

## IMDX Reports Q1 2026 Results and Update on Progress Toward GraftAssure Commercialization

- Progressing toward commercialization with third-party head-to-head data publications and GALACTIC registry study engagement
- Northeast kidney transplant center (among the top 10 in the U.S.) is first to sign clinical trial agreement to participate in GALACTIC study
- Booked research-use-only purchase by E.U. transplant center and APAC purchase expected in coming days
- Anticipate significant U.S. orders to follow FDA marketing authorization
- Encouraging dialogue with FDA supports expected authorization later in 2026

NASHVILLE, TN., May 13, 2026 -- Insight Molecular Diagnostics Inc., iMDx, (Nasdaq: IMDX), today published the following letter to shareholders in conjunction with its first quarter results:

Fellow shareholders,

We are pleased to report that customer demand for our kitted kidney transplant monitoring assay is growing and that we are moving quickly to capture what we believe to be a \$2 billion annual market opportunity.

iMDx is at a pivotal stage in commercializing GraftAssureDx, which we expect to be an industry-transforming transplanted organ rejection monitoring test. We aim to deliver proven, more affordable, faster tests that can be run in-house at local transplant center laboratories. To do this, we have designed a molecular test that we can sell as a high gross margin kit. These test kits enable transplant center laboratories to run tests locally and deliver critical test results far more quickly than the current standard of care tests. We are now seeking FDA authorization to sell these kits.

Since submitting GraftAssureDx for FDA review in late March, we have had productive dialogue with our FDA reviewers and have been encouraged by their swift engagement. As is the case with any *in vitro* diagnostic, the FDA is seeking to ensure that our test is safe, effective, and performs as intended. We expect to continue to have meaningful and frequent engagement with the FDA throughout the review process.

Meanwhile, the GraftAssureIQ research-use-only pilot program that launched in summer 2024 is beginning to produce tangible results. So far in the second quarter, we have seen new traction with one small commercial order outside of the U.S. and another that we expect soon. This summer, we expect to achieve our first significant U.S. order of GraftAssureIQ from a major transplant hospital.

Our goal with the pilot program was to put our dd-cfDNA technology into the hands of researchers and clinicians, which is something to which they historically did not have direct access. Since then, they have been using our GraftAssureIQ kits and we are seeing expanded research and development utilization of our dd-cfDNA technology by the experts closest to transplantation.

Researchers and laboratory clinicians enjoy this type of exploration. Our future potential customers are highly engaged and passionate about transplant medicine, advancing science, and helping patients.

Now, we are thrilled to share with our investors that independent researchers have begun to publish *their own* data using our assay. This spring, we were delighted to see a strong slate of international conference activity with new, *independent*, real-world data involving our assay being presented across leading global forums:

- Positive head-to-head data on our GraftAssure assay were presented at the 39<sup>th</sup> European Immunogenetics and Histocompatibility Conference (EFI2026), April 21–24, 2026, in Edinburgh, Scotland;
- Three posters are scheduled to be presented at the 63<sup>rd</sup> European Renal Association (ERA) Congress, June 3–6, 2026, in Glasgow, Scotland; and
- A favorable real-world evidence poster is scheduled to be presented at the American Transplant Congress (ATC), June 20–24, 2026, in Boston.

At EFI2026 in Scotland, referenced above, independent researchers presented two GraftAssureIQ posters. One poster, with researchers from Marseille, France, evaluated our technology head-to-head with a leading competing technology and supported both the accuracy and clinical differentiation of our technology. A second poster from a U.K. National Health Service laboratory highlighted GraftAssureIQ's quality, practical workflow and clinical performance.

We are pleased to share that head-to-head data generated using GraftAssure technology now demonstrates comparable performance to the *two* leading players in the field, supporting equivalence with two commercially available assays currently on the market. Notably, the above-referenced study represents the *second* head-to-head comparison between GraftAssure and other technologies on the market. In June 2025, we announced [separate favorable head-to-head data](#) that was presented at the European Society of Organ Transplantation (ESOT) Congress in London as well as at the European Renal Association (ERA) meeting. This data has now been accepted for publication in the major laboratory diagnostics journal, *Clinical Chemistry*.

Our [Q4 2025 shareholder letter](#), published six weeks ago on March 26, outlined six goals for 2026. We will briefly provide an update on each:

- 1) **Bring GraftAssureDx to market in the U.S.:** We are finalizing our pricing strategy after surveying more than 200 likely purchasers of our test kits. This market research affirmed our confidence in the value delivered by our kitted clinical assay and in our ability to gain adoption while also retaining value for our company and the

shareholders who have funded the development of this assay. Also, as noted above, dialogue with the FDA has been productive, and we continue to target receipt of FDA marketing authorization later this year, with the caveat that the timing of a government agency review is not completely within our control.

- 2) **Obtain GraftAssureDx regulatory approval in the U.K. and E.U.:** Following the receipt of TÜV SÜD ISO 13485 certification on February 26<sup>th</sup>, we are targeting receiving CE Mark under the U.K. In Vitro Diagnostic Directive (IVDD) in the coming months, and plan to submit for In Vitro Diagnostic Regulation (IVDR) approval in the E.U. soon thereafter.
- 3) **Commence GraftAssureIQ RUO sales:** In recent weeks, a transplant hospital in Switzerland purchased a small number of GraftAssureIQ research-use-only kits. In addition, a hospital in Southeast Asia began the process to purchase our kits. This milestone, though immaterial to revenue, is an important proof point for us. When disrupting a market, securing the first customers is often the most challenging and time-consuming task. While these initial orders are just the beginning, we anticipate that these sites will become repeat customers as they continue to establish dd-cfDNA testing in their respective countries. We expect to realize our first U.S. orders, in greater quantities, later this year.
- 4) **Make progress toward establishing absolute quantification as an important metric:** Our GALACTIC registry study (**GraftAssure Lowering Allograft rejeCTIon by Combination**) is designed to drive clinical adoption and build a scientific case for our combined score (CM-score). This self-funding study will help clinicians across the country to become familiar with our clinical reports and to evaluate the utility of having access to both the absolute quantification of dd-cfDNA in the blood *and* the CM-score. So far, 34 U.S. transplant centers have expressed interest in being part of our registry, which we believe represents remarkable progress toward our 50-center goal. In addition, we recently signed our first clinical trial agreement with a Northeast kidney transplant center that is among the largest 10 centers in the U.S. You may read more about the GALACTIC registry study by viewing [its listing on clinicaltrials.gov](#).
- 5) **Market GraftAssureCore and drive samples to our Tennessee clinical lab:** GraftAssureCore is the lab-developed test form of our assay. It can give customers an opportunity to see the benefits of our test in a format consistent with their current send-out testing modality with the future potential benefit of bringing our technology's fast turn-around time in-house. As a reminder, Medicare reimburses GraftAssureCore at a rate of \$2,753 per result.
- 6) **Commence R&D to expand GraftAssure utility into heart transplant rejection:** Our GraftAssure technology is designed to be organ agnostic. Clinicians and researchers at leading transplant institutions have expressed their excitement about our planned expansion into heart transplant rejection testing. We look forward to updating you on our progress with this over the next year.

Finally, in case you missed it, CEO Josh Riggs’s [second annual letter to shareholders](#) was published in our proxy statement, which was filed on April 30, 2026. We believe it provides a little more detail about the business that we are seeking to build — and why.

As Josh notes in that letter, transformational change in any industry rarely is obvious — at first. Three years ago, we saw a clear opportunity to strategically pursue high-value content that appeared to be trapped in inefficient business models. We believe that we are making notable progress towards launching our first *in vitro* diagnostic test kit and achieving this vision.

Sincerely,

iMDx Management

### **First Quarter 2026 Financial Overview**

- In Q1 2026, our revenues were approximately \$32,000.
  - All our revenues were derived from laboratory services performed at our clinical laboratory in Tennessee. Relative to our strategic goal of selling diagnostic test kits for clinical use, we remain essentially “pre-revenue.” Our laboratory services are performed at the request of select clients, and we see our laboratory services revenue as a testament to our team’s ability to achieve the on-time delivery of clear, scientifically sound, and accurate data sets to our clients.
  - In Q1 2026, our laboratory staff was focused on research and development work to support our FDA submission, inhibiting its ability to perform revenue-producing laboratory services on behalf of clients.
  - We did not realize any kitted product revenue in the first quarter. As previously communicated, we do not expect material revenue on our kitted product sales until after we have achieved regulatory authorization to market GraftAssureDx.
- We reported gross profit of \$15,000 in Q1 2026, representing a 46.9% gross margin.
- In Q1 2026, operating expenses of \$4.4 million included a non-cash gain of \$5.9 million from a change in the fair value of our contingent consideration, as well as \$615,000 in non-cash stock-based compensation expenses, and \$610,000 in non-cash depreciation and amortization expenses. Excluding the impact of these non-cash net adjustments in Q1 2026, our non-GAAP operating expenses decreased 1%

sequentially over the fourth quarter of 2025, and increased 45% year over year, as we invested more heavily in our FDA program ahead of commercial launch.

- In Q1 2026, research and development expenses decreased 15% sequentially, or by about \$876,000, to \$5.0 million, reflecting lower laboratory and supplies costs as we concluded our FDA submission work streams.
  - As noted last quarter, Q4 2025 represented higher-than-average research and development expenses as we approached FDA submission, including FDA-compliant software development expenses, laboratory supplies, kit production, and personnel costs associated with our clinical trial, including regulatory consulting fees. As expected, Q1 2026 R&D expenses declined sequentially and we expect these expenses to decline again in Q2 2026, as the heavy expenses associated with our FDA submission regarding GraftAssureDx for kidney are behind us.
- In Q1 2026, sales and marketing expenses increased \$111,000 sequentially to \$2.4 million. We continue to invest in go-to-market activities as we prepare for commercial launch, including marketing, advertising, travel, consulting fees and personnel.
- General and administrative expenses rose to \$3.0 million in Q1 2026. In the prior quarter, Q4 2025, general and administrative expenses of \$2.3 million reflected a favorable employee-retention credit of \$337,000 related to payroll taxes, which did not repeat in Q1 2026.
- Our Q1 2026 net loss was \$4.3 million, or \$0.12 net loss per share.
  - Non-GAAP Net Loss: Our Q1 2026 adjusted net loss of \$9.6 million represented a loss of \$0.28 per share. Our adjusted net loss excludes the non-cash charges of stock-based compensation expenses and the change in fair value of our contingent consideration (“Non-GAAP Net Loss”). Please refer to the table below, “Reconciliation of Non-GAAP Financial Measures,” for additional disclosures and information.
  - Non-GAAP Adjusted EBITDA Loss: Our Q1 2026 adjusted earnings or loss before interest, income taxes, depreciation, amortization, stock-based compensation, change in fair value of contingent consideration, and other non-operating items (“Adjusted EBITDA Loss”) was \$9.1 million. The sequential change in Adjusted EBITDA Loss represented cost discipline offset by lower gross profit in the quarter.
  - Please refer to the table below, “Reconciliation of Non-GAAP Financial Measures,” for additional disclosures and information.

- Our Q1 2026 per share results reflect 34.5 million weighted average shares outstanding and include the effects of 4.5 million pre-funded warrant shares that were issued in April 2024, February 2025, and February 2026 to a certain investor.
  - Inclusive of all outstanding shares, pre-funded warrants, and subsequent issues for stock awards, our pro-forma fully weighted share count would be 36.7 million shares.
- Our cash, cash equivalents, and restricted cash balance at the end of the first quarter was \$29.4 million. On February 12, 2026, we completed a \$26.0 million registered direct offering, which after deducting fees, resulted in net proceeds of approximately \$24.6 million.
- As expected and projected, our Q1 2026 outgoing cash flow from operations (net cash used in operating activities) of \$7.6 million, combined with capital expenditures of about \$613,000, resulted in outgoing free cash flow of \$8.3 million.
- As noted in our March update, in 2026, we expect to continue to be thoughtful about capital allocation, hiring, and expense growth.

### **Webcast and Conference Call Information**

Live Zoom Call and Webcast on Monday, May 13, 2026, at 2:00 p.m. PT / 5:00 p.m. ET.

Those interested may access the live Zoom call by registering here: [iMDx Q1 2026 Earnings Webinar](#)

A replay of the Zoom call will be available on the Company's website shortly after the call.

### **iMDx Transplant Products and Product Candidates in Development**

iMDx's flagship transplant testing technology quantifies a molecular biomarker known as donor-derived cell-free DNA (dd-cfDNA). The Company's scientists in Germany and the U.S. have played a critical role over the past decade in developing the science that helped establish dd-cfDNA as a trusted biomarker of transplant rejection. iMDx is commercializing this technology using a market-disruptive business strategy. Under the GraftAssure™ brand, iMDx's transplant diagnostics include the following:

- GraftAssureCore – The Company's laboratory-developed test (LDT), currently reimbursed by CMS and performed at iMDx's CLIA-certified laboratory in Franklin, Tennessee.
- GraftAssureIQ – A research-use-only (RUO) kit intended and labeled for non-clinical applications.

- GraftAssureDx – The in vitro diagnostic (IVD) kit currently in development for use in clinical decision-making.

### **About Insight Molecular Diagnostics, Inc.**

Insight Molecular Diagnostics is a pioneering diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes. Investors may visit <https://investors.imdxinc.com/> for more information.

GraftAssureCore™, GraftAssureIQ™, GraftAssureDx™, GraftAssure™, DetermaIO™, and DetermaCNI™ are trademarks of Insight Molecular Diagnostics Inc.

### **Forward-Looking Statements**

Any statements that are not historical fact (including, but not limited to, statements that contain words such as “will,” “believes,” “plans,” “anticipates,” “expects,” “estimates,” “may,” and similar expressions) are forward-looking statements. These statements include those pertaining to, among other things, demand for iMDx’s products and what the Company is building, the expectation that decentralized testing will deliver new value in the roughly \$2 billion-plus addressable market for kitted transplant rejection testing, the Company’s competitive advantage and path to supplying the world’s most widely used dd-cfDNA assay, iMDx’s expectations for FDA review and authorization and its 2026 goals (including but not limited to commercial, regulatory and R&D goals), iMDx’s expectations regarding orders of, and the timing of orders of, GraftAssureIQ in the U.S., iMDX’s beliefs regarding the timing of its launch of its *in vitro* diagnostic test kit, management’s thoughts on where transplant patient management is headed and why the Company is well-positioned, emerging clinical utility of dd-cfDNA testing, the belief that democratizing access to transplanted organ rejection testing creates a rapidly growing, high-margin, recurring business model, and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Insight Molecular Diagnostics’ third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients’ use of any diagnostic tests Insight Molecular Diagnostics or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential

failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly, such statements should be evaluated together with the many uncertainties that affect the business of Insight Molecular Diagnostics, particularly those mentioned in the “Risk Factors” and other cautionary statements found in Insight Molecular Diagnostics’ Securities and Exchange Commission (SEC) filings, which are available from the SEC’s website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Insight Molecular Diagnostics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

#### **FDA**

CAUTION: This shareholder letter concerns certain products that are under clinical investigation, and which have not yet been cleared or authorized for marketing by the U.S. Food and Drug Administration. These products are currently limited by federal law to investigational use, and no representation is made as to the safety or effectiveness of these products for the purposes for which they are being investigated.

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***Tables Follow***

**INSIGHT MOLECULAR DIAGNOSTICS INC.**  
**CONDENSED CONSOLIDATED BALANCE SHEETS**  
**(In thousands)**

	March 31, 2026 (Unaudited)	December 31, 2025
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash and cash equivalents	\$ 28,201	\$ 11,583
Accounts receivable, net of allowance for credit losses of \$2 and \$11, respectively	157	1,128
Inventories	382	446
Restricted cash, current	729	729
Prepaid expenses and other current assets	1,048	1,420
Total current assets	30,517	15,306
<b>NONCURRENT ASSETS</b>		
Right-of-use operating and financing lease assets, net	2,459	2,815
Machinery and equipment, net, and construction in progress	6,452	6,435
Restricted cash, noncurrent	425	607
Other noncurrent assets	574	593
<b>TOTAL ASSETS</b>	<b>\$ 40,427</b>	<b>\$ 25,756</b>
<b>LIABILITIES AND SHAREHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable	\$ 1,615	\$ 2,544
Due to related party	2,736	2,780
Accrued compensation	3,333	2,461
Accrued royalties	1,116	1,116
Accrued expenses and other current liabilities	1,284	939
Operating and financing lease liabilities, current	1,762	1,807
Contingent consideration liabilities, current	159	428
Total current liabilities	12,005	12,075
<b>NONCURRENT LIABILITIES</b>		
Operating and financing lease liabilities, noncurrent	1,307	1,690
Contingent consideration liabilities, noncurrent	37,806	43,455
<b>TOTAL LIABILITIES</b>	<b>51,118</b>	<b>57,220</b>
Commitments and contingencies		
<b>SHAREHOLDERS' DEFICIT</b>		
Preferred stock, no par value, 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, no par value, 230,000 shares authorized; 32,286 and 28,683 shares issued and outstanding at March 31, 2026 and December 31, 2025, respectively	394,289	369,211
Accumulated other comprehensive income	71	86
Accumulated deficit	(405,051)	(400,761)
Total shareholders' deficit	(10,691)	(31,464)
<b>TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT</b>	<b>\$ 40,427</b>	<b>\$ 25,756</b>

**INSIGHT MOLECULAR DIAGNOSTICS INC.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
(In thousands, except per share data)

	Three Months Ended March 31,	
	2026	2025
<b>Net revenue</b>	\$ 32	\$ 2,138
Cost of revenues	17	813
Gross profit	15	1,325
<b>Operating expenses:</b>		
Research and development	4,953	2,924
Sales and marketing	2,402	1,206
General and administrative	2,991	3,115
Change in fair value of contingent consideration	(5,918)	879
Total operating expenses	4,428	8,124
Loss from operations	(4,413)	(6,799)
<b>Other (expenses) income:</b>		
Interest expense	(23)	(29)
Other income, net	146	157
Total other income, net	123	128
<b>Loss before income taxes</b>	(4,290)	(6,671)
Income taxes	—	—
<b>Net loss</b>	\$ (4,290)	\$ (6,671)
<b>Net loss per share:</b>		
Net loss per share - basic and diluted	\$ (0.12)	\$ (0.26)
Weighted average shares outstanding - basic and diluted	34,519	25,694

**INSIGHT MOLECULAR DIAGNOSTICS INC.**  
**UNAUDITED CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**(In thousands)**

	Three Months Ended March 31,	
	2026	2025
<b>CASH FLOWS FROM OPERATING ACTIVITIES:</b>		
Net loss	\$ (4,290)	\$ (6,671)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	631	484
Amortization of intangible assets	—	7
Stock-based compensation	615	473
Equity compensation for bonus awards and consulting services	32	14
Change in fair value of contingent consideration	(5,918)	879
Unrealized foreign currency (gains) losses	(5)	39
Changes in operating assets and liabilities:		
Accounts receivable	971	(1,927)
Inventories	64	(49)
Prepaid expenses and other assets	449	(85)
Accounts payable and accrued liabilities	(105)	1,027
Operating lease assets and liabilities	(83)	(30)
Net cash used in operating activities	<u>(7,639)</u>	<u>(5,839)</u>
<b>CASH FLOWS FROM INVESTING ACTIVITIES:</b>		
Machinery and equipment purchases, and construction in progress	(613)	(307)
Net cash used in investing activities	<u>(613)</u>	<u>(307)</u>
<b>CASH FLOWS FROM FINANCING ACTIVITIES:</b>		
Proceeds from sale of common shares	26,024	29,143
Financing costs to issue common shares	(1,183)	(487)
Repayment of financing lease obligations	(143)	(98)
Net provided by financing activities	<u>24,698</u>	<u>28,558</u>
Effect of exchange rate changes on cash and cash equivalents	(10)	(19)
<b>NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH</b>	<b>16,436</b>	<b>22,393</b>
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING</b>	<b>12,919</b>	<b>10,336</b>
<b>CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING</b>	<b>\$ 29,355</b>	<b>\$ 32,729</b>

**INSIGHT MOLECULAR DIAGNOSTICS INC.**  
**RECONCILIATION OF NON-GAAP FINANCIAL MEASURES**  
**NON-GAAP NET LOSS AND ADJUSTED EBITDA LOSS**

In addition to financial results determined in accordance with U.S. generally accepted accounting principles (“GAAP”), this press release also includes non-GAAP financial measures (as defined under SEC Regulation G). We believe that disclosing the adjusted amounts is helpful in assessing our ongoing performance, providing insight into the Company’s core operating performance by excluding certain non-cash and other non-operating items that may obscure the underlying trends in the business. These non-GAAP financial measures, when viewed in a reconciliation to respective GAAP financial measures, provide an additional way of viewing the Company’s results of operations and factors and trends affecting the Company’s business. These non-GAAP financial measures should be considered as a supplement to, and not as a substitute for, or superior to, the respective financial results presented in accordance with GAAP.

The following is a reconciliation of the non-GAAP financial measures to the most directly comparable GAAP measure:

	Three Months Ended		
	March 31,	December 31,	March 31,
	2026	2025	2025 <sup>(1)</sup>
	(unaudited)	(unaudited)	(unaudited)
	(In thousands)		
<b>Net loss (GAAP)</b>	<b>\$ (4,290)</b>	<b>\$ (22,955)</b>	<b>\$ (6,671)</b>
Stock-based compensation	615	721	473
Change in fair value of contingent consideration	(5,918)	(1,115)	879
Impairment losses	—	14,600	—
<b>Non-GAAP net loss</b>	<b>(9,593)</b>	<b>(8,749)</b>	<b>(5,319)</b>
Depreciation and amortization expenses	631	563	491
Interest expense	23	26	29
Other income, net	(146)	(506)	(157)
Income taxes	—	—	—
<b>Adjusted EBITDA loss, a non-GAAP financial measure</b>	<b>\$ (9,085)</b>	<b>\$ (8,666)</b>	<b>\$ (4,956)</b>
<b>Net loss per share (GAAP)</b>	<b>\$ (0.12)</b>	<b>\$ (0.72)</b>	<b>\$ (0.26)</b>
<b>Non-GAAP net loss per share</b>	<b>\$ (0.28)</b>	<b>\$ (0.27)</b>	<b>\$ (0.21)</b>
Weighted average shares outstanding	34,519	32,065	25,694

<sup>(1)</sup> The March 2025 reconciliation line-items have been presented to conform to the current presentation. The newly titled total “Adjusted EBITDA loss, a non-GAAP financial measure” reported for March 2025 is unchanged from the March 2025 “Consolidated non-GAAP loss from operations, as adjusted” as previously reported.