A

...so let me let her jump in on this.

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

A

I just wanted to say too, we build some of these thoughts into when we're building out our TAM and what our go-forward models look like. But remember that our pricing power is tied to our reimbursement, and that remains true of whoever is running the test. And so...

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

A

Yeah.

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

A

...the pricing power largely holds up like would there be some volume discounts for guarantees and in return you get some visibility and predictability, which we all love. Sure. But remember, the reimbursement doesn't change. And so, as we seek to port the reimbursement for GraftAssureCore over to GraftAssureDx, that's going to port over to all of our customers as their revenue and their reimburse.

And as reimbursement grows, as you get more private payer coverage, that also helps your pricing power. So, it's not – it is – there are some things that are within our control so we can maintain our pricing power, can also grow the utility of the test, right. And so, as testing frequency grows, there's more of an economic incentive to adopt in-house testing. And so, all of those things we think are favorable.

Mike Matson
Analyst, Needham & Co. LLC

Q

Okay, got it. And then I had a follow-up on just on the TAM. So, I mean, you mentioned, $2 billion, but obviously we have this Medicare coverage or, I guess, Medicare reimbursement policy about covering more frequent tests. So – and you called out some other things. So I guess what I was wondering is like, is that $2 billion I mean, the $2 billion number, is that number going up? And I guess can you give us an estimate of what the size is taking all those things that you kind of listed into account or does it already do that?

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

A

Yeah. No, I mean, it is growing. And we think we have opportunities to grow the TAM over time, even as we develop new products in the future. I mean, right now we are published at a $2 billion TAM, and we talked about the things that grow that. But that $2 billion TAM, and this is why it's really, really important why we love talking about testing frequency. That's based on two tests per year per patient in kidney.

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

A

Yeah.

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

A

And so like it's this really, really simple thing. And so, once you start adding, you can read the MolDX LCD. As you start growing, the testing frequency and the reasons why you test per year, [ph] that 2 tests per year becomes 2.3, then it becomes 2.5, then it becomes 3 tests per year (00:24:34). And as that grows, it grows the TAM accordingly. Does that make sense?

Mike Matson
Analyst, Needham & Co. LLC

Q

Yeah, it does. Thank you. That's all I had.

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

A

Thank you. Are there any additional questions? Josh?

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

All right. So thanks, everybody, for taking the time to join us today. I'd like to thank our dedicated employees for their hard work. I also want to thank our clinician partners who have helped us with the development of the assay. And, finally, I'd like to thank our shareholders for giving us a chance to make managing kidney transplant easier and more accessible. We are excited about the progress we're making and look forward to sharing additional progress with you guys in the coming months and quarters. And we'll see you all on our KOL call on Monday, August 17. You guys have a good day. Thank you.