A letter to our shareholders from iMDx Chief Executive Officer Josh Riggs

June 17, 2025

Healthcare is full of uncertainty.

Uncertainty for patients –

What is going on? Will I get to keep my kidney? Is the drug working? How will I manage?

Uncertainty for physicians –

Is the transplanted organ healthy? Can anything be done to stop the current course? What should be the next course of treatment?

Insight Molecular Diagnostics exists to provide reliable insight into complex biology.

As developers of diagnostic technology, our company's job is to deliver insight into complex biology and reduce uncertainty as much as possible. If we do our job well, that next step in the patient journey will be on the right path.

We provide insights on a scale that is too small to even be seen with a microscope: We analyze molecules. We count DNA fragments. And we invent interpretive algorithms.

Our sector is more broadly known as "precision medicine." Because biology is so mathematically complex, much of medicine deals with probabilities based on population-based studies – which can be effective but are often not *precise*. Our field combines cutting-edge advances in genomics with data analysis to guide decisions with greater accuracy.

Serving patients and physicians in their community is good business.

While molecular diagnostic testing has advanced significantly in recent years, many times access remains limited — constrained by geography, cost, and the need for centralized labs. Our mission is to democratize access to molecular diagnostic testing to improve patient outcomes. We aim to lead in molecular diagnostics by doing what sets technology companies apart: developing proprietary *algorithms* that drive *scalable* value.

Pivoting towards untapped global demand makes sense.

This month, we changed our name to Insight Molecular Diagnostics Inc., or iMDx. We aim to put doctors, laboratory technicians, and researchers at the center of what we do, to give them more diagnostic tools to better serve their patients.

In January 2023, our company formerly known as Oncocyte Corporation, embarked upon a major strategic pivot through which we dramatically cut costs and narrowed our focus: choosing to invest in transplant rejection testing.

Two years prior, we had acquired a team in Germany, led by Chief Science Officer Prof. Dr. Ekkehard Schuetz, that was world-renowned at measuring a biomarker that indicates transplanted organ rejection. Since that acquisition, we had been issued U.S. patents for this technology, alongside those held in the E.U., and we obtained Medicare reimbursement through MolDx. Meanwhile, donor-derived cell-free DNA testing was rapidly becoming standard of care in the US. It was becoming clear to us that the team and technology we had acquired in 2021 pointed toward a major market opportunity.

Under the leadership of Dr. Schuetz, we saw an opportunity to better serve the organ transplant market with faster, more cost-effective tests. But first, we would have to re-design our lab-developed test for widespread distribution via test kits, put these kits in researchers' hands to try them out in research-use-only mode, and then submit the test kit design to the FDA to get authorization to market our test kits for clinical use. We knew all of this would be incredibly difficult, which made it all more worth doing.

Putting transplant centers in the rejection testing business is a $1B+ global market opportunity.

The reward for developing a regulated transplant assay would be the opportunity to open an untapped market for testing – **the transplant centers themselves!** For years, the transplant centers at major hospitals have been a critical part of the economic value chain in transplant testing, and yet those centers have not been able to capture their share of the testing value they created.

We estimate that about a half-billion in revenue is generated by service labs that provide donor-derived cell-free DNA testing for these transplant centers and their patients, but **the transplant centers don't see a dollar of that revenue. We think it's time for that to change.** With expected future FDA authorization of our test kits, we anticipate that transplant centers and reference labs all over the country will be able to purchase the kits to bring this testing in-house.

Now, after an eventful and productive 2.5 years – which is light-speed for the healthcare industry but admittedly slow to the public markets – **we are entering an inflection point.** We are on the cusp of submitting our first diagnostic kit to the FDA for authorization.

We are not doing this alone. We enjoy critical industry support.

Last year we launched the research-use-only version of our test kit. These kits are in capable hands at laboratories at ***10 major transplant centers around the world***. These beta sites have provided us with valuable feedback on the assay and software design.

We have signed a global strategic partnership with Bio-Rad Laboratories, which has invested in our equity three times and makes the digital PCR instrument upon which our assay is performed. And we also continue to have productive dialogue with additional potential corporate partners.

Our IVD program has attracted **three of the top ten transplant centers in the US** along with two top centers in Germany, who want to see a regulated test on market and in their on-site labs.

Precision investment in precision diagnostics.

We believe that the progress that we are making with the resources that we have is astounding, and that can only happen because we punch above our weight in terms of talent. The people who come to work for us are smart, motivated and driven.

Since our pivot, we have started to look and feel like an *in-vitro* diagnostics (IVD) company. We have built an IVD team, and we are productively engaged with the FDA regarding our first kitted product. And, with a suite of oncology products coming after transplant, we believe we are just getting started.

The investment we have made in both driving down molecular testing costs as well as turn-around times is gaining attention among key opinion leaders in our target-customer segment. We are coming out of meetings with transplant labs and with doctors, refreshed. Those doctors who are well versed in the biomarker that our test finds – dd-cfDNA – love what we are doing. **They are bullish and we are thrilled.**

We are also grateful for our investors' support and encouragement, and we are determined to deliver meaningful results.

Sincerely,

Josh Riggs
CEO, Insight Molecular Diagnostics

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