INSIGHT MOLECULAR DIAGNOSTICS INC.

Annual Report 2025

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2025**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number 001-37648

Insight Molecular Diagnostics Inc.
(Exact name of registrant as specified in its charter)

California	**27-1041563**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2 International Plaza Dr., Suite 510

Nashville, Tennessee 37217

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(615) 255-8880**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	IMDX	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act): Yes ☐ No ☒

The aggregate market value of shares of voting and non-voting common stock held by non-affiliates computed by reference to the price at which shares of common stock were last sold as of June 30, 2025 was approximately $32.4 million. Shares held by each executive officer and director and by each person who beneficially owns more than 10% of the outstanding common stock have been excluded in that such persons may under certain circumstances be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of shares of issuer's common stock, no par value, outstanding as of March 19, 2026 was 32,167,978.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its 2026 Annual Meeting of Shareholders (the "Proxy Statement"), to be filed with the Securities and Exchange Commission ("SEC") within 120 days after the end of the fiscal year ended December 31, 2025, are incorporated herein by reference in Part III of this Annual Report on Form 10-K.

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December 31, 2025

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain statements contained in this Annual Report on Form 10-K for the year ended December 31, 2025 (this "Report") are forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, including, but not limited to, statements pertaining to future financial and/or operating results, future growth in research, technology, clinical development, and potential opportunities for Insight Molecular Diagnostics Inc., or iMDx (f/k/a Oncocyte Corporation), along with other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management. Any statements that are not historical fact (including, but not limited to statements that contain words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "may," "plan," "project," "seek," "should," "strategy," "target," "will," "would" or similar expressions or the negative of such terms) should also be considered to be forward-looking statements. Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of potential products, uncertainty in the results of clinical trials or regulatory approvals, need and ability to obtain future capital, and maintenance of intellectual property rights. Actual results may differ materially from the results anticipated in these forward-looking statements and as such should be evaluated together with the many uncertainties that affect the businesses of iMDx, particularly those mentioned in this Report under "Risk Factors" in Part I, Item 1A. Except as required by law, iMDx undertakes no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

The forward-looking statements include, among other things, statements about:

- the timing and potential achievement of future milestones;
- the timing and our ability to obtain and maintain coverage and reimbursements from the Centers for Medicare and Medicaid Services and other third-party payers, including within the U.S. and outside of the U.S.;
- our plans to pursue research and development of diagnostic test candidates;
- the potential commercialization of diagnostic tests currently in development;
- the timing and success of future clinical research and the period during which the results of the clinical research will become available;
- the potential receipt of revenue from current sales of our diagnostic tests and/or diagnostic tests in development;
- our assumptions regarding obtaining reimbursement and reimbursement rates of our current diagnostic tests and/or diagnostic tests in development;
- our estimates regarding future orders of tests and our ability to perform a projected number of tests;
- our estimates and assumptions around the patient populations, market size and price points for reimbursement for our diagnostic tests;
- our estimates regarding future revenues, operating expenses, and future capital requirements;
- our intellectual property position;
- our ability to continue as a going concern;
- our dependency on our collaboration with Bio-Rad Laboratories, Inc. for the development and commercialization of products;
- the impact of government laws and regulations, including the impact of a prolonged government shutdown; and
- our competitive position.

Unless the context otherwise requires, all references to "iMDx," "we," "us," "our," "the Company" or similar words refer to Insight Molecular Diagnostics Inc., together with our consolidated subsidiaries.

The description or discussion, in this Report, of any contract or agreement is a summary only and is qualified in all respects by reference to the full text of the applicable contract or agreement.

iMDx™, DetermaIO™, DetermaCNI™, GraftAssureCore™, GraftAssureIQ™ and GraftAssureDx™ are trademarks of iMDx, regardless of whether the "TM" symbol accompanies the use of or reference to the applicable trademark in this Report.

We have rebranded our VitaGraft assay (VitaGraft Kidney and VitaGraft Liver), which is our lab developed test, under the name GraftAssureCore. We also rebranded our kitted research use only assay, GraftAssure, as "GraftAssureIQ," and our future kitted clinical assay as "GraftAssureDx."

INDUSTRY AND MARKET DATA

This Report contains market data and industry forecasts that were obtained from industry publications, third party market research and publicly available information. These publications generally state that the information contained therein has been obtained from sources believed to be reliable. While we believe that the information from these publications is reliable, we have not independently verified such information.

This Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other data about our industry. We obtained the industry and market data in this Report from our own research as well as from industry and general publications, surveys and studies conducted by third parties, some of which may not be publicly available. Such data involves a number of assumptions and limitations and contains projections and estimates of the future performance of the industries in which we operate that are subject to a high degree of uncertainty. We caution you not to give undue weight to such projections, assumptions and estimates.

PART I

Summary of Risk Factors

We face many risks and uncertainties, as more fully described in this section under the heading Item 1A. "Risk Factors." Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors."

Summary - Risks Related to Our Capital Resources

- We have incurred operating losses since inception, and we do not know if we will attain profitability.
- We have historically been dependent upon outside financing capital to fund our operations and until such time as our revenues are sufficient to finance our operating expenses, we may need to issue additional equity or debt securities to raise the capital needed to pay our operating expenses.
- We may incur significant cash payment and common stock issuance obligations under our agreements arising from our investments in IGI and Chronix.

Summary - Risks Related to Our Business Operations

- Our revenues in the near term will depend on our ability to commercialize a small number of diagnostic tests.
- The research and development work we are doing is costly, time consuming, and uncertain as to its results.
- Increased competition from, and technological advances by, our competitors could negatively affect our operating results.
- Sales of our diagnostic tests could be adversely impacted by the reluctance of physicians to adopt the use of our tests and by the availability of competing diagnostic tests.
- Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, product liability lawsuits and other litigation and negative publicity. If we are unable to obtain or maintain sufficient insurance, a product liability claim against us could adversely affect our business.
- We have limited capital, marketing, sales, and regulatory compliance resources for the commercialization of our diagnostic tests.
- We may face technology transfer challenges and expenses in adding new tests to our portfolio and in expanding our reach into new geographical areas on new instrument platforms.
- If our laboratory facilities become damaged or inoperable, or we are required to vacate any facility, our ability to provide services and pursue our research and development and commercialization efforts may be jeopardized.
- There is a limited number of manufacturers of molecular diagnostic testing equipment and related chemical reagents necessary for the provision of our diagnostic tests.
- If we fail to enter into and maintain successful strategic alliances for diagnostic tests that we elect to co-develop, co-market, or out-license, we may have to reduce or delay our diagnostic test development or increase our expenditures.
- We are, and may become, dependent on collaborations to develop and commercialize our diagnostic test candidates and to provide the manufacturing, regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.
- Our business could be adversely affected if we lose the services of the key personnel upon whom we depend.
- Our business and operations could suffer in the event of system failures.
- Security breaches and other disruptions could compromise our information and expose us to liability, and could cause our business and reputation to suffer.
- Failure of our internal control over financial reporting could harm our business and financial results.
- We are subject to laws and regulations governing corruption, which may require us to develop, maintain, and implement costly compliance programs.
- We may become subject to litigation, which could harm our stock price, business, results of operations and financial condition.
- We may undertake strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to achieve or sustain profitability.
- Our business could be adversely impacted by inflation.

Summary - Risks Related to Our Industry

- Our operations as a clinical laboratory in the United States are subject to oversight by CMS under CLIA, as well as certain state agencies, and our operation of clinical laboratories in any foreign jurisdictions are subject to similar regulatory oversight. Any failure to maintain our CLIA or applicable state or international permits and licenses may affect our ability to commercialize our diagnostic tests.
- While we believe our LDTs are within the scope of the FDA's enforcement discretion policy, and therefore not required to obtain clearance or approval before commercialization, the FDA may attempt to regulate LDTs in the future, which could lead to LDT product development delays and increased costs.

- We currently market certain IVDs for RUO that have not been cleared by the FDA in reliance on the regulatory exemption for IVDs intended for RUO, but if the FDA determines that our RUO tests do not meet the applicable requirements for exemption or have intended uses that are inconsistent with RUO tests, we may be required to suspend commercialization of such products until we can obtain the requisite FDA clearance and/or subject to FDA warning or untitled letters, seizure, injunction, fines, or other enforcement action.
- We will need to obtain FDA and other regulatory approvals for any IVDs that we may develop in order to market those IVD tests, and we may not be able to obtain those regulatory approvals in a timely manner or at all.
- Our ability to commercialize our products is dependent on availability and sufficiency of third-party payer coverage and our ability to ensure our tests remain reimbursed or attain reimbursement by Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare or the CMS would have a material adverse impact on our business.
- Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future diagnostic tests.
- Changes in healthcare laws may have a material adverse effect on our financial condition, results of operations and cash flows.
- Because of certain Medicare billing policies, we may not receive complete reimbursement for tests provided to Medicare patients.
- Long payment cycles of Medicare, Medicaid and other third-party payers, or other payment delays, could hurt our cash flows and increase our need for working capital.
- Private health insurance company policies may deny coverage or limit reimbursement for the performance of our diagnostic tests.
- We will be required to comply with federal and state laws governing the privacy of health information, and any failure to comply with these laws could result in material criminal and civil penalties.
- We are subject to numerous federal and state statutes and regulations pertaining to our business and are subject to government oversight and scrutiny for our compliance with such laws. Laboratory and health care regulatory compliance efforts are expensive and time-consuming, and failure to maintain compliance with applicable laws could result in enforcement action which could be detrimental to our business.
- Tariff policies and potential countermeasures could increase our costs and disrupt our global supply chain, which could negatively impact the results of our operations.

Summary - Risks Related to Intellectual Property

- We rely on patents and trade secrets, and our financial success will depend, in part, on our ability to obtain commercially valuable patent claims, protect our intellectual property rights and operate without infringing upon the proprietary rights of others.
- We may not be able to obtain patent protection for our diagnostic tests if our pending U.S. patent applications are found to be directed to unpatentable subject matter.
- Changes to the patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our diagnostic tests.
- Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from developing and commercializing our diagnostic tests.
- If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business would be harmed.
- We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.
- We may not be able to enforce our intellectual property rights throughout the world.
- If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our diagnostic tests.
- Failure to adequately protect, or disputes relating to, trademarks or patents, could harm our business.
- Patent terms may be inadequate to protect our competitive position on our diagnostic tests for an adequate amount of time.
- Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Summary - Risks Related to Our Common Stock

- The trading price of our common stock is highly volatile, and purchasers of our common stock could incur substantial losses.
- Because we do not pay dividends, our stock may not be a suitable investment for anyone who needs to earn dividend income.
- Securities analysts may not cover our common stock, and this may have a negative impact on the market price of our shares.
- You may experience dilution of your ownership interests if we issue additional shares of common stock or preferred stock.
- We are a “smaller reporting company” under the SEC’s disclosure rules and have elected to comply with the reduced disclosure requirements applicable to smaller reporting companies.
- Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.
- Failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.

Item 1. Business.

Overview

We are a pioneering diagnostics technology company. Our mission is to expand access to novel molecular diagnostic testing, most immediately in the transplanted organ rejection testing category.

We are developing molecular diagnostic test kits designed to empower our customers to run their own tests in-house to participate in the patient-care value chain, which is counter-positioned with the send-out-testing central laboratory model. Our decentralized approach also puts testing in the hands of researchers to enable more studies, which we believe can improve standards of care while also creating demand for more testing. We believe that combining innovative science with a simple, but disruptive, business model can create substantial value. Our initial targeted customer institutions are hospitals, transplant centers and labs. The decisions to deploy our tests come from doctors, including surgeons, nephrologists and oncologists, as well as researchers, pathologists, lab directors, medical directors, department heads, lab managers and chief medical officers.

We are a science-driven organization that champions scientific integrity and inquiry. We employ scientists who generate intellectual property in our strategic target markets. We have built and acquired an intellectual property portfolio that we believe will enable us to gain share in well-established clinical and research markets.

Our current intellectual property portfolio comprises three general areas: 1) organ transplant, 2) oncology therapy selection, and 3) oncology therapy monitoring. Within these categories, we have developed or are in the process of developing laboratory developed tests ("LDTs") that can be run at our Franklin, Tennessee laboratory, kitted research use only ("RUO") tests, and in vitro diagnostic ("IVD") kitted clinical tests that can be run by local labs.

Our primary near-term strategic market is organ transplant. We seek to deliver the industry-leading molecular diagnostic test kit for clinical use that decentralizes access to organ health testing for transplant patients. We expect that enabling in-house testing will deliver new value in the roughly $2 billion addressable market for kitted transplant rejection testing. We also believe that decentralizing access to transplanted organ rejection testing will bring care closer to the patient and help hospitals to operate more sustainably, as well as create a rapidly growing, high-margin, recurring business model.

iMDx's flagship transplant testing technology quantifies a molecular biomarker known as donor-derived cell-free DNA ("dd-cfDNA"). Our 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 transplanted organ rejection. Under the GraftAssure™ brand, iMDx's transplant diagnostics include the following:

- GraftAssureCore – The company's LDT, currently reimbursed by Centers for Medicare & Medicaid Services ("CMS") and performed at iMDx's Clinical Laboratory Improvements Amendment ("CLIA") certified laboratory in Franklin, Tennessee.
- GraftAssureIQ – An RUO kit intended and labeled for non-clinical applications.
- GraftAssureDx – The IVD kit currently in development for use in clinical decision-making.

Our GraftAssure family of assays are performed on a digital PCR instrument that is manufactured by Bio-Rad Laboratories, Inc. ("Bio-Rad"). Consequently, we have entered into a global strategic partnership agreement with Bio-Rad to collaborate in the development and the commercialization of kitted transplant products for clinical use (see Note 10, "Collaborative Arrangements," to our consolidated financial statements included elsewhere in this Report for additional information). In May 2025, we sold our first GraftAssureIQ kits to a research laboratory customer (see Note 2, "Revenue Recognition – Kitted Products," to our consolidated financial statements included elsewhere in this Report for additional information).

On February 20, 2026, we entered into a Specimen Collection Agreement with a national reference lab provider. Pursuant to the agreement, the lab provider will provide specimen collection-related services, which may include, among other things, the collection, handling, processing, and delivery of specimens upon which we will perform testing with our GraftAssureCore test. See Note 13, "Subsequent Events – Specimen Collection Agreement," to our consolidated financial statements included elsewhere in this Report for additional information.

Under strict regulatory rules, our kitted tests may not be used in a clinical treatment setting until they have attained marketing authorization from the Food and Drug Administration ("FDA") for U.S. sales, and In Vitro Diagnostic Medical Devices Regulation approval, for European Union ("EU") sales. As such, we are working with these regulatory bodies to attain such clearance and approval, as applicable, supporting future distribution and higher sales of our products for clinical use. In 2025, we started a clinical trial in conjunction with our IVD submission for GraftAssureDx. On March 25, 2026, we submitted a data package to the FDA seeking marketing authorization for GraftAssureDx, which is the kitted version of our transplanted organ rejection monitoring assay. We believe that our assays will perform across multiple tissue, or organ, types, and we are pursuing regulatory authorization in kidneys first.

We also have a services lab, certified under the CLIA and accredited by the College of American Pathologists ("CAP"), in Franklin, Tennessee, and research and development labs in Nashville, Tennessee and Göttingen, Germany. Our innovation centers in Nashville and Germany employ research scientists whom we believe are leaders in their fields.

Our secondary strategic market is in the field of oncology. The inherent uncertainties of developing and commercializing new diagnostic tests for medical use make it impossible to predict the amount of time and expense that will be required to complete the development and commercialization of our oncology tests. We continue to dedicate a minimum amount of resources to our oncology assays, DetermaIO and DetermaCNI, although currently we do not intend to commercialize either in the next 12 months.

We also perform other assay development and clinical testing services for life sciences and biotechnology companies through our Laboratory Services operations.

We believe that the experience of our team with diverse technologies through our Laboratory Services activities, strong scientific integrity regarding evidence generation and innovation mentality, alongside our flexibility in operations and regulatory strategy, will drive our success, differentiate us from our competition, and are foundational to our future. We are focusing on executing the technology priorities discussed herein, which have evolved to reflect our operations and strategic vision.

Billing, Coverage, and Reimbursement for our Laboratory Tests

We are currently in the process of developing and commercializing GraftAssureCore, GraftAssureIQ and GraftAssureDx.

Medicare

For diagnostic tests, CMS reimbursement is critically important. CMS relies on a network of Medicare Administrative Contractors ("MACs") to develop and implement local coverage determinations ("LCDs"), which are jurisdiction-specific coverage policies that define the clinical and technical criteria under which Medicare will reimburse for particular tests or services.

The MolDX Program was developed by the Palmetto GBA MAC to establish coverage and reimbursement for molecular diagnostic tests. MolDX has developed guidelines outlining the level of clinical evidence required to support positive coverage determinations under specific LCD policies. Its coverage and reimbursement decisions are followed by MACs overseeing healthcare reimbursement in 28 of 50 states.

MACs also serve as the primary operational contacts between the Medicare Fee-For-Service program, for paying Medicare claims, and the approximately 1.5 million healthcare providers enrolled in the program. Delays in obtaining MAC approval, or any changes made related to any favorable LCDs, could have a material adverse impact on our business. Any such decision could also cause affected clinicians treating Medicare-covered patients to reduce or discontinue the use of our tests. Further, third-party payers often follow Medicare coverage policy and payment limitations in setting their own coverage and payment rates and therefore their coverage and payment determinations may likewise be affected by any such decisions. See Part I, Item 1A. "Risk Factors – Risks Related to Our Industry – *Our ability to commercialize our products is dependent on availability and sufficiency of third-party payer coverage and our ability to ensure our tests remain reimbursed or attain reimbursement by Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare or the CMS would have a material adverse impact on our business*."

CMS issued a positive coverage decision for GraftAssureCore in August 2023, and since then, expanded coverage to include the test for organ rejection surveillance in certain high-risk transplant patients. In May 2025, CMS increased its reimbursement price for the assay to $2,753 per result.

Private Third-Party Payers

In addition to seeking Medicare reimbursement approval, we will seek reimbursement approval from private payers such as health insurance companies and HMOs. Private payers generally will determine whether to approve a diagnostic test for reimbursement based on the published results of clinical validity and utility studies and may base their decision on whether to cover a test, and at what level to reimburse, on the MAC's LCD. Obtaining private payer medical coverage generally takes twelve to twenty-four months from the time that sufficient evidence is demonstrated. In the interim, we will bill commercial payers and appeal any denials using the published clinical evidence supporting the utility of the test.

Reimbursement rates paid by private third-party payers can vary based on whether the laboratory is considered "in-network," "participating," "covered," "out-of-network" or "non-participating." Currently, we are out-of-network with all commercial payers. While these definitions can vary among payers, an in-network laboratory usually has a contract with the payer or benefits provider. Such contracts govern, among other things, service-level agreements and reimbursement rates. In certain instances, an insurance company may negotiate an in-network rate for our testing. An in-network laboratory may have per-test reimbursement rates that are lower than those that are out-of-network, and such rates can vary widely. Rates vary based on the payer, the testing type and often the specifics of the patient's insurance plan. If a laboratory agrees to contract as an in-network provider, it generally expects to receive faster payment and access to a larger population of covered patients. However, until we are able to negotiate contracts with commercial payers, we expect to be considered "out-of-network" or "non-participating" by payers who cover the vast majority of commercially insured patients.

We cannot predict whether, or under what circumstances, payers will reimburse for our tests or if our efforts to appeal denied claims will be successful. While we have a rigorous process for prior authorization, appeals to overturn denials, and contract negotiation with commercial payers, full or partial denial of coverage by payers, or reimbursement at inadequate levels, would have a material adverse impact on our business and on market acceptance of our tests.

Billing and Collection

Where there is a private or governmental third-party payer coverage policy in place, we will bill in accordance with the established policy. Where there is no coverage policy in place, we will pursue reimbursement on a case-by-case basis. Our efforts in obtaining reimbursement based on individual claims, including pursuing appeals or reconsideration of claims denials, could take a substantial amount of time, and bills may not be paid for many months, if at all. Furthermore, if a third-party payer denies coverage after final appeal, payment may not be received at all.

Corporate Information

We were incorporated in September 2009 in the state of California. Our principal executive offices are located at 2 International Plaza Dr., Suite 510, Nashville, Tennessee, 37217. Our telephone number is (615) 255-8880. Our website is www.imdxinc.com. Information contained on, or that can be accessed through, our website, is not, and shall not be deemed to be, incorporated into or be considered a part of this Report.

Competition

Our industry is highly competitive and characterized by rapid technological change, including the rapid expansion of the use of artificial intelligence ("AI") and machine learning. Key competitive factors in our industry include, among others, the ability to successfully complete clinical studies, the ability to obtain any required regulatory approval, average selling prices of competing tests, CLIA laboratory capacity and costs, intellectual property and patent rights, and sales and marketing capabilities. We are an early-stage company with limited resources and many of our competitors have substantially more resources than we do, including financial, technical and sales resources. In addition, many of our competitors have more experience than we have in the development and commercialization of diagnostic tests. We are also competing with academic institutions, governmental agencies and private organizations that conduct research in our field. Our competition will be determined in part by the potential indications for which our lead test candidates are developed and ultimately marketed. Additionally, the timing of market introduction of our diagnostic tests or of competitors' tests may be an important competitive factor.

Our organ transplant rejection monitoring tests compete with other methods of assessing graft organ health, such as performing a manual biopsy, as well as liquid biopsy tests from competitors that measure dd-cfDNA, including CareDx, Inc., Natera, Inc., Transplant Genomics, Omixon Inc. and Devyser. Three of our competitors (CareDx, Inc., Natera, Inc. and Transplant Genomics) have an established customer base. We aim to compete by selling test kits that enable labs to run patient samples locally. We believe that by leveraging digital PCR technology, our tests have attractive sample economics even at low volumes, offer fast turnaround times and offer native absolute quantification, which we expect may be differentiators in the marketplace. Based on our research of customer needs, we believe that turnaround time matters to practitioners and that sample economics are important to local labs.

Our oncology assets compete with multiple biomarkers already in clinical use or in development. We continue to dedicate a minimum amount of resources to our oncology assays, DetermaIO and DetermaCNI, however, we currently do not intend to begin commercializing our oncology assets in the next 12 months.

Facilities

We operate a CLIA-certified laboratory and maintain office space located in the Nashville, Tennessee area under multiple lease arrangements. Since June 2025, our Nashville location serves as our principal executive and administrative offices. We also operate a research and development laboratory and maintain office space in Göttingen, Germany under multiple lease arrangements. Our Germany lab serves as the center of excellence for our blood-based monitoring program.

Materials

There is a limited number of manufacturers of molecular testing equipment and related chemical reagents necessary for the provision of our tests. Additionally, the chemical reagents used with the testing equipment we choose are available only from the equipment manufacturer. This situation poses a risk to us. If we were to encounter inconsistent results using testing equipment and reagents from one manufacturer, we would need to switch to testing equipment from a different manufacturer. If issues were to arise with the testing equipment or with the reagents we are using, causing us to acquire different testing equipment again, we would need to conduct additional laboratory studies to determine whether our previous test results can be reproduced using the new equipment. If similar issues were to arise after commercialization of a test, we could experience a disruption in providing the tests to patients and we would lose revenue and potentially market share as a result. See Part I, Item 1A. "Risk Factors – Risks Related to Our Business Operations – *There is a limited number of manufacturers of molecular diagnostic testing equipment and related chemical reagents necessary for the provision of our diagnostic tests*."

Patents and Trade Secrets

We rely primarily on patents and contractual obligations with employees and third parties to protect our proprietary rights. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the United States and certain foreign countries. There can be no assurance that any of our patents will guarantee protection or market exclusivity for our diagnostic tests and diagnostic test candidates. We may also use license agreements both to access technologies developed by other companies and universities and to convey certain intellectual property rights to others. Our financial success will be dependent, in part, on our ability to obtain commercially valuable patent claims, to protect our intellectual property rights, and to operate without infringing upon the proprietary rights of others.

Through our acquisition of Insight Genetics, Inc. ("IGI") in January 2020 and Chronix Biomedical, Inc. ("Chronix") in April 2021, we obtained exclusive rights to additional intellectual property, including trade secrets, registered trademarks, domain names, copyrights, issued and reissued patents and pending applications, and software material, and have, since our acquisition of IGI, filed our own patents applications to protect DetermaIO in Australia, Canada, China, Europe, Japan, Korea, and the U.S.

Through our acquisition of Chronix in April 2021, we obtained intellectual property rights to nine patent families in the field of detection of cell-free tumor DNA and quantification of dd-cfDNA, with numerous already issued patents in the U.S. and EU, expiring between April 2031 and September 2035. In addition, we obtained trade secrets, registered trademarks, domain names, copyrights and proprietary software material.

On July 15, 2025, we were awarded U.S. Patent No. 12,359,252, which covers our method for detecting and treating colorectal cancer using circulating nucleic acid biomarkers. This patent reinforces our intellectual property around noninvasive cancer detection and supports our strategy to expand into blood-based cancer diagnostics. Protecting a method to identify and treat colorectal cancer using cell-free DNA from a simple blood draw opens the door for us for future screening tools that could broaden our clinical offerings and create new oncology market opportunities.

In addition to relying on patents, we rely on trade secrets, know-how, continuing technological advancement, and licensing opportunities to maintain our competitive position. The molecular diagnostics that we are developing use gene expression classifiers or algorithms, which are mathematical models that weigh the biomarkers to produce a score. We treat the mathematical models as trade secrets. We have entered into intellectual property, invention, and non-disclosure agreements with our employees, and it is our practice to enter into confidentiality agreements with our consultants. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of our trade secrets and know-how, or that others may not independently develop similar trade secrets and know-how or obtain access to our trade secrets, know-how, or proprietary technology.

General Risks Related to Obtaining and Enforcing Patent Protection

Our patents and patent applications are directed to compositions of matter, formulations, methods of use and/or methods of manufacturing. The patent positions of pharmaceutical and biotechnology companies, including ours, are generally uncertain and involve complex legal and factual questions. Our business could be negatively impacted by any of the following:

- The claims of any patents that are issued may not provide meaningful protection, may not provide a basis for commercially viable diagnostic tests or may not provide us with any competitive advantages;
- Our patents may be challenged by competitors or other third parties and, if the third parties are successful in their challenge, the patents could be invalidated, permitting third parties to use the patented inventions to compete with us;
- Others may have patents that relate to our technology or business that may prevent us from marketing our diagnostic test candidates unless we are able to obtain a license to those patents;
- Patent applications to which we have rights may not result in issued patents and the information disclosed in those applications could be used by our competitors;
- Changes in government regulations or patent laws; and
- We may not be successful in developing additional proprietary technologies that are patentable.

In addition, others may independently develop similar or alternative technologies, duplicate any of our technologies and, if patents are licensed or issued to us, design around the patented technologies licensed to or developed by us. Moreover, we could incur substantial costs in litigation if we have to defend ourselves in patent lawsuits brought by third parties or if we initiate such lawsuits. For additional information regarding the risks related to obtaining and enforcing patent protection, see Part I, Item 1A. “Risk Factors – Risks Related to Intellectual Property.”

The United States Supreme Court’s decisions in *Mayo Collaborative Services v. Prometheus Laboratories, Inc. and Association for Molecular Pathology v. Myriad Genetics* may limit our ability to obtain patent protection on diagnostic methods that merely recite a correlation between a naturally occurring event and a diagnostic outcome associated with that event. For example, in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, the Supreme Court ruled that patent protection is not available for the simple use of a mathematical correlation of the presence of a well-known naturally occurring metabolite (a body chemical) as a means of determining proper drug dosage, which may be relevant to our oncology assays under development. This ruling may limit the patentability of diagnostic methods relying on natural biological processes.

In *Association for Molecular Pathology v. Myriad Genetics*, the Supreme Court ruled that claims to isolated DNA are not patent eligible because the claims cover a product of nature. This may enable companies to develop and offer copycat-type DNA isolates and diagnostic tests for patented genes without fear of infringement because such previously existing patents are likely now invalid. In contrast, the Court held that a modified version of DNA is patent-eligible because it is not naturally occurring. This ruling may limit the patentability of composition claims on certain gene sequences.

The United States Patent and Trademark Office (the “USPTO”) has said that diagnostic processes based on natural principles can still be patentable if they include meaningful additional steps that go beyond the natural principle itself. For example, adding a specific limitation other than what is well-understood, routine, conventional activity in the field, or adding unconventional steps that confine the claim to a particular useful application can prove to be meaningful. Because our tests use new methods as well as newly discovered materials, we believe patent protection is still possible, but there is no guarantee that pending patent applications will be granted or that our existing patents would hold up if challenged.

The USPTO has also issued multiple Subject Matter Eligibility Updates, including new examples in the life sciences, to provide further guidance in determining subject matter eligibility. In one example related to diagnosing and/or treating julitis in a patient, claims that recited specific and unconventional reagents and/or treatments were determined to be patent eligible. Similarly, in another example related to screening for gene alterations, claims were considered patent eligible because they recited specific and unconventional ways of gathering data. These examples provide favorable exemplary subject matter eligibility analysis of hypothetical claims covering diagnostic tests and claims drawn from case law. This update from the USPTO does not change our opinion on our ability to obtain meaningful patent protection.

There is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third-party claims. A patent interference proceeding may be instituted with the USPTO when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent filed before March 16, 2013. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the USPTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and, if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. In addition to interference proceedings, the USPTO can review issued patents at the request of a third party seeking to have the patent invalidated. Currently an inter partes review proceeding will allow third parties to challenge the validity, based on issues of novelty and non-obviousness, in view of patents and printed publications, of an issued patent where there is a reasonable likelihood of invalidity. This means that patents owned or licensed by us may be lost if the outcome of the review is unfavorable to us.

Post Grant Review under the America Invents Act makes available opposition-like proceedings in the United States. As with the USPTO interference proceedings, Post Grant Review proceedings will be very expensive to contest and can result in invalidation of a recently issued patent. To invoke a post-grant review, a challenge must be filed within nine months of a patent's issuance or reissuance. Post-grant review can be sought based on any grounds that can be used to challenge the validity of a patent claim, with the exception of failure to disclose the best mode. Also, a derivation proceeding may be instituted by the USPTO based on a petition filed by an applicant alleging that an earlier patent or application was derived from the work of the applicant.

Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with the USPTO interference proceedings, these foreign proceedings can be very expensive to contest and can result in significant delays in obtaining a patent or can result in a denial of a patent application.

The enforcement of patent rights often requires litigation against third party infringers, and such litigation can be costly to pursue. Even if we succeed in having new patents issued or in defending any challenge to issued patents, there is no assurance that our patents will be comprehensive enough to provide us with meaningful patent protection against our competitors. Further, should we sue a third-party infringer for patent infringement, the infringer may assert counter claims and attempt to invalidate some or all of the asserted patent claims. There is always some risk that such a counter claim could result in invalidation of one or more claims of an asserted patent.

Government Regulation

CLIA—Clinical Laboratory Improvement Amendments of 1988 and State Regulation

We expect that GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO and DetermaCNI will continue to be regulated under the CLIA as LDTs. In 1988, Congress enacted CLIA, which established quality standards for all laboratories that provide testing services to ensure the accuracy, reliability and timeliness of patient test results regardless of where the test is performed.

Under CLIA, a laboratory is defined as any facility that performs laboratory testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease, or the impairment of, or assessment of health of human beings. Since our laboratory in Franklin, Tennessee meets this definition, CLIA requires that we hold a certificate applicable to the complexity of the categories of testing we perform and that we comply with certain standards. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. CLIA regulations require clinical laboratories like ours to comply with various operational, personnel, facilities administration, quality, and proficiency testing requirements intended to ensure that testing services are accurate, reliable and timely. CLIA certification is a prerequisite for reimbursement eligibility for services provided to state and federal health care program beneficiaries. CLIA is user-fee funded. Therefore, all costs of administering the program must be covered by the regulated facilities, including certification and survey costs. CMS enforces CLIA compliance. CMS granted the CAP Laboratory Accreditation Program deeming authority, which allows CAP inspection in lieu of a CMS inspection. Our laboratory in Franklin, Tennessee is CLIA-certified and CAP-accredited.

FDA Regulation of Diagnostic Tests

We believe we have designed, developed, and are validating our tests as LDTs and within the scope of the FDA's enforcement discretion policy, and therefore not required to comply with FDA requirements for medical devices, such as registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls.

However, there have been initiatives to end FDA's policy of enforcement discretion and subject IVDs to regulation as medical devices. Such initiatives have been unsuccessful, but we cannot predict whether there will be additional initiatives in the future and whether they will be successful in increasing the regulatory requirements for IVDs. For example, in May 2024, the FDA finalized a rule, amending its definition of "in vitro diagnostic products" in FDA regulations to state that IVDs are devices under the Federal Food, Drug, and Cosmetic Act "including when the manufacturer of these products is a laboratory" and announced that the general enforcement discretion approach should be phased out. Before the rule took effect, a federal district court vacated the rule, reinstating the FDA's policy of enforcement discretion.

In addition, Congress has previously considered, and may consider in the future, legislative proposals that would amend the regulatory framework for LDTs, including, among other requirements, FDA premarket review of certain LDTs. We cannot predict the outcome of any future legislation relating to the FDA's regulation of LDTs.

International Regulations

The EU has adopted the EU in vitro Diagnostics Regulation (the "EU IVDR"), which imposes stricter requirements for the marketing and sale of in vitro diagnostics products (as compared to the predecessor in vitro Diagnostics Directive), including in the areas of clinical evaluation requirements, quality systems, economic operators and post-market surveillance. Manufacturers of currently marketed in vitro diagnostics products had until May 2022 to meet the requirements of the EU IVDR, though the EU Council and Parliament signed an amendment that delays certain previously mandated deadlines to allow more time for Notified Body of EU countries to manage the entire portfolio of IVD products on the European market.

In addition, Russia has enacted more stringent medical product registration and labeling regulations, China has enacted stricter labeling requirements, and we expect other countries, such as Brazil and India, to impose more regulations that impact our product registrations. The United Kingdom's ("UK") withdrawal from the EU is resulting in additional regulatory requirements associated with goods manufactured and sold in the UK and additional complexities and delays with respect to goods, raw materials and personnel moving between the UK and the EU. In addition, new government administrations may interpret existing regulations or practices differently. Due to these evolving and diverse requirements, we face uncertain product approval timelines, additional time and effort to comply, as well as the potential for reduced sales and/or fines for noncompliance.

State Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, we are required to maintain licensure under Tennessee law for our laboratory in Franklin, Tennessee. State laws generally include standards for the day-to-day operation of a clinical reference laboratory, including the training and skills required of personnel and quality control. In addition, those laws often mandate proficiency testing, which involves testing of specimens that have been specifically prepared for the laboratory.

Some states require licensure of out-of-state laboratories that accept specimens from those states (e.g., Pennsylvania, Rhode Island, Maryland and California). Our laboratories will need to pass various state inspections in order to get licensed to provide LDTs in each of state that requires licensure. CLIA provides that a state may adopt laboratory regulations that are more stringent than those under federal law, and two states, New York and Washington, have met that standard and therefore substitute for the federal CLIA program. In addition, some, but not all, states require a separate state license or permit, which must be obtained in addition to a CLIA certificate, and some states require a laboratory doing business in that state to be licensed even if the laboratory is located in another state.

Our laboratory in Franklin, Tennessee is licensed by the appropriate state agencies in the states in which we do business, if such licensure is required. We may become aware from time to time of certain states that require out-of-state laboratories to obtain licensure to accept specimens from patients within the state. If we identify any other state with such requirements, or if we are contacted by any other state advising us of such requirements, we intend to follow all instructions from the state regulators regarding compliance with such requirements. If our laboratory is out of compliance with state laws or regulations governing licensed laboratories, a state may impose penalties, which vary from state to state but may include suspension, limitation, revocation or annulment of the license, assessment of financial penalties or fines, or imprisonment. We believe that we are in material compliance with all applicable licensing laws and regulations applicable to us.

International Laboratory Licensing

We also maintain laboratory operations in Germany and could expand our laboratory operations to other foreign jurisdictions. Therefore, we are subject to laboratory quality regulations and accreditation standards in Germany, and will be subject to such regulations and standards in any other jurisdictions where we may operate or accept samples from. These requirements may vary by jurisdiction and differ from those in the United States, and may require us to implement additional compliance measures. We believe that we are in material compliance with all applicable licensing laws and regulations applicable to us.

Regulation of Research Use Only Products

Some of our product development projects are intended to be sold for research purposes in the U.S., and labeled "For Research Use Only" or "for molecular biology applications." RUO refers to devices that are in the laboratory phase of development, while investigational use only, or IUO, refers to devices that are in the product testing phase of development. These types of devices are exempt from most regulatory controls pursuant to long-standing FDA guidance on RUO/IUO products. These products are exempt from FDA's premarket review and other requirements as long as they are not promoted for clinical diagnostic use, and iMDx does not provide technical assistance to clinical laboratories with respect to these tests. If FDA were to disagree with our designation of any of these products, we could be forced to obtain the appropriate regulatory clearances or approval prior to commercialization and could face enforcement action.

Regulation of In Vitro Diagnostics

Unless subject to an exemption, such as being labeled for research use only, IVDs are regulated by the FDA as medical devices and subject to the regulatory controls under CLIA and the Federal Food, Drug, and Cosmetic Act and the FDA's implementing regulations, including both premarket and post market regulatory controls.

The particular premarket requirements that must be met to market a medical device in the United States will depend on the classification of the device under FDA regulations based on the degree of risk it presents. Class I devices (lowest risk) are generally subject to "general controls"; Class II devices (moderate risk) are subject to general and "special controls"; and Class III devices (highest risk) typically require Premarket Approval ("PMA").

Most Class I and some Class II devices are exempt from premarket submission requirements, while most Class II devices and some Class I require a 510(k) premarket notification. while a more extensive PMA is required to market Class III devices. Class III devices typically require a PMA prior to commercialization, which is a more extensive and resource intensive process.

If we elect to develop additional IVDs or LDTs, commercialization of our future screenings diagnostics may require a 510(k) submission, authorization via the de novo pathway, or approval of a PMA, depending on classification and technology. In a 510(k) submission, the device sponsor must demonstrate that the new device is "substantially equivalent" to another device that is legally marketed in the United States, known as a predicate device. A device may be established as substantially equivalent if, in comparison to a predicate it (a) has the same intended use as the predicate and has the same technological characteristics, and safety and efficacy testing; or (b) has the same intended use as the predicate, has different technological characteristics, and the information submitted to the FDA does not raise new questions of safety and effectiveness. A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics.

A device may not be marketed in the United States until the submitter receives a letter from the FDA declaring the device substantially equivalent. If the FDA determines that a device is not substantially equivalent, the applicant may resubmit another 510(k) with new data, or request a Class I or II designation through the FDA's de novo process that allows a new device without a valid predicate to be classified into Class I or II if it meets certain criteria, or file a reclassification petition, or submit a PMA.

A new 510(k) submission is required for changes or modifications to an existing approved device, where the modifications could significantly affect the safety or effectiveness of the device or the device is to be marketed for a new or different indication for use.

A PMA for Class III devices is the most stringent type of premarket submission. Before the FDA approves a PMA, the sponsor must provide valid scientific evidence demonstrating reasonable assurance of safety and effectiveness for the device's intended use.

Health Insurance Portability and Accountability Act and Other Data Privacy and Security Laws

We are subject to an extensive and evolving framework of federal, state, and foreign laws and regulations governing the collection, use, disclosure, transfer, retention, and security of personal and sensitive information including those described further below. In the ordinary course of our operations, we collect and process health and other confidential data, which subjects us to certain federal, state, and foreign data privacy and security laws. These laws and regulations vary by jurisdiction, are frequently updated, and are interpreted and enforced differently over time. We expect to remain subject to heightened regulatory scrutiny, and any actual or perceived noncompliance with any applicable data privacy, security, or breach-notification requirements could result in significant penalties, litigation exposure, and adverse effects on our business.

Health Insurance Portability and Accountability Act

Under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), HHS has issued regulations to protect the privacy and security of protected health information ("PHI") and to address breach notification requirements. HIPAA also regulates standardization of data content, codes and formats used in health care transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA regulations include civil and criminal penalties.

The HIPAA privacy regulations cover the use and disclosure of PHI by covered entities as well as business associates, which are persons or entities that perform certain functions for or on behalf of a covered entity that involve the creation, receipt, maintenance, or transmittal of PHI. Business associates are defined to include a subcontractor to whom a business associate delegates a function, activity, or service, other than in the capacity of the business associate's workforce. As a general rule, a covered entity or business associate may not use or disclose PHI except as permitted or required under the privacy regulations. The privacy regulations also set forth certain rights that an individual has with respect to his or her PHI, including rights to access or amend certain records, to request restrictions on the use or disclosure of PHI, or to request an accounting of disclosures of his or her PHI.

Covered entities and business associates must also comply with the HIPAA's security regulations, which establish minimum requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. In addition, HITECH established, among other things, certain breach notification requirements with which covered entities and business associates must comply. In particular, a covered entity must notify any individual whose unsecured PHI is breached according to the specifications set forth in the breach notification rule. A covered entity must also notify the Secretary of the HHS and, under certain circumstances, the media of a breach of unsecured PHI.

CMS and the Office of Civil Rights issued a final rule in February 2014 to amend both the HIPAA and CLIA regulations. The final rule amended the HIPAA Privacy Rule to remove the CLIA laboratory exceptions, and as a result, HIPAA-covered laboratories are now required to provide individuals, upon request, with access to their completed test reports. Under the 2014 rule, CLIA laboratories and CLIA-exempt laboratories may provide copies of a patient's completed test reports that, using the laboratory's authentication process, can be identified as belonging to that patient. These changes to the CLIA regulations and the HIPAA Privacy Rule were intended to provide individuals with a greater ability to access their health information. CLIA laboratories must create and maintain policies, procedures, and other documentation necessary to inform patients of the right to access laboratory test reports and how to exercise that right.

HHS has pursued initiatives to update the HIPAA Privacy and Security Rules, resulting in a series of proposed and finalized changes over recent years. For example, in December 2020, HHS proposed further changes to the HIPAA Privacy Rule aiming to remove regulations that impede communication and data exchange between providers and health plans and expand individuals' rights to access their own digital health information. The public comment period for the proposed updates to the HIPAA Privacy Rule has closed, but it remains unclear how HHS has addressed those comments or when a final rule will be issued. On April 22, 2024, HHS issued a final rulemaking containing modifications to the HIPAA Privacy Rule to address the use or disclosure of PHI in relation to the provision of reproductive health care, which were later vacated in June 2025, and certain changes to Notices of Privacy Practices related to Substance Use Disorder patient records. In January 2025, HHS proposed to modify the HIPAA Security Rule to address prescriptive requirements for administrative, physical, and technical safeguards in response to increased cybersecurity incidents in the health care industry. The public comment period for the proposed updates to the HIPAA Security Rule has closed, but it remains unclear how HHS has addressed those comments or when a final rule will be issued. While final rules have not yet been issued for certain proposed updates to HIPAA Privacy and Security rules, any proposed changes, if adopted, would potentially require significant operational adjustments and costs to comply.

In addition, under the 21st Century Cures Act, the Office of the National Coordinator for Health Information Technology prohibits "information blocking," defined as practices likely to interfere with the access, exchange, or use of electronic health information ("EHI"). As a healthcare provider, our laboratory operations must comply with these regulations or face "appropriate disincentives" from HHS, which became effective in 2024 and 2025. Additionally, the HHS Office of Inspector General has the authority to impose civil monetary penalties of up to $1.0 million per violation on health information networks and developers of certified health IT. We continue to monitor our compliance with the evolving EHI exceptions and enforcement frameworks to mitigate potential regulatory and financial exposure.

State Privacy and Security Laws

The HIPAA privacy, security, and breach notification regulations establish a uniform federal "floor" for healthcare privacy and security and do not supersede state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or, insofar as such state laws apply, categories of personal information that are broader in scope than PHI as defined under HIPAA. Thus, there are a number of state laws regarding the privacy and security of health information and personal data that are applicable to clinical laboratories, and, the compliance requirements and associated penalties for violating such requirements under these state laws vary widely, with more states continuing to consider similar legislation.

For example, California has implemented comprehensive privacy laws and regulations, including the California Confidentiality of Medical Information Act ("CMIA"), which imposes restrictive requirements regulating the use and disclosure of health. In addition to fines and penalties imposed upon violators, some state laws, including the CMIA, provide private rights of action to individuals who believe their personal information has been misused.

California also enacted the California Consumer Privacy Act of 2018 ("CCPA"). The CCPA established a comprehensive privacy framework for covered businesses in the State of California, by creating an expanded definition of personal information, establishing new data privacy rights for consumers imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches. While data subject to HIPAA and federal regulations governing the conduct of clinical trials is exempt from CCPA, certain of our business activities may be subject to CCPA. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that result from a business' failure to implement and maintain reasonable data security procedures.

State laws regarding the privacy and security of personal information are also evolving. For example, in November 2020, California passed the California Privacy Rights Act ("CPRA") through a ballot initiative. The CPRA created a new California Privacy Protection Agency, an "independent watchdog" whose mission is both to "vigorously enforce" the CPRA and "ensure that businesses and consumers are well-informed about their rights and obligations." Among other things, the CPRA created a new category of "sensitive personal information" and offers consumers the right to limit processing of such information, impose purpose limitation, data minimization, data retention, and security compliance obligations on regulated businesses, and add or modify the rights available to consumers, including by providing a right to correct the information a business holds about them. The CPRA's amendments to the CCPA took effect on January 1, 2023, and generally apply to personal information collected by businesses on or after January 1, 2022. Similarly, Colorado, Connecticut, Utah and Virginia enacted comprehensive state privacy laws that took effect in 2023. Additional states including Delaware, Indiana, Iowa, Montana, New Jersey, Oregon, Tennessee and Texas have enacted similar comprehensive state privacy laws that have either taken effect or will take effect at various points between 2025 and 2026. In addition, every U.S. state has a data breach notification law that requires entities to report certain security breaches to affected consumers and, in some instances, state regulators and consumer reporting agencies. Failure to comply with applicable state laws that impose privacy, security, or breach notification requirements could result in significant civil or criminal penalties, administrative actions, or private causes of action by individuals, and adversely affect our business, results of operations and reputation.

Foreign Privacy and Security Laws

Similar health care and data privacy laws and regulations exist in Europe and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and requirements regarding the collection, distribution, use, security, and storage of personally identifiable information and other data relating to individuals, including the General Data Protection Regulation ("GDPR"), which went into effect in May 2018. The GDPR applies to any company established in the European Economic Area ("EEA"), as well as to those outside the EEA, if they collect and use personal data in connection with the offering of goods or services to individuals in the EEA or the monitoring of their behavior. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20.0 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. The GDPR provides that EU and EEA member states may introduce further conditions, including limitations, to the processing of genetic, biometric or health data, which could limit our ability to collect, use and share personal data, or could cause our compliance costs to increase, ultimately having an adverse impact on our business. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Privacy Shield was invalidated in July 2020 by the Court of Justice of the EU.

Further, from January 2021, companies have to comply with the GDPR and also the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in UK national law. The UK GDPR mirrors the fines under the GDPR, e.g. fines up to the greater of €20.0 million (£17.5 million) or 4% of global turnover. In June 2021, the European Commission implemented an adequacy decision enabling data transfers from EU member states to the UK without additional security measures. However, this adequacy decision includes a so-called "sunset-clause" stipulating that it will expire after four years, and providing that the European Commission will monitor the UK's legal situation and could intervene at any point if it determines the UK has deviated from the level of protections in place at the time of the decision. The revocation or expiration of the European Commission's adequacy decision for the UK could require additional measures to ensure adequate protection and GDPR compliance and may lead to additional costs and increases our overall risk exposure.

Physician Referral Prohibitions

Under a federal law directed at "self-referral," commonly known as the Stark Law, there are prohibitions, with certain exceptions, on Medicare and Medicaid payments for laboratory tests referred by physicians who personally, or through a family member, have a "financial relationship"—including an investment or ownership interest or a compensation arrangement—with the clinical laboratory performing the tests. Several Stark Law exceptions are relevant to arrangements involving clinical laboratories, including: (i) fair market value compensation for the provision of items or services; (ii) payments by physicians to a laboratory for clinical laboratory services; (iii) certain space and equipment rental arrangements that satisfy certain requirements, and (iv) personal services arrangements that satisfy certain requirements. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well. Penalties for violating the Stark Law include the return of funds received for all prohibited referrals, fines, civil monetary penalties and possible exclusion from the federal health care programs. Many states have comparable laws that are not limited to Medicare and Medicaid referrals.

In November 2020, CMS issued a final rule to modernize and clarify the regulations that interpret self-referral law. The final rule was issued in conjunction with the CMS Patients over Paperwork initiative and the HHS Regulatory Sprint to Coordinated Care and establishes exceptions to the physician self-referral law for certain value-based compensation arrangements between or among physicians, providers, and suppliers. It also established a new exception for certain arrangements under which a physician receives limited remuneration for items or services actually provided by the physician; established a new exception for donations of cybersecurity technology and related services; and amended the existing exception for electronic health records items and services.

Corporate Practice of Medicine

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the "corporate practice of medicine" is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, we could be required to restructure our contractual and other arrangements. In addition, violation of these laws may result in sanctions imposed against us and/or the professional through licensure proceedings, and we could be subject to civil and criminal penalties that could result in exclusion from state and federal health care programs.

Federal and State Fraud and Abuse Laws

A variety of federal and state laws prohibit fraud and abuse. These laws are interpreted broadly and enforced aggressively by various state and federal agencies, including CMS, the Department of Justice, the Office of Inspector General for HHS, and various state agencies. In addition, the Medicare and Medicaid programs increasingly use a variety of contractors to review claims data and to identify improper payments as well as fraud and abuse. These contractors include Recovery Audit Contractors, Medicaid Integrity Contractors and Zone Program Integrity Contractors. In addition, CMS conducts Comprehensive Error Rate Testing audits, the purpose of which is to detect improper Medicare payments. Any overpayments identified must be repaid unless a favorable decision is obtained on appeal. In some cases, these overpayments can be used as the basis for an extrapolation, by which the error rate is applied to a larger universe of claims, and which can result in even higher repayments.

The federal Anti-Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, to induce or in return for either the referral of an individual, or the furnishing, recommending, or arranging for the purchase, lease or order of any health care item or service reimbursable, in whole or in part, under a federal health care program. The definition of "remuneration" has been broadly interpreted to include anything of value, including gifts, discounts, credit arrangements, payments of cash, ownership interests and providing anything at less than its fair market value. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements within the health care industry, the Office of Inspector General for HHS has issued a series of regulatory "safe harbors." These safe harbor regulations set forth certain requirements that, if met, will assure immunity from prosecution under the federal Anti-Kickback Statute. Although full compliance with these provisions ensures against prosecution under the federal Anti-Kickback Statute, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the federal Anti-Kickback Statute will be pursued.

Federal civil and criminal false claims laws, including the False Claims Act, prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Violations of the False Claims Act can result in very significant monetary penalties and treble damages. Over the past few years, several healthcare companies have been prosecuted under these laws for a variety of alleged promotional and marketing activities, including without limitation, allegedly providing free trips, free goods, sham consulting fees and grants and other monetary benefits to prescribers. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Most states also have statutes or regulations similar to the federal anti-kickback law and false claims laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer.

Federal civil monetary penalties laws impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state healthcare program, unless an exception applies.

The Eliminating Kickbacks in Recovery Act ("EKRA") specifically targets laboratories, clinics, recovery centers, and other clinical treatment centers from accepting or paying kickbacks for referrals. EKRA is broader than the federal Anti-Kickback Statute because it applies to private health insurance plans in addition to the federal health care programs, and it prohibits arrangements that may otherwise be exempt from liability under the Anti-Kickback Statute's safe harbors, including certain compensation arrangements with laboratory sales and marketing personnel.

HIPAA also created federal crimes, including health care fraud and false statements relating to health care matters. The health care fraud statute prohibits knowingly and willfully executing a scheme to defraud any health care benefit program, including private third-party payers. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs, such as the Medicare and Medicaid programs. The false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. A violation of this statute is a felony and may result in fines, imprisonment or exclusion from federal health care programs.

Many states have laws similar to the federal laws described above, and state laws may be broader in scope and may apply regardless of payer.

Additionally, the U.S. Foreign Corrupt Practices Act ("FCPA") prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

Other Regulatory Requirements

Our laboratory is subject to federal, state and local regulations relating to the handling and disposal of regulated medical waste, hazardous waste and biohazardous waste, including chemical, biological agents and compounds, blood samples and other human tissue. Typically, we use outside vendors who are contractually obligated to comply with applicable laws and regulations to dispose of such waste. These vendors will be licensed or otherwise qualified to handle and dispose of such waste.

The Occupational Safety and Health Administration has established extensive requirements relating to workplace safety for health care employers, including requirements to develop and implement programs to protect workers from exposure to blood-borne pathogens by preventing or minimizing any exposure through needle stick or similar penetrating injuries.

Human Capital

As of December 31, 2025, we employed 58 persons, of which 55 were on a full-time basis and 3 were on a part-time basis.

Item 1A. Risk Factors.

Our business is subject to various risks, including those described below. The risks below are those that we believe are the material risks that we currently face but are not the only risks facing us and our business. You should consider the following risk factors, together with all of the other information included in this Report, which could materially adversely affect our proposed operations, our business prospects, our financial condition, and the value of an investment in our business. If any of the following risks, either alone or taken together, or other risks not presently known to us or that we currently believe to not be significant, develop into actual events, then our business, financial condition, results of operations or prospects could be materially adversely affected. If that happens, the market price of our common stock could decline, and stockholders may lose all or part of their investment.

Risks Related to Our Capital Resources

We have incurred operating losses since inception, and we do not know if we will attain profitability.

Since our inception in September 2009, we have incurred operating losses and negative cash flows and we expect to continue to incur losses and negative cash flows in the future. Our net losses for the years ended December 31, 2025 and 2024 were $50.2 million and $60.7 million, respectively, and we had an accumulated deficit of $400.8 million as of December 31, 2025. We finance our operations primarily through sales of our common stock. There is no assurance that we will be able to obtain any additional financing that we may need, or that any such financing that may become available will be on terms that are favorable to us and our shareholders. Ultimately, our ability to generate sufficient operating revenue to earn a profit depends upon our success in developing and marketing or licensing our diagnostic tests and technology.

We have historically been dependent upon outside financing capital to fund our operations and until such time as our revenues are sufficient to finance our operating expenses, we may need to issue additional equity or debt securities to raise the capital needed to pay our operating expenses.

We plan to continue to incur substantial research and development expenses, and we anticipate that we will be incurring significant sales and marketing costs as we develop and commercialize our diagnostic tests. Our research and development expenses may also increase if we work to develop tests for additional types of cancer or for other cancer-related diagnostic purposes. The period of time for which our current cash and marketable securities will be sufficient to finance our operations will depend on the extent to which we expend funds on commercializing our tests and conducting new research and development programs. We will need to raise additional capital to pay operating expenses unless we are able to generate sufficient revenues from diagnostic test sales, royalties, and license fees to meet our operating expenses.

Our ability to raise additional equity or debt capital will depend not only on the successful completion of development of our diagnostic tests and receiving reimbursement approval from Medicare and other third-party payers for those tests, but also will depend on access to capital and conditions in the capital markets. Obtaining Medicare reimbursement approval for our diagnostic tests could take two to three years, and investors may be reluctant to provide us with additional capital until we obtain Medicare reimbursement approval for those tests or until we can demonstrate that private payers such as health insurance companies or HMOs are willing to pay for the use of our diagnostic tests at prices sufficient for us to earn a reasonable return on our investments in our diagnostic test portfolio. There is no assurance that we will be able to raise capital at times and in amounts needed to finance the development and commercialization of our diagnostic tests and general operations. Even if capital is available, it may not be available on terms that we or our shareholders would consider favorable. If we are unable to obtain adequate financing or financing on terms satisfactory to us when and if we require it, our ability to continue to support our business growth and to respond to business challenges could be significantly impaired, and our business may be harmed.

Sales or other issuances of additional equity securities by us could result in the dilution of the interests of our stockholders, and any new equity securities we issue could have rights, preferences and privileges superior to those of holders of our common stock.

We may incur significant cash payment and common stock issuance obligations under our agreements arising from our investments in IGI and Chronix.

Under the merger agreement pursuant to which we acquired IGI, as described in Note 3 to the consolidated financial statements included elsewhere in this Report, based on current estimates, we agreed to pay contingent consideration of up to $4.5 million in any combination of cash or shares of our common stock if certain milestones related to DetermaIO are achieved, which consist of (i) $3.0 million for an affirmative final LCD from CMS for a specified lung cancer test, and (ii) up to $1.5 million for achieving certain CMS reimbursement milestones.

As additional consideration for the acquisition of Chronix, we agreed to pay to holders of other classes and series of Chronix's stock earnout consideration of (i) 10% of net collections for sales of specified tests and products, until the expiration of intellectual property related to such tests and products, and (ii) 5% of the gross proceeds received from any sale of all or substantially all of the rights, titles, and interests in and to Chronix's patents for use in transplantation medicine to such third party.

To meet these various cash payment obligations, we may need to sell additional shares of our common stock or other securities, or we may have to divert cash on hand that we would otherwise use for other business and operational purposes which could cause us to delay or reduce activities in the development and commercialization of our cancer tests. Any shares of common stock or other securities we sell to raise cash to meet our cash payment obligations will dilute the interests of our common stockholders.

Risks Related to Our Business Operations

Our revenues in the near term will depend on our ability to commercialize a small number of diagnostic tests.

Our near-term commercial efforts will focus on maximizing the opportunities for GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO and DetermaCNI. Our reliance on a small group of diagnostic tests as sources of revenue could limit our future revenue, make it more difficult for us to finance our operations, and impair our prospects for profitability and growth. DetermaIO and GraftAssureCore are currently available only in early access for non-clinical use. We plan to continue development of all five of such products for clinical and research use. However, there is no assurance that our development plans for GraftAssureCore, GraftAssureIQ, GraftAssureDx, DetermaIO or DetermaCNI will be successful or that we will generate sufficient revenues from commercialization of our diagnostic tests to finance our operations and earn a profit.

The research and development work we are doing is costly, time consuming, and uncertain as to its results.

We incurred research and development expenses amounting to approximately $15.9 million and $9.8 million during the years ended December 31, 2025 and 2024, respectively. The current focus of our research and development efforts is the development of GraftAssureCore, GraftAssureIQ and GraftAssureDx, and in 2025, we started a clinical trial in conjunction with our IVD submission for GraftAssureDx. If we are successful in developing a new technology or diagnostic tests for additional types of cancer, refinement of the new technology or diagnostic tests and definition of the practical applications and limitations of the technology or diagnostic tests may take years and require the expenditure of large sums of money. There is no assurance that we will be successful in completing the development of our current diagnostic tests or in developing additional diagnostic tests regardless of the amount of our expenditures.

Increased competition from, and technological advances by, our competitors could negatively affect our operating results.

We face intense competition, and we expect that future competition will become even more intense as new products, services and technologies become available, the use of AI and machine learning expands, and new competitors enter our industry. Our competitors in the diagnostics technology industry in the United States and abroad include companies that develop, manufacture, and sell diagnostic tests; commercial reference laboratories; certain large and well-funded pharmaceutical companies; and corporate hospital chains that operate reference laboratories that serve both their hospitals and unaffiliated hospitals. Consolidation among our competitors and our customers may intensify the competition we face. While we believe that our offerings are competitively differentiated due to our innovative products and services that offer an integrated, comprehensive diagnostic solution, there can be no assurance that increased consolidation among our competitors or customers would not have a negative impact on our ability to compete successfully.

Competition could negatively affect our sales and profitability in a number of ways. New competitors may emerge through the development of innovative new technology (such as the use of AI and machine learning), the acquisition of rights to use existing technologies or the use of existing technologies when patents protecting such existing technologies expire. New or existing competitors may introduce new, innovative, and competitive products and services more quickly, successfully and effectively, and these products and services could be superior, or be perceived by our customers to be superior, to our products and services or lead to the obsolescence of one or more of our products or services. Business combinations and mergers among our competitors may result in competitors that are better positioned to create, market, and sell more compelling product and service offerings. While an important aspect of our strategy is to continue, on a cost-effective and timely basis, to enhance our existing products and services and to develop and introduce new and innovative products and services, there can be no assurance that we will be able to successfully develop or introduce such products and services or that those products or services will be superior to our competitors' products or services or otherwise achieve customer acceptance. In addition, our ability to attract and retain customers depends on the effectiveness of our customer marketing and incentive programs, and multiple competitors could bundle product and service offerings through co-marketing or other arrangements, which could enhance their ability to compete with our broad product and service offerings. Certain of our competitors and potential competitors, including large diagnostic and pharmaceutical companies, also have substantially greater financial and managerial resources than us, as well as greater experience in manufacturing, marketing, research and development, and obtaining regulatory approvals than we do.

Sales of our diagnostic tests could be adversely impacted by the reluctance of physicians to adopt the use of our tests and by the availability of competing diagnostic tests.

Physicians and hospitals may be reluctant to try a new diagnostic test due to the high degree of risk associated with the application of new technologies and diagnostic tests in the field of human medicine, especially if the new tests differ from the current standard of care. Competing tests for organ transplant rejection monitoring and the initial diagnosis, reoccurrence diagnosis and optimal treatment of cancer are being manufactured and marketed by established companies and by other smaller biotechnology companies. In order to compete with other diagnostic tests, particularly any that sell at lower prices, our tests will have to provide medically significant advantages or be more cost effective. Even if we are able to overcome physician reluctance and compete with products that are currently on the market, our competitors may succeed in developing new safer, more accurate or more cost-effective diagnostic tests that could render our diagnostic tests and technologies obsolete or noncompetitive.

Defects, failures or quality issues associated with our products could lead to product recalls or safety alerts, adverse regulatory actions, product liability lawsuits and other litigation and negative publicity. If we are unable to obtain or maintain sufficient insurance, a product liability claim against us could adversely affect our business.

Our business exposes us to potential product liability risks that are inherent in the development, testing, manufacturing and marketing of diagnostic test kits and assays. Product liability claims could delay or prevent completion of our clinical development programs. In addition, if any of our collaboration partners face product liability claims, our programs could also be affected, and our business could be harmed. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs, and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used, or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources, substantial monetary awards to trial participants or patients and a decline in our share price.

We may not be able to maintain such insurance on acceptable terms or be able to secure increased coverage as commercialization of our products progresses, nor can we be sure that existing or future claims against us will be covered by our product liability insurance. Any insurance we obtain may not provide sufficient coverage against potential liabilities. Product liability insurance for the healthcare industry and for clinical trials may, and have become, become increasingly expensive, to the extent it is available at all. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain or maintain sufficient insurance at a reasonable cost or contractual indemnifications to protect us against losses caused by product liability claims that could adversely affect our business.

We have limited capital, marketing, sales, and regulatory compliance resources for the commercialization of our diagnostic tests.

We are building our own marketing and sales capability for our diagnostic tests and are devoting significant financial and management resources to recruiting, training, and managing our sales force and building a health care regulatory compliance program. However, due to our limited capital resources, we may need to enter into marketing arrangements with other diagnostic companies for one or more of our tests in domestic or foreign markets. Under such marketing arrangements we may license marketing rights to one or more of our diagnostic tests to other diagnostic companies or to one or more joint venture companies that may be formed to market our tests, and we might receive only a royalty on sales or an equity interest in a joint venture company. As a result, our revenues from the sale of our tests through such arrangements may be substantially less than the amount of revenues and gross profits that we might receive if we were to market our tests ourselves.

We may face technology transfer challenges and expenses in adding new tests to our portfolio and in expanding our reach into new geographical areas on new instrument platforms.

Our plan for expanding our business includes developing and acquiring additional tests that can be transferred into our current lab footprint in the United States and/or onto molecular testing instrument platforms for distribution in non-U.S. markets. Due to differences in the hardware and software platforms available at different laboratories for running molecular tests, we may need to make adjustments to the configuration of the reagents that make up our LDTs in our U.S. laboratory or as we convert them to kits, and there may be changes to the related software in order for the tests to be performed on particular hardware platforms. Making any such adjustments could take a considerable amount of time and expense, and there will be no assurance that we will succeed in running our tests on the hardware and software that we may encounter in different laboratories. To manage this issue and to attain uniformity among our laboratory locations, we may license or acquire our own instrument system and software from another company that has a platform that will be compatible with our tests. In addition to acquisition costs, operationally we will have to build out infrastructure for installing a new testing platform across multiple laboratory locations as well as support functions to help maintain these instrument systems in new customer labs, and we may also encounter unexpected technology issues in the process.

If our laboratory facilities become damaged or inoperable, or we are required to vacate any facility, our ability to provide services and pursue our research and development and commercialization efforts may be jeopardized.

We currently have a clinical laboratory facility in Franklin, Tennessee. We also have research and development labs in Nashville, Tennessee and Göttingen, Germany. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including earthquakes, power outages, wildfires, flooding, hurricanes, droughts and other extreme weather events and changing weather patterns, which are increasing in frequency due to the impacts of climate change, and may render it difficult or impossible for us to perform our tests for some period of time. The inability to perform our tests or the backlog of tests that could develop if any of our facilities is inoperable for even a short period of time may result in the loss of customers or harm to our reputation or relationships with key researchers, collaborators, and customers, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be costly and time-consuming to repair or replace.

Additionally, a key component of our research and development process involves using biological samples and the resulting data sets and medical histories, as the basis for our diagnostic test development. In some cases, these samples are difficult to obtain. If the parts of our laboratory facilities where we store these biological samples are damaged or compromised, our ability to pursue our research and development projects, commercialization of our diagnostic tests, as well as our reputation, could be jeopardized. We carry insurance for damage to our property and the disruption of our business, but this insurance may not be sufficient to cover all of our potential losses and may not continue to be available to us on acceptable terms, if at all.

Further, if our laboratories become inoperable, we may not be able to license or transfer our proprietary technology to a third-party, with established state licensure and CLIA certification under the scope of which our diagnostic tests could be performed following validation and other required procedures, to perform the tests.

Even if we find a third-party with such qualifications to perform our tests, such party may not be willing to perform the tests for us on commercially reasonable terms. Moreover, we believe our tests are currently subject to enforcement discretion by the FDA because we believe the tests currently qualify as LDTs. If, however, we are required to find a third-party laboratory to conduct our testing services, we believe this would change our status and the FDA would consider such tests offered through a third-party to then be a medical device subject to active FDA regulation and enforcement under its IVD authorities. In that case, we may be required to obtain premarket clearance or approval prior to offering, or continuing to offer, our tests, which would be time-consuming and costly and could result in interruptions and delays in our ability to sell or offer our tests.

There is a limited number of manufacturers of molecular diagnostic testing equipment and related chemical reagents necessary for the provision of our diagnostic tests.

There is a limited number of manufacturers of molecular testing equipment and related chemical reagents necessary for the provision of our tests. If issues were to arise with our equipment or if reagents we are using cause us to acquire different diagnostic testing equipment, we would need to conduct validation and analytic studies to determine whether our previous test results can be reproduced using the new equipment. As a result, we could experience delays again in developing our diagnostic tests. If similar issues were to arise after commercialization of a diagnostic test, we could experience a disruption in providing the diagnostic tests to patients and we would lose revenues and potentially market share as a result.

If we fail to enter into and maintain successful strategic alliances for diagnostic tests that we elect to co-develop, co-market, or out-license, we may have to reduce or delay our diagnostic test development or increase our expenditures.

In order to facilitate the development, manufacture and commercialization of our diagnostic tests we may enter into strategic alliances with diagnostic, pharmaceutical, or medical device companies to advance our programs and enable us to maintain our financial and operational capacity. We will face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our product development or research programs, or we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

If we are able to enter into development and marketing arrangements with diagnostic, pharmaceutical or medical device companies for our diagnostic tests, we may license product development, manufacturing, and marketing rights to the diagnostic, pharmaceutical or medical device company or to a joint venture company formed with the diagnostic, pharmaceutical or medical device company. Under such arrangements we might receive only a royalty on sales of the diagnostic tests developed or an equity interest in a joint venture company that develops the diagnostic test. As a result, our revenues from the sale of those diagnostic tests may be substantially less than the amount of revenues and gross profits that we might receive if we were to develop, manufacture, and market the diagnostic tests ourselves.

We are, and may become, dependent on collaborations to develop and commercialize our diagnostic test candidates and to provide the manufacturing, regulatory compliance, sales, marketing and distribution capabilities required for the success of our business.

We have entered into and may in the future enter into various kinds of collaborative research and development, manufacturing, and diagnostic test marketing agreements to develop and commercialize our diagnostic tests. For example, in 2024, we entered into an agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products using Bio-Rad's ddPCR instruments and reagents, pursuant to which we are dependent on Bio-Rad with respect to many of our ongoing operations and future target performance.

Any future milestone payments and cost reimbursements from collaboration agreements could provide an important source of financing for our research and development programs, thereby facilitating the application of our technology to the development and commercialization of our diagnostic tests, but there are risks associated with entering into collaboration arrangements.

There is a risk that we could become dependent upon one or more collaborative arrangements, in addition to the Bio-Rad arrangement, for diagnostic test development or manufacturing or as a source of revenues from the sale of any diagnostic tests that may be developed by us alone or through one of the collaborative arrangements. A collaborative arrangement upon which we currently, or might in the future, depend might be terminated by our collaboration partner or they might determine not to actively pursue the development or commercialization of our diagnostic tests, or they may determine to stop supporting technologies, such as instruments or consumables, upon which our diagnostic tests are reliant. A collaboration partner also may not be precluded from independently pursuing competing diagnostic tests or technologies.

There is a risk that a collaboration partner, including Bio-Rad, might fail to perform its obligations under the collaborative arrangements or may be slow in performing its obligations. In addition, a collaboration partner may experience financial difficulties at any time that could prevent it from having available funds to contribute to the collaboration. If a collaboration partner fails to conduct its diagnostic test or instrument-related development, manufacturing, commercialization, regulatory compliance, sales and marketing or distribution activities successfully and in a timely manner, or if it terminates or materially modifies its agreements with us, the development and commercialization of one or more diagnostic test candidates could be delayed, curtailed or terminated because we may not have sufficient financial resources or capabilities to continue diagnostic test development, manufacturing, and commercialization on our own.

Our business could be adversely affected if we lose the services of the key personnel upon whom we depend.

We presently rely on a small senior management team to direct our diagnostics program and our initial commercial activities. Accordingly, the loss of the services of one or more of the members of that management team could have a material adverse effect on our business.

Our business and operations could suffer in the event of system failures.

We depend on information technology and telecommunications systems, including a combination of on-site systems, managed data center systems, cloud-based systems, and the Internet, for significant elements of our operations, including processing, transmitting, and storing a wide variety of business-critical information. Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants are vulnerable to damage from computer viruses, ransomware, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruption of our operations, downtime of our information technology or telecommunications systems or those used by our third-party service providers, and could have an adverse effect on our business and results of operations. For example, the loss of data for our diagnostic test candidates could result in delays in our regulatory filings and development efforts and significantly increase our costs. To the extent that any disruption or security breach results in a loss of or damage to our data, or inappropriate disclosure of confidential or proprietary information, we could incur liability under federal or state laws, be subject to litigation, and the development of our diagnostic test candidates could be delayed.

In addition, in an effort to innovate and optimize operational efficiency, certain third parties with whom we work may integrate AI into various aspects of their work with us. We do not currently utilize AI tools in a significant way. While AI presents opportunities for enhanced productivity and innovation, it also introduces inherent risks, including legal and regulatory, that could adversely impact our business and reputation. Improper use of AI, including algorithmic biases, ethical considerations, data privacy issues, unknown or zero-day software vulnerabilities, and potential regulatory non-compliance, by our employees or third parties with whom we work could result in reputational damage, legal liabilities, and financial losses. The rapidly evolving regulatory landscape surrounding AI also poses a risk, as new laws and regulations could impose additional compliance burdens, resulting in increased operational costs. While we are committed to mitigating these risks, such measures may not adequately prevent or mitigate the adverse effects that the integration and use of AI may have on our business, financial condition, and results of operations.

Security breaches and other disruptions could compromise our information and expose us to liability, and could cause our business and reputation to suffer.

In the ordinary course of business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our business partners, PHI, and personally identifiable information of patients and employees. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based systems. We also communicate PHI and other sensitive data through our various tools and platforms. In addition to storing and transmitting sensitive data that is subject to legal protections, these applications and data encompass a wide variety of business-critical information, including research and development information, commercial information, and business and financial information. The secure processing, maintenance, and transmission of this information is critical to our operations and business strategy.

We face a number of risks relative to protecting our information, including loss of access, inappropriate disclosure, inappropriate modification, and the risk of our being unable to adequately monitor and modify our controls over our critical information. Despite our security measures, our information technology and infrastructure are also vulnerable to attacks by hackers, viruses, ransomware or breaches due to employee error, technical error, malfeasance, or other disruptions.

These types of problems may be caused by a variety of factors, including infrastructure changes, intentional or accidental human actions or omissions, software errors, malware, security attacks, fraud, spikes in customer usage and denial of service issues. From time to time, large third-party web hosting providers have also experienced outages or other problems that have resulted in their systems being offline and inaccessible. In addition to data security risks, we also face privacy risks. Should we violate, or be perceived to have violated, any privacy promises we make to patients or consumers, we could be subject to a complaint from an affected individual or interested privacy regulator, such as the FTC or a state Attorney General. This risk is heightened given the sensitivity of the data we collect.

Any problems that may arise in connection with our data and systems, including those that are hosted by third-party providers, could result in interruptions to our business and operations or exposure to security vulnerabilities. Any such breach or interruption, whether of our systems or that of our third-party service providers or their subcontractors, could also compromise our networks, and the information stored there could be accessed, publicly disclosed, lost, or stolen. Any such access, disclosure, theft, or other loss of information or privacy or security compromise could result in legal claims or proceedings or liability under federal or state laws that protect the privacy or security of personal information, including HIPAA, HITECH, and state data security and data breach notification laws. Any data privacy or security event could also disrupt our operations and damage our reputation, any of which could adversely affect our business.

If a privacy or security event occurs, we may be required to comply with state breach notification laws and become subject to mandatory corrective action. Penalties for failure to comply with a requirement of HIPAA or HITECH vary significantly, and, depending on the knowledge and culpability of the HIPAA-regulated entity, may include civil monetary penalties for each provision of HIPAA that is violated. A person who knowingly obtains or discloses individually identifiable health information in violation of HIPAA may face a criminal penalty including fines and potential imprisonment. The criminal penalties increase if the wrongful conduct involves false pretenses or the intent to sell, transfer or use identifiable health information for commercial advantage, personal gain or malicious harm. Penalties for unfair or deceptive acts or practices under the FTC Act or state Unfair and Deceptive Acts and Practices statutes may also vary significantly.

Also, even if we do not incur an interruption of our operations, or fines, penalties, or financial liability to third parties from a security breach, we could suffer a loss of confidence in our services, which could adversely affect our business and competitive position. A security event could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position.

Failure of our internal control over financial reporting could harm our business and financial results.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our consolidated financial statements; providing reasonable assurance that receipts and expenditures of our assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements would be prevented or detected on a timely basis. Due to its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our consolidated financial statements would be prevented or detected. Our growth and entry into new diagnostic tests, technologies and markets will place significant additional pressure on our system of internal control over financial reporting. Any failure to maintain an effective system of internal control over financial reporting could limit our ability to report our financial results accurately and timely or to detect and prevent fraud. Since we are a smaller reporting company, we are exempt from the requirement of having our internal controls over financial reporting audited by our independent registered public accountants, which means that material weaknesses or significant deficiencies in our internal controls that might be detected by an audit may not be detected and remedied.

We are subject to laws and regulations governing corruption, which may require us to develop, maintain, and implement costly compliance programs.

We must comply with a wide range of laws and regulations to prevent corruption, bribery, and other unethical business practices, including the FCPA, anti-bribery and anti-corruption laws in other countries. The creation and implementation of international business practices compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required.

Anti-bribery laws prohibit us, our employees, and some of our agents or representatives from offering or providing any personal benefit to covered government officials to influence their performance of their duties or induce them to serve interests other than the missions of the public organizations in which they serve. Certain commercial bribery rules also prohibit offering or providing any personal benefit to employees and representatives of commercial companies to influence performance of their duties or induce them to serve interests other than their employers. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring us to maintain books and records that accurately and fairly reflect all transactions of the corporation, including international subsidiaries, and devise and maintain an adequate system of internal accounting controls for international operations. The anti-bribery provisions of the FCPA are enforced primarily by the United States Department of Justice. The SEC is involved with enforcement of the books and records provisions of the FCPA.

Compliance with these anti-bribery laws is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the anti-bribery laws present particular challenges in the medical industry because in many countries including China, hospitals are state-owned or operated by the government, and doctors and other hospital employees are considered foreign government officials. Furthermore, in certain countries (China in particular), hospitals and clinics are permitted to sell pharmaceuticals to their patients and are primary or significant distributors of pharmaceuticals. Certain payments to hospitals in connection with clinical studies, procurement of pharmaceuticals and other work have been deemed to be improper payments to government officials that have led to vigorous anti-bribery law enforcement actions and heavy fines in multiple jurisdictions, particularly in the United States and China.

It is not always possible to identify and deter violations, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations.

In the medical industry, corrupt practices include, among others, offering or accepting kickbacks, bribes or other illegal gains or benefits by the hospitals and medical practitioners from manufacturers of pharmaceutical or other products, distributors or their third-party agents in connection with the prescription of certain pharmaceuticals or sale of products. If our employees, affiliates, distributors or third-party marketing firms violate these laws or otherwise engage in illegal practices with respect to their sales or marketing of our products or other activities involving our products, we could be required to pay damages or heavy fines by multiple jurisdictions where we operate, which could materially and adversely affect our financial condition and results of operations. There have been recent occurrences in which certain hospitals have denied access to sales representatives from pharmaceutical companies because the hospitals wanted to avoid the perception of corruption. If this attitude becomes widespread among our potential customers, our ability to promote our products to hospitals may be adversely affected.

If we and our subsidiaries further expand operations internationally, we will need to increase the scope of our compliance programs to address the risks relating to the potential for violations of the FCPA and other anti-bribery and anti-corruption laws and data protection laws. Our compliance programs will need to include policies addressing not only the FCPA, but also the provisions of a variety of anti-bribery and anti-corruption laws in multiple foreign jurisdictions, provisions relating to books and records that apply to us as a public company, and include effective training for our personnel throughout our organization. The creation and implementation of anti-corruption compliance programs is costly and such programs are difficult to enforce, particularly where reliance on third parties is required. Violation of the FCPA and other anti-corruption and data privacy laws can result in significant administrative and criminal penalties for us and our employees, including substantial fines, suspension or debarment from government contracting, prison sentences, or even the death penalty in extremely serious cases in certain countries. The SEC also may suspend or bar us from trading securities on U.S. exchanges for violation of the FCPA's accounting provisions. Even if we are not ultimately punished by government authorities, the costs of investigation and review, distraction of our personnel, legal defense costs, and harm to our reputation could be substantial and could limit our profitability or our ability to develop or commercialize our product candidates. In addition, if any of our competitors are not subject to the FCPA, they may engage in practices that will lead to their receipt of preferential treatment from foreign hospitals and enable them to secure business from foreign hospitals in ways that are unavailable to us.

We may become subject to litigation, which could harm our stock price, business, results of operations and financial condition.

We may be subject to litigation from time to time. In the past, following periods of volatility in the market price of their stock, many companies have been the subjects of securities class action litigation. Any such litigation can result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, results of operations and financial condition. As a result of these factors, holders of our common stock might be unable to sell their shares at or above the price they paid for such shares.

We may undertake strategic acquisitions in the future, and difficulties integrating such acquisitions could damage our ability to achieve or sustain profitability.

We may acquire businesses or assets that complement or augment our existing business. If we acquire businesses with promising products or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to move one or more products through preclinical and/or clinical development to regulatory approval and commercialization. Integrating any newly acquired businesses or technologies could be expensive and time-consuming, resulting in the diversion of resources from our current business. We may not be able to integrate any acquired business successfully, and we may not achieve revenues, specific net income or loss levels that justify the acquisition or that the acquisition will result in increased earnings, or reduced losses, for the combined company in any future period. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, which would result in dilution for stockholders or the incurrence of indebtedness and may not be available on terms which would otherwise be acceptable to us. We may not be able to operate acquired businesses profitably or otherwise implement our growth strategy successfully.

Our business could be adversely impacted by inflation.

Inflation rates, particularly in the United States, have increased recently. We may experience inflationary pressures, primarily in personnel costs, with certain laboratory supplies, from inventory costs related to certain raw materials, with essential vendors including audit fees and regulatory consultants, and from tariff policies and potential countermeasures. Prices for raw materials may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, fuel related delivery costs, competition, import duties, excises and other indirect taxes, currency exchange rates, and government regulation. The extent of any future impacts from inflation on our business and our results of operations will depend upon how long the elevated inflation levels persist and the extent to which the rate of inflation were to further increase, if at all, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents may be further diminished, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third-party payors, we may be unable to pass along cost increases for key components or raw materials through higher prices to our customers. Further, given the complexities of the reimbursement landscape in which we operate, our payers may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts. As such, the effects of inflation may adversely impact our results of operations, financial condition and cash flows.

Risks Related to Our Industry

Our operations as a clinical laboratory in the United States are subject to oversight by CMS under CLIA, as well as certain state agencies, and our operation of clinical laboratories in any foreign jurisdictions are subject to similar regulatory oversight. Any failure to maintain our CLIA or applicable state or international permits and licenses may affect our ability to commercialize our diagnostic tests.

We are subject to CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. Our clinical laboratories must be certified under CLIA in order for us to perform testing on human specimens. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. We have a current certificate under CLIA to perform routine chemistry. To renew these certificates, our diagnostic laboratories are subject to survey and inspection every two years. Moreover, CLIA inspectors may make periodic inspections of our clinical laboratories outside of the renewal process.

The law also requires us to maintain a state laboratory license to conduct testing in the states in which our laboratories are located. State laws establish standards for day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. In addition, several states require that we hold licenses to test specimens from patients in those states. We do not have immediate plans to market our tests for commercial use in the EU and as a result, at this time we do not believe we are subject to EU or EU member state post-market regulations related to our tests.

If we were to lose our CLIA certification or a required state license for a laboratory, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our tests from the affected laboratory, which would limit our revenue and harm our business. If we were to lose our license in other states where we are required to hold licenses, we would not be able to test specimens from those states. If we perform testing on samples originating in a state where we require a license, but do not currently have one, we could be subject to fines, sanctions, and may be denied permits or licenses in the future.

We also maintain laboratory operations in Germany and could expand our laboratory operations to other foreign jurisdictions. Therefore, we are subject to laboratory quality regulations and accreditation standards in Germany, and will be subject to such regulations and standards in any other jurisdictions where we may operate. These requirements may vary by jurisdiction and differ from those in the United States, and may require us to implement additional compliance measures. If we fail to comply with any foreign jurisdiction’s applicable laboratory regulations and standards it could limit our revenue and harm or business and we could be subject to fines and other sanctions.

While we believe our LDTs are within the scope of the FDA's enforcement discretion policy, and therefore not required to obtain clearance or approval before commercialization, the FDA may attempt to regulate LDTs in the future, which could lead to LDT product development delays and increased costs.

The FDA has a long-standing policy of enforcement discretion for LDTs, meaning the tests are not subject to the FDA's medical device regulations. In May 2024, the FDA published a final rule that proposed to phase out its enforcement discretion policy for LDTs, unless exempt, and proposed to amend the FDA's regulations to make explicit that IVDs are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the diagnostic product is a laboratory. This final rule would have subjected LDTs to the same regulatory requirements as medical devices, including, in some cases, requiring pre-market clearance or approval. However, in March 2025, following a legal challenge to the FDA's authority to regulate LDTs, the Eastern District of Texas vacated the final rule. The FDA did not appeal the decision to vacate the final rule, and, in September 2025, the FDA formally revoked the final rule, retaining the enforcement discretion policy for LDTs.

As a result, we do not believe our LDT products are currently required to receive FDA clearance or approval prior to use or otherwise comply with the FDA's medical device regulations. However, the FDA may try to regulate LDTs in the future, and we cannot be certain any future attempt to regulate LDTs will be vacated. Any future LDT rule could subject our current or future LDT products to additional regulatory requirements, including pre-market clearance or approval requirements, which could delay or halt commercialization of our tests, increase costs and materially and adversely affect our business, financial condition, and results of operations.

In addition, while we believe our LDTs are within the scope of the FDA's enforcement discretion policy, the FDA may disagree and consider our LDTs to be IVDs. If so, our tests would be required to obtain FDA clearance or approval to be marketed in the United States, which could interrupt commercialization of our tests pending such clearance or approval. Obtaining FDA clearance or approval can be unpredictable, time-consuming, and costly, and would likely materially and adversely affect our business, financial condition, and results of operations.

We currently market certain IVDs for RUO that have not been cleared by the FDA in reliance on the regulatory exemption for IVDs intended for RUO, but if the FDA determines that our RUO tests do not meet the applicable requirements for exemption or have intended uses that are inconsistent with RUO tests, we may be required to suspend commercialization of such products until we can obtain the requisite FDA clearance and/or subject to FDA warning or untitled letters, seizure, injunction, fines, or other enforcement action.

Some of our tests are marketed for RUO, which allows us to sell such products without the premarket clearance that FDA requires for the marketing of traditional devices. An RUO product may not be marketed for clinical diagnostic use and must be labeled "For Research Use Only. Not for use in diagnostic procedures." Products that are intended for research use only and are properly labeled as RUO are exempt from compliance with the FDA's pre- and post-market requirements to which traditional devices are subject, including the requirement that the product be cleared or approved before commercialization and Quality System Regulation requirements. However, merely including the required RUO labeling will not necessarily exempt the device from the FDA's 510(k) clearance, premarket approval, or other requirements if the circumstances surrounding the distribution of the product indicate an objective intent to market the product for clinical diagnostic use.

According to the FDA guidance, circumstances indicating manufacturer intent to market an in vitro device for diagnostic use may include written or verbal marketing claims regarding a product's clinical efficacy or performance in clinical applications, instructions for clinical interpretation, clinical information, product names, or descriptors that claim or suggest that the IVD product may be used for any clinical diagnostic use, including a clinical investigation that is not exempt from the FDA's investigational device exemption regulations. Other indications include a manufacturer's provision of technical support for clinical validation or clinical applications or solicitation of business from clinical laboratories that do not conduct research activities, all of which could be considered evidence of intended uses that conflict with RUO labeling.

In general, if (i) evidence shows that one or more of our IVDs are inappropriately labeled RUO (but marketed for clinical diagnostic use), such test(s) will not qualify for an IDE exemption and will be deemed misbranded under the Federal Food, Drug, and Cosmetic Act ("FDCA"). Device manufacturers found in violation of the FDCA may be subject to a wide range of enforcement action, including warning letters, seizure, injunction, criminal prosecution, monetary penalties, and others.

We believe that our promotional activities for our RUO products fall within the scope of the applicable premarket exemptions for RUO tests and the FDA's enforcement discretion, as described in its relevant guidance. However, the FDA could disagree and require us to (i) stop promoting our RUO devices unless/until we obtain FDA clearance or approval (among other possible outcomes). Any adverse determination in relation to our marketing of current or future products for RUO will likely have a material adverse impact on our business.

We will need to obtain FDA and other regulatory approvals for any IVDs that we may develop in order to market those IVD tests, and we may not be able to obtain those regulatory approvals in a timely manner or at all.

If we decide to develop IVDs, we will need to obtain regulatory clearance or approval to market each IVD test. This means that:

- The IVDs cannot be sold until the CMS or the FDA, and corresponding foreign regulatory authorities approve or authorize the IVDs for medical use;
- We will have to conduct expensive and time-consuming clinical trials of new diagnostic tests. The full cost of conducting and completing clinical trials necessary to obtain FDA clearance or approval of IVD tests or for gaining reimbursement from health insurance companies, health maintenance organizations, Medicare, and other third-party payers cannot be presently determined but could exceed our financial resources;
- Data obtained from preclinical and clinical studies is susceptible to varying interpretations that could delay, limit or prevent regulatory agency clearances or approvals. Delays or denials of the regulatory clearances or approvals may be encountered as a result of changes in regulatory agency policy, regulations, or laws;
- A diagnostic test that is cleared or approved for marketing may be subject to restrictions on use; and
- The FDA can withdraw approval of an FDA regulated product if problems arise.

We have submitted a De Novo request with the FDA to obtain authorization for GraftAssureDx. While we believe our submission will be sufficient to support FDA authorization, we cannot be certain that the FDA will clear or approve GraftAssureDx for commercialization in the United States. If the FDA determines that our submission is insufficient, we may be asked to update our submission with new information, including, but not limited to, new safety and efficacy data generated from additional clinical trials. As a result, the need for additional information could be costly and significantly delay, or prevent, obtaining authorization to commercialize GraftAssureDx in the United States.

In addition, the ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. In addition, the U.S. government has shut down multiple times in the past (including the shutdown that started on October 1, 2025 and became the longest government shutdown in history based on data going back to fiscal 1977) and certain regulatory agencies, such as the FDA, had to furlough employees and stop some of their activities. The effects of any prolonged government shutdown (including effects related to the shutdown that began October 2025) or a widespread freeze on federal funding could significantly impact the ability of the FDA to timely review and process our regulatory submissions, or cause other agencies that support the FDA to slow their work. Any such factors could have a material adverse effect on our business.

Further, presidential and congressional seat turnover may result in increased regulatory and economic uncertainty, including the spending priorities of the new U.S. presidential administration and Congress and what challenges budget reductions will present for us and our industry generally. For example, on January 20, 2025, President Trump announced an executive order establishing the "Department of Government Efficiency" to reform federal government processes and reduce expenditures. Changes in federal policy by the executive branch and regulatory agencies may occur over time through the new presidential administration's and/or Congress's policy and personnel changes, which could lead to changes involving our industry. However, the nature and timing of such potential changes remain highly uncertain. At this time, it is unclear whether and how any future changes or uncertainty surrounding future changes will adversely affect our business, but material adverse effects are possible.

Our ability to commercialize our products is dependent on availability and sufficiency of third-party payer coverage and our ability to ensure our tests remain reimbursed or attain reimbursement by Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare or the CMS would have a material adverse impact on our business.

Our ability to successfully commercialize our current diagnostic tests and any product candidates we receive regulatory approval to market will depend, in significant part, on the extent to which appropriate reimbursement levels can be obtained for patients. Physicians will be hesitant to order a diagnostic test for a patient when they may be left with a large out-of-pocket fee through co-payments or co-insurance or unreimbursed balances. Third-party payers, including Medicare, Medicaid and private insurers, are increasingly challenging the prices charged for healthcare products and services. In addition, legislative proposals to reform health care or reduce government insurance programs may result in lower prices or the actual inability of prospective customers to purchase our tests. Furthermore, even if reimbursement is available, it may not be available at price levels sufficient for us to realize a positive return on our investment.

Our primary near-term strategic market is organ transplant. We received a positive coverage decision from MolDx for GraftAssureCore (Kidney) in August of 2023, and it became commercially available for ordering in January 2024. In December 2024, we confirmed Medicare reimbursement for also monitoring certain high-risk patients, that is, those with newly developed donor-specific antibodies. However, we may not be able to ensure our tests remain reimbursed or attain reimbursement by Medicare for a variety of reasons, including changes in reimbursement practices, general policy shifts, or reductions in reimbursement amounts. We cannot predict whether Medicare reimbursements will continue at the same payment amount or with the same breadth of coverage in the future, if at all.

For diagnostics tests, Medicare or CMS reimbursement approval is critical. CMS relies on a network of MACs to make LCDs approving test for reimbursements. The MolDx Program was developed by Palmetto GBA (the previous MAC for California) to identify and establish coverage and reimbursement for molecular diagnostics tests. The program has developed guidelines for the level of evidence of efficacy required to be obtained through clinical trials. Palmetto, which contracted with CMS to administer the MolDx, issues LCDs that affect coverage, coding, and billing of many molecular tests and several MACs including the MAC for California, Noridian Healthcare Solutions, LLC, participate in the MolDX program. MACs also serve as the primary operational contact between the Medicare Fee-For-Service program, for paying Medicare claims, and approximately 1.5 million health care providers enrolled in the program. Delays in obtaining MAC approval, or any changes made related to any favorable LCDs, could have a material adverse impact on our business.

For example, on July 17, 2025, several MolDx MACs published a new "MolDX: Molecular Testing for Solid Organ Allograft Rejection" draft LCD (L38671), that, if adopted, would revise the existing foundational LCD, "MolDX: Molecular Testing for Solid Organ Allograft Rejection" (L38568 and L38629). In the draft LCD, surveillance use is explicitly contemplated and MolDx proposes capping the number of surveillance tests for kidney in year-one at four and subsequent years at two per year, and year-one tests for heart and lung would be capped at 12 tests per year. The comment period ran from July 17, 2025 through August 31, 2025 and an open meeting was held August 25, 2025.

If future reimbursement price levels are less than the current price, our revenues and our ability to achieve profitability could be impaired, and the market price of our common stock could decline. We may also not be able to maintain or increase the portion of our tests reimbursed by Medicare for a variety of other reasons, including changes in reimbursement practices and general policy shifts.

We cannot predict whether any current or future MAC will provide or continue to provide reimbursement for GraftAssureCore (Kidney) at the same payment amount or with the same breadth of coverage in the future, if at all. Additional changes in the MAC processing Medicare claims for GraftAssureCore (Kidney) could impact the coverage or payment amount for our tests and our ability to obtain Medicare coverage for any products we may launch in the future.

Any decision by CMS or its local contractors to reduce or deny coverage for our tests would have a significant adverse effect on our revenue and results of operations and ability to operate and access capital. Any such decision could also cause affected clinicians treating Medicare-covered patients to reduce or discontinue the use of our tests. Further, third-party payers often follow Medicare coverage policy and payment limitations in setting their own coverage and payment rates and therefore their coverage and payment determinations may likewise be affected by any such decisions.

Even if a diagnostic test receives coverage and reimbursement from third-party payers, such coverage policies and reimbursement rates may change at any time, might not be adequate, or less favorable coverage policies and reimbursement rates may be implemented in the future. We may need to conduct additional studies in order to demonstrate the cost-effectiveness of our diagnostic tests to the satisfaction of our target customers and their third-party payers. Such studies might require us to commit a significant amount of management time and financial and other resources. If we are unable to obtain and maintain sufficient third-party coverage and adequate reimbursement for a diagnostic test, its commercial success may be greatly hindered, and our financial condition and results of operations may be materially and adversely affected.

Clinical trial failures can occur at any stage of the testing and we may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent commercialization of our current or future diagnostic tests.

Clinical trial failures or delays can occur at any stage of the trials, and may be directly or indirectly caused by a variety of factors, including but not limited to:

- Delays in securing clinical investigators or trial sites for our clinical trials;
- Delays in obtaining Institutional Review Board and other regulatory approvals to commence a clinical trial;
- Slower than anticipated rates of patient recruitment and enrollment, or failing to reach the targeted number of patients due to competition for patients from other trials;

- Limited or no availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payers for the use of our diagnostic test candidates in our clinical trials;
- Negative or inconclusive results from clinical trials;
- Approval and introduction of new diagnostic tests or changes in standards of practice or regulatory guidance that render our clinical trial endpoints or the targeting of our proposed indications obsolete;
- Inability to monitor patients adequately during or after treatment or problems with investigator or patient compliance with the trial protocols;
- Inability to replicate in large controlled studies safety and efficacy data obtained from a limited number of patients in uncontrolled trials; and
- Inability or unwillingness of medical investigators to follow our clinical protocols.

Any of the foregoing factors as well as other unforeseen events could delay or prevent commercialization of our current or future diagnostic tests and adversely affect our business, financial condition and results of operations.

Changes in healthcare laws and policies may have a material adverse effect on our financial condition, results of operations and cash flows.

We cannot predict whether future healthcare initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The United States government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement and coverage. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could exclude or limit one or more of our diagnostic tests from coverage.

For instance, the payment reductions imposed by healthcare reform legislation known as the Patient Protection and Affordable Care Act ("ACA"), the expansion of the federal and state governments' role in the U.S. healthcare industry, and the changes to the reimbursement amounts paid by payers for our tests and future tests and products may reduce our profits and have a material adverse effect on our business, financial condition, results of operations and cash flows. Notably, Congress enacted legislation in 2017 that eliminated the ACA's "individual mandate," a provision that required individuals to buy health insurance or pay a fine, which has impacted the number of covered lives participating in exchange plans. In June 2021, the U.S. Supreme Court dismissed a judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. We cannot be certain that there will not be further legislative efforts or judicial challenges in the future.

The Trump administration may also significantly alter the current regulatory framework and the healthcare industry, including any further challenges of certain ACA provisions. These changes could have an adverse and material impact on our operations. For example, the staff of the Department of Government Efficiency (the "DOGE"), an executive administrative agency created by the second Trump Administration, have been provided access to key payment and contracting systems at CMS to look for opportunities for improving efficiency and to identify fraud and ineffective use of resources. While we cannot predict other actions of the DOGE, there is a possibility that additional changes will be made to CMS spending, which could ultimately affect our financial condition and results of operations.

In addition, the Trump administration previously issued a memorandum instructing U.S. executive agencies to prepare for reductions in workforce at governmental agencies, which included the FDA. If the current administration takes further actions that substantially reduces FDA's workforce, in particular, at the Center for Devices and Radiological Health, we may face significant delay in obtaining approval, if required, and subsequently marketing future product candidates.

Further, on July 4, 2025, President Trump signed the One Big Beautiful Bill Act into law which, among other things, is expected to reduce funding to federal healthcare programs and impose additional requirements to be eligible for healthcare, changes that could lead to decreased utilization of Medicare and Medicaid reimbursed items, and could ultimately affect our financial condition and results of operations.

Additionally, the Protecting Access to Medicare Act ("PAMA") significantly altered the payment methodology under the Clinical Laboratory Fee Schedule that determines Medicare coverage for laboratory tests. Under PAMA (as amended by the Further Consolidated Appropriations Act, 2020 and the Coronavirus Aid, Relief, and Economic Security Act, respectively) and its implementing regulations, clinical laboratories must report to the CMS, the administrator of CLIA, private payer rates for clinical diagnostic laboratory tests. Laboratories that fail to timely report the required payment information may be subject to substantial civil money penalties. Medicare payments for clinical diagnostic laboratory tests are paid based upon these reported private payer rates. For certain clinical diagnostic laboratory tests that are not designated as advanced diagnostic laboratory tests, initial payment rates will be assigned by the cross-walk or gap-fill methodology. For laboratory tests that are designated as new advanced diagnostic laboratory tests, initial payment rates will be based on the actual list charge for the laboratory test.

If future reimbursement price levels are less than the current price, our revenues and our ability to achieve profitability could be impaired, and the market price of our common stock could decline. Additionally, any decision by CMS or its local contractors to reduce or deny coverage for our tests would have a significant adverse effect on our revenue and results of operations and ability to operate and raise capital. Any such decision could also cause affected clinicians treating Medicare-covered patients to reduce or discontinue the use of our tests.

Because of certain Medicare billing policies, we may not receive complete reimbursement for tests provided to Medicare patients.

Medicare has coverage policies that can be national or regional in scope. Coverage means that the test or assay is approved as a benefit for Medicare beneficiaries. If there is no coverage, neither the supplier nor any other party, such as a diagnostic laboratory, may receive reimbursement from Medicare for the service. Regional policies are directed by Medicare's regional MACs. Reimbursement for our diagnostic testing may be negatively impacted by MAC policies and we may not receive complete reimbursement for tests provided to Medicare patients due to such policies.

Long payment cycles of Medicare, Medicaid and other third-party payers, or other payment delays, could hurt our cash flows and increase our need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that we will have to satisfy in order to receive payment. Failure to comply with these requirements and other laws applicable to billing may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and civil or criminal liabilities, any of which may have a material adverse effect on our revenues and earnings. Similarly, the failure of private health insurers or other private third-party payers to properly process our payment claims in a timely manner could delay our receipt of payment for our diagnostic tests and services, which may have a material adverse effect on our cash flows.

Private health insurance company policies may deny coverage or limit reimbursement for the performance of our diagnostic tests.

Patients who are not covered by Medicare will generally rely on health insurance provided by private health insurance companies. However, private third-party payers often follow Medicare coverage policy and payment limitations in setting their own coverage and payment rates. If we are considered a "non-contracted provider" by a third-party payer, that payer may not reimburse patients for diagnostic tests performed by us, or doctors within the payer's network of covered physicians may not use our services to perform diagnostic tests for their patients. As a result, we may need to enter into contracts with health insurance companies or other private payers to provide diagnostic tests to their insured patients at specified rates of reimbursement which may be lower than the rates we might otherwise collect.

We will be required to comply with federal and state laws governing the privacy of health information, and any failure to comply with these laws could result in material criminal and civil penalties.

HIPAA sets forth security regulations that establish administrative, physical and technical standards for maintaining the confidentiality, integrity and availability of PHI in electronic form. We also may be required to comply with state laws that are more stringent than HIPAA or that provide individuals with greater rights with respect to the privacy or security of, and access to, their health care records. HITECH established certain health information security breach notification obligations that require covered entities to notify each individual whose PHI is breached.

We may incur significant compliance costs related to HIPAA and HITECH privacy regulations and varying state privacy regulations and varying state privacy and security laws. Given the complexity of HIPAA and HITECH and their overlap with state privacy and security laws, and the fact that these laws are rapidly evolving and are subject to changing and potentially conflicting interpretation, our ability to comply with HIPAA, HITECH and state privacy requirements is uncertain and the costs of compliance are significant. The costs of complying with any changes to the HIPAA, HITECH and state privacy restrictions may have a negative impact on our operations. Noncompliance could subject us to criminal penalties, civil sanctions and significant monetary penalties as well as reputational damage.

We are subject to numerous federal and state statutes and regulations pertaining to our business and are subject to government oversight and scrutiny for our compliance with such laws. Laboratory and health care regulatory compliance efforts are expensive and time-consuming, and failure to maintain compliance with applicable laws could result in enforcement action which could be detrimental to our business.

We are subject to extensive and frequently changing federal and state laws governing various aspects of our business, including those related to reimbursements by third-party payers for any of our commercialized diagnostic tests. We are subject to ongoing compliance with laws addressing our laboratory licensure and certification at the federal and state level; advertising and promotion (including laws enforced by the FDA and Federal Trade Commission); and laws intended to prevent fraud, waste, and abuse in healthcare programs (including, among others, the Anti-Kickback Statute, False Claims Act, EKRA, the Stark Law, and applicable state law equivalents).

These laws and regulations are complex and are subject to interpretation by the courts and by government agencies. If one or more such agencies alleges that we may be in violation of any of these requirements, regardless of the outcome, it could damage our reputation and adversely affect important business relationships with third parties. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including civil and criminal penalties, damages and fines, and in some circumstances we could be required to refund payments received by us from payers, or even be excluded from participation in healthcare programs. Any of the foregoing consequences could seriously harm our business and our financial results.

We plan to adopt policies and procedures designed to comply with applicable laws and regulations. Developing a compliance infrastructure is costly and time-consuming, and even a well-designed and implemented compliance program cannot necessarily prevent all violations of relevant laws. We may be subject to enforcement action based on the actions or omissions of employees or contractors, including our anticipated sales force.

Tariff policies and potential countermeasures could increase our costs and disrupt our global supply chain, which could negatively impact the results of our operations.

President Trump has increased, and has indicated his willingness to continue to increase, the use of tariffs by the U.S. to accomplish certain U.S. policy goals. Such tariffs and any countermeasures could increase the cost of raw materials and components necessary for our operations, disrupt our global supply chain and create additional operational challenges. Further, it is possible that government policy changes and related uncertainty about policy changes could increase market volatility. Because of these dynamics, we cannot predict the impact of any future changes to the U.S.'s or other countries' trading relationships or the impact of new laws or regulations adopted by the U.S. or other countries on our business. Such changes in tariffs and trade regulations could have a material adverse effect on our financial condition, results of operations and cash flows.

Risks Related to Intellectual Property

We rely on patents and trade secrets, and our financial success will depend, in part, on our ability to obtain commercially valuable patent claims, protect our intellectual property rights and operate without infringing upon the proprietary rights of others.

We rely primarily on patents and contractual obligations with employees and third parties to protect our proprietary rights. We have sought, and intend to continue to seek, appropriate patent protection for important and strategic components of our proprietary technologies by filing patent applications in the United States and certain foreign countries. We may also use license agreements both to access technologies developed by other companies and universities and to convey certain intellectual property rights to others. Our financial success will depend, in part, on our ability to obtain commercially valuable patent claims, protect our intellectual property rights and operate without infringing upon the proprietary rights of others.

The patent positions of biotechnology companies, including our patent position, involve complex legal and factual questions, and, therefore, the issuance, scope, validity and enforceability of any patent claims that we may obtain cannot be predicted with certainty. Patents, if issued, may be challenged, deemed unenforceable, invalidated, or circumvented. A third-party may submit prior art, or we may become involved in opposition, derivation, reexamination, inter partes review, post-grant review, supplemental examination, or interference proceedings challenging our patent rights or the patent rights of our licensors or development partners. The costs of defending or enforcing our proprietary rights in these proceedings can be substantial, and the outcome can be uncertain. An adverse determination in any such submission or proceeding could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, or reduce our ability to manufacture or commercialize products. Furthermore, if the scope or strength of protection provided by our patents and patent applications is threatened, it could discourage companies from collaborating with us to license, develop or commercialize current or future products. The ownership of our proprietary rights could also be challenged.

Moreover, the issuance of a patent, while presumed valid and enforceable, is not conclusive as to its validity or its enforceability and it may not provide us with adequate proprietary protection or competitive advantages against competitors with similar products. Competitors may also be able to design around our patents. Other parties may develop and obtain patent protection for more effective technologies, designs or methods.

We may not be able to obtain patent protection for our diagnostic tests if our pending U.S. patent applications are found to be directed to unpatentable subject matter.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. For example, recent cases have held that diagnostic methods merely reciting a correlation between a naturally occurring event and a diagnostic outcome associated with that event is not patentable subject matter. If our pending U.S. patent applications are found to be directed to unpatentable subject matter by the USPTO, or any patents issuing from our pending patent applications are invalidated based on these decisions, we may be unable to prevent competitors from using the biomarkers or other subject matter disclosed in the patent applications to develop similar diagnostic tests that would compete with our tests. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Changes to the patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our diagnostic tests.

Our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is costly, time-consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act ("Leahy-Smith Act"), signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. In addition, the Leahy-Smith Act has transformed the U.S. patent system into a "first to file" system, which became effective in March 2013. The Leahy-Smith Act and its implementation may make it more difficult to obtain patent protection for our inventions and increase the uncertainties and costs surrounding the prosecution of our or our collaboration partners' patent applications and the enforcement or defense of our or our collaboration partners' issued patents, all of which could harm our business, results of operations and financial condition.

Other companies or organizations may challenge our patent rights or may assert patent rights that prevent us from developing and commercializing our diagnostic tests.

Any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third-party claims. A patent interference proceeding may be instituted with the USPTO when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent filed before March 16, 2013. At the completion of the interference proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are complex, highly contested legal proceedings, and the USPTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a patent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. In addition to interference proceedings, the USPTO can review issued patents at the request of a third party seeking to have the patent invalidated. An *inter partes* review proceeding allows third parties to challenge the validity of an issued patent where there is a reasonable likelihood of invalidity. This means that patents owned or licensed by us may be subject to administrative review and may be lost if the outcome of the review is unfavorable to us.

Post Grant Review under the Leahy-Smith Act makes available opposition-like proceedings in the United States. As with the USPTO interference proceedings, Post Grant Review proceedings will be very expensive to contest and can result in significant delays in obtaining patent protection or can result in a denial of a patent application. Further, a derivation proceeding may be instituted by the USPTO or an inventor alleging that a patent or application was derived from the work of another inventor.

Oppositions to the issuance of patents may be filed under European patent law and the patent laws of certain other countries. As with the USPTO interference proceedings, these foreign proceedings can be very expensive to contest and can result in significant delays in obtaining a patent or can result in a denial of a patent application.

The enforcement of patent rights often requires litigation against third party infringers, and such litigation can be costly to pursue. Even if we succeed in having new patents issued or in defending any challenge to issued patents, our patents may not be comprehensive enough to provide us with meaningful patent protection against our competitors.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, and our business would be harmed.

In addition to patents, we rely on trade secrets, know-how, and continuing technological advancement to maintain our competitive position. The molecular diagnostics that we are developing use gene expression classifiers or algorithms, which are mathematical models that weight the biomarkers to produce a score. We will treat the mathematical models as trade secrets. We have also entered into intellectual property, invention, and non-disclosure agreements with our employees, and it is our practice to enter into confidentiality agreements with our consultants. These measures, however, may not prevent the unauthorized disclosure or use of our trade secrets and know-how, or that others may not independently develop similar trade secrets and know-how or obtain access to our trade secrets, know-how, or proprietary technology.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. Even if the validity of such patents is upheld, the court may construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors, and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question, in which case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we may not have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may not be able to enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents, if issued, on our diagnostic test candidate in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly in developing countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our diagnostic tests in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws. Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and certain developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These products may compete with our diagnostic test, and our patents, if issued, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our diagnostic test, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our diagnostic tests. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our diagnostic tests.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our current or future diagnostic test, including interference proceedings before the USPTO, misappropriation claims, or other allegations. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. For example, the biotechnology and pharmaceutical industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our diagnostic tests or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

We may not have identified all patents, published applications or published literature that affect our business either by blocking our ability to commercialize our products or potential products, by preventing the patentability of one or more aspects of our products or potential products to us or our licensors, or by covering the same or similar technologies that may affect our ability to market our products and potential products. For example, we (or the licensor of a product or potential product to it) may not have conducted a patent clearance search sufficient to identify potentially obstructing third party patent rights. Moreover, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the USPTO, for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside of the United States are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in scientific or patent literature often lags behind actual discoveries. We cannot be certain that we or our licensors were the first to invent, or the first to file, patent applications covering our products. We also may not know if our competitors filed patent applications for technology covered by our pending applications or if we were the first to invent the technology that is the subject of our patent applications. Competitors may have filed patent applications or received patents and may obtain additional patents and proprietary rights that block or compete with our patents.

If we are found to infringe a third party's intellectual property rights, we may have to pay monetary damages, lose valuable intellectual property rights or personnel, or be forced to cease developing, manufacturing or commercializing the infringing diagnostic test. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing diagnostic test. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our diagnostic tests or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated confidential information or trade secrets of third parties could have a similar negative impact on our business.

Failure to adequately protect, or disputes relating to, trademarks or patents, could harm our business.

We cannot be certain that the legal steps we are taking are sufficient to protect our trademark and patent rights or that, notwithstanding legal protection, others will not infringe or misappropriate our intellectual property rights. In addition, we could come into conflict with third parties over trademark or patent rights, which could result in disruptive and expensive litigation. Challenges to our trademarks or patents could result in significant costs related to the prosecution or defense of the registrations of our trademarks or patents or rebranding if we need to abandon or modify a trademark or patent.

Even if we have or obtain trademarks and patents covering our products, we may still be prevented from making, using, selling, offering for sale, or importing our products or technologies because of the trademark and patent rights of others. Others may have filed, and in the future may file, trademark or patent applications covering technologies or products that are similar or identical to ours. These filings could materially affect our ability to develop or sell our products. Because trademark and patent applications can take many years to issue and are not published for a period of time after filing, there may be currently pending applications unknown to us that may later result in issued trademarks or patents that our products or technologies may infringe. These trademark and patent applications may have priority over trademark and patent applications filed by us.

Patent terms may be inadequate to protect our competitive position on our diagnostic tests for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new diagnostic tests, patents protecting such candidates might expire before or shortly after such candidates are commercialized. We expect to seek extensions of patent terms in the United States and, if available, in other countries where we are prosecuting patents. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, which is limited to the approved indication or any additional indications approved during the period of extension. However, the applicable authorities, including the FDA and the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and pre-clinical data and launch their product earlier than might otherwise be the case.

Obtaining and maintaining patent protection depends on compliance with various procedures and other requirements, and our patent protection could be reduced or eliminated in case of non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the relevant patent agencies in several stages over the lifetime of the patents and/or applications. The relevant patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which failure to comply with the relevant requirements can result in the abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to use our technologies and know-how which could have a material adverse effect on our business, prospects, financial condition and results of operation.

Risks Related to Our Common Stock

The trading price of our common stock is highly volatile, and purchasers of our common stock could incur substantial losses.

The market price of our common stock has been and is likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by us or by our competitors, including announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships or capital commitments;
- additions or departures of key personnel;
- changes in expectations as to our future financial performance;
- sales of our common stock;
- our ability to execute our business plan;
- loss of any strategic relationship;
- industry developments;
- changes in financial estimates by any securities analysts who follow our common stock, our failure to meet these estimates or failure of those analysts to initiate or maintain coverage of our common stock;
- general market conditions, including market volatility and inflation;
- fluctuations in stock market prices and trading volumes of similar companies;
- economic, political and other external factors;
- period-to-period fluctuations in our financial results;
- applicable regulatory developments in the United States and foreign countries, both generally or specific to us and our products; and
- intellectual property, product liability or other litigation against us.

Although publicly traded securities are subject to price and volume fluctuations, it is likely that our common stock will experience these fluctuations to a greater degree than the securities of more established and better capitalized organizations.

Because we do not pay dividends, our stock may not be a suitable investment for anyone who needs to earn dividend income.

We do not pay cash dividends on our common stock. For the foreseeable future we anticipate that any earnings generated in our business will be used to finance the growth of our business and will not be paid out as dividends to our shareholders. Consequently, shareholders' ability to achieve a return on their investment will depend on appreciation in the price of our common stock.

Securities analysts may not initiate coverage or continue to cover our common stock, and this may have a negative impact on the market price of our shares.

The market for our common stock will depend, in part, on the research and reports that securities analysts publish about our business and our common stock. We do not have any control over these analysts. Certain securities analysts cover our shares and they could issue reports or recommendations that are unfavorable to the price of our shares, and they could downgrade a previously favorable report or recommendation, and in either case our share price could decline as a result of the report. If one or more of these analysts ceases to cover our shares or fails to publish regular reports on our business, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

You may experience dilution of your ownership interests if we issue additional shares of common stock or preferred stock.

In the future, we may issue our authorized but previously unissued equity securities, resulting in the dilution of the ownership interests of our present shareholders. We are currently authorized to issue an aggregate of 235,000,000 shares of capital stock consisting of 230,000,000 shares of common stock and 5,000,000 "blank check" shares of preferred stock. As of December 31, 2025, there were 28,682,844 shares of common stock outstanding, 760,866 shares of common stock reserved for issuance upon the exercise of warrants, 3,412,814 shares of common stock reserved for issuance upon the exercise of pre-funded warrants, 2,251,000 shares of common stock reserved for issuance upon the exercise of options under our equity incentive plan, and 852,000 shares of common stock reserved for issuance upon the vesting of restricted stock units under our equity incentive plan. No shares of preferred stock are presently outstanding.

We may issue additional common stock or other securities that are convertible into or exercisable for common stock in order to raise additional capital, or in connection with hiring or retaining employees, directors, or consultants, or in connection with future acquisitions of licenses to technology or diagnostic tests in connection with future business acquisitions, or for other business purposes. The future issuance of any such additional common stock or other securities may create downward pressure on the trading price of our common stock.

We may also issue preferred stock having rights, preferences, and privileges senior to the rights of our common stock with respect to dividends, rights to share in distributions of our assets if we liquidate our company, or voting rights. Any preferred stock may also be convertible into common stock on terms that would be dilutive to holders of common stock.

We are a "smaller reporting company" under the SEC's disclosure rules and have elected to comply with the reduced disclosure requirements applicable to smaller reporting companies.

As a smaller reporting company, we have elected to adopt the accommodations for scaled-back disclosure in our SEC filings, resulting in less information about our Company being available compared to other public companies. We are also a non-accelerated filer and are not required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. Our internal controls over financial reporting will not receive the level of review provided by the process relating to the auditor attestation included in annual reports of issuers that are subject to these requirements.

We cannot predict if investors will find our common stock less attractive because we are not required to comply with more robust disclosure or the auditor attestation requirements. If investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and trading prices may be negatively affected.

Failure to establish and maintain adequate finance infrastructure and accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in a demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002 and related rules and regulations, expanded disclosure requirements, accelerated reporting requirements and complex accounting rules. Responsibilities imposed by the Sarbanes-Oxley Act include establishing and maintaining corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud.

In particular, our compliance with Section 404 of the Sarbanes-Oxley Act has required and will continue to require that we incur substantial accounting-related expenses and expend significant management efforts. Our testing, or the testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls that we would be required to remediate in a timely manner. If we are not able to comply with the requirements of the Sarbanes-Oxley Act, we could be subject to sanctions or investigations by the SEC, the Nasdaq Stock Market or other regulatory authorities, which would require additional financial and management resources and could adversely affect the market price of our securities. Furthermore, if we cannot provide reliable financial reports or prevent fraud, our business and results of operations would likely be materially adversely affected.

Failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a delisting of our common stock.

Our shares of common stock are currently listed for trading on The Nasdaq Capital Market under the symbol "IMDX." If we fail to satisfy the continued listing requirements of The Nasdaq Stock Market, LLC ("Nasdaq"), such as the corporate governance requirements, the shareholder's equity requirement or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting or even notification of failure to comply with such requirements would likely have a negative effect on the price of our common stock and would impair our shareholders' ability to sell or purchase our common stock when our shareholders wish to do so. In the event of a delisting, we expect that we would take actions to restore our compliance with Nasdaq s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future noncompliance with Nasdaq's listing requirements.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity.

We develop and maintain a cyber risk management program designed to identify, assess, manage, mitigate and respond to cybersecurity threats. The program is one component of our enterprise risk management system. The technical, administrative and physical controls underlying our program are based on nationally recognized practices and standards for cybersecurity.

Trusted partners are an important part of our cyber risk management program. We partner with leading cybersecurity advisors and service providers to conduct periodic risk assessments and to monitor and maintain the performance and effectiveness of security controls used in our environment.

In addition, we maintain processes to assess and manage risks relating to third-party service providers, including based on the nature of the engagement with the third party and based on the information and information systems to which the third party will have access. We conduct due diligence before onboarding new service providers and maintain ongoing evaluations to ensure compliance with our security standards.

The Audit Committee of the Board of Directors (the "Audit Committee") oversees our management of enterprise risks, including cybersecurity risks. Members of the management team, including our IT director and General Counsel, brief the Audit Committee and the Board of Directors on the effectiveness of risk management efforts on a regular basis.

Our cyber risk management program helps mitigate risks that could have a material adverse effect on our business, financial condition, results or operations, cash flows or reputation. See "Risk Factors – Risks Related to Our Business Operations – *Security breaches and other disruptions could compromise our information and expose us to liability, and could cause our business and reputation to suffer*."

Item 2. Properties.

Our principal executive and administrative offices and our CLIA-certified laboratory are located in the Nashville, Tennessee area under multiple lease arrangements. We maintain an aggregate of 12,881 square feet of rentable space in the Nashville area with expiration dates through September 2028. Lab space represents approximately 6,586 square feet of the total rentable space in the Nashville area.

We also have a research and development laboratory and office space located in Göttingen, Germany, under multiple lease arrangements. We maintain an aggregate of 3,455 square feet of rentable space in Germany with expiration dates through September 2030. Lab space represents approximately 2,077 square feet of the total rentable space in Germany.

Our former principal executive and administrative offices were located in Irvine, California under a 26,800 square feet lease that expires on October 31, 2027. Effective in September 2023, we entered into a sublease agreement with a subtenant to initially sublet approximately 13,400 square feet. In June 2025, the portion of the Irvine lease that was subleased automatically increased to include the remaining portion of the premises, which consists of approximately 13,400 square feet for a term that will continue to the expiration of the Irvine lease on October 31, 2027. The sublease agreement is subject and subordinate to the Irvine lease. In June 2025, in connection with the subtenant's full usage of the Irvine premises, we relocated our offices to Nashville, Tennessee.

See Note 6, "Commitments and Contingencies – Office and Facilities Leases," to our consolidated financial statements included elsewhere in this Report for additional information regarding our lease arrangements and properties.

Item 3. Legal Proceedings.

From time to time, we may be involved in routine litigation incidental to the conduct of our business. We are not presently involved in any material pending litigation or proceedings. See Note 6, "Commitments and Contingencies – Litigation – General," to our consolidated financial statements included elsewhere in this Report for additional information.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our new common stock trading symbol "IMDX" became effective on The Nasdaq Capital Market on June 18, 2025. On February 7, 2023, our common stock began trading on The Nasdaq Capital Market under the symbol "OCX."

Dividends

We have not declared or paid any cash dividends on our common stock. Any future decision to declare or pay dividends will be at the sole discretion of our Board of Directors.

Holders

As of March 19, 2026, we had approximately 170 holders of record of our common stock. This number does not include shareholders whose shares of our common stock are held in "street name" in accounts with securities broker-dealers or other financial institutions or fiduciaries.

Recent Sales of Unregistered Securities

On October 24, 2025, November 24, 2025, December 24, 2025, January 26, 2026 and March 16, 2026, we issued to LifeSci Advisors, LLC ("LifeSci") 1,207 shares, 1,309 shares, 1,375 shares, 1,218 shares and 1,418 shares of our common stock, respectively, in exchange for investor relations services. The shares issued to LifeSci were issued without registration under the Securities Act in reliance on the exemption from registration under Section 4(a)(2).

Repurchases

None.

Item 6. [RESERVED]

Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following Management's Discussion and Analysis of Financial Condition and Results of Operations is intended to provide information necessary to understand our consolidated financial statements for the years ended December 31, 2025 and 2024 included elsewhere in this Report, and highlight certain other information which, in the opinion of management, will enhance a reader's understanding of our financial condition, changes in financial condition and results of operations. These historical consolidated financial statements may not be indicative of our future performance. This Management's Discussion and Analysis of Financial Condition and Results of Operations contains a number of forward-looking statements, all of which are based on our current expectations and could be affected by the uncertainties and risks described throughout this filing, particularly under "Risk Factors" in Part I, Item 1A. of this Report. For additional information, refer to the section above entitled "Cautionary Note Regarding Forward-Looking Statements." The following discussion should be read in conjunction with our consolidated financial statements and the related notes thereto provided under Part IV, Item 15(a)(1) of this Report.

Overview

We are a pioneering diagnostics technology company. Our mission is to expand access to novel molecular diagnostic testing, most immediately in the transplanted organ rejection testing category.

We are developing molecular diagnostic test kits designed to empower our customers to run their own tests in-house to participate in the patient-care value chain, which is counter-positioned with the send-out-testing central laboratory model. Our decentralized approach also puts testing in the hands of researchers to enable more studies, which we believe can improve standards of care while also creating demand for more testing. We believe that combining innovative science with a simple, but disruptive, business model can create substantial value. Our initial targeted customer institutions are hospitals, transplant centers and labs. The decisions to deploy our tests come from doctors, including surgeons, nephrologists and oncologists, as well as researchers, pathologists, lab directors, medical directors, department heads, lab managers and chief medical officers.

We are a science-driven organization that champions scientific integrity and inquiry. We employ scientists who generate intellectual property in our strategic target markets. We have built and acquired an intellectual property portfolio that we believe will enable us to gain share in well-established clinical and research markets.

Our current intellectual property portfolio comprises three general areas: 1) organ transplant, 2) oncology therapy selection, and 3) oncology therapy monitoring. Within these categories, we have developed or are in the process of developing LDTs that can be run at our Franklin, Tennessee laboratory, kitted RUO tests, and IVD kitted clinical tests that can be run by local labs.

Our primary near-term strategic market is organ transplant. We seek to deliver the industry-leading molecular diagnostic test kit for clinical use that decentralizes access to organ health testing for transplant patients. We expect that enabling in-house testing will deliver new value to the market for kitted transplant rejection testing. We also believe that decentralizing access to transplanted organ rejection testing will bring care closer to the patient and help hospitals to operate more sustainably, as well as create a rapidly growing, high-margin, recurring business model.

iMDx's flagship transplant testing technology quantifies a molecular biomarker known as dd-cfDNA. Our 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 transplanted organ rejection. Under the GraftAssure™ brand, iMDx's transplant diagnostics include the following:

- GraftAssureCore – The company's LDT, currently reimbursed by CMS and performed at iMDx's CLIA certified laboratory in Franklin, Tennessee.
- GraftAssureIQ – An RUO kit intended and labeled for non-clinical applications.
- GraftAssureDx – The IVD kit currently in development for use in clinical decision-making.

Our GraftAssure family of assays are performed on a digital PCR instrument that is manufactured by Bio-Rad. Consequently, we have entered into a global strategic partnership agreement with Bio-Rad to collaborate in the development and the commercialization of kitted transplant products for clinical use (see Note 10, "Collaborative Arrangements," to our consolidated financial statements included elsewhere in this Report for additional information). In May 2025, we sold our first GraftAssureIQ kits to a research laboratory customer (see Note 2, "Revenue Recognition – Kitted Products," to our consolidated financial statements included elsewhere in this Report for additional information).

On February 20, 2026, we entered into a Specimen Collection Agreement with a national reference lab provider. Pursuant to the agreement, the lab provider will provide specimen collection-related services, which may include, among other things, the collection, handling, processing, and delivery of specimens upon which we will perform testing with our GraftAssureCore test. See Note 13, "Subsequent Events – Specimen Collection Agreement," to our consolidated financial statements included elsewhere in this Report for additional information.

Under strict regulatory rules, our kitted tests may not be used in a clinical treatment setting until they have attained marketing authorization from the FDA for U.S. sales, and In Vitro Diagnostic Medical Devices Regulation approval, for European Union sales. As such, we are working with these regulatory bodies to attain such clearance and approval, as applicable, supporting future distribution and higher sales of our products for clinical use. In 2025, we started a clinical trial in conjunction with our IVD submission for GraftAssureDx. On March 25, 2026, we submitted a data package to the FDA seeking marketing authorization for GraftAssureDx, which is the kitted version of our transplanted organ rejection monitoring assay. We believe that our assays will perform across multiple tissue, or organ, types, and we are pursuing regulatory authorization in kidneys first.

We also have a services lab, certified under the CLIA and accredited by the CAP, in Franklin, Tennessee, and research and development labs in Nashville, Tennessee and Göttingen, Germany. Our innovation centers in Nashville and Germany employ research scientists whom we believe are leaders in their fields.

Our secondary strategic market is in the field of oncology. The inherent uncertainties of developing and commercializing new diagnostic tests for medical use make it impossible to predict the amount of time and expense that will be required to complete the development and commercialization of our oncology tests. We continue to dedicate a minimum amount of resources to our oncology assays, DetermaIO and DetermaCNI, although currently we do not intend to commercialize either in the next 12 months.

We also perform other assay development and clinical testing services for life sciences and biotechnology companies through our Laboratory Services operations.

We believe that the experience of our team with diverse technologies through our Laboratory Services activities, strong scientific integrity regarding evidence generation and innovation mentality, alongside our flexibility in operations and regulatory strategy, will drive our success, differentiate us from our competition, and are foundational to our future. We are focusing on executing the technology priorities discussed herein, which have evolved to reflect our operations and strategic vision.

Recent Developments

February 2025 Offering

On February 10, 2025, we consummated a private placement of our securities to certain accredited investors for the issuance and sale of 7,536,706 shares of our common stock and pre-funded warrants to purchase 3,069,926 shares of our common stock, with an exercise price of $0.0001 per share (the "February 2025 Offering"). The purchase price for one common share was $2.05, and the purchase price for one pre-funded warrant was $2.05. Further, on February 10, 2025, we consummated a registered direct offering of our securities to certain investors for the issuance and sale of 3,609,755 shares of our common stock, priced at-the-market under the rules of the Nasdaq. The purchase price for one common share was $2.05. The aggregate gross proceeds from the February 2025 Offering were approximately $29.1 million. After deducting offering expenses of $487,000, the resulting net proceeds were approximately $28.7 million. See Note 7, "Common Stock – February 2025 Offering," to our consolidated financial statements included elsewhere in this Report for additional information.

Renaming and Relocation of Principal Executive Office

In June 2025, we changed our name from "Oncocyte Corporation" to "Insight Molecular Diagnostics Inc." Our new trading symbol "IMDX" became effective on the Nasdaq on June 18, 2025. In addition, in June 2025, we moved our headquarters from Irvine, California, to Nashville, Tennessee. Tennessee is home to our CLIA certified lab and a growing hub for healthcare innovation. On June 13, 2025, we amended and restated our Second Amended and Restated Bylaws solely to reflect the name change.

February 2026 Offering

On February 12, 2026, we consummated a registered direct offering of our securities to certain investors for the issuance and sale of 3,482,498 shares of our common stock and pre-funded warrants to purchase 1,043,478 shares of our common stock, with an exercise price of $0.0001 per share (the "February 2026 Offering"). The purchase price for one common share was $5.75, and the purchase price for one pre-funded warrant was $5.75, minus the $0.0001 exercise price per pre-funded warrant. The gross proceeds from the February 2026 Offering were approximately $26.0 million. After deducting placement agent fees and offering expenses payable of $1.4 million, the resulting net proceeds were approximately $24.6 million. See Note 13, "Subsequent Events – Registered Direct Offering," to our consolidated financial statements included elsewhere in this Report for additional information.

Specimen Collection Agreement

On February 20, 2026, we entered into a Specimen Collection Agreement with a national reference lab provider. Pursuant to the agreement, the lab provider will provide specimen collection-related services, which may include, among other things, the collection, handling, processing, and delivery of specimens upon which we will perform testing with our GraftAssureCore test. See Note 13, "Subsequent Events – Specimen Collection Agreement," to our consolidated financial statements included elsewhere in this Report for additional information.

Results of Operations

Summary Results of Operations

	Years Ended December 31,			
	2025	2024	$ Change	% Change
	(In thousands, except percentage change values)			
Net revenue	$ 4,055	$ 1,881	$ 2,174	116%
Cost of revenues	1,750	1,053	697	66%
Cost of revenues – amortization of acquired intangibles	7	88	(81)	(92)%
Research and development	15,900	9,839	6,061	62%
Sales and marketing	6,343	3,944	2,399	61%
General and administrative	10,633	10,204	429	4%
Change in fair value of contingent consideration	5,946	(4,275)	10,221	(239)%
Impairment losses	14,600	41,900	(27,300)	(65)%
Impairment loss on held for sale assets	—	169	(169)	(100)%
Loss from operations	(51,124)	(61,041)	9,917	(16)%
Total other income, net	902	378	524	139%
Loss before income taxes	(50,222)	(60,663)	10,441	(17)%
Income taxes	—	—	—	—
Net loss	$ (50,222)	$ (60,663)	$ 10,441	(17)%

Results of Operations – Year Ended December 31, 2025 Compared with the Year Ended December 31, 2024

Total net revenue increased to $4.1 million for the year ended December 31, 2025, compared to $1.9 million in the comparable prior period primarily from Laboratory Services as further discussed below. Future Laboratory Services revenue is expected to be impacted as a result of our shift in strategic focus on commercializing our transplant kitted tests, and deploying our sales personnel toward signing new laboratory customers.

Net loss was $50.2 million for the year ended December 31, 2025, compared to $60.7 million for the comparable prior period. Net loss decreased by $10.4 million primarily due to a decrease in impairment losses and an increase in Laboratory Services revenue, which were partially offset by increases in operating expenses and the change in fair value of contingent consideration. Further details related to the change in net loss are as follows:

- Laboratory Services revenue increased by $2.2 million. We earned Laboratory Services revenue primarily from one existing customer in the amount of approximately $4.0 million during 2025. In addition, we earned our first Kitted Products revenue in the amount of approximately $24,000 during 2025. See below for additional revenue information.
- Cost of revenues increased by $697,000, primarily related to labor and allocated overhead associated with performing our Laboratory Services, and Kitted Products inventory costs and royalties based on net product sales. See below for additional cost of revenues information.

- Cost of revenues - amortization of acquired intangibles decreased by $81,000. This relates to noncash amortization of our customer relationship intangible assets acquired as part of our merger with IGI, which became fully amortized in the first quarter of 2025.
- Research and development expenses increased by $6.1 million, as we continue development of GraftAssureCore, GraftAssureIQ and GraftAssureDx. The main drivers of the increase were professional fees, laboratory costs, and clinical trial costs, partially offset by stock-based compensation. See below for additional details.
- Sales and marketing expenses increased by $2.4 million, primarily attributable to continued ramp up in sales, marketing and advertising activities related to the transplant business. The main drivers of the increase were personnel-related expenses, depreciation and amortization, marketing and advertising, professional fees, and travel and entertainment. See below for additional details.
- General and administrative expenses increased by $429,000, primarily due to increases in personnel-related expenses and board fees, and stock-based compensation, partially offset by facilities and insurance, and professional fees. See below for additional details.
- Change in fair value of contingent consideration was a loss of $5.9 million in 2025 compared to a gain of $4.3 million in 2024. This change was due to changes in the fair value model inputs and revised estimates on if and when future payouts will occur. See below for additional information.
- For the periods presented, impairment losses relate to our in-process research and development intangible assets. During the fourth quarter of 2025, it was determined that our DetermaIO and DetermaCNI intangible assets were fully impaired, amounting to $14.6 million. During the fourth quarter of 2024, it was determined that our DetermaIO and DetermaCNI intangible assets were impaired by $41.9 million. See Note 5 to our consolidated financial statements included elsewhere in this Report for additional information.
- Impairment loss on held for sale assets in 2024 relates to various agreements to sell laboratory equipment and the subsequent fair value adjustments. See Note 2, “Assets Held for Sale,” to our consolidated financial statements included elsewhere in this Report for additional information.
- Total other income, net increased by $524,000, primarily due to additional interest income related to higher cash balances from our February 2025 Offering, partially offset by additional foreign currency losses and interest expense related to our financing leases. See below for additional details.

Revenues

The following table shows our revenues by type:

	Years Ended December 31,			
	2025	2024	$ Change	% Change
	(In thousands, except percentage change values)			
Laboratory Services	$ 4,031	$ 1,859	$ 2,172	117%
Laboratory Developed Test Services	—	22	(22)	(100)%
Kitted Products	24	—	24	100%
Total	$ 4,055	$ 1,881	$ 2,174	116%

Laboratory Services are generally performed on a time and materials basis. Upon our completion of the service to the customer in accordance with the contract, we have the right to bill the customer for the agreed upon price (either on a per test or per deliverable basis) and recognize the Laboratory Services revenue at that time, on an accrual basis. Laboratory Services revenues are generated under discrete agreements for particular customer projects that generally expire with the completion or termination of the customer’s project. Accordingly, different customers may account for greater or lesser portions of Laboratory Services during different accounting periods, and Laboratory Services revenues may exhibit a larger variance from accounting period to accounting period than other revenues. Future Laboratory Services revenue is expected to be impacted as a result of our shift in strategic focus on commercializing our transplant kitted tests, and deploying our sales personnel toward signing new laboratory customers. See Note 2, “Revenue Recognition – Laboratory Services” and “Disaggregation of Revenues and Concentrations of Credit Risk,” to our consolidated financial statements included elsewhere in this Report for additional information.

Laboratory Developed Test Services generally related to payments received from sales prior to the Razor Sale Transaction (see Note 2, "Investments in Privately Held Companies," to our consolidated financial statements included elsewhere in this Report). We generated revenue from performing DetermaRx tests on clinical samples through orders received from physicians, hospitals, and other healthcare providers. For all payers other than Medicare, we needed to consider the novelty of the test, the uncertainty of receiving payment, or being subject to claims for a refund, from payers with whom iMDx did not have a sufficient payment collection history or contractual reimbursement agreements. Accordingly, for those payers, we recognized revenue upon payment. See Note 2, "Revenue Recognition – Laboratory Developed Test Services," to our consolidated financial statements included elsewhere in this Report for additional information.

Kitted Products include our GraftAssureIQ RUO kitted tests sold to research laboratory customers, which are clearly labeled and intended for research purposes. GraftAssureIQ is a transplant monitoring assay to measure the dd-cfDNA molecular biomarker. See Note 2, "Revenue Recognition – Kitted Products," to our consolidated financial statements included elsewhere in this Report for additional information.

Cost of Revenues

Cost of revenues generally consists of cost of materials, direct labor including benefits, bonus and stock-based compensation, equipment and infrastructure expenses, clinical sample related costs associated with performing Laboratory Services and Laboratory Developed Test Services, providing deliverables according to our licensing agreements, license fees due to third-parties, amortization of acquired intangible assets, and Kitted Products inventory costs and royalties based on net product sales. Infrastructure expenses include depreciation of laboratory equipment, allocated rent costs, leasehold improvements, and allocated information technology costs for operations at iMDx's CLIA-certified laboratory in Tennessee. Costs associated with generating service revenue are recorded as the tests or services are performed regardless of whether revenue was recognized. Royalties or revenue share payments for licensed technology calculated as a percentage of revenues generated using the associated technology, or from product sales, are recorded as expenses at the time the related revenues are recognized. Cost of revenues for Laboratory Services varies depending on the nature, timing, and scope of customer projects.

Research and Development Expenses

A summary of the main drivers of the change in research and development expenses is as follows:

	Years Ended December 31,			
	2025	2024	$ Change	% Change
	(In thousands, except percentage change values)			
Personnel-related expenses	$ 4,417	$ 4,352	$ 65	1%
Depreciation and amortization	1,244	1,043	201	19%
Stock-based compensation	721	810	(89)	(11)%
Laboratory supplies and expenses	3,930	1,826	2,104	115%
Facilities and insurance	750	695	55	8%
Professional fees, legal, and outside services	4,265	1,152	3,113	270%
Travel and entertainment	107	80	27	34%
Severance	83	—	83	100%
Other	82	(121)	203	(168)%
Clinical trial site fees	301	2	299	14950%
Total	$ 15,900	$ 9,839	$ 6,061	62%
% of Net Revenue	392%	523%		(131)%

We expect to continue to incur a significant amount of research and development expenses for the foreseeable future. We will continue development of GraftAssureCore, GraftAssureIQ and GraftAssureDx. Our future research and development efforts and expenses will also depend on the amount of capital that we are able to raise to finance those activities and whether we acquire rights to any new diagnostic tests. A portion of our costs for leasing and operating our CLIA-certified laboratory in Tennessee, and in Germany, will also be included in research and development expenses to the extent allocated to the development of our diagnostic tests.

In 2025, we started a clinical trial in conjunction with our IVD submission for GraftAssureDx. On March 25, 2026, we submitted a data package to the FDA seeking marketing authorization for GraftAssureDx, which is the kitted version of our transplanted organ rejection monitoring assay.

Sales and Marketing Expenses

A summary of the main drivers of the change in sales and marketing expenses is as follows:

	Years Ended December 31,			
	2025	2024	$ Change	% Change
	(In thousands, except percentage change values)			
Personnel-related expenses	$ 3,803	$ 2,691	$ 1,112	41%
Depreciation and amortization	597	121	476	393%
Stock-based compensation	181	174	7	4%
Facilities and insurance	152	108	44	41%
Professional fees, legal, and outside services	397	209	188	90%
Marketing and advertising	582	257	325	126%
Travel and entertainment	503	335	168	50%
Other	128	49	79	161%
Total	$ 6,343	$ 3,944	$ 2,399	61%
% of Net Revenue	156%	210%		(53)%

We expect to continue to incur sales and marketing expenses for the foreseeable future, especially as we continue to commercialize GraftAssureCore, GraftAssureIQ and GraftAssureDx. Our commercialization efforts and expenses will also depend on the amount of capital that we are able to access to finance commercialization of our tests. Our future expenditures on sales and marketing will also depend on the amount of revenue that those efforts are likely to generate. Because physicians are more likely to prescribe a test for their patients if the cost is covered by Medicare or health insurance, demand for our diagnostic and other tests and our expenditures on sales and marketing are likely to increase if our diagnostic or other tests qualify for reimbursement by Medicare or private health insurance companies.

General and Administrative Expenses

A summary of the main drivers of the change in general and administrative expenses is as follows:

	Years Ended December 31,			
	2025	2024	$ Change	% Change
	(In thousands, except percentage change values)			
Personnel-related expenses and board fees	$ 4,603	$ 3,957	$ 646	16%
Depreciation and amortization	267	242	25	10%
Stock-based compensation	1,317	769	548	71%
Facilities and insurance	856	1,268	(412)	(32)%
Professional fees, legal, and outside services	3,312	3,647	(335)	(9)%
Travel and entertainment	239	170	69	41%
Other	39	151	(112)	(74)%
Total	$ 10,633	$ 10,204	$ 429	4%
% of Net Revenue	262%	542%		(280)%

Change in Fair Value of Contingent Consideration

We will pay contingent consideration if various payment milestones are triggered under the merger agreements through which we acquired IGI and Chronix. In 2025, we earned our first Kitted Products revenue, accordingly we began to pay related royalties to Chronix. Changes in the fair value of the contingent consideration will be based on our reassessment of the key assumptions underlying the determination of this liability as changes in circumstances and conditions occur from the IGI and Chronix acquisition dates to the reporting periods being presented, with the subsequent changes in fair value recorded as part of our consolidated results from operations for such periods. See Note 3 to our consolidated financial statements included elsewhere in this Report for additional information.

Other Income and Expenses

Other income and expenses are primarily comprised of interest income, interest expense, and foreign currency gains and losses (see Note 2, “Foreign Currency Gains and Losses,” to our consolidated financial statements included elsewhere in this Report). Interest income is earned from money market funds we hold for capital preservation. Interest expense is incurred from our financing lease obligations (see Note 6 to our consolidated financial statements included elsewhere in this Report) and insurance financing activity.

Income Taxes

We did not record any provision or benefit for income taxes for the years ended December 31, 2025 and 2024, as we had a full valuation allowance for the periods presented. A valuation allowance is provided when it is more-likely-than-not that some portion of the deferred tax assets will not be realized. We established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from our net operating loss carry-forwards and other deferred tax assets. See Note 2, "Income Taxes," to our consolidated financial statements included elsewhere in this Report for additional information.

Inflation

Although historically not significant to our results of operations, financial condition and cash flows, we may experience inflationary pressures, primarily in personnel costs, with certain laboratory supplies, from inventory costs related to certain raw materials, with essential vendors including audit fees and regulatory consultants, and from tariff policies and potential countermeasures. Prices for raw materials may fluctuate based on a number of factors beyond our control, including changes in supply and demand, general economic conditions, labor costs, fuel related delivery costs, competition, import duties, excises and other indirect taxes, currency exchange rates, and government regulation. The extent of any future impacts from inflation on our business and our results of operations will depend upon how long elevated inflation levels persist and the extent to which the rate of inflation were to increase, if at all, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents may be diminished, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Due to the highly competitive nature of the healthcare industry and the cost containment efforts of our customers and third-party payors, we may be unable to pass along cost increases for key components or raw materials through higher prices to our customers. Further, given the complexities of the reimbursement landscape in which we operate, our payers may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts. As such, the effects of inflation may adversely impact our results of operations, financial condition and cash flows. See Note 1, "Business Risks," to our consolidated financial statements included elsewhere in this Report for additional information about the risks that may impact our business.

Liquidity and Capital Resources

Our foreseeable material cash requirements as of December 31, 2025, are recognized as liabilities in the consolidated balance sheet or generally are otherwise described in Note 6, "Commitments and Contingencies," to our consolidated financial statements included elsewhere in this Report. Our cash requirements are generally derived from our operating and investing activities including expenditures for working capital, human capital, equipment purchases, lease payments, business development, investments in intellectual property, and business combinations. Our office lease obligations (net of sublease payments) and financing lease obligations, and contingent consideration obligations are further described in Note 6 and Note 3, respectively, to our consolidated financial statements included elsewhere in this Report. As of December 31, 2025 and 2024, other than certain equity-classified warrants (see Note 7, "Common Stock Purchase Warrants," to our consolidated financial statements included elsewhere in this Report), we had no off-balance sheet arrangements, and historically we have not entered into any such arrangements other than the noted warrants. As of December 31, 2025 and 2024, we had unrecognized tax benefits totaling $1.6 million and $1.1 million, respectively (see Note 12, "Income Taxes," to our consolidated financial statements included elsewhere in this Report).

Since formation, we have financed our operations primarily through the sale of our common stock, preferred stock and warrants to acquire common stock (see Note 7 to our consolidated financial statements included elsewhere in this Report). We have incurred operating losses and negative operating cash flows since inception and had an accumulated deficit of $400.8 million as of December 31, 2025. At December 31, 2025, we had $11.6 million of cash and cash equivalents. On February 12, 2026, we raised additional capital as discussed below. Management anticipates that we may continue to incur operating losses and negative operating cash flows for the near future. Although it is difficult to predict our liquidity requirements, based on the going concern evaluation discussed in Note 1, "Liquidity," to our consolidated financial statements included elsewhere in this Report, management believes that it will have sufficient cash to meet its projected operating requirements for at least the next twelve months following the issuance of these consolidated financial statements.

On February 10, 2025, we consummated the February 2025 Offering. The aggregate gross proceeds from the February 2025 Offering were approximately $29.1 million. After deducting offering expenses payable of $487,000, the resulting net proceeds were approximately $28.7 million. We are using the net proceeds received for general corporate purposes and working capital. See Note 7, "Common Stock – February 2025 Offering," to our consolidated financial statements included elsewhere in this Report for additional information.

On February 12, 2026, we consummated the February 2026 Offering. The gross proceeds from the February 2026 Offering were approximately $26.0 million. After deducting placement agent fees and offering expenses payable of $1.4 million, the resulting net proceeds were approximately $24.6 million. We plan to use the net proceeds primarily for general corporate purposes, including but not limited to research and development in the transplantation category. The net proceeds from the offering will allow us to invest in research and development with the goal of expanding our GraftAssure product offering beyond kidney transplant rejection testing into other organs, and most immediately, into heart transplant rejection testing. See Note 13, "Subsequent Events – Registered Direct Offering," to our consolidated financial statements included elsewhere in this Report for additional information.

Our remaining restricted cash balance in the total amount of $1.3 million as of December 31, 2025 relates to a bank letter of credit required under our Irvine office lease. From July 1, 2025 and continuing on the first day of each calendar month thereafter, the letter of credit will be reduced by an amount equal to $60,714.29 on each such date, until the letter of credit is fully reduced, after which the letter of credit arrangement will terminate and we will have no further obligation to maintain or deliver the letter of credit. See Note 6, "Office and Facilities Leases – Irvine Office Lease," to our consolidated financial statements included elsewhere in this Report for additional information.

We expect that our general operating expenses will be commensurate with the market opportunity as we continue to manage our available cash. Although we intend to market our diagnostic tests in the United States through our own sales force, we are also making marketing arrangements with distributors in other countries. We are exploring a range of other commercialization options in order to enter overseas markets and to reduce our capital needs and expenditures, and the risks associated with the timelines and uncertainty for attaining the Medicare reimbursement approvals that will be essential for the successful commercialization of additional diagnostic tests. Those alternative arrangements could include marketing arrangements with other diagnostic companies through which we might receive a licensing fee and royalty on sales, or through which we might form a joint venture to market one or more tests and share in net revenues, in the United States or abroad.

In April 2024, we entered into a global strategic partnership agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products using Bio-Rad's ddPCR instruments and reagents. In November 2024, iMDx and Bio-Rad entered into a memorandum of understanding with respect to such agreement to establish additional activities to be performed by each party pursuant to such agreement. Due to the significance of our arrangement with Bio-Rad, we are dependent on them with respect to many of our ongoing operations and future target performance, which also results in a concentration in the volume of business transacted with Bio-Rad. In addition, Bio-Rad is a significant investor in our common stock. For more information regarding our transactions and business with Bio-Rad, see Note 9, "Related Party Transactions" and Note 10, "Collaborative Arrangements," to our consolidated financial statements included elsewhere in this Report.

On February 20, 2026, we entered into a Specimen Collection Agreement with a national reference lab provider. Pursuant to the agreement, the lab provider will provide specimen collection-related services, which may include, among other things, the collection, handling, processing, and delivery of specimens upon which we will perform testing with our GraftAssureCore test. The agreement provides for certain fees to be paid to the lab provider for services rendered. See Note 13, "Subsequent Events – Specimen Collection Agreement," to our consolidated financial statements included elsewhere in this Report for additional information.

In addition to research, development, sales and marketing expenses, we will incur expenses from leasing and improving our offices and laboratory facilities in the Nashville, Tennessee area and Göttingen, Germany. In 2024 and 2025, we have expanded our Nashville and Germany facilities by extending and adding new office and laboratory leases. In 2024 and 2025, we added various new laboratory instruments to be used in our transplant operations, under new financing leases or from purchases. As of December 31, 2025, we have acquired a total of 32 new lab instruments for use in our transplant operations. As of December 31, 2024, we had a total of seven new lab instruments. See Note 6, "Commitments and Contingencies," to our consolidated financial statements included elsewhere in this Report for additional operating and financing lease information.

We may need to meet significant cash payment or stock obligations to former IGI and Chronix shareholders in connection with our acquisition of those companies, as disclosed in Note 3 to the consolidated financial statements included elsewhere in this Report. To meet the future cash payment obligations, we may have to utilize cash on hand that would otherwise be available to us for other business and operational purposes, which could cause us to delay or reduce activities in the development and commercialization of our tests. In 2025, we earned our first Kitted Products revenue, accordingly, we began to pay related royalties to Chronix.

We may need to continue to access additional forms of capital, beyond what is provided by cash flow from operations, to finance our operations, including the development and commercialization of our diagnostic tests, and making payments that may become due under our obligations to former IGI and Chronix shareholders, until such time as we are able to generate sufficient revenues to cover our operating expenses. Delays in our collaborative arrangement for the development and the commercialization of RUO and IVD kitted transplant products, or delays in obtaining regulatory approval to distribute our products for clinical use, or delays in the development of, or in obtaining reimbursement coverage from Medicare for future laboratory tests that we may develop or acquire, could prevent us from raising sufficient additional capital to finance the completion of development and commercial launch of those tests. However, additional financing may not be available on acceptable terms, if at all, including due to difficult conditions in the capital markets, particularly with respect to securities of biotechnology and life sciences companies on the U.S. stock exchanges. Investors may be reluctant to provide us with capital until our tests are approved for reimbursement by Medicare or reimbursement by private healthcare insurers or healthcare providers, or until we begin generating significant amounts of revenue from selling and performing those tests.

The unavailability or inadequacy of financing or revenues to meet future capital needs could force us to modify, curtail, delay, or suspend some or all aspects of our planned operations. Sales of additional equity securities could result in the dilution of the interests of our shareholders.

See Note 1 and Note 7 to our consolidated financial statements included elsewhere in this Report for additional information about our liquidity discussion and equity offerings, respectively.

Cash Flow from Operating Activities

During the year ended December 31, 2025, our total research and development expenses were $15.9 million, our sales and marketing expenses were $6.3 million, and our general and administrative expenses were $10.6 million. We also incurred $1.8 million in total cost of revenues, including $7,000 for amortization of intangible assets. Net loss for the period was $50.2 million, and our net cash used in operating activities amounted to $22.2 million. Our cash used in operating activities during 2025 did not include the following noncash items: $2.2 million in depreciation and amortization expenses, $2.2 million in stock-based compensation, $164,000 in other equity compensation expenses, $5.9 million loss from the change in fair value of contingent consideration, $14.6 million loss from intangible asset impairments, and unrealized foreign currency losses of $185,000. Net changes in operating assets and liabilities for the period were $2.7 million as a source of additional cash.

During the year ended December 31, 2024, our total research and development expenses were $9.8 million, our sales and marketing expenses were $3.9 million, and our general and administrative expenses were $10.2 million. We also incurred $1.1 million in total cost of revenues, including $88,000 for amortization of intangible expenses. Net loss for the period was $60.7 million, and our net cash used in operating activities amounted to $20.7 million. Our cash used in operating activities during 2024 did not include the following noncash items: $1.6 million in depreciation and amortization expenses, $1.8 million in stock-based compensation, $160,000 in other equity compensation expenses, $4.3 million gain from change in fair value of contingent consideration, $41.9 million loss from intangible asset impairments, $169,000 impairment loss on held for sale assets, and unrealized foreign currency gains of $4,000. Net changes in operating assets and liabilities for the period were $1.3 million as an additional use of cash.

Cash Flow from Investing Activities

During the year ended December 31, 2025, net cash used in investing activities was $3.2 million from cash paid for construction in progress and purchases of machinery and equipment.

During the year ended December 31, 2024, net cash used in investing activities was $512,000, primarily from cash paid for construction in progress and purchases of machinery and equipment.

Cash Flow from Financing Activities

During the year ended December 31, 2025, net cash provided by financing activities was $28.1 million from $28.7 million of net cash proceeds from the February 2025 Offering, partially offset by repayments of financing lease obligations of $510,000 and taxes paid related to net share settlement of stock-based awards.

During the year ended December 31, 2024, net cash provided by financing activities was $20.4 million from $26.0 million of net cash proceeds from the April 2024 Offering, the August 2024 Offering and the October 2024 Offering, partially offset by the redemption of our remaining Series A Preferred Stock of $5.4 million and repayments of financing lease obligations of $201,000.

Critical Accounting Estimates

Our consolidated financial statements are prepared in conformity with U.S. generally accepted accounting principles. In preparing these financial statements, we make assumptions, judgments and estimates that involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial condition or results of operations. We base our assumptions, judgments and estimates on historical experience and various other factors that we believe to be reasonable under the circumstances. Actual results could differ materially from these estimates under different assumptions or conditions. On a regular basis, we evaluate our assumptions, judgments and estimates and make changes accordingly.

We believe that of the significant accounting policies discussed in Note 1 and Note 2 to our consolidated financial statements included elsewhere in this Report, the following accounting policies involve a significant level of estimation uncertainty and require our most difficult, subjective or complex assumptions, judgments and estimates:

- Going Concern Assessment;
- Contingent Consideration Liabilities;
- Intangible Assets;
- Impairment of Long-Lived Assets;
- Revenue Recognition and Allowance for Credit Losses;
- Stock-Based Compensation; and
- Income Taxes.

Going Concern Assessment

We assess going concern uncertainty in our consolidated financial statements to determine if we have sufficient cash and cash equivalents on hand and working capital, including available loans or lines of credit, if any, to operate for a period of at least one year from the date our consolidated financial statements are issued (the "look-forward period"). As part of this assessment, based on conditions that are known and reasonably knowable to us, we consider various scenarios, forecasts, projections and estimates, including stress tests, and we make certain key assumptions, including the timing and nature of projected cash expenditures or programs, and our ability to delay or curtail those expenditures or programs, if necessary, among other factors. Based on this assessment, as necessary or applicable, we make certain assumptions around implementing curtailments or delays in the nature and timing of programs and expenditures to the extent we deem probable those implementations can be achieved and we have the proper authority to execute them within the look-forward period. For additional information, including our current assessment results, see Note 1 to our consolidated financial statements included elsewhere in this Report.

Contingent Consideration Liabilities

Contingent consideration is estimated and recorded at fair value as of the acquisition date as part of the total consideration transferred. Contingent consideration is an obligation of the acquirer to transfer additional assets or equity interests to the selling shareholders in the future if certain future events occur or conditions are met, such as the attainment of product development milestones. Contingent consideration also includes additional future payments to selling shareholders based on achievement of components of earnings, such as "earn-out" provisions or percentage of future revenues, including royalties paid to the selling shareholders based on a percentage of certain revenues generated.

The fair value of milestone-based contingent consideration was determined using a scenario analysis valuation method which incorporates our assumptions with respect to the likelihood of achievement of the milestones, as defined in the merger agreements, credit risk, timing of the contingent consideration payments and a risk-adjusted discount rate to estimate the present value of the expected payments, all of which require significant management judgment and assumptions. Since the contingent consideration payments are based on nonfinancial, binary events, management believes the use of the scenario analysis method is appropriate.

The fair value of royalty or revenue share-based contingent consideration was determined using a single scenario analysis method to value those payments. The single scenario method incorporates our assumptions with respect to specified future revenues generated over their respective useful lives, credit risk, and a risk-adjusted discount rate to estimate the present value of the expected royalty payments, all of which require significant management judgment and assumptions. Since the royalty-based contingent consideration payments are based on future revenues and linear payouts, management believes the use of the single scenario method is appropriate.

The fair value of contingent consideration after the acquisition date is reassessed by us as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in our consolidated statements of operations. Changes in key assumptions can materially affect the estimated fair value of contingent consideration liabilities and, accordingly, the resulting gain or loss that we record in our consolidated financial statements. During the years ended December 31, 2025 and 2024, we recorded a loss of $5.9 million and a gain of $4.3 million, respectively, related to the fair value of contingent consideration. As of December 31, 2025 and 2024, total contingent consideration liabilities were $43.9 million and $37.9 million, respectively. As of December 31, 2025, a hypothetical 2% increase and 2% decrease in the discount rate would have resulted in total contingent consideration liabilities of $39.7 million and $48.6 million, respectively. For additional information, see Note 3 to our consolidated financial statements included elsewhere in this Report.

Intangible Assets

We consider various factors and risks for potential impairment of in-process research and development ("IPR&D") intangible assets, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays or inability to obtain LCD from the Centers for Medicare and Medicaid Services for Medicare reimbursement for a diagnostic test, the inability to bring a diagnostic test to market and the introduction or advancement of competitors' diagnostic tests could result in partial or full impairment of the related intangible assets. Consequently, the eventual realized value of the IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods. During the period between completion or abandonment, the IPR&D assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if we become aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts.

During the fourth quarter of 2024, the IPR&D balances were reassessed using the multi-period excess earnings method ("MPEEM") approach and the results of the valuations noted that the carrying values of certain oncology related IPR&D intangible assets were greater than the fair market values. We recorded a total impairment of $41.9 million during the year ended December 31, 2024. During the fourth quarter of 2025, the IPR&D balances were reassessed using the MPEEM approach and the results of the valuations noted that the carrying values of our oncology related IPR&D intangible assets were greater than the fair market values, resulting in a full impairment of such assets. We recorded a total impairment of $14.6 million during the year ended December 31, 2025. For additional information, see Note 5 to our consolidated financial statements included elsewhere in this Report.

Impairment of Long-Lived Assets

We assess the impairment of long-lived assets, which consists primarily of right-of-use assets, machinery and equipment, and finite-lived intangible assets, whenever events or changes in circumstances indicate that such assets might be impaired and the carrying value may not be recoverable. When such events or changes in circumstances are present, we estimate the future cash flows expected to result from the use of the asset (or asset group) and its eventual disposition. If the sum of the expected undiscounted future cash flows is less than the carrying amount, we recognize an impairment based on the fair value of such assets. During the year ended December 31, 2024, we recognized an impairment loss on held for sale assets of $169,000. We recorded no such impairments during 2025. For additional information, see Note 2, "Assets Held for Sale," to our consolidated financial statements included elsewhere in this Report.

Revenue Recognition and Allowance for Credit Losses

Laboratory Services

Laboratory Services are generally performed under individual scope of work ("SOW") arrangements or license agreements (together with SOW the "Laboratory Services Agreements") with specific deliverables defined by the customer. Laboratory Services are performed on a (i) time and materials basis or (ii) per test completed basis. Upon completion of the service to the customer in accordance with a Laboratory Services Agreement, we have the right to bill the customer for the agreed upon price (either on a per test or per deliverable basis) and recognize Laboratory Service revenue at that time. Depending on the Laboratory Services Agreement, we may identify the services offered as a single performance obligation, or identify the processing of test samples as a separate performance obligation (considered a series) within license agreements. Completion of the service and satisfaction of the performance obligation is typically evidenced by acknowledgment of completed services, and access to the report or test made available to the customer or any other form or applicable manner of delivery defined in the Laboratory Services Agreements. However, for certain SOWs under which work is performed pursuant to the customer's highly customized specifications, we have the enforceable right to bill the customer for work completed, rather than upon completion of the SOW. For those SOWs, we recognize revenue over a period during which the work is performed using a formula that accounts for expended efforts, generally measured in labor hours, as a percentage of total estimated efforts for the completion of the SOW. As performance obligations are satisfied under the Laboratory Services Agreements, any amounts earned as revenue and billed to the customer are included in accounts receivable.

We establish an allowance for credit losses based on the evaluation of the collectability of its Laboratory Services accounts receivables after considering a variety of factors, including the length of time receivables are past due, significant events that may impair the customer's ability to pay, such as a bankruptcy filing or deterioration in the customer's operating results or financial condition, reasonable and supportable forecast that affect the collectability of the reported amount, and historical experience. We continuously monitor collections and payments from customers and maintain a provision for estimated credit losses and uncollectible accounts, if any, based upon its historical experience and any specific customer collection issues that have been identified. Amounts determined to be uncollectible are written off against the credit loss reserve accounts. As of December 31, 2025 and 2024, we had an allowance for credit losses of $11,000 and $16,000, respectively, related to Laboratory Services.

Stock-Based Compensation

We recognize compensation expense related to stock-based payment awards made to employees, board directors and other non-employees based on estimated fair values. We estimate the fair value of stock-based payment awards on the grant date and recognize the resulting fair value over the requisite service period on a straight-line basis. For stock-based awards that vest only upon the attainment of one or more performance goals, compensation cost is recognized if and when we determine that it is probable that the performance condition or conditions will be, or have been, achieved. For grants with market-based and time-based vesting conditions, the fair value is estimated using the Monte Carlo simulation model, which includes the estimated period to achievement of the performance and market conditions, which are subject to the achievement of the market-based goals established by us and continued employment. We utilize the Black-Scholes option pricing model for determining the fair value of standard time-based stock options. Our determination of fair value of stock-based payment awards on the date of grant using an option pricing model is affected by our stock price as well as assumptions regarding a number of complex and subjective variables. These variables include, but are not limited to, expected stock price volatility over the term of the awards, and actual and projected employee stock option exercise behaviors. We estimate the expected volatility using our own stock price volatility for a period equal to the expected term of the options. The expected term of options granted is based on our own experience. The risk-free rate is based on the U.S. Treasury rates in effect during the corresponding period of grant. Key inputs and assumptions may change as we continue to develop our Company estimates, experience and key inputs including our expected term, and stock price volatility based on the trading history of our stock in the public market. Changes in these subjective assumptions can materially affect the estimated value of equity grants and the stock-based compensation that we record in our consolidated financial statements. During the years ended December 31, 2025 and 2024, we recognized total stock-based compensation of $2.2 million and $1.8 million, respectively. For additional information, see Note 8 to our consolidated financial statements included elsewhere in this Report.

Income Taxes

We account for income taxes in accordance with Accounting Standards Codification 740, *Income Taxes*, which prescribes the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect. Valuation allowances are established when necessary to reduce deferred tax assets when it is more-likely-than-not that a portion or all of the deferred tax assets will not be realized. Our judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If our assumptions and consequently our estimates change in the future, the valuation allowance may be increased or decreased, which may have a material impact on our statements of operations.

The guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. We will recognize accrued interest and penalties, if any, related to unrecognized tax benefits as income tax expense. No amounts were accrued for the payment of interest and penalties as of the financial statement periods presented herein. We account for uncertain tax positions by assessing all material positions taken in any assessment or challenge by relevant taxing authorities. We are currently unaware of any tax issues under review. For additional information, see Note 12, "Income Taxes," to our consolidated financial statements included elsewhere in this Report.

Recent Accounting Pronouncements

The effects of accounting standards adopted in 2025 and the potential effects of accounting standards to be adopted in the future are described in Note 2, "Recent Accounting Pronouncements," to our consolidated financial statements included elsewhere in this Report.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Under the SEC rules and regulations, as a smaller reporting company, we are not required to provide the information required by this item.

Item 8. Financial Statements and Supplementary Data.

The financial statements and related financial information required to be filed hereunder are indexed under Item 15 of this report and are incorporated herein by reference.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Based on information provided by Marcum LLP ("Marcum"), our independent registered public accounting firm, CBIZ CPAs P.C. ("CBIZ CPAs") acquired the attest business of Marcum, effective November 1, 2024. Marcum continued to serve as the Company's independent registered public accounting firm through April 11, 2025. On April 11, 2025, the Company terminated its relationship with Marcum as the Company's independent registered public accounting firm and, with the approval of the Audit Committee of the Company's Board of Directors, engaged CBIZ CPAs on April 16, 2025 as the Company's independent registered public accounting firm for the fiscal year ending December 31, 2025.

Prior to engaging CBIZ CPAs, the Company did not consult with CBIZ CPAs regarding (i) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's consolidated financial statements, or (ii) any matter that was either the subject of a disagreement (as described in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K and the related instructions).

The report of Marcum regarding the Company's consolidated financial statements for the fiscal years ended December 31, 2024, included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025, does not contain any adverse opinion or disclaimer of opinion and were not qualified or modified as to uncertainty, audit scope, or accounting principles.

During the fiscal year ended December 31, 2024, and through April 11, 2025, the date of Marcum's termination, there were (a) no disagreements (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) between the Company and Marcum on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedures, which disagreements, if not resolved to the satisfaction of Marcum, would have caused Marcum to make reference to such disagreement in its reports and (b) no "reportable events" (as defined in Item 304(a)(1)(v) of Regulation S-K and the related instructions).

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

It is management's responsibility to establish and maintain adequate internal control over all financial reporting pursuant to Rule 13a-15 under the Exchange Act. Our management, including our principal executive officer and our principal financial officer, have reviewed and evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2025. Following this review and evaluation, management collectively determined that our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act (i) is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms; and (ii) is accumulated and communicated to management, including our principal executive officer and our principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting, as defined in Exchange Act Rule 13a-15(f), is a process designed by, or under the supervision of, our principal executive officer and our principal financial officer, and effected by our Board of Directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. All internal control systems, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Our management conducted an assessment of the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria set forth in the Internal Control Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the assessment, our management has concluded that our internal control over financial reporting was effective as of December 31, 2025.

Exemption from Attestation Report of Independent Registered Public Accounting Firm

This Report does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our independent registered public accounting firm pursuant to the rules of the SEC that permit us to provide only Management's Annual Report because we are a non-accelerated filer.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting that occurred during the fourth quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

(a) None.

(b) None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item will be contained in our definitive Proxy Statement or an amendment to this Report, which will be filed with the SEC within 120 days after December 31, 2025, and is incorporated herein by reference.

We have a written Code of Business Conduct and Ethics ("Code of Ethics") that applies to our principal executive officer, our principal financial officer and principal accounting officer, our other executive officers, our other employees, and our directors. The purpose of the Code of Ethics is to deter wrongdoing and to promote (i) honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships; (ii) full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with or submit to the SEC and in our other public communications; (iii) compliance with applicable governmental rules and regulations; (iv) prompt internal reporting of violations of the Code of Ethics to an appropriate person or persons identified in the Code of Ethics; and (v) accountability for adherence to the Code of Ethics. A copy of our Code of Ethics has been posted on our internet website and can be found at www.imdxinc.com. If we amend or waive a provision of our Code of Ethics that applies to our chief executive officer or chief financial officer, we will post the amended Code of Ethics or information about the waiver on our internet website.

Information about our compliance with Section 16(a) of the Securities Exchange Act of 1934 reported under the caption "Delinquent Section 16(a) Reports" in our definitive Proxy Statement or an amendment to this Report, which will be filed with the SEC within 120 days after December 31, 2025, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be contained in our definitive Proxy Statement or an amendment to this Report, which will be filed with the SEC within 120 days after December 31, 2025, and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be contained in our definitive Proxy Statement or an amendment to this Report, which will be filed with the SEC within 120 days after December 31, 2025, and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be contained in our definitive Proxy Statement or an amendment to this Report, which will be filed with the SEC within 120 days after December 31, 2025, and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be contained in our definitive Proxy Statement or an amendment to this Report, which will be filed with the SEC within 120 days after December 31, 2025, and is incorporated herein by reference.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)(1) Financial Statements.

The following consolidated financial statements of iMDx are filed as part of this Report:

(a)(2) Financial Statement Schedules.

Financial statement schedules are omitted because they are not applicable or the required information is shown in the Financial Statements or the Notes thereto.

(a)(3) Exhibits.

Refer to Item 15(b) below.

(b) Exhibits. The following exhibits are either filed herewith or incorporated herein by reference:

Exhibit Numbers	Exhibit Description
2.1	Agreement and Plan of Merger, dated January 10, 2020, by and among Insight Molecular Diagnostics Inc., Cancer DX Sub, Inc., Insight Genetics, Inc., the Shareholders who became a Party to the Merger Agreement and the Equityholder Representative. (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 5, 2020)
2.2	Agreement and Plan of Merger dated February 2, 2021, amended February 23, 2021, and amended and restated as of April 15, 2021, by and among Insight Molecular Diagnostics Inc., CNI Monitor Sub, Inc., Chronix Biomedical, Inc., the Stockholders who became a party to the Merger Agreement and the Equityholder Representative (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 19, 2021)
2.3	Amendment No. 1 to Amended and Restated Agreement and Plan of Merger dated February 8, 2023, by and between Insight Molecular Diagnostics Inc. and David MacKenzie, solely in his capacity as Equityholder Representative (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 3, 2023)
2.4	Stock Purchase Agreement, dated December 15, 2022, by and among Dragon Scientific, LLC, Insight Molecular Diagnostics Inc. and Razor Genomics Inc. (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 21, 2022)
2.5	First Amendment to Stock Purchase Agreement, dated December 15, 2022, by and among Dragon Scientific, LLC, Insight Molecular Diagnostics Inc. and Razor Genomics Inc. (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 13, 2023)
2.6	Second Amendment to Stock Purchase Agreement, dated February 16, 2023, by and among Dragon Scientific, LLC, Insight Molecular Diagnostics Inc. and Razor Genomics Inc. (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 23, 2023)

3.1	Articles of Incorporation with all amendments (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Registration Statement on Form S-3 filed with the Securities and Exchange Commission on July 14, 2021)
3.2	Certificate of Amendment of Articles of Incorporation of Insight Molecular Diagnostics Inc., as filed with the Secretary of State of the State of California on July 24, 2023 (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 24, 2023)
3.3	Certificate of Ownership, as filed with the Secretary of State of the State of California on June 13, 2025 (incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2025)
3.4	Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 13, 2022)
3.5	Third Amended and Restated Bylaws of Insight Molecular Diagnostics Inc.(incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 17, 2025)
4.1	Specimen of Common Stock Certificate (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
4.2	Silicon Valley Bank Warrant (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)
4.3	Warrant to Purchase Common Stock, dated October 17, 2019, between Insight Molecular Diagnostics Inc. and Silicon Valley Bank (Incorporated by Reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2019)
4.4	Form of Common Stock Warrant (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 19, 2022)
4.5	Form of Pre-Funded Warrant (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 12, 2024)
4.6	Form of Pre-Funded Warrant (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 10, 2025)
4.7	Form of Pre-Funded Warrant, dated February 10, 2026 (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 12, 2026)
4.8*	Description of Securities
10.1#	2010 Stock Option Plan (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Form 10 12(g) filed with the Securities and Exchange Commission on October 7, 2015)
10.2#	2017 Amendment to 2010 Stock Option Plan (Incorporated by reference to Registration Statement on Form S-8, File Number 333-219109 filed with the Securities and Exchange Commission on June 30, 2017)
10.3#	Form of Stock Option Agreement (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.4#	Form of Incentive Stock Option Agreement (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.5#	Amended and Restated 2018 Equity Incentive Plan (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 15, 2024)

10.6#	Form of 2018 Equity Incentive Plan Employee Stock Option Agreement (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018)
10.7#	Form of 2018 Equity Incentive Plan Non-Employee Director Stock Option Agreement (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018)
10.8#	Form of 2018 Equity Incentive Plan Restricted Stock Unit Agreement (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on August 29, 2018)
10.9#	Insight Molecular Diagnostics Inc. Change in Control and Severance Plan (Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 26, 2020)
10.10#	Form of Change in Control and Severance Agreement (Incorporated by Reference to Annual Report on Form 10-K Filed with the Securities and Exchange Commission on March 26, 2020)
10.11#	Amended and Restated Employment Agreement, dated June 6, 2023, by and between Insight Molecular Diagnostics Inc. and Joshua Riggs (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on June 9, 2023)
10.12#	Amendment to Amended and Restated Employment Agreement, dated July 13, 2023, by and between Insight Molecular Diagnostics Inc. and Joshua Riggs (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on July 14, 2023)
10.13	Registration Rights Agreement dated October 15, 2009 (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.14	Amendment of Registration Rights Agreement, dated August 23, 2011 (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.15	Second Amendment of Registration Rights Agreement, dated May 8, 2015 (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Form 10 12(b) filed with the Securities and Exchange Commission on November 23, 2015)
10.16	Third Amendment to Registration Rights Agreement, dated November 16, 2015 (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Form 10 12(b) A-1 filed with the Securities and Exchange Commission on December 29, 2015)
10.17	Loan and Security Agreement, dated February 21, 2017, by and between Insight Molecular Diagnostics Inc. and Silicon Valley Bank (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on February 27, 2017)
10.18+	First Amendment to Loan and Security Agreement, dated October 17, 2019, between Insight Molecular Diagnostics Inc. and Silicon Valley Bank (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 21, 2019)
10.19	Loan Deferral Agreement, dated April 2, 2020, by and between Insight Molecular Diagnostics Inc. and Silicon Valley Bank (Incorporated by Reference to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 12, 2020)
10.20	Office Lease Agreement, dated December 23, 2019, as amended between Insight Molecular Diagnostics Inc. and Cushing Ventures, LLC (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on December 27, 2019)
10.21	Amendment to and Waiver of Right to Extend Original Lease, dated as of December 26, 2024, effective as of January 2, 2025, by and among Insight Molecular Diagnostics Inc., Induce Biologics USA, Inc. and Cushing Ventures, LLC (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 8, 2025)

10.22	Sublease Agreement, dated August 8, 2023, by and between Insight Molecular Diagnostics Inc. and Induce Biologics USA, Inc. (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2023)
10.23	Lease Agreement for Suite 103, dated January 1, 2024, between Insight Genetics, Inc. and MPC Holdings, LLC (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2024)
10.24	Lease Agreement for Suite 410, dated January 1, 2024, between Insight Genetics, Inc. and MPC Holdings, LLC (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2024)
10.25	Lease Agreement for Suite 510, dated January 1, 2024, between Insight Genetics, Inc. and MPC Holdings, LLC (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2024)
10.26	Form of Securities Purchase Agreement dated April 13, 2022, by and among Insight Molecular Diagnostics Inc. and certain investors (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 13, 2022)
10.27	Securities Purchase Agreement, dated April 3, 2023, by and among Insight Molecular Diagnostics Inc. and each purchaser identified on the signatures pages thereto (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2023)
10.28	Securities Purchase Agreement, dated April 11, 2024, by and among the Company and the investors signatory thereto (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on April 12, 2024)
10.29#	Employment Agreement, dated May 20, 2024, by and between Insight Molecular Diagnostics Inc. and Ekkehard Schütz (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2024)
10.30#	Employment Agreement, dated June 17, 2024, by and between Insight Molecular Diagnostics Inc. and Andrea James (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on August 8, 2024)
10.31+	Securities Purchase Agreement, dated October 2, 2024, by and among the Company and the investors signatory thereto (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 3, 2024)
10.32+	Collaboration Agreement, dated April 5, 2024, between the Company and Bio-Rad Laboratories, Inc. (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 15, 2024)
10.33+	Memorandum of Understanding, dated November 8, 2024, between the Company and Bio-Rad Laboratories, Inc. (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 12, 2024)
10.34	Amendment to and Waiver of Right to Extend Original Lease, dated as of December 26, 2024, effective as of January 2, 2025, by and among Insight Molecular Diagnostics Inc., Induce Biologics USA, Inc. and Cushing Ventures, LLC (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on January 8, 2025)
10.35+	Securities Purchase Agreement, dated February 7, 2025, by and among the Company and the investors signatory thereto (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 10, 2025)

10.36+	Securities Purchase Agreement, dated February 7, 2025, by and among the Company and the investors signatory thereto (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 10, 2025)
10.37#	Amendment to Employment Agreement, effective September 29, 2025, by and between Insight Molecular Diagnostics Inc. and Ekkehard Schütz (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on October 2, 2025)
10.38+	Form of Securities Purchase Agreement, dated as of February 10, 2026, by and between the Company and the purchasers thereto (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Current Report on Form 8-K filed with the Securities and Exchange Commission on February 12, 2026)
19.1	Insider Trading Policy (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 24, 2025)
21	Subsidiaries (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 12, 2023)
23.1*	Consent of CBIZ CPAs P.C.
23.2*	Consent of Marcum LLP
31.1*	Certification of the Principal Executive Officer of Insight Molecular Diagnostics Inc. pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Rule 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of the Principal Financial Officer of Insight Molecular Diagnostics Inc. pursuant to Rule 13a-14 of the Securities Exchange Act of 1934, as amended, as adopted pursuant to Rule 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certifications pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1	Insight Molecular Diagnostics Inc. Clawback Policy (Incorporated by reference to Insight Molecular Diagnostics Inc.'s Annual Report on Form 10-K filed with the Securities and Exchange Commission on April 16, 2024)
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

** The certifications attached as Exhibit 32.1 that accompany this Report are not deemed filed with the SEC and are not to be incorporated by reference into any filing of iMDx under the Securities Act, or the Exchange Act, whether made before or after the date of this Report, regardless of any general incorporation language contained in any filing.

The referenced exhibit is a management contract, compensatory plan or arrangement.

+ Schedules have been omitted from this filing pursuant to Item 601(a)(5) of Regulation S-K. The Company agrees to furnish supplementally a copy of any omitted schedule to the SEC upon its request; provided, however, that the Company may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule so furnished. Certain portions of this exhibit (indicated by "[*]" or "[***]") have been omitted pursuant to Item 601(b)(10) because they are both (i) not material and (ii) would be competitively harmful if publicly disclosed.

(c) Other financial statement schedules.

Not applicable.

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Item 16. Form 10-K Summary.

Not applicable.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

INSIGHT MOLECULAR DIAGNOSTICS INC.

Date: March 26, 2026

By: */s/ Joshua Riggs*
Joshua Riggs
President and Chief Executive Officer
(Principal Executive Officer)

Date: March 26, 2026

By: */s/ Andrea James*
Andrea James
Chief Financial Officer
(Principal Financial Officer)

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Joshua Riggs JOSHUA RIGGS	President and Chief Executive Officer and Director (Principal Executive Officer)	March 26, 2026
/s/ Andrea James ANDREA JAMES	Chief Financial Officer (Principal Financial Officer)	March 26, 2026
/s/ James Liu JAMES LIU	Vice President Accounting, Controller, Treasurer and Principal Accounting Officer (Principal Accounting Officer)	March 26, 2026
/s/ Andrew Arno ANDREW ARNO	Director	March 26, 2026
/s/ Andrew J. Last ANDREW J. LAST	Director	March 26, 2026
/s/ Louis E. Silverman LOUIS E. SILVERMAN	Director	March 26, 2026

Report of Independent Registered Public Accounting Firm (PCAOB ID No. 199)

To the Shareholders and Board of Directors of
Insight Molecular Diagnostics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Insight Molecular Diagnostics Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations, comprehensive loss, Series A redeemable convertible preferred stock and stockholders' deficit, and cash flows for the year ended December 31, 2025 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Contingent consideration – Fair valuation of contingent consideration liabilities

As described in Note 3 to the financial statements, the Company reported certain contingent consideration liabilities at their estimated fair value as of year-end. The Company used a discounted cash flow model, which is an income approach, in determining the fair value of the contingent consideration liabilities.

The principal consideration for our determination that the fair value of contingent consideration liabilities is a critical audit matter is that there is significant judgment by management in estimating possible future payouts, the discount rate, and the likelihood of certain milestones being met. This in turn led to high degree of auditor judgment, subjectivity, and effort in performing audit procedures in evaluating audit evidence related to management's estimates and assumptions used in the valuation model. Furthermore, evaluating the related audit evidence required significant auditor judgment as the nature of the evidence is highly subjective, and audit effort involved the use of professionals with specialized skills and knowledge to assist in evaluating the audit evidence obtained.

Addressing the matter involved performing procedures and evaluating evidence in connection with forming our overall audit opinion on the financial statements. These procedures included (i) evaluating the methodology management used to develop its estimate, (ii) testing the significant inputs and assumptions to management's estimate, and (iii) involving the use of auditor-employed valuation specialists in assessing the estimate.

Intangible assets – Impairment of certain indefinite-lived intangible assets

As described in Note 5 to the financial statements, the Company recognized impairment expense related to its indefinite-lived intangible assets. The Company used a multi-period excess earnings method, which is an income approach, to determine the fair value of the intangible assets in such evaluation.

The principal consideration for our determination that the impairment evaluation is a critical audit matter is that there is significant judgment by management in estimating forecasted cash flows and assumptions such as the discount rate. This in turn led to high degree of auditor judgment, subjectivity, and effort in performing audit procedures in evaluating audit evidence related to management's estimates and assumptions used in the forecasted cash flows and valuation model. Furthermore, evaluating the audit evidence related to impairment evaluation required significant auditor judgment as the nature of the evidence is highly subjective.

Addressing the matter involved performing procedures and evaluating evidence in connection with forming our overall audit opinion on the financial statements. These procedures included (i) developing an independent estimate of the fair value of the indefinite-lived intangible assets and comparing it to management's own estimate.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2023 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Costa Mesa, CA
March 26, 2026

Report of Independent Registered Public Accounting Firm (PCAOB ID No. 688)

To the Shareholders and Board of Directors of
Insight Molecular Diagnostics Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Insight Molecular Diagnostics Inc., formerly known as Oncocyte Corporation, (the "Company") as of December 31, 2024, the related consolidated statements of operations, comprehensive loss, Series A redeemable convertible preferred stock and shareholders' equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We served as the Company's auditor from 2023 through 2025.

Costa Mesa, CA
March 24, 2025

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

	December 31, 2025	December 31, 2024
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 11,583	$ 8,636
Accounts receivable, net of allowance for credit losses of $11 and $16, respectively	1,128	1,613
Inventories	446	410
Deferred financing costs	—	279
Restricted cash, current	729	—
Prepaid expenses and other current assets	1,420	821
Total current assets	15,306	11,759
NONCURRENT ASSETS		
Right-of-use operating and financing lease assets, net	2,815	2,757
Machinery and equipment, net, and construction in progress	6,435	3,567
Intangible assets, net	—	14,607
Restricted cash, noncurrent	607	1,700
Other noncurrent assets	593	691
TOTAL ASSETS	$ 25,756	$ 35,081
LIABILITIES AND SHAREHOLDERS' DEFICIT		
CURRENT LIABILITIES		
Accounts payable	$ 2,544	$ 1,641
Due to related party (Note 9)	2,780	638
Accrued compensation	2,461	1,939
Accrued royalties	1,116	1,116
Accrued expenses and other current liabilities	939	418
Operating and financing lease liabilities, current	1,807	1,295
Contingent consideration liabilities, current	428	228
Total current liabilities	12,075	7,275
NONCURRENT LIABILITIES		
Operating and financing lease liabilities, noncurrent	1,690	2,369
Contingent consideration liabilities, noncurrent	43,455	37,711
TOTAL LIABILITIES	57,220	47,355
Commitments and contingencies (Note 6)		
SHAREHOLDERS' DEFICIT		
Preferred stock, no par value, 5,000 shares authorized; no shares issued and outstanding	—	—
Common stock, no par value, 230,000 shares authorized; 28,683 and 17,453 shares issued and outstanding at December 31, 2025 and 2024, respectively	369,211	338,244
Accumulated other comprehensive income	86	21
Accumulated deficit	(400,761)	(350,539)
Total shareholders' deficit	(31,464)	(12,274)
TOTAL LIABILITIES AND SHAREHOLDERS' DEFICIT	$ 25,756	$ 35,081

The accompanying notes are an integral part of these consolidated financial statements.

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

	Years Ended December 31,	
	2025	2024
Net revenue	$ 4,055	$ 1,881
Cost of revenues	1,750	1,053
Cost of revenues – amortization of acquired intangibles	7	88
Gross profit	2,298	740
Operating expenses:		
Research and development	15,900	9,839
Sales and marketing	6,343	3,944
General and administrative	10,633	10,204
Change in fair value of contingent consideration	5,946	(4,275)
Impairment losses	14,600	41,900
Impairment loss on held for sale assets	—	169
Total operating expenses	53,422	61,781
Loss from operations	(51,124)	(61,041)
Other (expenses) income:		
Interest expense	(109)	(84)
Other income, net	1,011	462
Total other income, net	902	378
Loss before income taxes	(50,222)	(60,663)
Income taxes	—	—
Net loss	$ (50,222)	$ (60,663)
Net loss per share (Note 2):		
Net loss attributable to common stockholders - basic and diluted	$ (50,222)	$ (60,926)
Net loss attributable to common stockholders per share - basic and diluted	$ (1.65)	$ (4.66)
Weighted average shares outstanding - basic and diluted	30,476	13,071

The accompanying notes are an integral part of these consolidated financial statements.

INSIGHT MOLECULAR DIAGNOSTICS INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS
(In thousands)

	Years Ended December 31,	
	2025	2024
Net loss	$ (50,222)	$ (60,663)
Foreign currency translation adjustments	65	(28)
Comprehensive loss	$ (50,157)	$ (60,691)

The accompanying notes are an integral part of these consolidated financial statements.

INSIGHT MOLECULAR DIAGNOSTICS INC.
CONSOLIDATED STATEMENTS OF SERIES A REDEEMABLE CONVERTIBLE PREFERRED STOCK AND SHAREHOLDERS' DEFICIT
(In thousands)

	Year Ended December 31, 2025						
	Series A Redeemable Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Deficit
	Shares	Amount	Shares	Amount			
Balance at December 31, 2024	**—**	**$ —**	**17,453**	**$ 338,244**	**$ 21**	**$ (350,539)**	**$ (12,274)**
Net Loss	—	—	—	—	—	(50,222)	(50,222)
Foreign currency translation adjustment	—	—	—	—	65	—	65
Stock-based compensation	—	—	—	2,219	—	—	2,219
Vesting of bonus awards	—	—	—	56	—	—	56
Sale of common shares, net of financing costs	—	—	11,146	28,656	—	—	28,656
Shares issued upon vesting of RSUs	—	—	66	—	—	—	—
Shares issued for consultant services	—	—	30	108	—	—	108
Shares withheld related to net share settlement of stock-based awards	—	—	(12)	(72)	—	—	(72)
Balance at December 31, 2025	**—**	**$ —**	**28,683**	**$ 369,211**	**$ 86**	**$ (400,761)**	**$ (31,464)**

	Year Ended December 31, 2024						
	Series A Redeemable Convertible Preferred Stock		Common Stock		Accumulated Other Comprehensive Income	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount	Shares	Amount			
Balance at December 31, 2023	**5**	**$ 5,126**	**8,261**	**$ 310,295**	**$ 49**	**$ (289,876)**	**$ 20,468**
Net loss	—	—	—	—	—	(60,663)	(60,663)
Foreign currency translation adjustment	—	—	—	—	(28)	—	(28)
Stock-based compensation	—	—	—	1,753	—	—	1,753
Vesting of bonus awards	—	—	—	52	—	—	52
Sale of common shares, net of financing costs	—	—	8,538	24,638	—	—	24,638
Sale of common shares under at-the-market transactions, net of financing costs	—	—	611	1,661	—	—	1,661
Shares issued upon vesting of RSUs	—	—	4	—	—	—	—
Shares issued for consultant services	—	—	39	108	—	—	108
Redemption of Series A redeemable convertible preferred stock	(5)	(5,389)	—	—	—	—	—
Accretion of Series A convertible preferred stock to redemption value	—	263	—	(263)	—	—	(263)
Balance at December 31, 2024	**—**	**$ —**	**17,453**	**$ 338,244**	**$ 21**	**$ (350,539)**	**$ (12,274)**

The accompanying notes are an integral part of these consolidated financial statements.

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

	Years Ended December 31,	
	2025	2024
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (50,222)	$ (60,663)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	2,190	1,476
Amortization of intangible assets	7	88
Stock-based compensation	2,219	1,753
Equity compensation for bonus awards and consulting services	164	160
Change in fair value of contingent consideration	5,946	(4,275)
Impairment losses	14,600	41,900
Impairment loss on held for sale assets	—	169
Unrealized foreign currency losses (gains)	185	(4)
Changes in operating assets and liabilities:		
Accounts receivable	485	(1,129)
Inventories	(36)	(410)
Prepaid expenses and other assets	(226)	(430)
Accounts payable and accrued liabilities	2,646	967
Operating lease assets and liabilities	(142)	(291)
Net cash used in operating activities	(22,184)	(20,689)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Proceeds from sale of equipment	—	4
Machinery and equipment purchases, and construction in progress	(3,185)	(516)
Net cash used in investing activities	(3,185)	(512)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from sale of common shares	29,143	26,012
Financing costs to issue common shares	(487)	(1,374)
Proceeds from sale of common shares under at-the-market transactions	—	1,802
Financing costs for at-the-market sales	—	(421)
Redemption of Series A redeemable convertible preferred shares	—	(5,389)
Contingent consideration liability payments	(2)	—
Taxes paid related to net share settlement of stock-based awards	(72)	—
Repayment of financing lease obligations	(510)	(201)
Net provided by financing activities	28,072	20,429
Effect of exchange rate changes on cash and cash equivalents	(120)	(24)
NET CHANGE IN CASH, CASH EQUIVALENTS AND RESTRICTED CASH	2,583	(796)
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, BEGINNING	10,336	11,132
CASH, CASH EQUIVALENTS AND RESTRICTED CASH, ENDING	$ 12,919	$ 10,336
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid for interest	$ 91	$ 42
Cash paid for income taxes	$ —	$ —
SUPPLEMENTAL SCHEDULE OF NONCASH INVESTING AND FINANCING ACTIVITIES		
Machinery and equipment purchases, and construction in progress included in accounts payable and accrued liabilities	$ 1,442	$ 570
Accretion of Series A convertible preferred stock	$ —	$ 263
Lease assets obtained in exchange for lease liabilities	$ 1,138	$ 1,794

The accompanying notes are an integral part of these consolidated financial statements.

INSIGHT MOLECULAR DIAGNOSTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Organization and Description of the Business

Insight Molecular Diagnostics Inc. (f/k/a Oncocyte Corporation) ("iMDx," the "Company," "we," "our" or "us"), incorporated in 2009 in California, is a pioneering diagnostics technology company. Our mission is to expand access to novel molecular diagnostic testing, most immediately in the transplanted organ rejection testing category. Our current intellectual property portfolio comprises three general areas: 1) organ transplant, 2) oncology therapy selection, and 3) oncology therapy monitoring. Within these categories, we have developed or are in the process of developing laboratory developed tests ("LDTs") that can be run at our Franklin, Tennessee laboratory, kitted research use only ("RUO") tests, and in vitro diagnostic ("IVD") kitted clinical tests that can be run by local labs.

In June 2025, we changed our name from "Oncocyte Corporation" to "Insight Molecular Diagnostics Inc." Our new trading symbol "IMDX" became effective on the Nasdaq Stock Market, LLC ("Nasdaq") on June 18, 2025. In addition, in June 2025, we moved our headquarters from Irvine, California, to Nashville, Tennessee. Tennessee is home to our Clinical Laboratory Improvements Amendment ("CLIA") certified lab and a growing hub for healthcare innovation.

Business Risks

Tariff policies and potential countermeasures could increase our costs and disrupt our global supply chain, which could negatively impact the results of our operations as well as our asset valuations and other fair value measurements. In addition, our business could be adversely impacted by other inflationary factors. The Company will continue to monitor these risks. Refer to Item 1A. "Risk Factors" included elsewhere in this Annual Report on Form 10-K for the year ended December 31, 2025 (this "Report") for additional information about the risks that may impact our business.

Liquidity

iMDx has incurred operating losses and negative operating cash flows since its inception and had an accumulated deficit of $400.8 million as of December 31, 2025. iMDx expects to continue to incur operating losses and negative operating cash flows for the foreseeable future. Since its formation, iMDx has financed its operations primarily through the sale of shares of its common stock, convertible preferred stock and warrants to acquire common stock. As of December 31, 2025, iMDx had $11.6 million of cash and cash equivalents and $1.3 million in remaining restricted cash that started to be released in the third quarter of 2025 (see Note 6, "Office and Facilities Leases – Irvine Office Lease" for additional information). On February 12, 2026, we raised substantial additional capital as discussed below.

On April 5, 2024, the Company entered into a global strategic partnership agreement with Bio-Rad Laboratories, Inc. ("Bio-Rad") to collaborate in the development and the commercialization of RUO and IVD kitted transplant products for clinical use. On November 8, 2024, the Company and Bio-Rad entered into a memorandum of understanding with respect to such agreement to establish additional activities to be performed by each party pursuant to such agreement. See Note 10, "Collaborative Arrangements" for additional information.

On February 10, 2025, the Company consummated a registered direct offering and concurrent private placement of its securities to certain accredited investors (the "February 2025 Offering"). The aggregate gross proceeds from the February 2025 Offering were approximately $29.1 million. After deducting offering expenses payable by the Company of $487,000, the resulting net proceeds were approximately $28.7 million. These net proceeds are inclusive of an investment from Bio-Rad (see Note 9), our aforementioned global strategic partner. The Company is using the net proceeds received for general corporate purposes and working capital. See Note 7, "Common Stock – February 2025 Offering" for additional information.

On February 12, 2026, the Company consummated a registered direct offering of its securities to certain accredited investors (the "February 2026 Offering"). The gross proceeds from the February 2026 Offering were approximately $26.0 million. After deducting placement agent fees and offering expenses payable by the Company of $1.4 million, the resulting net proceeds were approximately $24.6 million. These net proceeds are inclusive of an investment from Bio-Rad (see Note 9), our aforementioned global strategic partner. The Company plans to use the net proceeds primarily for general corporate purposes, including but not limited to research and development in the transplantation category. See Note 13, "Subsequent Events – Registered Direct Offering" for additional information.

INSIGHT MOLECULAR DIAGNOSTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

In addition to general economic and capital market trends and conditions, iMDx's ability to raise sufficient additional capital to finance its operations from time to time will depend on a number of factors specific to iMDx's operations such as operating revenues and expenses, progress in our collaborative arrangement for the development and the commercialization of RUO and IVD kitted transplant products, progress in obtaining regulatory approval to distribute our products for clinical use, and progress in the development of, or in obtaining reimbursement coverage from Medicare for future laboratory tests that iMDx may develop or acquire.

The unavailability or inadequacy of financing or revenues to meet future capital needs could force iMDx to modify, curtail, delay, or suspend some or all aspects of planned operations. Sales of additional equity securities could result in the dilution of the interests of iMDx's current stockholders. iMDx cannot assure that adequate long-term financing will be available on favorable terms, if at all.

In accordance with Accounting Standards Codification ("ASC") 205-40, *Going Concern*, we evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern within one year after the date that the consolidated financial statements included in this Report are issued. This evaluation initially does not take into consideration the potential mitigating effect of our plans that have not been fully implemented as of the date the consolidated financial statements included in this Report are issued. When substantial doubt exists under this methodology, we evaluate whether the mitigating effect of our plans sufficiently alleviates substantial doubt about our ability to continue as a going concern. The mitigating effect of our plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that such financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about our ability to continue as a going concern within one year after the date that such financial statements are issued. In performing this analysis, we excluded certain elements of our operating plan that cannot be considered probable.

Although it is difficult to predict the Company's liquidity requirements, based on the going concern evaluation discussed above, management believes that it will have sufficient cash to meet its projected operating requirements for at least the next twelve months following the issuance of these consolidated financial statements. The factors that previously raised substantial doubt about the Company's ability to continue as a going concern in the prior year were resolved in part as a result of the February 2026 Offering described above. Accordingly, management has concluded that substantial doubt does not exist about the Company's ability to continue as a going concern for a period of at least one year from the date of issuance of these consolidated financial statements. However, the Company anticipates that it will continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues the development of its various programs and incurs additional costs associated with being a public company.

2. Summary of Significant Accounting Policies

Accounting Principles

The consolidated financial statements and accompanying notes are prepared on the accrual basis of accounting in accordance with U.S. generally accepted accounting principles ("GAAP").

Principles of Consolidation and Basis of Presentation

On January 31, 2020, with the acquisition of Insight Genetics, Inc. ("IGI") through a merger with a newly incorporated wholly-owned subsidiary of iMDx (the "IGI Merger") under the terms of an Agreement and Plan of Merger (the "IGI Merger Agreement"), IGI became a wholly-owned subsidiary of iMDx, and on that date iMDx began consolidating IGI's operations and results with iMDx's operations and results. See Note 3, "Business Combinations and Contingent Consideration Liabilities – Acquisition of IGI"

On April 15, 2021, with the acquisition of Chronix Biomedical, Inc. ("Chronix") pursuant to an Agreement and Plan of Merger dated February 2, 2021, amended February 23, 2021, and amended and restated as of April 15, 2021 (as amended and restated, the "Chronix Merger Agreement"), by and among iMDx and CNI Monitor Sub, Inc., a Delaware corporation and wholly-owned subsidiary of iMDx, Chronix became a wholly-owned subsidiary of iMDx (the "Chronix Merger"), and on that date iMDx began consolidating Chronix's operations and results with iMDx's operations and results. See Note 3, "Business Combinations and Contingent Consideration Liabilities – Acquisition of Chronix."

All material intercompany accounts and transactions have been eliminated in consolidation.

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Reclassifications

Certain prior period amounts in the consolidated financial statements and notes to consolidated financial statements have been reclassified to conform to the current period presentation. These changes had no impact on the previously reported consolidated financial condition, results of operations or total cash flows.

In connection with the retrospective adoption of Accounting Standards Update ("ASU") No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* as of December 31, 2025 (see "Recent Accounting Pronouncements" below), the Company has also reclassified certain 2024 amounts to conform to the 2025 presentation in our federal income tax rate reconciliation table included in Note 12, "Income Taxes."

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, and contingent assets and liabilities, at the date of the consolidated financial statements, and the reported amounts of revenues and expenses during the reporting period. On an ongoing basis, management evaluates estimates which are subject to significant judgment, including, but not limited to, valuation methods used, assumptions requiring the use of judgment to prepare financial projections and forecasted financial information, timing of potential commercialization of acquired in-process intangible assets, applicable discount rates, probabilities of the likelihood of multiple outcomes of certain events related to contingent consideration, comparable companies or transactions, determination of fair value of the assets acquired and liabilities assumed (including those relating to contingent consideration), the carrying value of any goodwill and other intangibles and related impairments, assumptions related to going concern assessments, revenue recognition, allowances for credit losses, allocation of direct and indirect expenses, useful lives associated with long-lived intangible and other assets, key assumptions in operating and financing leases including incremental borrowing rates, loss contingencies, valuation allowances related to deferred income taxes, and assumptions used to value stock-based awards and other equity instruments. These assessments are made in the context of information reasonably available to iMDx. Actual results may differ materially from those estimates.

Segment Reporting

In accordance with ASC 280, *Segment Reporting*, iMDx's management views its operations as one reportable segment that includes the research, development and commercialization of diagnostic tests, including molecular diagnostic testing products and services. See Note 11 for additional information.

Fair Value Measurements, Business Combinations and Contingent Consideration Liabilities

iMDx accounts for business combinations in accordance with ASC 805, which requires the purchase consideration transferred to be measured at fair value on the acquisition date in accordance with ASC 820, *Fair Value Measurement*. ASC 820 establishes a single authoritative definition of fair value, sets out a framework for measuring fair value and expands on required disclosures about fair value measurement. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. ASC 820 describes a fair value hierarchy based on three levels of inputs, of which the first two are considered observable and the last unobservable, that may be used to measure fair value, which are the following:

- *Level 1* – Quoted prices in active markets for identical assets and liabilities.
- *Level 2* – Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted market prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- *Level 3* – Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. Such inputs reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date. Consideration is given to the risk inherent in the valuation technique and the risk inherent in the inputs to the model. Management estimates include certain pricing models, discounted cash flow methodologies and similar techniques that use significant unobservable inputs, including the entity's own assumptions in determining fair value.

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When a part of the purchase consideration consists of shares of iMDx common stock, iMDx calculates the purchase price attributable to those shares, a Level 1 security, by determining the fair value of those shares as of the acquisition date based on prices quoted on the principal national securities exchange on which the shares traded. iMDx recognizes estimated fair values of the tangible assets and identifiable intangible assets acquired, including in-process research and development ("IPR&D"), and liabilities assumed, including any contingent consideration, as of the acquisition date. Goodwill is recognized as any amount of excess consideration transferred over the fair value of the tangible and identifiable intangible assets acquired net of the liabilities assumed. ASC 805 precludes the recognition of an assembled workforce as an asset, effectively subsuming any assembled workforce value into goodwill.

In determining fair value, iMDx utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible, and also considers counterparty credit risk in its assessment of fair value. As of December 31, 2025 and 2024, iMDx had no financial assets recorded at fair value on a recurring basis, except for money market funds. These assets are reported as cash equivalents and are measured at fair value using the period-end quoted market prices as a Level 1 input. iMDx's financial liabilities recorded at fair value on a recurring basis include contingent consideration, and are discussed below.

The carrying amounts of cash and cash equivalents, restricted cash, net accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities approximate fair values because of the short-term nature of these items.

In accordance with GAAP, from time to time, iMDx measures certain assets at fair value on a nonrecurring basis. iMDx reviews the carrying value of intangibles, including IPR&D (see "Intangible Assets" below and Note 5), and other long-lived assets for indications of impairment at least annually. Refer to related discussions of impairments below.

Contingent Consideration Liabilities

Certain of iMDx's asset and business acquisitions involve the potential for future payment of consideration to third-parties and former selling shareholders in amounts determined as a percentage of future net revenues generated, or upon attainment of revenue milestones, from laboratory services or tests, as applicable, or annual minimum royalties to certain licensors, as provided in the applicable agreements. The fair value of such liabilities is determined using unobservable inputs. These inputs include the estimated amount and timing of projected cash flows and the risk-adjusted discount rate used to present value the cash flows. These obligations are referred to as contingent consideration, which are carried at fair value based on Level 3 inputs on a recurring basis.

ASC 805 requires that contingent consideration be estimated and recorded at fair value as of the acquisition date as part of the total consideration transferred. Contingent consideration is an obligation of the acquirer to transfer additional assets or equity interests to the selling shareholders in the future if certain future events occur or conditions are met, such as the attainment of product development milestones. Contingent consideration also includes additional future payments to selling shareholders based on achievement of components of earnings, such as "earn-out" provisions or percentage of future revenues, including royalties paid to the selling shareholders based on a percentage of certain revenues generated.

The fair value of contingent consideration after the acquisition date is reassessed by iMDx as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in the consolidated statements of operations. Changes in key assumptions can materially affect the estimated fair value of contingent consideration liabilities and, accordingly, the resulting gain or loss that iMDx records in its consolidated financial statements. See Note 3 for a full discussion of these liabilities and additional Level 3 fair value disclosures.

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Cash, Cash Equivalents and Restricted Cash

iMDx considers all highly liquid securities with original maturities of three months or less when purchased to be cash equivalents. For the periods presented, iMDx's cash equivalents are comprised of investments in AAA rated money market funds that invest in first-tier only securities, which primarily include domestic commercial paper and securities issued or guaranteed by the U.S. government or its agencies. Restricted cash balances, as reported in the consolidated balance sheets, relate to a bank letter of credit required under an office lease arrangement, see Note 6 for additional information.

For cashflow reporting purposes, the Company combines the reported balance sheet amounts from cash and cash equivalents with restricted cash (current and noncurrent). Accordingly, as of December 31, 2025 and 2024, the aggregate amount of such ending balances were $12.9 million and $10.3 million, respectively, as presented in the consolidated statements of cash flows.

Investments in Privately Held Companies

iMDx evaluates whether investments held in common stock of other companies require consolidation of the company under, first, the variable interest entity ("VIE") model, and then under the voting interest model in accordance with accounting guidance for consolidations under ASC 810-10. If consolidation of the entity is not required under either the VIE model or the voting interest model, iMDx determines whether the equity method of accounting should be applied in accordance with ASC 323, *Investments – Equity Method and Joint Ventures*. The equity method applies to investments in common stock or in-substance common stock if iMDx exercises significant influence over, but does not control, the entity, where significant influence is typically represented by ownership of 20% or more, but less than majority ownership, of the voting interests of a company. iMDx initially records equity method investments at fair value on the date of the acquisition with subsequent adjustments to the investment balance based on iMDx's pro rata share of earnings or losses from the investment.

iMDx's first product for commercial release was a proprietary treatment stratification test called DetermaRx that identified which patients with early-stage non-small cell lung cancer may benefit from chemotherapy, resulting in a significantly higher, five-year survival rate. Beginning in September 2019 through February 23, 2021, iMDx held a 25% equity interest in Razor Genomics, Inc. ("Razor"), a privately held company, that had developed and licensed to iMDx the lung cancer treatment stratification laboratory test that iMDx was commercializing as DetermaRx. On February 24, 2021, iMDx completed the purchase of all the remaining issued and outstanding shares of common stock of Razor. As a result of the purchase of the Razor common stock, iMDx became the sole shareholder of Razor. On December 15, 2022, the Company entered into a Stock Purchase Agreement (the "Razor Stock Purchase Agreement") with Dragon Scientific, LLC, a Delaware limited liability company ("Dragon"), and Razor. Pursuant to the Razor Stock Purchase Agreement, iMDx agreed to sell to Dragon, 3,188,181 shares of common stock of Razor, which constituted approximately 70% of the issued and outstanding equity interests of Razor on a fully-diluted basis, and transfer to Razor all of the assets and liabilities related to DetermaRx (the "Razor Sale Transaction"). On February 16, 2023, iMDx completed the Razor Sale Transaction (the "Razor Closing"). In connection with the Razor Closing, iMDx transferred to Razor all of the assets and liabilities related to DetermaRx. While no monetary consideration was received for the sale of 70% of the equity interests of Razor, the transaction allowed the Company to eliminate all development and commercialization costs with respect to DetermaRx. Following the Razor Closing, iMDx continues to own 1,366,364 shares of common stock of Razor, which constitutes approximately 30% of the issued and outstanding equity interests of Razor on a fully-diluted basis, however, the remaining common stock held is accounted for at historical cost less impairment, which is currently zero.

Inventories

Inventories include raw materials, work-in-process and finished goods and are valued at the lower of cost or net realizable value. In September 2024, the Company began to capitalize certain RUO inventory costs in connection with its collaboration arrangement with Bio-Rad to develop and commercialize its GraftAssureIQ RUO kitted tests and eventual IVD kitted transplant testing products. See Note 10, "Collaborative Arrangements" for additional information. As of December 31, 2025, inventories were comprised of raw materials of $368,000 and finished goods of $78,000. As of December 31, 2024, inventories were comprised of raw materials of $207,000 and finished goods of $203,000.

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Assets Held for Sale

In accordance with ASC subtopic 360-10, *Property, Plant, and Equipment*, assets and liabilities are classified as held for sale when all of the following criteria for a plan of sale have been met: (1) management, having the authority to approve the action, commits to a plan to sell the assets; (2) the assets are available for immediate sale, in their present condition, subject only to terms that are usual and customary for sales of such assets; (3) an active program to locate a buyer and other actions required to complete the plan to sell the assets have been initiated; (4) the sale of the assets is probable and is expected to be completed within one year; (5) the assets are being actively marketed for a price that is reasonable in relation to their current fair value; and (6) actions required to complete the plan indicate that it is unlikely that significant changes to the plan will be made or the plan will be withdrawn. When all of these criteria have been met, the assets and liabilities are classified as held for sale in the consolidated balance sheet. Assets classified as held for sale are reported at the lower of their carrying value or fair value less costs to sell. Depreciation and amortization of assets ceases upon designation as held for sale.

Historically, the Company has entered into agreements to sell certain laboratory equipment. As a result, the Company classified the equipment as held for sale current assets in the consolidated balance sheet, when all the criteria of ASC 360-10 had been met. As such, certain laboratory equipment in 2024 was written down to its fair value, less cost to sell. As of December 31, 2025 and 2024, the Company had no assets held for sale. During the year ended December 31, 2024, the Company recorded an impairment loss on held for sale assets of $169,000 in the consolidated statement of operations.

Property and Equipment

Machinery and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization is computed using the straight-line method over the estimated useful lives of the assets, generally over a period of 3 to 10 years. For equipment purchased under financing leases, iMDx amortizes the equipment based on the shorter of the useful life of the equipment or the term of the lease, ranging from 3 to 5 years, depending on the nature and classification of the financing lease (see Note 6). Maintenance and repairs are expensed as incurred whereas significant renewals and betterments are capitalized. When assets are retired or otherwise disposed of, the cost and the related accumulated depreciation or amortization are removed from the respective accounts and any resulting gain or loss is reflected in the results of operations.

Construction in progress, comprised primarily of leasehold improvements under construction, is not depreciated or amortized until the underlying asset is placed into service.

Intangible Assets

In accordance with ASC 350, *Intangibles – Goodwill and Other*, IPR&D projects acquired in a business combination that are not complete as of the acquisition date are capitalized and accounted for as indefinite-lived intangible assets until completion or abandonment of the related research and development efforts. Upon successful completion of the project, the capitalized amount is amortized over its estimated useful life. If a project is abandoned, all remaining capitalized amounts are written off immediately. iMDx considers various factors and risks for potential impairment of IPR&D assets, including the current legal and regulatory environment and the competitive landscape. Adverse clinical trial results, significant delays or inability to obtain local coverage determination (“LCD”) from the Centers for Medicare and Medicaid Services (“CMS”) for Medicare reimbursement for a diagnostic test, the inability to bring a diagnostic test to market and the introduction or advancement of competitors’ diagnostic tests could result in partial or full impairment of the related intangible assets. Consequently, the eventual realized value of the IPR&D project may vary from its fair value at the date of acquisition, and IPR&D impairment charges may occur in future periods. During the period between completion or abandonment, the IPR&D assets will not be amortized but will be tested for impairment on an annual basis and between annual tests if iMDx becomes aware of any events occurring or changes in circumstances that would indicate a reduction in the fair value of the IPR&D projects below their respective carrying amounts.

iMDx does not have intangible assets with indefinite useful lives other than the acquired IPR&D discussed in Note 5, which as of December 31, 2025, were fully impaired.

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In accordance with ASC 350, we review and evaluate our intangible assets for impairment whenever events or changes in circumstances indicate that we may not recover their net book value. When applicable, we test for impairment on an annual basis in the fourth quarter of each year, and between annual tests, if indicators of potential impairment exist, using a fair-value approach. We typically use an income method to estimate the fair value of these assets, which is based on forecasts of the expected future cash flows attributable to the respective assets. Significant estimates and assumptions inherent in the valuations reflect a consideration of other marketplace participants and include the amount and timing of future cash flows (including expected growth rates). Estimates utilized in the projected cash flows include consideration of macroeconomic conditions, overall category growth rates, competitive activities, cost containment and margin expansion, Company business plans, the underlying product or technology life cycles, economic barriers to entry, and the discount rate applied to the cash flows. Unanticipated market or macroeconomic events and circumstances may occur, which could affect the accuracy or validity of the estimates and assumptions.

When applicable, goodwill represents the excess of the purchase price over the fair value of net identifiable assets and liabilities. Goodwill, similar to IPR&D, is not amortized but is tested for impairment at least annually, or if circumstances indicate that it is more-likely-than-not that the carrying value of the associated reporting unit exceeds its fair value. Qualitative factors considered in this assessment include industry and market conditions, overall financial performance, and other relevant events and factors affecting iMDx's business. Based on the qualitative assessment, if it is determined that the fair value of goodwill is more-likely-than-not to be less than its carrying amount, the fair value of a reporting unit will be calculated and compared with its carrying amount and an impairment charge will be recognized for the amount that the carrying value exceeds the fair value. iMDx continues to operate in one segment (see Note 11) and is considered to be the sole reporting unit and, therefore, goodwill will be tested for impairment at the enterprise level, when applicable.

Long-Lived Intangible Assets

Long-lived intangible assets subject to amortization are stated at acquired cost, less accumulated amortization. iMDx amortizes intangible assets not considered to have an indefinite useful life using the straight-line method over their estimated period of benefit, which generally ranges from 1 to 9 years. Each reporting period, we evaluate the estimated remaining useful life of intangible assets and assess whether events or changes in circumstances warrant a revision to the remaining period of amortization or indicate that impairment exists. Long-lived intangible assets currently consist of fully amortized acquired customer relationships (see Note 5).

Impairment of Long-Lived Assets

iMDx's long-lived assets consist primarily of right-of-use assets for operating and financing leases, machinery and equipment, and finite-lived intangible assets. If events or changes in circumstances indicate that the carrying amount of a long-lived asset may not be recoverable and the expected undiscounted future cash flows attributable to the asset are less than the carrying amount of the asset, an impairment loss, equal to the excess of the carrying value of the asset over its fair value, is recorded.

Leases

iMDx accounts for leases in accordance with ASC 842, *Leases*. iMDx determines if an arrangement is a lease at inception. Leases are classified as either financing or operating, with classification affecting the pattern of expense recognition in the consolidated statements of operations. iMDx accounts for the lease and non-lease components as a single lease component. iMDx recognizes right-of-use ("ROU") assets and lease liabilities for leases with terms greater than twelve months in the consolidated balance sheets. ROU assets represent the right to use an underlying asset during the lease term and lease liabilities represent the obligation to make lease payments arising from the lease. ROU assets and lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most leases do not provide an implicit rate, iMDx uses an incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. iMDx uses the implicit rate when it is readily determinable. The ROU asset also includes any lease payments made and excludes lease incentives. Lease terms may include options to extend or terminate the lease when it is reasonably certain that iMDx will exercise that option. Operating lease expense and financing lease amortization expense are recognized on a straight-line basis over the lease term. Operating leases include ROU office lease assets and related lease liabilities, current and long-term, in the consolidated balance sheets. Financing leases include ROU machinery and equipment and related financing lease liabilities, current and long-term, in the consolidated balance sheets (see "Property and Equipment" above for more information). iMDx discloses the amortization of operating lease ROU assets and the related repayments of lease obligations as a net amount in the consolidated statements of cash flows. iMDx has entered into various operating and financing leases in accordance with ASC 842 as further discussed in Note 6.

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Accounting for Warrants

iMDx determines the accounting classification of warrants it issues, as either liability or equity classified, by first assessing whether the warrants meet liability classification in accordance with ASC 480-10, *Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity*, then in accordance with ASC 815-40, *Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock*. Under ASC 480, warrants are considered liability classified if the warrants are mandatorily redeemable, obligate iMDx to settle the warrants or the underlying shares by paying cash or other assets, or for warrants that must or may require settlement by issuing a variable number of shares. If warrants do not meet liability classification under ASC 480, iMDx assesses the requirements under ASC 815-40, which states that contracts that require or may require the issuer to settle the contract for cash are liabilities recorded at fair value, irrespective of the likelihood of the transaction occurring that triggers the net cash settlement feature. This liability classification guidance also applies to financial instruments that may require cash or other form of settlement for transactions outside of the company's control and, in which the form of consideration to the warrant holder may not be the same as to all other shareholders in connection with the transaction. However, if a transaction is not within the company's control but the holder of the financial instrument can solely receive the same type or form of consideration as is being offered to all the shareholders in the transaction, then equity classification of the financial instrument is not precluded, if all other applicable equity classification criteria are met.

After all relevant assessments, iMDx concludes whether the warrants are classified as liability or equity. Liability classified warrants require fair value accounting at issuance and subsequent to initial issuance with all changes in fair value after the issuance date recorded in the consolidated statements of operations. Equity classified warrants only require fair value accounting at issuance with no changes recognized subsequent to the issuance date. Based on the above guidance and, among other factors, the fact that our warrants cannot be cash settled under any circumstance but require share settlement, all of our outstanding warrants meet the equity classification criteria and have been classified as equity. See Note 7 for details about our outstanding warrants.

Revenue Recognition

Pursuant to ASC 606, *Revenue from Contracts with Customers*, revenues are recognized when control of goods or services is transferred to customers, in an amount that reflects the consideration iMDx expects to be entitled to in exchange for those goods or services. ASC 606 provides for a five-step model that includes:

(i) identifying the contract with a customer,

(ii) identifying the performance obligations in the contract,

(iii) determining the transaction price,

(iv) allocating the transaction price to the performance obligations, and

(v) recognizing revenue when, or as, an entity satisfies a performance obligation.

iMDx determines transaction prices based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. Consideration may be fixed, variable, or a combination of both. The Company considers any constraints on the variable consideration and includes in the transaction price variable consideration to the extent it is deemed probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainty associated with the variable consideration is subsequently resolved.

The following table presents consolidated revenues by type:

	Years Ended December 31,	
	2025	2024
	(In thousands)	
Laboratory Services	$ 4,031	$ 1,859
Laboratory Developed Test Services	—	22
Kitted Products	24	—
Total	$ 4,055	$ 1,881

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Laboratory Services

Revenues recognized include Laboratory Services performed by iMDx for life sciences customers, including testing for biomarker discovery, assay design and development, clinical trial support, and a broad spectrum of biomarker tests. These Laboratory Services are generally performed under individual scope of work ("SOW") arrangements or license agreements (together with SOW the "Laboratory Services Agreements") with specific deliverables defined by the customer. Laboratory Services are performed on a (i) time and materials basis or (ii) per test completed basis. Upon completion of the service to the customer in accordance with a Laboratory Services Agreement, iMDx has the right to bill the customer for the agreed upon price (either on a per test or per deliverable basis) and recognizes Laboratory Service revenue at that time. Depending on the Laboratory Services Agreement, iMDx may identify the services offered as a single performance obligation, or identify the processing of test samples as a separate performance obligation (considered a series) within license agreements.

Completion of the service and satisfaction of the performance obligation is typically evidenced by acknowledgment of completed services, and access to the report or test made available to the customer or any other form or applicable manner of delivery defined in the Laboratory Services Agreements. However, for certain SOWs under which work is performed pursuant to the customer's highly customized specifications, iMDx has the enforceable right to bill the customer for work completed, rather than upon completion of the SOW. For those SOWs, iMDx recognizes revenue over a period during which the work is performed using a formula that accounts for expended efforts, generally measured in labor hours, as a percentage of total estimated efforts for the completion of the SOW. As performance obligations are satisfied under the Laboratory Services Agreements, any amounts earned as revenue and billed to the customer are included in accounts receivable. Any revenues earned but not yet billed to the customer as of the date of iMDx's consolidated financial statements are recorded as contract assets and are included in other current assets as of the financial statement date. Amounts recorded in contract assets are reclassified to accounts receivable in iMDx's consolidated balance sheets when the customer is invoiced according to the billing schedule in the contract.

As of December 31, 2025, 2024 and 2023, iMDx had gross accounts receivable from Laboratory Services customers of $1.1 million, $1.6 million and $489,000, respectively.

Allowance for Credit Losses

iMDx establishes an allowance for credit losses based on the evaluation of the collectability of its Laboratory Services accounts receivables after considering a variety of factors, including the length of time receivables are past due, significant events that may impair the customer's ability to pay, such as a bankruptcy filing or deterioration in the customer's operating results or financial condition, reasonable and supportable forecast that affect the collectability of the reported amount, and historical experience. If circumstances related to customers change, estimates of the recoverability of receivables would be further adjusted. iMDx continuously monitors collections and payments from customers and maintains a provision for estimated credit losses and uncollectible accounts, if any, based upon its historical experience and any specific customer collection issues that have been identified. Amounts determined to be uncollectible are written off against the credit loss reserve accounts. As of December 31, 2025, 2024 and 2023, iMDx had an allowance for credit losses of $11,000, $16,000 and $5,000, respectively, related to Laboratory Services.

Laboratory Developed Test Services

Prior to the Razor Sale Transaction (see "Investments in Privately Held Companies" above), iMDx generated revenue from performing DetermaRx tests on clinical samples through orders received from physicians, hospitals, and other healthcare providers. In determining whether all the revenue recognition criteria in (i) through (v) above was met with respect to DetermaRx tests, each test result was considered a single performance obligation and was generally considered complete when the test result was delivered or made available to the prescribing physician electronically, and, as such, there were no shipping or handling fees incurred by iMDx or billed to customers. Although iMDx billed a list price for all tests ordered and completed for all payer types, iMDx considered constraints on the variable consideration when it recognized revenue for DetermaRx. Because DetermaRx was a novel test and there were no current reimbursement arrangements with third-party payers other than Medicare, the transaction price represented variable consideration. Application of the constraint for variable consideration was an area that required significant judgment. For all payers other than Medicare, iMDx needed to consider the novelty of the test, the uncertainty of receiving payment, or being subject to claims for a refund, from payers with whom iMDx did not have a sufficient payment collection history or contractual reimbursement agreements. Accordingly, for those payers, iMDx recognized revenue upon payment because it had insufficient history to reliably estimate payment patterns. The remaining Medicare and Medicare Advantage accounts receivable net balance was written-off in the first quarter of 2023. Laboratory Developed Test Services revenue recorded during the year ended December 31, 2024 was the result of payments received.

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Kitted Products

Revenues recognized include our GraftAssureIQ RUO kitted tests, which are clearly labeled and intended for research purposes. GraftAssureIQ is a transplant monitoring assay to measure the donor-derived cell-free DNA ("dd-cfDNA") molecular biomarker. iMDx recognizes revenue to depict the transfer of goods to a customer at an amount that reflects the consideration which it expects to receive for providing those goods. As of December 31, 2025 and 2024, iMDx had no accounts receivable from Kitted Products customers. See Note 10, "Collaborative Arrangements" for additional Kitted Products information.

Licensing

Revenues that may be recognized include licensing revenue derived from agreements with customers for exclusive rights to market iMDx's proprietary testing technology. Under the agreements, iMDx grants exclusive rights to certain trademarks and technology of iMDx for the purpose of marketing iMDx's tests within a defined geographic territory. A license agreement may specify milestone deliverables or performance obligations, for which iMDx recognizes revenue when its licensee confirms the completion of iMDx's performance obligation. A licensing agreement may also include ongoing sales support from iMDx and typically includes non-refundable licensing fees and per-test Laboratory Services revenues discussed above, for which iMDx treats the licensing of the technology, trademarks, and ongoing support as a single performance obligation satisfied by the passage of time over the term of the agreement.

Disaggregation of Revenues and Concentrations of Credit Risk

The following table presents the percentage of consolidated revenues by type:

	Years Ended December 31,	
	2025	2024
Laboratory Services	99%	99%
Laboratory Developed Test Services	0%	1%
Kitted Products	1%	0%
Total	100%	100%

The following table presents the percentage of consolidated revenues generated by unaffiliated customers, based on the respective periods presented, that individually represented greater than ten percent of consolidated revenues:

	Years Ended December 31,	
	2025	2024
Company A	99%	84%
Company B	*	*

* Less than 10%

The following table presents the percentage of consolidated revenues attributable to geographical locations, based on country of domicile:

	Years Ended December 31,	
	2025	2024
United States	99%	89%
Outside of the United States	1%	11%
Total	100%	100%

See Note 11, "Segment Reporting" for additional information about geographical revenues and long-lived tangible assets.

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Financial instruments that potentially subject the Company to concentrations of credit risk are cash and cash equivalents and accounts receivable. The Company places its cash equivalents primarily in highly rated money market funds. Cash and cash equivalents are also invested in deposits with certain financial institutions and may, at times, exceed federally insured limits. The Company has not experienced any significant losses on its deposits of cash and cash equivalents.

One customer individually represented approximately 100% of accounts receivable as of December 31, 2025. One customer individually represented approximately 97% of accounts receivable as of December 31, 2024. No other customers individually represented greater than ten percent of total accounts receivable.

The Company had accounts payable to two vendors that represented approximately 50% and 10% of accounts payable as of December 31, 2025, and three vendors that represented approximately 37%, 28% and 14% of accounts payable as of December 31, 2024. No other vendors individually represented greater than ten percent of total accounts payable.

The Company has a concentration in the volume of business transacted with Bio-Rad, its global strategic partner. In 2024, the Company entered into an agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products using Bio-Rad's ddPCR instruments and reagents, pursuant to which it is dependent on Bio-Rad with respect to many of its ongoing operations and future target performance. In addition, Bio-Rad is a significant investor in the Company's common stock. See Note 9, "Related Party Transactions" and Note 10, "Collaborative Arrangements" for additional information.

Cost of Revenues

Cost of revenues generally consists of cost of materials, direct labor including benefits, bonus and stock-based compensation, equipment and infrastructure expenses, clinical sample related costs associated with performing Laboratory Services and Laboratory Developed Test Services, providing deliverables according to our licensing agreements, license fees due to third-parties, amortization of acquired intangible assets such as the customer relationship intangible assets (see Note 5), and Kitted Products inventory costs (see "Inventories" above) and royalties based on net product sales. Infrastructure expenses include depreciation of laboratory equipment, allocated rent costs, leasehold improvements, and allocated information technology costs for operations at iMDx's CLIA-certified laboratory in Tennessee. Costs associated with generating service revenue are recorded as the tests or services are performed regardless of whether revenue was recognized. Royalties or revenue share payments for licensed technology calculated as a percentage of revenues generated using the associated technology, or from product sales, are recorded as expenses at the time the related revenues are recognized. Certain cost of revenues are attributed to our global strategic collaboration arrangement with Bio-Rad for commercializing our kitted test products. See Note 10, "Collaborative Arrangements" for additional information.

Research and Development Expenses

Research and development expenses are comprised of costs incurred to develop technology, which include salaries and benefits, stock-based compensation, laboratory expenses (including reagents and supplies used in research and development laboratory work), consumed kitted products for clinical trials, infrastructure expenses (including depreciation expense and allocated facility occupancy costs), and contract services and other outside costs. Indirect research and development expenses are allocated primarily based on headcount, as applicable, and include rent and utilities, common area maintenance, telecommunications, property taxes and insurance. Research and development costs are expensed as incurred. Certain research and development expenses are attributed to our global strategic collaboration arrangement with Bio-Rad for commercializing our kitted test products. See Note 10, "Collaborative Arrangements" for additional information.

Sales and Marketing Expenses

Sales and marketing expenses consist primarily of personnel costs and related benefits, including stock-based compensation, trade show expenses, branding and positioning expenses, free kitted products, travel expenses, and consulting fees. Sales and marketing expenses also include indirect expenses for applicable overhead allocated based on headcount, and include allocated costs for rent and utilities, common area maintenance, depreciation expense, telecommunications, property taxes and insurance. During the years ended December 31, 2025 and 2024, iMDx's total advertising expenses were $590,000 and $258,000, respectively. Certain sales and marketing expenses are attributed to our global strategic collaboration arrangement with Bio-Rad for commercializing our kitted test products. See Note 10, "Collaborative Arrangements" for additional information.

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General and Administrative Expenses

General and administrative expenses consist primarily of compensation and related benefits, including stock-based compensation, for executive and corporate personnel, professional and consulting fees, travel expenses, rent and utilities, common area maintenance, depreciation expense, telecommunications, property taxes and insurance. Certain general and administrative expenses are attributed to our global strategic collaboration arrangement with Bio-Rad for commercializing our kitted test products. See Note 10, "Collaborative Arrangements" for additional information.

Stock-Based Compensation

iMDx recognizes compensation expense related to employee, Board of Director and other non-employee option grants and restricted stock grants in accordance with ASC 718, *Compensation – Stock Compensation.*

iMDx estimates the fair value of stock-based payment awards on the grant date and recognizes the resulting fair value over the requisite service period, which is generally a three or four-year vesting period. For stock-based awards that vest only upon the attainment of one or more performance goals set by iMDx at the time of the grant (sometimes referred to as milestone vesting), compensation cost is recognized if and when iMDx determines that it is probable that the performance condition or conditions will be, or have been, achieved. iMDx uses the Black-Scholes option pricing model for estimating the fair value of time-based options granted under iMDx's equity plan. The fair value of each restricted stock unit ("RSU") or award ("RSA") is determined by the product of the number of units or shares granted and the grant date market price of the underlying common stock. iMDx has elected to treat stock-based payment awards with graded vesting schedules and time-based service conditions as a single award and recognizes stock-based compensation ratably on a straight-line basis over the requisite service period. Options have a maximum contractual term of ten years. Forfeitures are accounted for as they occur. See Note 8 for additional information.

The Black-Scholes option pricing model requires iMDx to make certain assumptions including the expected option term, the expected volatility, the risk-free interest rate and the dividend yield. The expected term of employee stock options represents the weighted average period that the stock options are expected to remain outstanding. iMDx estimates the expected term of options granted based on its own experience. iMDx estimates the expected volatility using its own stock price volatility for a period equal to the expected term of the options. The risk-free interest rate assumption is based upon observed interest rates on the United States government securities appropriate for the expected term of iMDx's stock options. The dividend yield assumption is based on iMDx's history and expectation of dividend payouts. iMDx has never declared or paid any cash dividends on its common stock, and iMDx does not anticipate paying any cash dividends in the foreseeable future.

All excess tax benefits and tax deficiencies from stock-based compensation awards accounted for under ASC 718 are recognized as income tax benefit or expense, respectively, in the consolidated statements of operations. An excess income tax benefit arises when the tax deduction of a stock-based award for income tax purposes exceeds the compensation cost recognized for financial reporting purposes and, a tax deficiency arises when the compensation cost exceeds the tax deduction. Because iMDx has a full valuation allowance for all periods presented (see "Income Taxes" below), there was no impact to iMDx's consolidated statements of operations for any excess tax benefits or deficiencies, as any excess benefit or deficiency would be offset by the change in the valuation allowance.

Retirement Plan

iMDx has an employee savings and retirement plan under Section 401(k) of the Internal Revenue Code. The plan is a defined contribution plan in which eligible employees may elect to have a percentage of their compensation contributed to the plan, subject to certain guidelines issued by the Internal Revenue Service. During the years ended December 31, 2025 and 2024, iMDx's total contributions to the plan were $321,000 and $318,000, respectively.

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Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, *Collaborative Arrangements*, which includes determining whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. To the extent that the arrangement falls within the scope of ASC 808, the Company assesses whether the payments between the Company and its collaboration partner fall within the scope of other accounting literature. If the Company concludes that payments from the collaboration partner to the Company would represent consideration from a customer, the Company accounts for those payments within the scope of ASC 606. However, if the Company concludes that its collaboration partner is not a customer for certain activities and associated payments, the Company presents such payments as a reduction of the related expense, based on where the Company presents the underlying expense. See Note 10, "Collaborative Arrangements" for additional information.

Foreign Currency Gains and Losses

Foreign currency gains and losses primarily relate to our Chronix subsidiary in Germany, where the local currency is the functional currency. Assets and liabilities are translated from the foreign currency into U.S. dollar at the exchange rates in effect at the balance sheet date, while income and expenses are translated at the weighted average exchange rates for the period. The net effects of translating the foreign currency financial statements are included in the consolidated shareholders' deficit as a component of accumulated other comprehensive income or loss. Gains and losses for all transactions denominated in a currency other than the U.S. dollar are recognized in the period incurred and included in the consolidated statements of operations as a component of other income or expense.

Other Income and Expenses

Other income and expenses are primarily comprised of interest income, interest expense, and foreign currency gains and losses. Interest income is earned from money market funds we hold for capital preservation. Interest expense is primarily incurred from our financing lease obligations (see Note 6).

Income Taxes

iMDx and its subsidiaries will file a consolidated U.S. federal income tax return and combined California state return for the year ending December 31, 2025. iMDx accounts for income taxes in accordance with ASC 740, *Income Taxes*, which prescribes the use of the asset and liability method, whereby deferred tax asset or liability account balances are calculated at the balance sheet date using current tax laws and rates in effect.

iMDx did not record any provision or benefit for income taxes for the years ended December 31, 2025 and 2024, as iMDx had a full valuation allowance for the periods presented.

Valuation allowances are established when necessary to reduce deferred tax assets when it is more-likely-than-not that a portion or all of the deferred tax assets will not be realized. iMDx's judgments regarding future taxable income may change over time due to changes in market conditions, changes in tax laws, tax planning strategies or other factors. If iMDx's assumptions and consequently its estimates change in the future, the valuation allowance may be increased or decreased, which may have a material impact on iMDx's consolidated statements of operations. iMDx established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from its net operating loss carry-forwards and other deferred tax assets.

The guidance also prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more-likely-than-not sustainable upon examination by taxing authorities. iMDx will recognize accrued interest and penalties related to unrecognized tax benefits as income tax expense. No amounts were accrued for the payment of interest and penalties as of December 31, 2025 and 2024. iMDx is not aware of any uncertain tax positions that could result in significant additional payments, accruals, or other material deviation as of December 31, 2025. iMDx is currently unaware of any tax issues under review. As of December 31, 2025 and 2024, iMDx had unrecognized tax benefits totaling $1.6 million and $1.1 million, respectively. See Note 12, "Income Taxes" for additional information.

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On July 4, 2025, the U.S. enacted H.R. 1, "A bill to provide for reconciliation pursuant to Title II of H. Con. Res. 14," commonly referred to as the One Big Beautiful Bill. Changes in tax laws may affect recorded deferred tax assets and deferred tax liabilities and iMDx's effective tax rate in the future. iMDx continues to evaluate the impacts the new legislation will have on the consolidated financial statements. As a result of the enactment of H.R. 1, iMDx anticipates an impact to the deferred tax asset related to the full expensing of domestic research and experimental expenditures in 2025. iMDx does not expect this change to result in any material impact to its overall tax expense.

Net Loss Per Common Share

Basic loss per share is computed by dividing the net loss applicable to common stockholders after deducting cumulative unpaid dividends and accretion of the preferred stock, when applicable, by the weighted average number of shares of common stock outstanding during the period. The weighted average shares outstanding - basic in the following table includes the effects of pre-funded warrants that were issued in April 2024 and February 2025 (see Note 7, "Common Stock Purchase Warrants" for additional information). Diluted loss per share is computed by dividing the net loss applicable to common stockholders after deducting cumulative unpaid dividends and accretion of the preferred stock, when applicable, by the weighted average number of common shares outstanding plus the number of additional common shares that would have been outstanding if all dilutive potential common shares had been issued, using the treasury stock method or the if-converted method, or the two-class method for participating securities, whichever is more dilutive. Potential common shares are excluded from the computation if their effect is antidilutive.

On February 12, 2026, the Company consummated the February 2026 Offering that included the issuance of 3,482,498 shares of common stock and pre-funded warrants to purchase up to 1,043,478 shares of common stock. See Note 13, "Subsequent Events – Registered Direct Offering" for additional information.

For the years ended December 31, 2025 and 2024, all common stock equivalents are antidilutive because iMDx reported a net loss. The following table presents the calculation of basic and diluted loss per share of common stock:

	Years Ended December 31,	
	2025	2024
	(In thousands, except per share data)	
Numerator:		
Net loss	$ (50,222)	$ (60,663)
Accretion of Series A redeemable convertible preferred stock	—	(263)
Net loss attributable to common stockholders - basic and diluted	$ (50,222)	$ (60,926)
Denominator:		
Weighted average shares outstanding - basic and diluted	30,476	13,071
Net loss per share:		
Net loss attributable to common stockholders per share - basic and diluted	$ (1.65)	$ (4.66)
Anti-dilutive potential common shares excluded from the computation of diluted net loss per common share:		
Stock options	2,251	1,091
RSUs	852	100
Warrants	761	761
Total	3,864	1,952

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Recent Accounting Pronouncements

Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, to address investor requests for more transparency about income tax information by requiring improvements to income tax disclosures, including, (i) consistent categories and greater disaggregation of information in the rate reconciliation, and (ii) income taxes paid disaggregated by jurisdiction. Additional amendments in this Update improve the effectiveness and comparability of disclosures by, (i) adding disclosures of pretax income (or loss) and income tax expense (or benefit), and (ii) removing disclosures that no longer are considered cost beneficial or relevant. The Company adopted this new standard as of December 31, 2025 on a retrospective basis and has included the new disclosure requirements in Note 12, "Income Taxes." The adoption of this new standard did not have an impact on the Company's consolidated balance sheets and consolidated statements of operations, comprehensive loss, shareholders' deficit and cash flows.

Not Yet Adopted

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, to address investor requests for more detailed information about certain types of reported costs and expenses. The amendments in this Update require disclosure, in the notes to financial statements, at each interim and annual reporting period an entity: 1) disclose the amounts of (a) purchases of inventory, (b) employee compensation, (c) depreciation, and (d) intangible asset amortization included in each expense caption presented on the face of the income statement within continuing operations; 2) include certain amounts that are already required to be disclosed under current GAAP in the same disclosure as the other disaggregation requirements; 3) disclose a qualitative description of the amounts remaining that are not separately disaggregated quantitatively; and 4) disclose the total amount of selling expenses and, in annual reporting periods, an entity's definition of selling expenses. The amendments in this Update should be applied either prospectively or retrospectively, and are effective for annual periods beginning after December 15, 2026, and interim periods beginning after December 15, 2027, with early adoption permitted. Management is currently evaluating the impact that the amendments in this Update will have on the Company's financial statement disclosures. The adoption of this new standard will not have an impact on the Company's consolidated balance sheets and consolidated statements of operations, comprehensive loss, shareholders' deficit and cash flows.

In September 2025, the FASB issued ASU No. 2025-06, *Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software*, to modernize the accounting for internal-use software costs. The amendments in this Update remove all references to prescriptive and sequential software development stages (referred to as "project stages"). Therefore, an entity is required to start capitalizing software costs when both of the following occur: 1) management has authorized and committed to funding the software project, and 2) it is probable that the project will be completed and the software will be used to perform the function intended (the "probable-to-complete recognition threshold"). In evaluating the probable-to-complete recognition threshold, an entity is required to consider whether there is significant uncertainty associated with the development activities of the software. In addition, the amendments supersede the website development costs guidance and incorporate the recognition requirements for website-specific development costs from Subtopic 350-50 into Subtopic 350-40. The amendments in this Update are effective for annual periods beginning after December 15, 2027, and interim periods within those annual periods, with early adoption permitted. The amendments may be applied prospectively, using a modified transition approach, or retrospectively. Management is currently evaluating the impact that the amendments in this Update will have on the Company's consolidated balance sheets and consolidated statements of operations, comprehensive loss, shareholders' deficit and cash flows, and related disclosures.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements*. The amendments in this Update: 1) clarify that the guidance in Topic 270 applies to all entities that provide interim financial statements and notes in accordance with GAAP, 2) create a comprehensive list in Topic 270 of interim disclosures that are required in interim financial statements and notes in accordance with GAAP, 3) incorporate a disclosure principle, which is modeled after previous SEC guidance, that requires entities to disclose events and changes that occur after the end of the most recent fiscal year that have a material impact on the entity, and 4) improve guidance about information included in and the format of interim financial statements. The amendments in this Update are effective for interim periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted either prospectively or retrospectively. Management is currently evaluating the impact that the amendments in this Update will have on the Company's interim consolidated balance sheets and interim consolidated statements of operations, comprehensive loss, shareholders' deficit and cash flows, and related interim disclosures.

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3. Business Combinations and Contingent Consideration Liabilities

Acquisition of IGI

On January 31, 2020 (the "IGI Merger Date"), iMDx completed its acquisition of IGI pursuant to the IGI Merger Agreement. iMDx determined there were two types of contingent consideration in connection with the IGI Merger, the Milestone Contingent Consideration and the Royalty Contingent Consideration. There were three milestones comprising the Milestone Contingent Consideration, in connection with the IGI Merger which iMDx valued and recorded as part of the contingent consideration as of the IGI Merger Date (see table below), which consisted of (i) a payment for clinical trial completion and related data publication ("Milestone 1"), (ii) a payment for an affirmative final LCD from CMS for a specified lung cancer test ("Milestone 2"), and (iii) a payment for achieving specified CMS reimbursement milestones ("Milestone 3"). If achieved, any respective Milestone will be paid at the contractual value shown below, with the payment made either in cash or in shares of iMDx's common stock as determined by iMDx. There can be no assurance that any of the Milestones will be achieved.

The following table shows the IGI Merger Date contractual payment amounts, as applicable, and the corresponding fair value of each respective contingent consideration liability:

	Contractual Value	Fair Value on the Merger Date
	(In thousands)	
Milestone 1 [(a) (c)]	$ 1,500	$ 1,340
Milestone 2 [(a)]	3,000	1,830
Milestone 3 [(a)]	1,500	770
Royalty 1 [(b)]	See(b)	5,980
Royalty 2 [(b) (c)]	See(b)	1,210
Total	$ 6,000	$ 11,130

(a) Indicates the maximum amount payable if the Milestone is achieved.
(b) As defined, Royalty Payments are based on a percentage of future revenues of DetermaIO and Laboratory Services over their respective useful life, accordingly there is no fixed contractual value for the Royalty Contingent Consideration.
(c) Contingent consideration is currently not expected to be paid out.

The fair value of the contingent consideration after the IGI Merger Date is reassessed by iMDx as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in iMDx's consolidated statements of operations. Since December 2023, Milestone 1 and Royalty 2 (Laboratory Services) are not expected to be paid and are excluded from the current fair value. During 2025, based on iMDx's reassessment of significant assumptions, there was a decrease of approximately $786,000 to the fair value of the contingent consideration primarily attributable to revised estimates of the possible future payouts and, accordingly, this amount was recorded as a change in fair value of contingent consideration in the consolidated statement of operations for the year ended December 31, 2025.

iMDx uses a discounted cash flow valuation technique to determine the fair value of its Level 3 contingent consideration liabilities. The significant unobservable inputs used in IGI's contingent consideration valuation on December 31, 2025, included: (i) a discount period, based on the expected Milestone payment dates, ranging from 1.7 years to 1.9 years, (ii) a discount rate of 12.3%, and (iii) a management probability estimate of 25% to 50%. The significant unobservable inputs used in IGI's contingent consideration valuation on December 31, 2024, included: (i) a discount period, based on the expected Milestone payment dates, ranging from 1.7 years to 7.8 years, (ii) a discount rate of 13.2% to 13.5%, and (iii) a management probability estimate of 25% to 50%. Changes to significant unobservable inputs to different amounts could result in a significantly higher or lower fair value measurement at the reporting date.

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The following tables reflect the activity for the IGI contingent consideration measured at fair value using Level 3 inputs:

	Fair Value (In thousands)
Balance at December 31, 2023	$ 2,040
Change in estimated fair value	553
Balance at December 31, 2024	$ 2,593
Balance at December 31, 2024	$ 2,593
Change in estimated fair value	(786)
Balance at December 31, 2025	$ 1,807

Acquisition of Chronix

On April 15, 2021 (the "Chronix Merger Date"), iMDx completed its acquisition of Chronix pursuant to the Chronix Merger Agreement. As additional consideration for holders of certain classes and series of Chronix capital stock, the Chronix Merger Agreement required iMDx to pay certain contingent consideration. On February 8, 2023, the Company and the equity holder representative named in the Chronix Merger Agreement entered into Amendment No. 1 to the Chronix Merger Agreement, pursuant to which the parties agreed that (i) Chronix's equity holders will be paid earnout consideration of 10% of net collections for sales of specified tests and products, until the expiration of intellectual property related to such tests and products, (ii) Chronix's equity holders will be paid 5% of the gross proceeds received from any sale of all or substantially all of the rights, titles, and interests in and to Chronix's patents for use in transplantation medicine to such third-party, and (iii) all of the previous payment obligations were eliminated.

The fair value of the Chronix contingent consideration after the Chronix Merger Date is reassessed by iMDx as changes in circumstances and conditions occur, with the subsequent change in fair value recorded in iMDx's consolidated statements of operations. During 2025, based on iMDx's reassessment of significant assumptions, there was an increase of approximately $6.7 million to the fair value of the contingent consideration primarily attributable to revised estimates of the possible future payouts and, accordingly, this amount was recorded as a change in fair value of contingent consideration in the consolidated statement of operations for the year ended December 31, 2025.

iMDx uses a discounted cash flow valuation technique to determine the fair value of its Level 3 contingent consideration liabilities. The significant unobservable inputs used in Chronix's contingent consideration valuation on December 31, 2025, included: (i) a discount period, based on the related patent expiration dates, ranging from 8.8 years to 9.7 years, (ii) a discount rate of 12.3% to 13.0%, and (iii) a payout percentage of 10% based on the earnout provision. The significant unobservable inputs used in Chronix's contingent consideration valuation on December 31, 2024, included: (i) a discount period, based on the related patent expiration dates, ranging from 9.8 years to 10.7 years, (ii) a discount rate of 13.1% to 13.6%, and (iii) a payout percentage of 10% based on the earnout provision. Changes to significant unobservable inputs to different amounts could result in a significantly higher or lower fair value measurement at the reporting date.

The following tables reflect the activity for the Chronix contingent consideration measured at fair value using Level 3 inputs:

	Fair Value (In thousands)
Balance at December 31, 2023	$ 40,174
Change in estimated fair value	(4,828)
Balance at December 31, 2024	$ 35,346
Balance at December 31, 2024	$ 35,346
Earnout payments	(2)
Change in estimated fair value	6,732
Balance at December 31, 2025	$ 42,076

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The accompanying consolidated balance sheets separately present the IGI and Chronix total contingent consideration liabilities as current and noncurrent based on our expectations of the timing of product commercialization and subsequent revenues that trigger the payouts. Contingent consideration is not deductible for tax purposes, even if paid; therefore, no deferred tax assets related to the contingent consideration were recorded.

4. Property and Equipment, Net

ROU operating and financing lease assets, net, machinery and equipment, net, and construction in progress were as follows:

	December 31,	
	2025	2024
	(In thousands)	
ROU operating and financing lease assets	$ 5,623	$ 5,323
Machinery, equipment and leasehold improvements	12,516	8,366
Accumulated depreciation and amortization	(9,654)	(7,705)
	8,485	5,984
Construction in progress	765	340
Property and equipment, net	$ 9,250	$ 6,324

Property and equipment depreciation and amortization expense amounted to $2.2 million and $1.5 million for the years ended December 31, 2025 and 2024, respectively.

5. Intangible Assets, Net

As part of the IGI and Chronix acquisitions completed on January 31, 2020 and April 15, 2021, respectively, the Company acquired IPR&D and customer relationships (see Note 3). During the fourth quarter of 2024, the IPR&D balances were reassessed using the multi-period excess earnings method ("MPEEM") approach and the results of the valuations noted that the carrying values of the DetermaIO and DetermaCNI IPR&D intangible assets were greater than the fair market values. Accordingly, the Company recorded impairments of $6.8 million and $35.1 million related to DetermaIO and DetermaCNI, respectively, as of December 31, 2024.

The MPEEM valuation approach is a discounted cash flow valuation technique and was used to determine the Level 3 fair values of the IPR&D. The significant unobservable inputs used related to DetermaIO as of December 31, 2024, included: (i) a discount period of 19.5 years, based on the expected life of patent, and (ii) a weighted average cost of capital rate of 29.0%, as well as certain assumptions about future cash flows. This valuation approach yielded a fair value of $2.9 million as of December 31, 2024. The significant unobservable inputs used related to DetermaCNI as of December 31, 2024, included: (i) a discount period of 19.5 years, based on the expected life of patent, and (ii) a weighted average cost of capital rate of 19.5%, as well as certain assumptions about future cash flows. This valuation approach yielded a fair value of $11.7 million as of December 31, 2024.

As of December 31, 2025, due to growing competitive pressure in the oncology market, although not abandoned, management does not foresee substantial near term investment in, or revenue generating opportunities from, DetermaIO and DetermaCNI. Due to this current market condition, the Company's long range plan forecasts were updated, resulting in a significant reduction to anticipated future benefits derived from the Company's IPR&D assets. The IPR&D balances were reassessed based on the updated long range plan using the MPEEM approach and the results of the valuations noted that the carrying values of the DetermaIO and DetermaCNI IPR&D intangible assets were greater than the fair market values, resulting in the full impairment of both assets. Accordingly, the Company recorded impairments of $2.9 million and $11.7 million related to DetermaIO and DetermaCNI, respectively, as of December 31, 2025.

The significant unobservable inputs used related to DetermaIO and DetermaCNI as of December 31, 2025, included: (i) a discount period of 15.0 years, based on the long range plan forecast, and (ii) a discount rate of 29.0%, as well as certain assumptions about future cash flows in the related long range plan forecast. This valuation approach yielded a fair value of zero for both DetermaIO and DetermaCNI as of December 31, 2025. See Note 2, "Intangible Assets" for additional IPR&D information.

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Intangible assets, net, consisted of the following:

	December 31,	
	2025	2024
	(In thousands)	
Intangible assets:		
Acquired IPR&D - DetermaIO [1]	$ —	$ 2,900
Acquired IPR&D - DetermaCNI [2]	—	11,700
Intangible assets subject to amortization:		
Acquired intangible assets - customer relationship	440	440
Total intangible assets	440	15,040
Accumulated amortization - customer relationship [3]	(440)	(433)
Intangible assets, net	$ —	$ 14,607

(1) See Note 3 for information on the IGI Merger.
(2) See Note 3 for information on the Chronix Merger.
(3) Amortization of intangible assets is included in "Cost of revenues – amortization of acquired intangibles" in the consolidated statements of operations because the intangible assets pertain directly to the revenues generated from the acquired intangibles.

Intangible asset amortization expense amounted to $7,000 and $88,000 for the years ended December 31, 2025 and 2024, respectively.

6. Commitments and Contingencies

Office and Facilities Leases

Irvine Office Lease

On December 23, 2019, iMDx and Cushing Ventures, LLC ("Landlord") entered into an Office Lease Agreement (the "Irvine Lease") of a building containing approximately 26,800 square feet of rentable space located at 15 Cushing in Irvine, California (the "Premises") that served as iMDx's principal executive and administrative offices until June 2025 (see "Nashville Office and Facilities Leases" below). The Irvine Lease has a term of 89 calendar months (the "Term"), which commenced on June 1, 2020 (the "Commencement Date") and will end on October 31, 2027. iMDx agreed to pay base monthly rent in the amount of $61,640 during the first 12 months of the Term. Base monthly rent increases annually, over the base monthly rent then in effect, by 3.5%. In June 2025, in connection with the Subtenant's (as defined below under the caption "Irvine Office Sublease") full usage of, and iMDx's exit of, the Premises, iMDx performed a recoverability test of the remaining lease related assets. Such lease asset group carrying amount was compared to the total undiscounted future expected cash flows from the sublease income, which resulted in no impairment.

Effective as of January 2, 2025, iMDx, Landlord and Subtenant (defined below) entered into an amendment to the Irvine Lease, dated December 26, 2024 (the "Amendment"). Pursuant to the terms of the Amendment, among other things: (a) iMDx and Subtenant agreed that all rights to extend the Term of the Irvine Lease for a period of five years were terminated, and (b) Landlord and iMDx agreed that, provided iMDx is not in default under any of the terms and conditions of the Irvine Lease that is continuing beyond any and all applicable notice and cure periods, then, commencing on July 1, 2025 and continuing on the first day of each calendar month thereafter, the provided letter of credit (as further discussed below) in the amount of $1.7 million (the "Letter of Credit Amount") shall be reduced by an amount equal to $60,714.29 on each such date, until the Letter of Credit Amount is fully reduced, after which the letter of credit shall be deemed to have been terminated and iMDx shall have no further obligation to maintain or deliver the letter of credit under the Irvine Lease. The new Letter of Credit Amount will correspond to the Company's restricted cash on the accompanying consolidated balance sheet and the reductions in the Letter of Credit Amount would correspondingly reduce the associated amount of such restricted cash.

In addition to base monthly rent, iMDx agreed to pay in monthly installments (a) all costs and expenses, other than certain excluded expenses, incurred by the lessor in each calendar year in connection with operating, maintaining, repairing (including replacements if repairs are not feasible or would not be effective) and managing the Premises and the building in which the Premises are located ("Expenses"), and (b) all real estate taxes and assessments on the Premises and the building in which the Premises are located, all personal property taxes for property that is owned by lessor and used in connection with the operation, maintenance and repair of the Premises, and costs and fees incurred in connection with seeking reductions in such tax liabilities ("Taxes"). Subject to certain exceptions, Expenses shall not be increased by more than 4% annually on a cumulative, compounded basis.

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iMDx was entitled to an abatement of its obligations to pay Expenses and Taxes while constructing improvements to the Premises constituting "Tenant's Work" under the Irvine Lease prior to the Commencement Date, except that iMDx was obligated to pay 43.7% of Expenses and Taxes during the period prior to the Commencement Date for its use of the second floor of the Premises, which was already built out as office space. The lessor provided iMDx with a "Tenant Improvement Allowance" in the amount of $1.3 million to pay for the plan, design, permitting, and construction of the improvements constituting Tenant's Work. The lessor retained 1.5% of the Tenant Improvement Allowance as an administrative fee as provided in the Irvine Lease. As of June 2021, the lessor had provided $1.3 million of the total Tenant Improvement Allowance, which is being amortized over the Term.

iMDx provided the lessor with a security deposit in the amount of $150,000 and a letter of credit in the initial amount of $1.7 million. The lessor may apply the security deposit, in whole or in part, for the payment of rent and any other amount that iMDx is or becomes obligated to pay under the Irvine Lease but fails to pay when due and beyond any cure period. The lessor may draw on the letter of credit from time to time to pay any amount that is unpaid and due, or if the original issuing bank notifies the lessor that the letter of credit will not be renewed or extended for the period required under the Irvine Lease and iMDx fails to timely provide a replacement letter of credit, or an "event of default" under the Irvine Lease occurs and continues beyond the applicable cure period, or if certain instances of insolvency or bankruptcy with respect to iMDx occur. iMDx is required to restore any portion of the security deposit that is applied by the lessor to payments due under the Irvine Lease, and iMDx is required to restore the amount available under the letter of credit to the required amount if any portion of the letter of credit is drawn by the lessor. The Letter of Credit Amount shall be reduced as described in the Amendment above.

To obtain the letter of credit, iMDx has provided the issuing bank with a restricted cash deposit that the bank will hold to cover its obligation to pay any draws on the letter of credit by the lessor. The restricted cash may not be used for any other purpose. Corresponding to the Letter of Credit Amount, iMDx has reflected $1.3 million as the total remaining current and noncurrent restricted cash balances in the accompanying consolidated balance sheet as of December 31, 2025. The total restricted cash balance in the accompanying consolidated balance sheet as of December 31, 2024 was $1.7 million.

Irvine Office Sublease

On August 8, 2023, iMDx and Induce Biologics USA, Inc. ("Subtenant") entered into a Sublease Agreement (the "Sublease Agreement"), which subsequently became effective as of September 14, 2023, upon the execution and delivery by the Company, Subtenant, and Landlord, of that certain Landlord's Consent to Sublease dated September 12, 2023 (the "Consent Agreement"), under which Landlord consented to the Sublease Agreement, on the terms and subject to the conditions set forth therein. The Sublease Agreement is subject and subordinate to the Irvine Lease.

Under the Sublease Agreement, the Company agreed to initially sublet to Subtenant a portion of the Premises consisting of approximately 13,400 square feet of rentable space for a term (the "Initial Period") commencing on the date that is 120 days after the effective date of the Consent Agreement (the "Sublease Commencement Date") and ending on the date that is 18 months following the Sublease Commencement Date (June 20, 2025, the date on which the Initial Period ends, and the "Expansion Date"). On the Expansion Date, the portion of the Premises that is subleased to Subtenant under the Sublease Agreement automatically increased to include the remaining portion of the Premises, which consists of approximately 13,400 square feet of additional rentable space for a term (the "Expansion Period") beginning on the Expansion Date through the expiration of the Irvine Lease on October 31, 2027, unless earlier terminated.

The Sublease Agreement provides that, from and after the Sublease Commencement Date, Subtenant will pay to the Company monthly base rent in the following amounts: (i) $36,850 for rental periods beginning on the Sublease Commencement Date and ending on or before December 31, 2024; (ii) $37,955 for rental periods beginning on or after January 1, 2025 and ending on or before June 20, 2025; (iii) $75,844 for rental periods beginning on or after July 1, 2025 and ending on or before December 31, 2025; (iv) $78,188 for rental periods beginning on or after January 1, 2026 and ending on or before December 31, 2026; and (v) $80,534 for rental periods beginning on or after January 1, 2027 and ending on or before October 31, 2027.

Following the Sublease Commencement Date, Subtenant is responsible for the payment of Additional Rent, including Expenses and Taxes (as each such term is defined in the Irvine Lease), provided that, with respect to the Initial Period, Subtenant was responsible for only 50% of the Expenses and Taxes due. In addition, Subtenant paid the Company a security deposit in the amount of $101,987 in connection with the transactions contemplated by the Sublease Agreement.

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The Sublease Agreement contains customary provisions with respect to, among other things, Subtenant's obligation to comply with the Irvine Lease and applicable laws, the payment of utilities and similar services utilized by Subtenant with respect its use of the Premises, the indemnification of the Company by Subtenant, and the right of the Company to terminate the Sublease Agreement in its entirety and retake the Premises if Subtenant fails to remedy certain defaults of its obligations under the Sublease Agreement within specified time periods.

Nashville Office and Facilities Leases

iMDx operates a CLIA-certified laboratory and office space located in the Nashville, Tennessee area under multiple lease arrangements. Since June 2025, iMDx's Nashville location also serves as our principal executive and administrative offices. iMDx maintains an aggregate of 12,881 square feet of rentable space in the Nashville area. Lab space represents approximately 6,586 square feet of the total rentable space in the Nashville area.

In January 2024, iMDx renewed its existing leases and added a new lease agreement to expand its Nashville area office space. The new lease agreements each have an initial term of 36 months, which commenced on January 1, 2024 and will end in January 2027. iMDx has the option to renew the term of each lease for four additional one year periods. iMDx agreed to pay an aggregate base monthly rent in the amount of $22,252 during the first 12 months of the term. Base monthly rent increases annually, over the base monthly rent then in effect, by approximately 3.0%.

In September 2025, iMDx added a new lease agreement to expand its Nashville area laboratory and office space. The new lease agreement has an initial term of 36 months, which commenced on October 1, 2025 and will end in September 2028. iMDx has the option to renew or extend the term upon request. iMDx agreed to pay a base monthly rent in the amount of $6,200 during the first 24 months of the term, and $6,700 per month thereafter.

Germany Office and Facilities Leases

iMDx operates a research and development laboratory and office space located in Göttingen, Germany. In August 2025, iMDx added a new lease agreement to expand our Germany laboratory and office space. With the new lease, iMDx maintains an aggregate of 3,455 square feet of rentable space in Germany. Lab space represents approximately 2,077 square feet of the total rentable space in Germany. The new lease agreement has an initial term of 60 months, which commenced on October 1, 2025 and will end in September 2030. iMDx has the option to renew the term for two additional three year periods. iMDx agreed to pay an aggregate base monthly rent in the approximate amount of $7,158 over the full 60 month term. Base rent may increase or decrease based the German consumer price index annual rate of change. Any adjustments to the base rent in subsequent years will be recognized in operations as variable lease payments.

The office and facilities leases discussed above are operating leases under ASC 842. The tables below provide the amounts recorded in connection with the application of ASC 842 for iMDx's operating leases (see Note 2, "Leases" for additional policy information).

Financing Leases

iMDx has various financing leases for certain laboratory and other equipment. iMDx's financing lease obligations are collateralized by the equipment financed under the lease schedules. The tables below provide the amounts recorded in connection with the application of ASC 842 for iMDx's financing leases (see Note 2, "Leases" for additional policy information).

In August 2025, iMDx entered into a lease line agreement to provide equipment leasing in the aggregate amount of $2.5 million during an availability period that expires on June 30, 2026. iMDx paid a commitment fee of $25,000. All costs relating to the installation, freight, training, insurance, appraisals and any other cost related to the acquisition, installation or operation of the leased equipment will be paid directly by iMDx. The minimum requirement for each lease schedule is $50,000. The lease line amount includes three options: (i) international equipment up to $500,000; (ii) sale and leaseback up to $1.0 million, whereby a liquidation value, based on a third-party appraiser of lessor's choice, of the equipment will be utilized for the capitalized cost; both (i) and (ii) have an initial term of 24 months and a monthly rental factor of .0471; and (iii) new equipment up to $1.0 million with an initial term of 36 months and a monthly rental factor of .033. Actual monthly rentals will be determined by multiplying the original equipment capitalized cost by the applicable monthly rental factor, plus any monthly maintenance charges. At the end of an initial term, iMDx may return the equipment, exercise a purchase option, or extend for an additional 12 months at a monthly rental factor of .0175, plus any monthly maintenance charges. Currently, iMDx has not executed any lease schedules under the lease line agreement.

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Operating and Financing Leases

The following table presents supplemental balance sheet information related to operating and financing leases:

	December 31,	
	2025	2024
	(In thousands)	
Operating leases		
ROU assets, net	$ 1,707	$ 1,789
Lease liabilities, current	$ 1,180	$ 914
Lease liabilities, noncurrent	1,079	1,713
Total operating lease liabilities	$ 2,259	$ 2,627
Financing leases		
ROU machinery and equipment	$ 1,981	$ 1,673
ROU accumulated depreciation	(873)	(705)
ROU machinery and equipment, net	$ 1,108	$ 968
Lease liabilities, current	$ 551	$ 381
Lease liabilities, noncurrent	509	554
Total financing lease liabilities	$ 1,060	$ 935
Weighted average remaining lease term:		
Operating lease	2.2 years	2.6 years
Financing lease	2.0 years	2.4 years
Weighted average discount rate:		
Operating lease	9.59%	10.44%
Financing lease	7.97%	10.23%

Future minimum lease commitments are as follows:

	Operating Leases	Financing Leases
	(In thousands)	
Year Ending December 31,		
2026	$ 1,343	$ 607
2027	857	404
2028	146	116
2029	86	4
2030	65	—
Total minimum lease payments	2,497	1,131
Less amounts representing interest	(238)	(71)
Present value of net minimum lease payments	$ 2,259	$ 1,060

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The following table presents supplemental cash flow information related to operating and financing leases:

	Years Ended December 31,	
	2025	2024
	(In thousands)	
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	$ 1,184	$ 1,106
Operating cash flows from financing leases	$ 91	$ 42
Financing cash flows from financing leases	$ 510	$ 201

The Company incurred total operating lease cost, including short-term lease expense, of $333,000 and $607,000, which was net of sublease income of $683,000 and $442,000, for the years ended December 31, 2025 and 2024, respectively.

Financing lease amortization expense amounted to $496,000 and $168,000 for the years ended December 31, 2025 and 2024, respectively.

Litigation – General

iMDx may be subject to various claims and contingencies in the ordinary course of its business, including those related to litigation, business transactions, employee-related matters, and other matters. When iMDx is aware of a claim or potential claim, it assesses the likelihood of any loss or exposure. If it is probable that a loss will result and the amount of the loss can be reasonably estimated, iMDx will record a liability for the loss. If the loss is not probable or the amount of the loss cannot be reasonably estimated, iMDx discloses the claim if the likelihood of a potential loss is reasonably possible and the amount involved could be material.

Tax Filings

iMDx tax filings are subject to audit by taxing authorities in jurisdictions where it conducts business. These audits may result in assessments of additional taxes that are subsequently resolved with the authorities or potentially through the courts. Management believes iMDx has adequately provided for any ultimate amounts that are likely to result from these audits; however, final assessments, if any, could be significantly different than the amounts recorded in the consolidated financial statements. See Note 2, “Income Taxes” for additional information.

Employment Contracts

iMDx has entered into employment and severance benefit contracts with certain executive officers. Under the provisions of the contracts, iMDx may be required to incur severance obligations for matters relating to changes in control, as defined in the respective contracts, and certain terminations of executives. As of December 31, 2025 and 2024, iMDx accrued approximately $2.3 million, in severance obligations for certain executive officers, in accordance with the severance benefit provisions of their respective employment and severance benefit agreements, primarily related to iMDx’s acquisition of Chronix in 2021. For the periods presented, management has included $2.3 million of the accrued severance obligations related to the Chronix acquisition as contingent consideration in the consolidated balance sheets under contingent consideration liabilities, current and noncurrent. See Note 3, “Business Combinations and Contingent Consideration – Acquisition of Chronix” for additional information.

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Indemnification

In the normal course of business, iMDx may provide indemnification of varying scope under iMDx's agreements with other companies or consultants, typically iMDx's clinical research organizations, investigators, clinical sites, suppliers and others. Pursuant to these agreements, iMDx will generally agree to indemnify, hold harmless, and reimburse the indemnified parties for losses and expenses suffered or incurred by the indemnified parties arising from claims of third parties in connection with the use or testing of iMDx's diagnostic tests. Indemnification provisions could also cover third party infringement claims with respect to patent rights, copyrights, or other intellectual property pertaining to iMDx's diagnostic tests. iMDx's office and laboratory facility leases also will generally contain indemnification obligations, including obligations for indemnification of the lessor for environmental law matters and injuries to persons or property of others, arising from iMDx's use or occupancy of the leased property. The term of these indemnification agreements will generally continue in effect after the termination or expiration of the particular research, development, services, lease, or license agreement to which they relate. The Razor Stock Purchase Agreement (see Note 2, "Investments in Privately Held Companies") also contains provisions under which iMDx has agreed to indemnify Razor and Encore Clinical, Inc., a former stockholder of Razor, from losses and expenses resulting from breaches or inaccuracy of iMDx's representations and warranties and breaches or nonfulfillment of iMDx's covenants, agreements, and obligations under the Razor Stock Purchase Agreement. iMDx periodically enters into underwriting and securities sales agreements with broker-dealers in connection with the offer and sale of iMDx securities. The terms of those underwriting and securities sales agreements include indemnification provisions pursuant to which iMDx agrees to indemnify the broker-dealers from certain liabilities, including liabilities arising under the Securities Act of 1933, as amended (the "Securities Act"), in connection with the offer and sale of iMDx securities.

The potential future payments iMDx could be required to make under these indemnification agreements will generally not be subject to any specified maximum amounts. Historically, iMDx has not been subject to any claims or demands for indemnification. iMDx also maintains various liability insurance policies that limit iMDx's financial exposure. As a result, iMDx management believes that the fair value of these indemnification agreements is minimal. Accordingly, iMDx has not recorded any liabilities for these agreements as of December 31, 2025 and 2024.

7. Series A Redeemable Convertible Preferred Stock and Shareholders' Deficit

Series A Redeemable Convertible Preferred Stock

On April 13, 2022, the Company entered into a Securities Purchase Agreement with institutional accredited investors (the "Investors") in a registered direct offering of 11,765 shares of the Company's Series A Preferred Stock, which shares of Series A Preferred Stock are convertible into a total of 384,477 shares of the Company's common stock, at a conversion price of $30.60 per share. The purchase price of each share of Series A Preferred Stock was $850, which included an original issue discount to the stated value of $1,000 per share. The rights, preferences and privileges of the Series A Preferred Stock are set forth in the Company's Certificate of Determination, which the Company filed with the Secretary of State of the State of California. The Securities Purchase Agreement provided that the closing of the Series A Preferred Stock offering will occur, subject to the satisfaction of certain closing conditions, in two equal tranches of $5,000,000 each for aggregate gross proceeds from both closings of $10,000,000. The first closing occurred on June 1, 2022, and iMDx received net proceeds of approximately $4.9 million from the Series A Preferred Stock issued from the first tranche. The second closing did not occur due to certain closing conditions. The Series A Preferred Stock was convertible into shares of the Company's common stock at any time at the holder's option.

In the event of the Company's liquidation, dissolution, or winding up, holders of Series A Preferred Stock would have received a payment equal to the stated value of the Series A Preferred Stock plus accrued but unpaid dividends and any other amounts that may have become payable on the Series A Preferred Stock. Shares of Series A Preferred Stock were entitled to receive cumulative dividends at a rate per share (as a percentage of stated value) of 6% per annum, payable quarterly in cash or, at our option, by accreting such dividends to the stated value.

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Shares of Series A Preferred Stock generally had no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Preferred Stock would be required to amend any provision of our certificate of incorporation that would have had a materially adverse effect on the rights of the holders of the Series A Preferred Stock. Additionally, as long as any shares of Series A Preferred Stock remained outstanding, unless the holders of at least 51% of the then outstanding shares of Series A Preferred Stock shall have otherwise given prior written consent, we, on a consolidated basis with our subsidiaries, were not permitted to (1) have less than $8 million of unrestricted, unencumbered cash on hand ("Cash Minimum Requirement"); (2) other than certain permitted indebtedness, incur indebtedness to the extent that our aggregate indebtedness exceeds $15 million; (3) enter into any agreement (including any indenture, credit agreement or other debt instrument) that by its terms prohibited, prevented, or otherwise limited our ability to pay dividends on, or redeem, the Series A Preferred Stock in accordance with the terms of the Certificate of Determination; or (4) authorize or issue any class or series of preferred stock or other capital stock of the Company that ranks senior or pari passu with the Series A Preferred Stock.

The Company was required to redeem, for cash, the shares of Series A Preferred Stock on the earlier to occur of (1) April 8, 2024, (2) the commencement of certain a voluntary or involuntary bankruptcy, receivership, or similar proceedings against the Company or its assets, (3) a Change of Control Transaction (as defined) and (4) at the election and upon notice of 51% in interest of the holders, if the Company failed to meet the Cash Minimum Requirement. Additionally, the Company had the right to redeem the Series A Preferred Stock for cash upon 30 days prior notice to the holders; provided if the Company undertakes a capital raise in connection with such redemption, the Investors will have the right to participate in such financing.

On April 5, 2023, the Company redeemed 1,064 shares of the Series A Preferred Stock for approximately $1.1 million. In connection with the April 2023 redemption, the Company recorded a deemed dividend of $118,000 based on the difference between the Series A Preferred Stock redemption value and carrying value. On April 15, 2024, Company redeemed the remaining 4,818 shares of the Series A Preferred Stock for approximately $5.4 million (see "Common Stock – April 2024 Offering" below). As of April 15, 2024, the Company accreted dividends of $570,000, net of the April 2023 redemption.

The issuance and sale of the Series A Preferred Stock was completed pursuant to the Company's effective "shelf" registration statement on Form S-3 (Registration No. 333-256650), filed with the Securities and Exchange Commission ("SEC") on May 28, 2021 and declared effective by the SEC on June 8, 2021, and an accompanying prospectus dated June 8, 2021 as supplemented by a prospectus supplement dated April 13, 2022.

Preferred Stock

As of December 31, 2025 and 2024, iMDx had 5,000,000 shares of preferred stock, no-par value, authorized. As of December 31, 2025 and 2024, iMDx had no shares of preferred stock issued and outstanding.

Common Stock

As of December 31, 2025 and 2024, iMDx had 230,000,000 shares of common stock, no-par value, authorized. As of December 31, 2025 and 2024, iMDx had 28,682,844 and 17,452,824 shares of common stock issued and outstanding, respectively.

April 2024 Offering

On April 15, 2024, the Company consummated a private placement of its securities to certain accredited investors for the issuance and sale of 5,076,900 shares of the Company's common stock and pre-funded warrants to purchase 342,888 shares of the Company's common stock, with an exercise price of $0.0001 per share (the "April 2024 Offering"). The purchase price for one common share was $2.9164, and the purchase price for one pre-funded warrant was $2.9163. Certain insiders of the Company subscribed for 42,373 of the shares of common stock sold in the private placement, at a purchase price of $2.95 per share (see Note 9). The related securities purchase agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the accredited investors, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

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A holder of the pre-funded warrants may not exercise any portion of such holder's pre-funded warrants to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company's outstanding shares of common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to the Company, the holder may increase the beneficial ownership limitation to up to 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise. The pre-funded warrants are exercisable immediately and will expire when exercised in full. As of December 31, 2025, none of such pre-funded warrants have been exercised.

The gross proceeds to the Company from the April 2024 Offering were approximately $15.8 million, before deducting approximately $538,000 in placement agent fees and expenses and offering expenses payable by the Company. The Company used the net proceeds received for general corporate purposes and working capital. In addition, approximately $5.4 million of the net proceeds was used to redeem the outstanding shares of the Company's Series A Redeemable Convertible Preferred Stock.

August 2024 Offering

On August 9, 2024, the Company entered into a sales agreement with a sales agent, pursuant to which the Company could offer and sell from time to time up to an aggregate of $7.5 million of shares of the Company's common stock (the "Placement Shares"), through the sales agent (the "August 2024 Offering").

Sales of the Placement Shares were made in sales deemed to be "at-the-market offerings" as defined in Rule 415 promulgated under the Securities Act. The sales agent used commercially reasonable efforts to sell, on the Company's behalf, all of the Placement Shares requested to be sold by the Company, consistent with its normal trading and sales practices, the terms of the sales agreement, and applicable law and regulations. The Company could also sell Placement Shares to the sales agent as principal in negotiated transactions. The Company had no obligation to sell any Placement Shares, and could at any time suspend offers under the sales agreement or terminate the sales agreement. The sales agreement would terminate, and offer and sale of the Placement Shares pursuant to the sales agreement would cease, upon the earlier of (a) the issuance and sale of all of the Placement Shares subject to the sales agreement or (b) the termination of the sales agreement by the sales agent or the Company pursuant to the terms thereof. The sales agreement contained customary representations, warranties and agreements by the Company, as well as indemnification obligations of the Company for certain liabilities under the Securities Act. On February 6, 2025, the Company provided notice of its intention to terminate the sales agreement. As a result, on February 8, 2025, the sales agreement terminated in accordance with its terms.

Under the terms of the sales agreement, the Company paid the sales agent a commission equal to 3.0% of the aggregate gross proceeds from each sale of Placement Shares. As of February 8, 2025, the Company sold 610,622 Placement Shares for net proceeds of approximately $1.7 million, at an average purchase price of $3.05 per share. In addition, the Company agreed to pay certain expenses incurred by the sales agent in connection with the offering. Total offering expenses incurred in the amount of $367,000 were being deferred and expensed ratably over a one year period. On February 8, 2025, the remaining deferred financing costs of $279,000 were recognized as a general and administrative expense in the consolidated statement of operations.

The Placement Shares were registered under the Securities Act pursuant to the registration statement on Form S-3 (File No. 333-281159) filed with the SEC on August 1, 2024 and declared effective by the SEC on August 7, 2024, the base prospectus contained within the registration statement, and a prospectus supplement dated August 9, 2024.

October 2024 Offering

On October 4, 2024, the Company consummated a private placement of its securities to certain accredited investors for the issuance and sale of 3,461,138 shares of the Company's common stock (the "October 2024 Offering"). The purchase price for one common share was $2.948. Certain insiders of the Company subscribed for 37,037 of the shares of common stock sold in the private placement, at a purchase price of $2.97 per share (see Note 9). The related securities purchase agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the investors, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

The gross proceeds to the Company from the October 2024 Offering were approximately $10.2 million, before deducting approximately $836,000 in placement agent fees and expenses and offering expenses payable by the Company. The Company used the net proceeds received of approximately $9.4 million for general corporate purposes and working capital.

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February 2025 Offering

On February 10, 2025, the Company consummated a private placement of its securities to certain accredited investors for the issuance and sale of 7,536,706 shares of the Company's common stock and pre-funded warrants to purchase 3,069,926 shares of the Company's common stock, with an exercise price of $0.0001 per share. The purchase price for one common share was $2.05, and the purchase price for one pre-funded warrant was $2.05. Certain officers of the Company subscribed for 109,756 of the shares of common stock sold in the private placement, at a purchase price of $2.05 per share (see Note 9). The related securities purchase agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the investors, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

A holder of the pre-funded warrants may not exercise any portion of such holder's pre-funded warrants to the extent that the holder, together with its affiliates, would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of the Company's outstanding shares of common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to the Company, the holder may increase the beneficial ownership limitation to up to 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise. As of December 31, 2025, none of such pre-funded warrants have been exercised.

Further, on February 10, 2025, the Company consummated a registered direct offering of its securities to certain investors for the issuance and sale of 3,609,755 shares of the Company's common stock, priced at-the-market under the rules of The Nasdaq Stock Market. The purchase price for one common share was $2.05. The related securities purchase agreement contains customary representations, warranties and agreements by the Company, indemnification obligations of the Company and the investors, including for liabilities under the Securities Act, other obligations of the parties and termination provisions.

The registered shares of common stock were offered by the Company pursuant to its shelf registration statement on Form S-3 (File No. 333-281159), which was filed with the SEC on August 1, 2024, and declared effective by the SEC on August 7, 2024, including the base prospectus contained therein, and a related prospectus supplement, dated February 7, 2025, filed with the SEC on February 10, 2025.

The aggregate gross proceeds from the February 2025 Offering were approximately $29.1 million. After deducting offering expenses payable by the Company of $487,000, the resulting net proceeds were approximately $28.7 million. The Company is using the net proceeds received for general corporate purposes and working capital.

February 2026 Offering

On February 12, 2026, the Company consummated the February 2026 Offering. The gross proceeds from the February 2026 Offering were approximately $26.0 million. After deducting placement agent fees and offering expenses payable by the Company of $1.4 million, the resulting net proceeds were approximately $24.6 million. See Note 13, "Subsequent Events – Registered Direct Offering" for additional information.

Unregistered Restricted Stock Issuance

During the year ended December 31, 2025, the Company issued 9,547 shares of restricted common stock for a total fair value of $40,000 in connection with an ongoing investor relations consulting service arrangement. During 2025, the Company has issued an additional 20,464 RSUs to this and another consulting firm under the Company's amended and restated 2018 incentive plan, see Note 8, "Stock-Based Compensation – Plan Activity – RSU Awards" for additional information.

During the year ended December 31, 2024, the Company issued 26,664 shares of restricted common stock in connection with an ongoing investor relations consulting service arrangement for a total fair value of $72,000. During 2024, the Company issued an additional 12,677 RSUs to this consulting firm under the Company's amended and restated 2018 incentive plan, see Note 8, "Stock-Based Compensation – Plan Activity – RSU Awards" for additional information.

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Common Stock Purchase Warrants

As of December 31, 2025 and 2024, iMDx had common stock purchase warrants issued and outstanding of 760,866. During the year ended December 31, 2025, no warrants were exercised or expired. As of December 31, 2025, the outstanding warrants had exercise prices ranging from $30.60 to $109.20 per share, are set to expire on various dates ranging from February 2027 to October 2029 and have a weighted average remaining life of 1.31 years. Certain warrants have "cashless exercise" provisions meaning that the value of a portion of warrant shares may be used to pay the exercise price rather than payment in cash, which may be exercised under any circumstances in the case of the Bank Warrants discussed below or, in the case of certain other warrants, only if a registration statement for the warrants and underlying shares of common stock is not effective under the Securities Act or a prospectus in the registration statement is not available for the issuance of shares upon the exercise of the warrants. All of the outstanding warrants meet the equity classification criteria and have been classified as equity, see Note 2, "Accounting for Warrants" for additional information.

In connection with the April 2024 Offering, the Company issued pre-funded warrants to purchase 342,888 shares of common stock. In connection with the February 2025 Offering, the Company issued additional pre-funded warrants to purchase 3,069,926 shares of common stock. For accounting purposes, the pre-funded warrants are equity-classified, contain no contingencies to exercise and are therefore considered outstanding for purposes of calculating basic earnings per share (see Note 2, "Net Loss Per Common Share"). As of December 31, 2025, none of such pre-funded warrants have been exercised. In connection with the February 2026 Offering, the Company issued additional pre-funded warrants to purchase 1,043,478 shares of common stock. See Note 13, "Subsequent Events – Registered Direct Offering" for additional information.

Bank Warrants

In connection with a loan that matured in September 2022 from Silicon Valley Bank (the "Bank"), in February 2017, iMDx issued common stock purchase warrants to the Bank (the "2017 Bank Warrants"). The Bank was issued warrants to purchase 412 shares of iMDx common stock at an exercise price of $97.00 per share, through February 21, 2027. In March 2017, the Bank was issued warrants to purchase an additional 366 shares at an exercise price of $109.20 per share, through March 23, 2027. In October 2019, iMDx issued a common stock purchase warrant to the Bank (the "2019 Bank Warrant") entitling the Bank to purchase 4,928 shares of iMDx common stock at an exercise price of $33.80 per share, through October 17, 2029. The Bank may elect to exercise the 2017 Bank Warrants and the 2019 Bank Warrant on a "cashless exercise" basis and receive a number of shares determined by multiplying the number of shares for which the Bank Warrant is being exercised by (A) the excess of the fair market value of the common stock over the applicable Warrant Price, divided by (B) the fair market value of the common stock. The fair market value of the common stock will be last closing or sale price on a national securities exchange, interdealer quotation system, or over-the-counter market. These warrants meet the equity classification criteria and have been classified as equity. As of December 31, 2025, no Bank Warrants have been exercised.

8. Stock-Based Compensation

Equity Incentive Plan

In August 2018, iMDx shareholders approved an Equity Incentive Plan to replace the 2010 Stock Option Plan (the "2010 Plan") and in October 2024, iMDx shareholders approved an amendment and restatement of such Equity Incentive Plan (as amended and restated, the "2018 Incentive Plan"). The 2018 Incentive Plan will expire on July 2, 2028. In initially adopting the 2018 Incentive Plan, iMDx terminated the 2010 Plan and ceased to grant any additional stock options or sell any stock under restricted stock purchase agreements under the 2010 Plan; however, stock options issued under the 2010 Plan continue in effect in accordance with their terms and the terms of the 2010 Plan until the exercise or expiration of the individual options. Total remaining stock options outstanding under the 2010 Plan as of December 31, 2025 and 2024, were 5,652 and 16,217, respectively.

As of December 31, 2025, 4,060,000 aggregate shares of common stock have been reserved for issuance under the equity incentive plans for the grant of stock options or the sale of restricted stock or for the settlement of RSUs. iMDx may also grant stock appreciation rights under the 2018 Incentive Plan. Upon the exercise of stock options, the issuance of RSAs, or the delivery of shares pursuant to vested RSUs or performance-based restricted stock units ("PSUs"), it is iMDx's policy to issue new shares of common stock. The Board may amend or modify the 2018 Incentive Plan at any time, subject to any required stockholder approval. Shares available for grant under the 2018 Incentive Plan as of December 31, 2025 and 2024, were 528,200 and 1,026,314, respectively.

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Plan Activity

A summary of iMDx's 2010 Plan and 2018 Incentive Plan activity and related information follows:

	Options				Nonvested RSUs	
	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value	Number Outstanding	Weighted Average Grant Date Fair Value
	(In thousands, except weighted average amounts)					
Balance at December 31, 2024	1,091	$ 12.42	8.56 years	$ —	100	$ 1.73
Awards granted	1,308	$ 3.38			838	$ 3.14
Options exercised	—	$ —		$ —	n/a	n/a
RSUs vested	n/a	n/a			(86)	$ 2.55
Options forfeited/expired	(148)	$ 13.28			n/a	n/a
RSUs forfeited	n/a	n/a			—	$ —
Balance at December 31, 2025	2,251	$ 7.11	8.92 years	$ 8,537	852	$ 3.03
Options vested and expected to vest at December 31, 2025	2,251	$ 7.11	8.92 years	$ 8,537		
Options exercisable at December 31, 2025	566	$ 18.21	7.38 years	$ 1,523		
Stock-based compensation expense for the period	$ 1,423				$ 796	
Unrecognized stock-based compensation expense	$ 3,857				$ 1,923	
Weighted average remaining recognition period	2.58 years				2.55 years	

Option Awards

During the year ended December 31, 2025, the Company granted 1,307,836 total stock options with a weighted average grant date fair value of $2.59 per option. During the year ended December 31, 2024, the Company granted 604,000 total stock options with a weighted average grant date fair value of $2.13 per option. The assumptions used to calculate the Black-Scholes grant date fair value for such time-based awards were as follows:

	Years Ended December 31,	
	2025	2024
Expected life	6.19 years	7.37 years
Risk-free interest rates	3.83%	4.31%
Volatility	89.98%	106.32%
Dividend yield	0%	0%

In October 2024, the Company awarded a 200,000 stock option grant with standard time-based vesting conditions, a grant date market price of $3.05 and an exercise price of $2.87 to a Company executive. The fair value of such award was estimated using the Monte Carlo simulation model and the following assumptions: estimated risk-free interest rate of 4.10 percent; term of 9.7 years; expected volatility of 105.0 percent; and expected dividend yield of 0 percent. The risk-free interest rate was determined based on the yields available on U.S. Treasury zero-coupon issues. The term is based on the contractual life. The expected stock price volatility was determined using historical volatility. The expected dividend yield was based on expectations regarding dividend payments. The grant date fair value of the award was $1.65, amounting to a total fair value of $330,000.

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In August 2023, the Company awarded 120,000 stock option grants with market-based and time-based vesting conditions, and a grant date market price and exercise price of $3.34 to certain executives. The fair value of such awards was estimated using the Monte Carlo simulation model. Assumptions and estimates utilized in the model include the risk-free interest rate, dividend yield, expected stock volatility and the estimated period to achievement of the performance and market conditions, which are subject to the achievement of the market-based goals established by the Company and the continued employment of the executives through December 31, 2025. These awards would vest only to the extent that the market-based conditions are satisfied as specified in the vesting conditions. The grant date fair value and associated compensation cost of the market-based awards reflected the probability of the market condition being achieved, and the Company recognized this compensation cost regardless of the actual achievement of the market-based conditions. Assumptions utilized in connection with the Monte Carlo valuation technique included: estimated risk-free interest rate of 4.81 percent; term of 6.19 years; expected volatility of 91.0 percent; and expected dividend yield of 0 percent. The risk-free interest rate was determined based on the yields available on U.S. Treasury zero-coupon issues. The expected stock price volatility was determined using historical volatility. The expected dividend yield was based on expectations regarding dividend payments. Based on the market-based conditions, the grant date fair values of these awards ranged from $1.09 to $1.74, amounting to a total fair value of approximately $156,000. As of December 31, 2025, no awards vested as none of the market-based conditions were satisfied, accordingly all awards have forfeited.

RSU Awards

The weighted average grant date fair value of RSUs granted during the year ended December 31, 2025 was $3.14 per unit. The weighted average grant date fair value of RSUs granted during the year ended December 31, 2024 was $1.85 per unit. The aggregate fair value of RSUs vested during the years ended December 31, 2025 and 2024, was $486,000 and $47,000, respectively.

During the year ended December 31, 2025, the Company issued 20,464 shares of unregistered common stock upon settlement of RSU awards granted from the 2018 Incentive Plan under immediate vest RSU awards in connection with two ongoing investor relations consulting service arrangements for a total fair value of $68,000. The Company issued 12,677 such shares during the year ended December 31, 2024. During 2025 and 2024, the Company issued additional restricted shares to these consulting firms under unregistered restricted stock arrangements, see Note 7, “Common Stock – Unregistered Restricted Stock Issuance” for additional information. Total shares issued to these consulting firms during the years ended December 31, 2025 and 2024, were 30,011 and 39,341, respectively. The total related expense, included in general and administrative expenses, for these consulting firms was $108,000 for both of the years ended December 31, 2025 and 2024.

In October 2024, the Company awarded 100,000 PSUs with market-based and service-based vesting conditions, and a grant date market price of $3.05 to a Company executive. Vesting is subject to continuous service as an employee of iMDx or a subsidiary thereof from hire date through the applicable vesting date, and shall performance vest as follows: (i) 50% will vest upon the Company’s achievement of an aggregate market value of voting and non-voting common equity held by non-affiliates of the Company of $75.0 million or more, such that the Company is no longer subject to the “Baby Shelf Rules” of Form S-3, and (ii) 50% will vest upon the Company’s achievement of a market capitalization of $200.0 million, which shall be determined based on the 30-day volume weighted average price of the common stock measured as of the end of each full calendar month following the date of grant. No units will vest prior to June 20, 2025, and any units that are not performance vested on December 31, 2026 shall automatically be forfeited. The fair value of such award was estimated using the Monte Carlo simulation model. Assumptions and estimates utilized in the model include the risk-free interest rate, dividend yield, expected stock volatility and the expected period to achievement of the market conditions. The grant date fair value and associated compensation cost of the market-based award reflect the probability of the market condition being achieved, and the Company will recognize this compensation cost regardless of the actual achievement of the market-based conditions. Assumptions utilized in connection with the Monte Carlo valuation technique included: estimated risk-free interest rate of 3.93 percent; term of 2.2 years; expected volatility of 90.0 percent; and expected dividend yield of 0 percent. The risk-free interest rate was determined based on the yields available on U.S. Treasury zero-coupon issues. The expected stock price volatility was determined using historical volatility. The expected dividend yield was based on expectations regarding dividend payments. Based on the two described performance vesting conditions, the grant date fair values were $2.03 and $1.43, respectively, amounting to a total fair value of $173,000. On October 31, 2025, 50,000 PSUs vested based on the achievement of an aggregate market value of common equity held by non-affiliates of $75.0 million or more, as described above. As of December 31, 2025, no additional awards have vested.

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Stock-Based Compensation Expense

iMDx recorded stock-based compensation expense in the following categories on the accompanying consolidated statements of operations:

	Years Ended December 31,	
	2025	2024
	(In thousands)	
Cost of revenues	$ —	$ —
Research and development	721	810
Sales and marketing	181	174
General and administrative	1,317	769
Total	$ 2,219	$ 1,753

Total unrecognized stock-based compensation expense as of December 31, 2025 was $5.8 million, which will be amortized over a weighted average remaining recognition period of 2.57 years.

Other Information

The determination of stock-based compensation is inherently uncertain and subjective and involves the application of valuation models and assumptions requiring the use of judgment. If iMDx had made different assumptions, its stock-based compensation expense and results for the periods presented may have been significantly different. See Note 2, “Stock-Based Compensation” for additional information.

iMDx does not recognize deferred income taxes for incentive stock option compensation expense and records a tax deduction only when a disqualified disposition has occurred.

9. Related Party Transactions

Financing Transactions

On April 13, 2022, iMDx entered into the Securities Purchase Agreement with the Investors, including Broadwood Partners, L.P. (“Broadwood”), for the Series A Preferred Stock offering. Broadwood had a direct material interest in the Series A Preferred Stock offering and agreed to purchase 5,882 in the Series A Preferred Stock offering and on the same terms as other investors. In April 2024, Company redeemed the remaining shares of the Series A Preferred Stock, see Note 7 for additional information.

Further, on April 13, 2022, iMDx entered into an underwriting agreement pursuant to which the Company agreed to issue and sell certain shares of common stock and warrants to purchase common stock (“April 2022 Warrants”). The April 2022 Warrants have an exercise price of $30.60 per share and will expire on April 19, 2027. Pursuant to the underwritten offering, Broadwood acquired from us (i) 261,032 shares of common stock, and (ii) 300,187 April 2022 Warrants to purchase up to 150,093 shares of common stock. However, the total number of shares of common stock that Broadwood purchased in the underwritten offering was 300,187, of which 39,154 existing shares were acquired by the underwriters in the open market and re-sold to Broadwood. Pura Vida acquired from us (i) 249,204 shares of common stock, and (ii) 286,585 April 2022 Warrants to purchase up to 143,292 shares of common stock. However, the total number of shares of common stock that Pura Vida purchased in the underwritten offering was 286,585, of which 37,380 existing shares were acquired by the underwriters in the open market and re-sold to Pura Vida. See Note 7, “Common Stock Purchase Warrants” for additional information.

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On April 3, 2023, iMDx entered into a securities purchase agreement with certain investors, including Broadwood, Pura Vida and entities affiliated with AWM, and certain individuals, including iMDx's Chairman, Andrew Arno, and certain of their affiliated parties, which provided for the sale and issuance by the Company of an aggregate of 2,274,709 shares of common stock at an offering price of: (i) $6.03 to investors who are not considered to be "insiders" of the Company pursuant to Nasdaq Listing Rules ("Insiders"), which amount reflected the average closing price of our common stock on Nasdaq during the five trading day period immediately prior to pricing, and (ii) $7.08 to Insiders, which amount reflected the final closing price of our common stock on Nasdaq on the last trading day immediately prior to pricing. Broadwood purchased 1,341,381 shares of common stock for $8,093,362, Pura Vida purchased 33,150 shares of common stock for $200,014 and entities affiliated with AWM purchased 472,354 shares of common stock for $2,850,000. Mr. Arno and his affiliated parties purchased 21,162 shares of common stock for $150,001.

On April 15, 2024, iMDx consummated a private placement of its securities to certain investors, including Broadwood, entities affiliated with AWM, Bio-Rad, and certain individuals, including iMDx's Chairman, Andrew Arno, for the issuance and sale of 5,076,900 shares of its common stock and pre-funded warrants to purchase 342,888 shares of its common stock. The purchase price for one share of common stock was $2.9164, and the purchase price for one pre-funded warrant was $2.9163. Insiders subscribed for 42,373 of the shares of common stock sold in the private placement, at a purchase price of $2.95 per share of common stock, which amount reflected the final closing price of the common stock on Nasdaq on the last trading day immediately prior to pricing. Broadwood purchased 2,420,000 shares of common stock for $7,057,688, entities affiliated with AWM purchased 342,889 shares of common stock and 342,888 pre-funded warrants for $2,000,000, and Bio-Rad purchased 1,200,109 shares of common stock for $3,499,998. Mr. Arno purchased 33,898 shares of common stock for $100,000. One of iMDx's directors, Andrew Last, served as the Executive Vice President and Chief Operating Officer of Bio-Rad before retiring on September 6, 2024. See Note 7, "Common Stock – April 2024 Offering" for additional information.

On October 4, 2024, iMDx consummated the October 2024 Offering involving certain investors, including Broadwood, Bio-Rad, entities affiliated with AWM, Unterberg Legacy Capital, LLC ("Unterberg") and certain affiliated parties, Patrick W. Smith, and certain other individuals, including iMDx's Chief Financial Officer, Andrea James, and Chief Science Officer, Ekkehard Schütz. The gross proceeds from the October 2024 Offering were approximately $10.2 million. The purchase price for one share of common stock was $2.948 or $2.97 to certain Insiders. Broadwood purchased 1,315,339 shares of common stock for approximately $3,878,000, Bio-Rad purchased 310,835 shares of common stock for approximately $916,000, entities affiliated with AWM purchased 275,000 shares of common stock for approximately $811,000, Unterberg and its affiliated parties purchased 33,921 shares of common stock for $100,000, Patrick W. Smith purchased 678,426 shares of common stock for $2,000,000, Ms. James purchased 33,670 shares of common stock for $100,000, and Mr. Schütz purchased 3,367 shares of common stock for $10,000. iMDx's Chairman, Andrew Arno, has served as a Managing Member of Unterberg since October 2023. See Note 7, "Common Stock – October 2024 Offering" for additional information.

On February 10, 2025, iMDx consummated the February 2025 Offering involving certain investors, including Broadwood, Bio-Rad, entities affiliated with AWM, Unterberg and certain affiliated parties, Patrick W. Smith, and certain other individuals, including iMDx's Chief Financial Officer, Andrea James, and Chief Science Officer, Ekkehard Schütz. The gross proceeds from the February 2025 Offering were approximately $29.1 million. Officers of the Company subscribed for 109,756 of the shares of common stock in the aggregate sold in the February 2025 Offering, at a purchase price of $2.05 per share of common stock. Broadwood purchased 5,165,695 shares of common stock for approximately $10,590,000, Bio-Rad purchased 1,253,134 shares of common stock for approximately $2,569,000, entities affiliated with AWM purchased 2,052,026 shares of common stock and pre-funded warrants to purchase up to 3,069,926 shares of common stock for approximately $10,500,000, Unterberg and its affiliated parties purchased 73,169 shares of common stock for $150,000, and Patrick W. Smith purchased 1,463,414 shares of common stock for $3,000,000. Ms. James purchased 97,561 shares of common stock for $200,000 and Mr. Schütz purchased 12,195 shares of common stock for $25,000. See Note 7, "Common Stock – February 2025 Offering" for additional information.

On February 12, 2026, iMDx consummated the February 2026 Offering involving certain investors, including Broadwood, Bio-Rad, and entities affiliated with AWM. The gross proceeds from the February 2026 Offering were approximately $26.0 million. Broadwood purchased 521,739 shares of common stock for approximately $3,000,000, Bio-Rad purchased 439,020 shares of common stock for approximately $2,524,000, and entities affiliated with AWM purchased pre-funded warrants to purchase up to 1,043,478 shares of common stock for approximately $6,000,000. See Note 13, "Subsequent Events – Registered Direct Offering" for additional information.

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Bio-Rad Transactions

During the year ended December 31, 2025, the Company purchased $3.5 million in laboratory equipment, and incurred $1.3 million in laboratory related costs and $1,000 in royalty expenses, from Bio-Rad. During the year ended December 31, 2025, the Company also made financing lease payments to a third-party of $458,000, under various Bio-Rad laboratory equipment leases, with a remaining financing lease liability of $716,000 as of December 31, 2025.

During the year ended December 31, 2024, the Company purchased $538,000 in laboratory equipment and incurred $413,000 in laboratory related costs from Bio-Rad. During the year ended December 31, 2024, the Company also made financing lease payments to a third-party of $217,000, under various Bio-Rad laboratory equipment leases, with a remaining financing lease liability of $796,000 as of December 31, 2024.

As of December 31, 2025 and 2024, the Company had accounts payable and accruals due to Bio-Rad of $2.8 million and $638,000, respectively.

On April 5, 2024, the Company entered into an agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products (the “Collaboration Agreement”). Under the Collaboration Agreement, Bio-Rad agreed to purchase shares of our common stock equal to 9.99% of the total number of shares of common stock issued and outstanding immediately after the closing of such investment, provided that the total purchase price would not exceed $3,500,000 unless Bio-Rad chooses to exceed such limit (the “Bio-Rad Investment”) (see "Financing Transactions" above). The Bio-Rad Investment was completed in connection with a private placement (see Note 7, “Common Stock – April 2024 Offering”). In addition, we will pay Bio-Rad a single digit royalty payment based on certain net sales under the Collaboration Agreement, and Bio-Rad has an option for the exclusive right to promote, market and sell certain kits worldwide subject to certain conditions. If and when such option is exercised, Bio-Rad will purchase additional shares of our common stock, at the then-current market price per share, up to a specified maximum aggregate purchase price. On November 8, 2024, the Company and Bio-Rad entered into a memorandum of understanding with respect to the Collaboration Agreement to establish additional activities to be performed by each party pursuant to the Collaboration Agreement. Andrew Last, an iMDx director, recused himself from all Board discussions related to transactions with Bio-Rad. See Note 10, "Collaborative Arrangements" for additional information.

10. Collaborative Arrangement

On April 5, 2024, the Company entered into the Collaboration Agreement with Bio-Rad to collaborate in the development and the commercialization of RUO and IVD kitted transplant products using Bio-Rad’s ddPCR instruments and reagents. The Collaboration Agreement has a term of 10 years unless earlier terminated pursuant to customary termination provisions.

The Collaboration Agreement provides that through the oversight of a joint steering committee comprised of representatives from both parties, the parties will collaborate on the development of (i) the Company’s series of GraftAssureIQ Transplant Monitoring Assays to measure and test the concentration of dd-cfDNA for RUO (the “RUO Assays”); and (ii) the Company’s GraftAssureDx Transplant Monitoring Assays that have received regulatory approval as an in vitro diagnostic device (the “IVD Kits”) for use on one or more Bio-Rad ddPCR instruments. Pursuant to the Collaboration Agreement, and toward the development of the RUO Assays and the IVD Kits, the Company will collect and screen samples, conduct feasibility testing and stability studies, and perform analytical validation, among other things; and Bio-Rad will supply its ddPCR instruments and platforms as well as manufacture and supply all consumables.

Prior to the commercial launch of the RUO Assays, under the Collaboration Agreement, the parties will develop a plan to market and sell the RUO Assays. The Company will be responsible for the manufacture and supply of all RUO Assays, and Bio-Rad will supply to the Company Bio-Rad’s ddPCR instruments and reagents for use in commercializing the RUO Assays, which products will be purchased by the Company exclusively from Bio-Rad. The Company and Bio-Rad will be jointly responsible for co-promoting and co-marketing the RUO Assays within the United States and Germany (the “Territory”). The Company has the exclusive right to sell the RUO Assays in the Territory exclusively with the use of Bio-Rad ddPCR instruments and reagents. Bio-Rad will be responsible for promoting and marketing, and has the exclusive right to sell, the RUO Assays outside the Territory. For the sales of the RUO Assays in the Territory, the Company will pay to Bio-Rad a single digit royalty payment based on net sales. The Company will manufacture and supply the RUO Assays to Bio-Rad for resale outside the Territory.

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Additionally, the Collaboration Agreement provides Bio-Rad a 90-day exclusive negotiating period, post regulatory clearance, for the right to exclusively promote, market and sell IVD Kits worldwide subject to certain conditions. If and when such option is exercised, Bio-Rad will purchase additional shares of the Company's common stock, no par value per share, at the then-current market price per share, up to a specified maximum aggregate purchase price, and the Company will manufacture and supply IVD Kits exclusively for Bio-Rad. See Note 9, "Related Party Transactions – Financing Transactions" for additional information.

On November 8, 2024, iMDx and Bio-Rad entered into a binding Memorandum of Understanding (the "Memorandum") in connection with the Collaboration Agreement. The Memorandum establishes additional activities (described below) to be performed by iMDx and Bio-Rad prior to the commercial launch of the RUO Assays specifically related to pilot study sites outside the Territory (the "Pilot Sites").

Pursuant to the Memorandum, iMDx (i) will setup commercialization of Pilot Sites to use the RUO Assays, (ii) may sell RUO Assays to Pilot Sites, (iii) will train and support the Pilot Sites on the use of the RUO Assays, and (iv) if iMDx receives any net sales from the sale of the RUO Assays to the Pilot Sites, then iMDx shall pay to Bio-Rad a royalty payment based on a percentage of such net sales under the terms and conditions of the Collaboration Agreement. In addition, pursuant to the Memorandum, Bio-Rad will evaluate commercialization efforts for the RUO Assays, which will include (i) supporting installation and training for Pilot Sites, and (ii) evaluating distribution of the RUO Assays to Pilot Sites. In May 2025, the Company sold its first RUO Assays to a Pilot Site (see Note 2, "Revenue Recognition – Kitted Products" for additional information).

For the year ended December 31, 2025, the income statement amounts attributable to Bio-Rad transactions arising from the Collaboration Agreement, included cost of revenues, research and development expenses, sales and marketing expenses, general and administrative expenses, and interest expense, and in the aggregate have not been significant. See Note 9, "Related Party Transactions – Bio-Rad Transactions" for additional information. In addition, the Company is capitalizing RUO Assay related inventory costs (see Note 2, "Inventories" for additional information).

11. Segment Reporting

The Company operates and reports its results in one reportable segment, on a consolidated basis. The Company reports segment information based on the management approach and organizes its business based on products and services. The management approach designates the internal reporting information regularly reviewed by the chief operating decision maker (the "CODM") to make decisions about resources to be allocated to the segment and assess its performance as the basis for determining a company's reportable segments. The Company's CODM is the senior executive management team that includes the Chief Executive Officer and Chief Financial Officer. iMDx is an early-stage diagnostics technology company with core operations that include the research, development and commercialization of diagnostic tests. Currently, the Company's revenues include Laboratory Services from its life sciences customers, including testing for biomarker discovery, assay design and development, clinical trial support, and a broad spectrum of biomarker tests, and to a lesser extent from Kitted Products (see Note 2, "Revenue Recognition" for additional information). Additionally, the Company is primarily focused on developing and commercializing new diagnostic tests for medical use related to organ transplant and in the field of oncology, accordingly, extensive resources, time and expense will be required to complete the development and commercialization of those tests.

Adjusted earnings or loss before interest, income taxes, depreciation and amortization is the singular measure of segment profit or loss that the CODM uses in assessing segment performance and deciding how to allocate resources. This measure of segment profit or loss is used to monitor budget versus actual results and for long range planning. Segment loss in the table below includes revenues, cost of revenues, research and development, and other significant operating expenses directly attributable to our reportable segment. Such operating expenses exclude depreciation and amortization expenses, stock-based compensation, the change in fair value of contingent consideration, and impairments. As an early-stage company with limited revenue, management believes this measure of profit or loss is helpful in assessing our ongoing performance, providing insight into the Company's core operating costs and performance by excluding certain noncash and other non-operating items that may obscure the underlying trends in the business. The reconciling items and significant segment expense categories and amounts, as included in the table below, are based on the Company's internal general ledger reporting system that is used in preparing our consolidated financial statements and are included in determining the measure of segment profit or loss that is used by the CODM.

The measure of segment assets is reported in the consolidated balance sheets as total assets. Total segment expenditures for additions to long-lived assets is reported in the consolidated statements of cash flows as a component of cash used in investing activities.

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The Company's single reportable segment profit or loss information is as follows:

	Years Ended December 31,	
	2025	2024
	(In thousands)	
Laboratory Services	$ 4,031	$ 1,859
Laboratory Developed Test Services	—	22
Kitted Products	24	—
Total net revenues	**4,055**	**1,881**
Less:		
Cost of revenues, as adjusted	1,668	983
Personnel-related expenses and board fees	12,823	11,000
Professional fees, legal, and outside services	7,974	5,008
Facilities and insurance	1,758	2,071
Laboratory supplies and expenses	3,930	1,826
Marketing and advertising	582	257
Travel and entertainment	849	585
Other segment items [(1)]	633	81
Segment loss	**(26,162)**	**(19,930)**
Reconciliation of segment profit and loss:		
Depreciation and amortization expenses	(2,197)	(1,564)
Stock-based compensation	(2,219)	(1,753)
Change in fair value of contingent consideration	(5,946)	4,275
Impairment losses	(14,600)	(41,900)
Impairment loss on held for sale assets	—	(169)
Interest expense	(109)	(84)
Other income, net	1,011	462
Income taxes	—	—
Net loss	**$ (50,222)**	**$ (60,663)**

(1) Other segment items primarily includes clinical trial expenses, delivery expenses, other business taxes and tax credits, and severance costs. For the years ended December 31, 2025 and 2024, clinical trial expenses were $301,000 and $2,000, respectively.

The Company's revenues and long-lived tangible assets by geographic area are presented below. Revenues are based on the customer country of domicile. Assets are based on the location of held assets.

	Years Ended December 31,	
	2025	2024
	(In thousands)	
Revenues by geographic area:		
United States	$ 4,031	$ 1,673
Europe	24	18
United Kingdom	—	45
Asia-Pacific	—	145
Total net revenues	**$ 4,055**	**$ 1,881**

INSIGHT MOLECULAR DIAGNOSTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

	December 31,	
	2025	2024
	(In thousands)	
Long-lived tangible assets by geographic area:		
United States	$ 7,177	$ 5,543
Europe	1,577	611
United Kingdom	433	—
Asia-Pacific	63	170
Total	**$ 9,250**	**$ 6,324**

12. Income Taxes

In 2025, the Company incurred $50.2 million of pretax book losses in the United States and $16,000 of net operating loss internationally. In 2024, the Company incurred $60.7 million of pretax book losses in the United States and $37,000 of net operating income internationally.

The Company did not record any provision or benefit for income taxes for the years ended December 31, 2025 and 2024, as the Company had a full valuation allowance for the periods presented. iMDx will file a consolidated return with its subsidiaries for the year ended December 31, 2025.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The primary components of the deferred tax assets and liabilities were as follows:

	December 31,	
	2025	2024
	(In thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 59,350	$ 49,953
Research and development credit carryforwards	2,494	1,951
Stock-based and other compensation	3,131	1,997
Lease liabilities	669	828
Razor investment	—	2,303
Capitalized R&D [(1)]	5,800	6,711
Capital loss carryforward	7,675	5,372
Intangibles and fixed assets	926	—
Other	70	1
Total deferred tax assets	80,115	69,116
Valuation allowance	(79,637)	(64,436)
Deferred tax assets, net of valuation allowance	478	4,680
Deferred tax liabilities:		
ROU assets	(478)	(564)
Intangibles and fixed assets	—	(4,116)
Total deferred tax liabilities	(478)	(4,680)
Net deferred taxes	$ —	$ —

(1) Relates to research and development expenditures required to be capitalized as of December 31, 2025 and 2024.

INSIGHT MOLECULAR DIAGNOSTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

Income taxes differed from the amounts computed by applying the applicable U.S. federal income tax rates indicated to pretax losses. A reconciliation of the difference between the federal statutory tax rates and the Company's effective tax rates is as follows:

	Years Ended December 31,			
	2025		2024 [1]	
	Amount	Percent	Amount	Percent
	(Amounts in thousands)			
U.S. federal statutory tax rate	$ (10,547)	21%	$ (12,739)	21%
State and local income taxes, net of federal income tax effect [2]	(182)	0%	(113)	0%
Foreign tax effects				
Germany				
Statutory tax rate difference between Germany and the U.S.	4	0%	(8)	0%
Effect of changes in tax laws or rates enacted in the current period	—	—	—	—
Effect of cross-border tax laws	—	—	—	—
Tax Credits				
Research and development tax credits	(721)	1%	(151)	0%
Changes in valuation allowances	9,179	(18)%	(472)	1%
Nontaxable or nondeductible items				
Permanent adjustments	31	0%	54	0%
Stock-based payment awards	445	(1)%	310	(1)%
Change in fair value of contingent consideration	1,249	(2)%	(898)	2%
Section 382 limitation	—	—	15,225	(25)%
Changes in unrecognized tax benefits	542	(1)%	(1,208)	2%
Effective tax rates	$ —	0%	$ —	(0)%

(1) The 2024 numbers have been reclassified to conform to the 2025 presentation in connection with the adoption of ASU 2023-09, see Note 2, "Principles of Consolidation and Basis of Presentation – Reclassifications" for additional information.
(2) State taxes in California, Tennessee and Florida made up 100 percent of the tax effect in this category.

As of December 31, 2025, iMDx had net operating loss ("NOL") carryforwards of approximately $240.6 million for U.S. federal income tax purposes and $112.4 million for state income tax purposes. The federal net operating losses generated on or prior to December 31, 2017 expire in varying amounts, while the federal net operating losses generated after December 31, 2017 carryforward indefinitely. The state net operating losses expire in varying amounts between 2029 and 2045. iMDx also has capital loss carryforwards of approximately $25.7 million, for both federal and state income tax purposes, which expire in 2028.

As of December 31, 2025, iMDx has research and development credit carryforwards for federal and state purposes of $871,000 and $3.3 million, respectively. The federal credits will expire in 2045, while the state credits have no expiration.

A valuation allowance is provided when it is more-likely-than-not that some portion of the deferred tax assets will not be realized. iMDx has established a full valuation allowance for all periods presented due to the uncertainty of realizing future tax benefits from its net operating loss carryforwards and other deferred tax assets. The change in the valuation allowance was a $15.2 million increase and a $2.9 million decrease for the years ended December 31, 2025 and 2024, respectively.

iMDx has unrecognized tax benefits ("UTBs") totaling $1.6 million and $1.1 million as of December 31, 2025 and 2024, respectively, which were netted against deferred tax assets subject to a valuation allowance. The UTBs had no effect on the effective tax rate and there would be no cash tax impact for any period presented. iMDx recognizes interest and penalties related to UTBs, when they occur, as a component of income tax expense. There were no interest or penalties recognized for the years ended December 31, 2025 and 2024.

INSIGHT MOLECULAR DIAGNOSTICS INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

A reconciliation of the annual beginning and ending UTBs is as follows:

	Years Ended December 31,	
	2025	2024
	(In thousands)	
Balance at the beginning of the year	$ 1,087	$ 2,296
Additions based on tax positions related to current year	542	189
Adjustments based on tax positions related to prior years	—	(1,398)
Settlements	—	—
Balance at end of year	$ 1,629	$ 1,087

Income Taxes Paid

Income taxes paid, net of refunds received, for the years ended December 31, 2025 and 2024 were zero. No individual state represents 5% or more of the total income taxes paid, net of refunds received.

Other Income Tax Matters

Internal Revenue Code Section 382 places a limitation ("Section 382 Limitation") on the amount of taxable income that can be offset by NOL carryforwards after a change in control (generally greater than 50% change in ownership within a three-year period) of a loss corporation. California has similar rules. Generally, after a change in control, a loss corporation cannot deduct NOL carryforwards in excess of the Section 382 Limitation. Due to these "change in ownership" provisions, utilization of the NOL and tax credit carryforwards may be subject to an annual limitation regarding their utilization against taxable income in future periods. iMDx has performed a 382 analysis as of December 31, 2025 and determined an ownership change as of October 2024. The federal and state NOL and tax credit carryforwards are stated net of any such anticipated limitations.

In general, iMDx is no longer subject to tax examination by the Internal Revenue Service or state taxing authorities for years before 2020. Although the federal and state statutes are closed for purposes of assessing additional income tax in those prior years, the taxing authorities may still make adjustments to the NOL and credit carryforwards used in open years. Therefore, the tax statutes should be considered open as it relates to the NOL and credit carryforwards used in open years. For tax years that remain open to examination, potential examinations may include questioning of the timing and amount of deductions, the nexus of income among various tax jurisdictions and compliance with the Internal Revenue Code or state tax laws.

13. Subsequent Events

Registered Direct Offering

On February 10, 2026, the Company entered into securities purchase agreements with certain institutional investors, pursuant to which the Company agreed to issue and sell (i) 3,482,498 shares of the Company's common stock, no par value per share, and (ii) pre-funded warrants to purchase up to 1,043,478 shares of common stock in a registered direct offering, pursuant to an effective shelf registration statement on Form S-3 (File No. 333-281159), a base prospectus and a related prospectus supplement, in each case filed with the SEC. The offering price was (i) $5.75 per share and (ii) $5.7499 per pre-funded warrant, which is the price of each share sold, minus the $0.0001 exercise price per pre-funded warrant. The closing occurred on February 12, 2026.

The pre-funded warrants may be exercised at any time until exercised in full, except that a holder (together with its affiliates) will not be entitled to exercise any portion of any pre-funded warrant, which, upon giving effect to such exercise would cause the aggregate number of shares of the Company's common stock beneficially owned by the holder (together with its affiliates) to exceed 4.99% (or, upon election of the holder, 9.99%) of the number of shares of common stock outstanding immediately prior to or after giving effect to the exercise, subject to such holder's rights under the pre-funded warrants to increase or decrease such percentage to another percentage not in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants upon at least 61 days' prior notice from such holder to the Company.

INSIGHT MOLECULAR DIAGNOSTICS INC.
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The gross proceeds to the Company from the registered direct offering were approximately $26.0 million, before deducting $1.4 million in placement agent fees and offering expenses payable by the Company. The Company plans to use the net proceeds received of approximately $24.6 million primarily for general corporate purposes, including but not limited to research and development in the transplantation category.

Specimen Collection Agreement

On February 20, 2026, the Company entered into a Specimen Collection Agreement (the "Collection Agreement") with a national reference lab provider. Pursuant to the Collection Agreement, the lab provider will provide specimen collection-related services, which may include, among other things, the collection, handling, processing, and delivery of specimens upon which the Company will perform testing with its GraftAssureCore test, a blood test designed to measure dd-cfDNA using a novel PCR-based measurement platform, for potential patient registrants. The Collection Agreement provides for certain fees to be paid to the lab provider for services rendered. The lab provider will not bill any other party for the services it provides, and patients will be billed by the Company.

Exhibit 4.8

DESCRIPTION OF SECURITIES

The following description of certain terms of Insight Molecular Diagnostics Inc. ("iMDx" or the "Company") common stock is a summary and is qualified in its entirety by reference to (i) iMDx's Articles of Incorporation, as amended, (ii) iMDx's Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock, (iii) iMDx's Third Amended and Restated Bylaws, and (iv) the California General Corporation Law.

Common Stock

The iMDx Articles of Incorporation currently authorize the issuance of up to 230,000,000 shares of common stock, no par value. Each holder of record of common stock is entitled to one vote for each outstanding share owned, on every matter properly submitted to the shareholders for their vote; provided, that if any shareholder entitled to vote at a meeting at which directors are to be elected gives timely notice of their intention to cumulate votes in the election of directors, shareholders may cumulate votes for the election of directors. Subject to the dividend rights of holders of any preferred stock that may be issued from time to time, holders of common stock are entitled to any dividend declared by the iMDx Board of Directors out of funds legally available for that purpose. Subject to the prior payment of the applicable liquidation preference to holders of any preferred stock that may be issued from time to time, holders of common stock are entitled to receive on a pro rata basis all remaining assets available for distribution to the holders of common stock in the event of the liquidation, dissolution, or winding up of iMDx's operations. Holders of common stock do not have any preemptive, subscription, redemption, or conversion rights. There are no redemption or sinking fund provisions applicable to the common stock. The rights, powers, preferences and privileges of holders of iMDx common stock will be subject to those of the holders of any shares of iMDx preferred stock that may be issued in the future.

Preferred Stock

The iMDx Articles of Incorporation currently authorize the issuance of up to 5,000,000 shares of preferred stock, no par value. The Preferred Stock may be issued in one or more series as the iMDx Board of Directors may by resolution designate. The iMDx Board of Directors is authorized to fix the number of shares of any series of Preferred Stock and to determine or alter the rights, preferences, privileges, and restrictions granted to or imposed upon the Preferred Stock as a class, or upon any wholly unissued series of Preferred Stock. The iMDx Board of Directors may, by resolution, increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series of Preferred Stock subsequent to the issue of shares of that series.

Series A Convertible Preferred Stock

On May 27, 2022, iMDx filed a Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock with the California Secretary of State, establishing the rights, preferences and privileges relating to 11,765 shares of iMDx's Series A Convertible Preferred Stock, no par value. The Series A Convertible Preferred Stock ranked senior to iMDx common stock, with respect to rights as to as to dividends, distributions, redemptions and payments upon the liquidation, dissolution and winding up of iMDx.

The Series A Convertible Preferred Stock generally had no voting rights, except as required by law and except that the consent of holders of a majority of the outstanding Series A Convertible Preferred Stock were required to amend any provision of the iMDx Articles of Incorporation that would have a materially adverse effect on the rights of the holders of the Series A Convertible Preferred Stock. Additionally, as long as any shares of Series A Convertible Preferred Stock remained outstanding, unless the holders of at least 51% of the then outstanding shares of Series A Convertible Preferred Stock shall have otherwise given prior written consent, iMDx, on a consolidated basis with its subsidiaries, was not permitted to (1) have less than $8 million of unrestricted, unencumbered cash on hand ("Cash Minimum Requirement"); (2) other than certain permitted indebtedness, incur indebtedness to the extent that iMDx's aggregate indebtedness exceeds $15 million; (3) enter into any agreement (including any indenture, credit agreement or other debt instrument) that by its terms prohibits, prevents, or otherwise limits our ability to pay dividends on, or redeem, the Series A Convertible Preferred Stock in accordance with the terms of the Certificate of Determination of Preferences, Rights and Limitations of Series A Convertible Preferred Stock; or (4) authorize or issue any class or series of preferred stock or other capital stock that ranks senior or pari passu with the Series A Convertible Preferred Stock.

iMDx was required to redeem, for cash, the shares of Series A Convertible Preferred Stock on the earlier to occur of (1) April 8, 2024, (2) the commencement of certain a voluntary or involuntary bankruptcy, receivership, or similar proceedings against the Company or its assets, (3) a Change of Control Transaction (as defined) and (4) at the election and upon notice of 51% in interest of the holders, if the Company failed to meet the Cash Minimum Requirement. Additionally, the Company had the right to redeem the Series A Convertible Preferred Stock for cash upon 30 days prior notice to the holders; provided if the Company undertakes a capital raise in connection with such redemption, the Investors will have the right to participate in such financing.

On April 5, 2023, iMDx redeemed 1,064 shares of the Series A Convertible Preferred Stock for approximately $1.1 million. On April 15, 2024, iMDx redeemed the remaining 4,818 shares of the Series A Convertible Preferred Stock for approximately $5.4 million.

Warrants

Generally

The Company may issue warrants to purchase the Company's common stock or preferred stock. Warrants may be issued independently or together with any other securities and may be attached to, or separate from, such securities. Each series of warrants will be issued under a separate warrant agreement to be entered into between the Company and a warrant agent. The terms of any warrants to be issued and a description of the material provisions of the applicable warrant agreement will be set forth in applicable filings with the Securities and Exchange Commission. The number of shares of the Company's common stock to be received upon the exercise of each warrant may be adjusted from time to time upon the occurrence of certain events, including but not limited to the payment of a dividend or other distribution in respect of common stock, subdivisions, reclassifications, combinations of the Company's common stock or subsequent rights offerings. The securities receivable upon exercise of each warrant may be adjusted in the event of any reorganization, consolidation, merger, liquidation or similar event.

Outstanding Warrants

As of December 31, 2025, the Company has outstanding warrants to purchase 760,866 shares of the Company's common stock. The warrants are exercisable at prices ranging from $30.60 to $109.20 per share and expire on dates ranging from February 2027 to October 2029. The Company has authorized and reserved for issuance all shares of common stock issuable upon exercise of each warrant. Certain warrants have "cashless exercise" provisions meaning that the value of a portion of warrant shares may be used to pay the exercise price rather than payment in cash, which may be exercised under any circumstances in the case of the 2017 Bank Warrants and 2019 Bank Warrants or, in the case of certain other warrants, only if a registration statement for the warrants and underlying shares of common stock is not effective under the Securities Act or a prospectus in the registration statement is not available for the issuance of shares upon the exercise of the warrants.

In April 2024, the Company issued pre-funded warrants to purchase 342,888 shares of common stock to funds associated with a certain investor. In February 2025, the Company issued additional pre-funded warrants to purchase 3,069,926 shares of common stock to funds associated with the same investor. For accounting purposes, the pre-funded warrants are equity-classified, contain no contingencies to exercise and are therefore considered outstanding for purposes of calculating basic earnings per share. As of December 31, 2025, none of such pre-funded warrants have been exercised. In February 2026, the Company issued additional pre-funded warrants to purchase 1,043,478 shares of common stock to funds associated with the same investor.

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File Nos. 333-286251 and 333-213810), Form S-3 (File Nos. 333-282683, 333-281159, 333-279350, 333-257905, and 333-240207) and Form S-8 (File Nos. 333-289687, 333-257740, 333-227118, 333-232773, 333-219109, and 333-208935) of our report dated March 26, 2026, with respect to the consolidated financial statements of Insight Molecular Diagnostics Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.
Costa Mesa, CA
March 26, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No. 333-286251 and 333-213810), Form S-3 (File Nos. 333-282683, 333-281159, 333-279350, 333-257905 and 333-240207) and Form S-8 (File Nos. 333-289687, 333-257740, 333-232773, 333-227118, 333-219109, and 333-208935) of our report dated March 24, 2025, with respect to the consolidated financial statements of Insight Molecular Diagnostics Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

Costa Mesa, CA
March 26, 2026

Exhibit 31.1

CERTIFICATION

I, Joshua Riggs, certify that:

1. I have reviewed this annual report on Form 10-K of Insight Molecular Diagnostics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this periodic report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2026

/s/ Joshua Riggs
Joshua Riggs
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Andrea James, certify that:

1. I have reviewed this annual report on Form 10-K of Insight Molecular Diagnostics Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this periodic report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2026

/s/ Andrea James
Andrea James
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Insight Molecular Diagnostics Inc. (the "Company") for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Joshua Riggs, President and Chief Executive Officer of the Company, and Andrea James, Chief Financial Officer of the Company, certify pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2026

/s/ Joshua Riggs
Joshua Riggs
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Andrea James
Andrea James
Chief Financial Officer
(Principal Financial Officer)

CORPORATE INFORMATION	
BOARD OF DIRECTORS	**EXECUTIVE OFFICERS**
Joshua Riggs President, Chief Executive Officer and Director Insight Molecular Diagnostics Inc. **Andrew Arno Andrew J.** **Last** **Louis E. Silverman**	**Joshua Riggs** President and Chief Executive Officer and Director **Andrea James** Chief Financial Officer and Principal Financial Officer **James Liu** Vice President Accounting, Controller, Treasurer & Principal Accounting Officer
SHAREHOLDER INFORMATION	
Corporate Office Insight Molecular Diagnostics, Inc. 2 International Plaza Dr., Suite 510, Nashville, Tennessee 37217 (615) 255-8880	**Virtual Annual Meeting** Thursday, June 11, 2026, at 12:00 p.m., Central Time. *https://edge.media-server.com/mmc/p/k94peovi* Holders of record of our common stock on April 27, 2026, are entitled to notice of and to vote at the 2026 Annual Meeting.
Independent Public Accountants: CBIZ CPAs P.C. **Stock Transfer Agent and Registrar**: Equiniti Trust Company, LLC Attn: Proxy Tabulation Department 55 Challenger Road 2nd floor Ridgefield Park, New Jersey 07660 Website: https://equiniti.com/us/ **Stock Listing:** Nasdaq Capital Market: IMDX	**10-K Availability** A copy of the Company's Annual Report on Form 10-K for the 2025 fiscal year is available on the Company's website at: *www.imdxinc.com*. The Company will also furnish to any shareholder, without charge, a copy of the Company's Annual Report on Form 10-K for the 2025 fiscal year upon written request from the shareholder. Please send your written request to: Secretary: 2 International Plaza Dr., Suite 510 Nashville, Tennessee 37217 (615) 255-8880