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Insight Molecular Diagnostics, Inc. (IMDX)

Q1 2026 Earnings Call

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Mike Matson
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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 First Quarter 2026 results. If you have not seen today's shareholder letter, please visit Insight Molecular Diagnostics Investors 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 statement. 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 Form 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 that 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 excited to share with you this business update and our progress creating value at iMDx for patients, clinicians, our employees and our shareholders.

Since submitting GraftAssureDX to the FDA in late March, we've had a high degree of engagement from them and expect that that will continue as we move through the review process. We continue to enroll patients under the study protocol, building the dataset and sample bank to support potential future publications, research and claims expansion. We've committed to delivering software like margins with GraftAssure. Over the past several months, we surveyed over 200 likely US purchasers working through multiple pricing and purchasing scenarios to guide our pricing strategy.

This market research has affirmed our confidence in GraftAssure's perceived value and our ability to translate that into strong margin for both the company and the shareholders who funded its development. We expect our first US orders for GraftAssure later this year. Outside of the US, we've seen some encouraging market access progress for sites using the research use only version of our technology, GraftAssureIQ.

In recent weeks, a Swiss transplant hospital purchased a small number of kits, and we are expecting our first orders out of Southeast Asia. These early milestones, though immaterial to revenue, represent important proof points to us about the need being addressed by GraftAssure. At least one of these centers was able to establish coverage and reimbursement for the test in its market.

Purchase decisions are being driven by demand for faster turnaround time, access to absolute quantification, and the ability to get reimbursed. We anticipate that these sites will become repeat customers as they continue to establish dd-cfDNA testing in their respective countries.

On the back of receiving TÜV SÜD ISO 13485 certification in February, we are targeting regulatory compliance in the UK under IVDD in the coming months and plan to submit for in-vitro diagnostic regulation or IVDR approval in the EU soon thereafter.

In our March update, I explained that to be prepared for the successful launch of GraftAssureDX, we want to achieve or witness three key trends. Those are strong engagement in the GALACTIC registry study, early adopters using GraftAssureIQ, and seeing more head-to-head data establishing parity with legacy technology. We continue to make progress against all three.

First, our GALACTIC registry is designed to drive the clinical adoption and understanding of our absolute and combined measurements of donor-derived cell-free DNA. The current standard of care is the fractional or percentage measurement. We believe these alternative measures offer incremental information for the clinician and could prove to have additional utility in certain clinical contexts.

This self-funding study will help more clinicians become familiar with our clinical reports and establish their usefulness in diverse, real world clinical situations. So far, 34 US transplant centers have expressed interest in being part of our registry. This is up from 28 centers just six weeks ago and represents remarkable progress toward our 50 center goal.

In addition, we recently signed our first clinical trial agreement with one of those 34, putting us closer to first patient in. This is encouraging since successful enrollment generates revenue for the company this year. As a reminder, Medicare reimburses GraftAssureCore at a rate of $2,753 per result.

Second, later this year, we expect to see initial orders of GraftAssureIQ and larger volumes that we've seen before from our first US customers. Third, we are seeing the emergence of head-to-head data comparing our GraftAssure assay with other commercially available technologies. We mentioned these studies in our shareholder letter just to emphasize generating head-to-head data is the fastest path to establishing trust for a new diagnostic. So we are very enthusiastic about what's been reported to-date.

Finally, I will close my remarks by touching briefly upon our expansion into heart transplant testing. As a reminder, our GraftAssure technology is designed to be organ agnostic, so the assay that we built for kidney will work in heart. Clinicians and researchers at leading transplant institutions have expressed their excitement about our planned expansion. We are working with them to get the protocol finalized and first patient in as quickly as possible.

We have made a lot of progress this year and look forward to updating shareholders as we push to make managing patients post transplant easier for clinicians here in the US and abroad.

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

Andrea James

Chief Financial Officer, Insight Molecular Diagnostics, Inc.

Thanks, Josh. Hi, everyone.

Our first quarter results are in line with what we told you they would be in our preliminary release of our cash balance and revenue, which we made on April 14. From where we sit today, our financial projections remain consistent with the update that we provided in late March. Our Q2 2026 revenue projection is for about $0.25 million, comprised mostly of laboratory services and a very low level of GraftAssureIQ sales. We're projecting second quarter cash burn above $9 million, which will be the high watermark for the year.

In the second quarter, we paid out bonuses and addressed other working capital needs associated with the GraftAssureDX FDA submission expenses, which we incurred in prior quarters. We expect cash burn to come down in the back half of the year closer to historical levels of $6 million per quarter, driven by working capital favorability and reduced research and development expenses as many of our FDA program expenses will not repeat.

This, of course, is also subject to revenue that can be difficult to predict. As revenue ramps, of course, this will significantly reduce our quarterly cash burn. This management team remains highly thoughtful about extending our cash runway and focusing our commercialization investments toward the areas that we believe will drive optimal ROI for the company.

Finally, I'll close by reflecting on my almost two-year anniversary with this company, which is coming up in June. We have been building a foundation from which we expect to launch a rapidly growing company that has the potential to be highly profitable. And I am incredibly excited about our future.

I told you on my first earnings call in summer of 2024 that we have a compelling opportunity to achieve market disruption and in so doing create a multibillion dollar company. We are closer than ever to that vision, and we continue to retire risk on the path to initial and then material revenue.

Gabby, we can now take questions. And, Eric, if you could please bring us up into gallery view. Thank you.

QUESTION AND ANSWER SECTION

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

Thank you, Andrea. And with that, Thomas Flaten from Lake Street.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC
Q

Hey, guys, appreciate you taking the questions. Josh, I apologize if I missed this. Any clock stoppages in the FDA review so far? I know it hasn't been very long, but just curious.

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

Yeah, no. We're going to treat sort of all the back and forth with the FDA is as confidential. But I'd say we're pleased with the conversation. All those have been productive so far.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC
Q

I know this has come up previously, but how are you balancing the desire of accounts to participate in the registry study versus getting commercial wins? And I know you're going to make money on the registry study, but how are you thinking about that? Are you going to exclude anyone from the registry study, or is that an all comers type of approach?

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

Yeah, I'd say we aren't being selective on the sites that we're bringing into the registry, but I would say the commercial success is kind of one and the same for us. And we expect that most of these centers that join in the registry are going to be customers for us long term. It's something that we talk to them about as they're coming into the study where we say that the purpose of this is to introduce our new scores, but also give you a chance to bring this in-house once there's a regulated product out there. So we see that both things are serving sort of one end goal, which is to get instruments into the field and kits out there.

Thomas Flaten
Analyst, Lake Street Capital Markets LLC
Q

Great. Appreciate it.

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

Thanks, Thomas. Let's go with Mason Carrico from Stephens, please.

Mason Carrico
Analyst, Stephens, Inc.
Q

Hey, guys. Yeah, appreciate the questions here. Josh, on the survey you conducted around pricing, any incremental detail you're willing to share around maybe the learnings from that survey and your updated thoughts on pricing?

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

Yeah. Thanks for the question, Mason. I would say, the guidance that we've kind of given before around how centers are going to look at pricing on day one, which is kind of relative to what they expect they'll get reimbursed from CMS and then what they won't get reimbursed from the private payers on day one is kind of playing out.

And so everybody is kind of seeing the same math that we saw, and the pricing is going to be well into the hundreds for the DX product. And I think Andrea wants to massage that a little bit, so I'll let her.

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

No, it's great. Just wanted to add one more thing. We've given you that $2 billion total addressable market, and the pricing research is really affirming the numbers that we've already given you on the size of the market.

Mason Carrico
Analyst, Stephens, Inc.
Q

Got it. Okay. And then you guys have also referenced the software-like, longer-term gross margins. I guess, could you talk about how we should be thinking about what gross margins will look like maybe in the first 12 to 24 months post-commercialization when volumes are ramping?

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

Yeah. Andrea, if you want to take a look at that. I know you've spent a lot of time with the numbers.

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

Yeah. So you're going to model in an ASP that's in the hundreds and then you're going to model in a cost of goods sold slightly under $100. Now, we can bring that cost of goods sold per result down overtime.

The other thing you want to think through is that our initial go-to-market customers will or maybe will get some sort of leader pricing. And so we're obviously going to grow into that gross margin profile over time.

The other thing to note is that we do have a revenue share with the former Chronix shareholders from which we acquired the IP. And so that also takes 10% off the top. So, we have a long-term target gross margin of around 70% or higher. I don't know if the initial contracts will come in at that. So I wouldn't model that for your first 6 to 12 months.

Mason Carrico
Analyst, Stephens, Inc.
Q

Got it. Thank you, guys.

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

Thank you.

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

Thank you. Mike Matson from Needham.

Mike Matson Q
Analyst, Needham & Co. LLC

Yeah, thanks. So just once you get the FDA clearance, how quickly can you start to drive sales of the kits? And are there any hurdles you have to cross once you get the FDA clearance in place, or can you kind of hit the ground running there?

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

I'd say one of the rate limiters that we'll face is, you know the placement of the instrument. And so that's where – and we've talked about in the past the sites that are participating in the FDA study itself are the most likely day one adopters just because they'll have the instrument on hand.

I think what you'll expect to see from us is to take advantage of all of these instruments that we've had in-house to support the FDA program, and we've now finished all of that work. And so we're starting to try and get those out in the field, and I think we'll be able to update you guys on sort of progress of sort of getting some additional instruments out there as we go forward throughout the year.

Mike Matson Q
Analyst, Needham & Co. LLC

Okay, great. And then with the EU IVDR – can't talk – the EU IVDR submission – kind of a mouthful there – if you submit it later this year, I mean, how long do you think that process will take?

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

Yeah. [indiscernible] (00:23:57) been given – yeah. I would say what we've been given is guidance. And I mean, this can change, but is somewhere between six and nine months all the way up to a year, depending on how much the backlog builds with TUV SUD. So I'd say once we submit, we'll probably have a better idea. We'll get the guidance from them at that point. And so we'll be able to update you there.

Mike Matson Q
Analyst, Needham & Co. LLC

Okay. All right. And then just next steps for the heart [indiscernible] (00:24:25), and what impact would that have on your operating expense and cash burn?

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

Yeah, thanks. I'd say it's baked into the numbers that Andrea has given you. You know, fortunately, 95% of the work that goes on between the sort of heart and kidney is copy and paste. So because the underlying information

is all the same, I'd say the clinical piece is a much simpler study here where it looks more like a head to head, where we believe we have a 510(k) pathway available.

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

Yeah. Just to build on what we said last quarter, we had done the capital raise in February that allows us to sustain our research and development spending at a higher level than it was, say, back in 2024. And so we expect research and development expenses to come back down closer to first half 2026 levels, but not go all the way back to where they were at 2024 levels.

And so we expect research and development to continue to come down in the back half of the year, but not back to where it was a couple of years ago. So sustaining investment in heart is what that looks like on the R&D line, if that helps.

Mike Matson
Analyst, Needham & Co. LLC
Q

Thank you.

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

Thanks, Mike. Mark Massaro from BTIG.

Mark Anthony Massaro
Analyst, BTIG LLC
Q

Hey, guys, thanks for the questions. Josh, one for you. Can you just speak to your latest thoughts on the IOTA model and whether or not you think that can be sort of one of the growth drivers for your business? And if so, is there anything about your particular strategy relative to send-outs that you think you could capitalize on?

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

It's a great question, and thanks for it, Mark. I would say, we are encouraged by sort of some of the volume growth that we're seeing around IOTA. I think any time you can create a high risk pool of patients, the more likely it is that the payers will support a higher screening protocol. And I think that's where we've been focused is on identifying higher risk groups like the de novo DSA-positive patients as kind of a ground for we really need to be screening these people more aggressively.

And so I think us and other dd-cfDNA companies are going to lean into this going forward and try to push those numbers up a bit because we know that catching AMR early is going to become more and more important as these anti-CD38 drugs come to market. And so I think that'll have a much bigger clinical impact for those patients that are potentially getting the marginal organs out of the IOTA program.

So I think it's a rising tide scenario. I think we talked a little bit about this on the last call. And I think if that's where you're going with it, I completely agree with you that there's opportunity for increased screening across the board.

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

And if I could just throw out some acronym help for some of the generalists that have come into the stock in the recent months, increasing organ transplant access model and then AMR is antibody mediated rejection.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Awesome. Thank you for that, guys. It's nice to see you move the ball forward in Europe. This is sort of a theoretical question, but assuming – and I know that these won't have the same start dates, but assuming that like Europe and US had a similar start date, which market are you now thinking will probably pull forward the biggest volume in your initial launch?

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

A

Yeah. I'd say the reimbursement question being solved in the United States makes things a lot easier here for the initial adopters. I would say the pent-up demand in Europe is strong. I think you've got several countries where you have very loud clinical groups that are kind of banging on the door with their payers saying that we need access to this technology. We need better access to this technology.

And there's competitive technology out there that competes with ours. And they've been out there for years working on the same argument. I think the what we saw in Europe, which is kind of the first crack in the door, that there are centers that are getting paid at this point is a great positive sign. And I think we're very hopeful that we'll see a couple of more cracks in the door here in the second half of this year.

We know that there was a recommendation made to NICE in the fall of last year. We're hopeful that they finally come to that positive decision. And I'd say we have a strong presence in Germany and a lot of work that's been going on there. We've been fortunate to have a good group of clinicians that understand the payer system and have been pushing there as well.

I mean, obviously, we can't predict when the payers are going to finally break on this topic. But it seems like the evidence is overwhelming at this point that there is clinical utility here, that there is clinical need to address this. And so we'll keep our fingers crossed that the year – that the European market starts to look a lot more like the US over the next, call it, 12 months. And I think we've seen some early positive signs.

Mark Anthony Massaro
Analyst, BTIG LLC

Q

Awesome. All right. That's it from me. Congrats on the progress.

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

A

Thanks, Mark.

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

Any additional questions? Thank you so much, analysts. And, Josh, I'll turn the call back over to you.

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

Sure. Thanks, Gabby, and thanks, everybody. Appreciate you guys taking time with us today. I want to thank our dedicated employees for their hard work. I also want to thank our clinician partners who have helped with the development of our assay. And finally, thanks to our shareholders for believing that we have the opportunity to disrupt and transform transplant testing and for providing us with the capital to help make that a reality.

We are excited about the progress being made and look forward to sharing additional updates with you in the coming months and quarters. You guys have a good day. Thank you.