

## Risk Factors Comparison 2025-02-28 to 2024-02-28 Form: 10-K

Legend: **New Text** ~~Removed Text~~ Unchanged Text **Moved Text Section**

Below is a summary of the principal factors that make an investment in our common stock speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading “ Risk Factors ” and should be carefully considered, together with other information in this Annual Report on Form 10- K, or this Form 10- K, and our other filings with the SEC before making an investment decision regarding our common stock. • We have a history of losses, and we expect to incur net losses for the next several years. • We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance. • Our financial results currently are largely dependent on sales of AlloSure Kidney, AlloMap Heart, AlloSure Heart, **HeartCare** and AlloSure Lung tests and products, and we will need to generate sufficient revenues from these and other solutions and tests we develop to grow our business. • We are and could become subject to legal proceedings that could be time- consuming, result in costly litigation and settlements / judgments, require significant amounts of management attention and result in the diversion of significant operational resources, which could adversely affect our business, financial condition and results of operations. • The development and commercialization of additional diagnostic solutions are key to our growth strategy. New test or product development involves a lengthy and complex process, and we may not be successful in our efforts to develop and commercialize additional diagnostic solutions. • The field of diagnostic testing in transplantation is evolving and is subject to rapid technological change. If we are unable to develop solutions to keep pace with rapid medical and scientific change, our operating results could be harmed. • If clinicians, hospital administrators, medical centers and laboratories do not adopt our diagnostic solutions, we will not achieve future sales growth. • **We have identified a material weakness in our internal control over financial reporting as of December 31, 2022, which was not remediated at December 31, 2024. If we are unable to remediate this material weakness and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner.** • Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline. • Transplant centers may not adopt AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~AlloMap Heart, AlloSure Heart,~~ or our other solutions due to historical practices or due to more favorable reimbursement policies associated with other means of monitoring transplants. • If we ~~cannot maintain existing~~ **are unable to successfully compete with established players in the clinical surveillance of the transplantation field collaborations and enter into new ones**, we may ~~our efforts to commercialize and develop products could be delayed~~ **unable to increase or sustain our revenues or achieve profitability.** • If we are unable to successfully manage our growth and support demand for our tests, our business may suffer. • Our past revenue growth rates may not be indicative of future growth, and we may not grow at all, and revenue may decline. • If our laboratory facility in the U. S. becomes inoperable, we will be unable to perform AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~AlloMap Heart, AlloSure Heart,~~ and future testing solutions, if any, and our business will be harmed. • Investors’ expectations of our performance relating to environmental, social and governance factors may impose additional costs and expose us to new risks. • Performance issues, service interruptions or price increases by our shipping carriers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis. • If we seek to and are unable to raise additional capital on acceptable terms in the future, it may limit our ability to develop and commercialize new diagnostic solutions and technologies, and we may have to curtail or cease operations. • The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists, clinicians and laboratory and field personnel could adversely affect our business. • Recent and future acquisitions and investments could disrupt our business, harm our financial condition and operating results, dilute your ownership of us and increase our debt or cause us to incur significant expense. • We rely extensively on third- party service providers. Failure of these parties to perform as expected, or interruptions in our relationship with these providers or their provision of services or supplies to us, could interfere with our ability to provide test results for our testing services business and kits for our products business. • We face four primary risks relative to protecting critical information: loss of access risk, inappropriate disclosure risk, inappropriate modification risk and the risk of our being unable to identify and audit our controls over the first three risks. In addition, an application, data security or network incident may allow unauthorized access to our systems or data or our customers’ data, disable access to our service, harm our reputation, create additional liability and adversely impact our financial results. • International expansion of our business exposes us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States. • Our operating results may be adversely affected by unfavorable economic and market conditions. • Billing complexities associated with obtaining payment or reimbursement for our current and future solutions may negatively affect our revenue, cash flows and profitability. • Healthcare reform measures could hinder or prevent the commercial success of AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare and** AlloSure Lung, ~~AlloMap Heart and AlloSure Heart.~~ • To operate our laboratory, we have to comply with the CLIA and federal and state laws and regulations governing clinical laboratories and laboratory- developed tests, including FDA regulations. • We are subject to numerous fraud and abuse and other laws and regulations pertaining to our business, the violation of any one of which could harm our business. • Our competitive position depends on maintaining intellectual property protection. • Our business is dependent on licenses from third parties. • Our operating results may fluctuate, which could cause our stock price to decrease. • The market price of our common stock has been and will likely continue to be volatile, and you could lose all or part

of your investment. Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, together with all of the other information in this Annual Report on Form 10-K, including the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and related notes, before investing in our common stock. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially harmed. In that event, the market price of our common stock could decline, and you could lose part or all of your investment.

**Risks Related to Our Business** We have incurred substantial net losses since our inception, and we may continue to incur additional losses for the next several years. For the year ended December 31, **2024, our net income was \$ 52.5 million and, for the year ended December 31, 2023, our net loss was \$ 190.3 million.** As of December 31, **2023-2024**, we had an accumulated deficit of \$ **678-626.3-2** million. We expect to continue to incur significant operating expenses and anticipate that our expenses will increase due to costs relating to, among other things:

- researching, developing, validating and commercializing potential new testing services, products and patient and digital solutions, including additional expenses in connection with our continuing development and commercialization of KidneyCare, HeartCare, AlloSeq, AiTraC and other future solutions;
- developing, presenting and publishing additional clinical and economic utility data intended to increase payer coverage and clinician adoption of our current and future solutions;
- expansion of our operating capabilities;
- maintenance, expansion and protection of our intellectual property portfolio and trade secrets;
- the process of fully integrating acquired companies and operations and the associated potential disruptions to our business;
- future clinical trials;
- expansion of the size and geographic reach of our sales force and our marketing capabilities to commercialize our existing and future solutions;
- employment of additional clinical, quality control, scientific, customer service, laboratory, billing and reimbursement and management personnel;
- compliance with existing and changing laws, regulations and standards, including those relating to corporate governance and public disclosure and regulations implemented by the Securities and Exchange Commission, or the SEC, and The Nasdaq Stock Market LLC;
- ongoing litigation;
- employment of operational, financial, accounting and information systems personnel, consistent with expanding our operations and our status as a public company; and
- failure to achieve expected operating results may cause a future impairment of goodwill or other assets.

Even if we achieve significant revenues, we may not become profitable, and even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain consistently profitable could adversely affect the market price of our common stock and could significantly impair our ability to raise capital, expand our business or continue to pursue our growth strategy or even continue to operate. For a detailed discussion of our financial condition and results of operations, see “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

For the year ended December 31, **2023-2024**, revenue from Medicare for **AlloSure Kidney, AlloMap Heart, AlloSure Kidney Heart, HeartCare** and **AlloSure Heart Lung** represented **53-50** % of testing services revenue. However, we may not be able to maintain or increase our tests reimbursed 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. The Protecting Access to Medicare Act of 2014, or PAMA, included a substantial new payment system for clinical laboratory tests under the Clinical Laboratory Fee Schedule, or CLFS. ~~Under PAMA, the reimbursement rate for AlloMap Heart is currently \$ 3,240 for Medicare beneficiaries.~~ AlloSure Kidney has been a covered service for Medicare beneficiaries since October 2017 through a Local Coverage Determination, or LCD, first issued by Palmetto MoIDX, or MoIDX, which was formed to identify and establish coverage and reimbursement for molecular diagnostics tests, and then adopted by Noridian Healthcare Solutions, our Medicare Administrative Contractor, or Noridian. ~~The Medicare reimbursement rate for AlloSure Kidney is currently \$ 2,841. In March and May 2023, MoIDX issued new billing articles related to the LCD entitled Molecular Testing for Solid Organ Allograft Rejection. The billing article issued in May 2023, or the Revised Billing Article, and together with the billing article issued in March 2023, the Billing Articles, impacted Medicare coverage for AlloSure Kidney, AlloSure Heart, AlloMap Heart and AlloSure Lung, and required certain companies, including us, to implement new processes to address the requirements related to Medicare claim submissions. Noridian adopted the Revised Billing Article on August 17, 2023, with a retroactive effective date of March 31, 2023. Although we believe the Billing Articles are inconsistent with the LCDs, Noridian’s and MoIDX’s responses to public comments explaining the intended scope of various LCDs, and medical necessity, we determined to pause our Medicare reimbursement submissions for AlloSure Kidney commencing on March 7, 2023 to allow us further time to evaluate the implications of the Billing Article and update our billing processes for AlloSure Kidney tests by educating clinicians and working with centers to update our test order forms to capture the new information required under the Billing Article. Accordingly, we did not submit claims for approximately 3,200 AlloSure Kidney tests for Medicare reimbursement for the period from March 7, 2023 through March 31, 2023 and did not recognize revenue on these claims in the first quarter of 2023 aggregating to approximately \$ 8.9 million, or the Impacted March Tests. On May 18, 2023, we submitted a letter to Noridian explaining, among other things, (i) our belief that the Billing Articles impose new restrictions on Medicare coverage for the CareDx tests from those contained in the existing LCDs, (ii) that we planned to submit claims for reimbursement for the Impacted March Tests for which we had not obtained additional information from the ordering physicians to be able to specifically determine whether these tests meet the new coverage restrictions contained in the Billing Articles, and (iii) that AlloSure Kidney orders with a date of service on or after March 31, 2023 for other indications outside the parameters of the Revised Billing Article, or where the reason for testing is not specified by the ordering physician, will either not be billed pending the receipt of additional information regarding whether the orders meet the coverage restrictions contained in the Revised Billing Article or be submitted with a test description that is intended to identify those tests as falling outside the parameters of the Revised Billing Article. Following the submission of this letter to Noridian on May 18, 2023, we submitted claims for reimbursement for the Impacted March Tests for which we subsequently received payment from Noridian and recognized revenue totaling approximately \$ 7.8 million in the second quarter of 2023.~~

On August 10, 2023, MolDX and Noridian released a draft proposed revision to the LCD (DL38568, Palmetto; DL38629, Noridian) that, if adopted, would revise the existing foundational LCD, MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568 and L38629). On August 14-16, 2023-2024, CMS issued a press release entitled “MolDX Local released a draft billing article (DA58019) to accompany the proposed draft LCD, which generally reflected the changes in coverage **Coverage included in Determination Statement,**” announcing that after careful consideration of the Revised Billing Article. The feedback received from interested parties, as well as the public comment comments period-end date and further review of evidence, the Medicare Administrative Contractors, for or this MACs, decided not to finalize the proposed LCD was September 23 issued on August 10, 2023. We presented at CMS further stated that due to the importance of identifying solid organ allograft rejection early and to ensure the public meetings regarding has additional opportunities to comment on the proposed draft policy, the MACs intend to issue a new LCD held on September 18 in the coming months. CMS stated that neither it nor the MACs have changed coverage for the blood tests that monitor for organ transplantation rejection when ordered by their physicians in medically appropriate circumstances, 2023 and explained that transplant patients would continue to have access to these blood tests, including: when there are signs or symptoms of rejection; after a physician- assessed pretest, including for surveillance testing; after and- an indeterminate biopsy; as a replacement for a biopsy when deemed clinically appropriate by September 20, 2023, with MolDX and Noridian, respectively. We also submitted written comments on the proposed draft LCD **patient’s qualified physician; and for evaluation of the adequacy of immunosuppression.** 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, including the Billing Articles. On a five- year rotational basis, Medicare requests bids for its regional Medicare Administrative Contractors, or MAC, services. The MAC for California is currently Noridian Healthcare Solutions. Our current Medicare coverage through Noridian provides for reimbursement for tests performed for qualifying Medicare patients throughout the U. S. so long as the tests are performed in our California laboratory. We cannot predict whether Noridian or any future MAC will continue to provide reimbursement for **AlloSure Kidney, AlloMap Heart, AlloSure Kidney, AlloSure Heart, HeartCare,** or AlloSure Lung 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 AlloSure Kidney, AlloMap Heart, AlloSure Heart, **HeartCare** or AlloSure Lung 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 the Centers for Medicare and Medicaid Services, or CMS, or its local contractors to reduce or deny coverage for our tests, including as a result of the Billing Articles or otherwise, 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. We expect that sales of testing services and products will account for a substantial portion of our revenue for at least the next two years. If we are unable to increase sales of our testing services or products or successfully develop and commercialize other solutions, tests or enhancements, or if we do not continue our Medicare reimbursement submissions for AlloSure Kidney at the same levels in place prior to the Billing Articles **issued by Palmetto MolDX in 2023 (the “ Billing Articles ”)**, our revenues and ability to achieve profitability would be impaired, and the market price of our common stock could decline. Health insurers and other third- party payers may decide to revoke coverage of our existing **test-tests,** decide not to cover our future solutions or may provide inadequate reimbursement, which could jeopardize our commercial prospects. Successful commercialization of AlloSure Kidney, **AlloMap Heart and AlloSure Heart, HeartCare and** AlloSure Lung, ~~AlloMap Heart and AlloSure Heart~~ depends, in large part, on the availability of coverage and adequate reimbursement from government and private payers. Favorable third- party payer coverage and reimbursement are essential to meeting our immediate objectives and long- term commercial goals. For new diagnostic testing services, each private and government payer decides whether to cover the test, the amount it will reimburse for a covered test and the specific conditions for reimbursement. Clinicians and recipients may not be likely to order a diagnostic test unless third- party payers pay a substantial portion of the test price. Therefore, coverage determinations and reimbursement levels and conditions are critical to the commercial success of a diagnostic testing service, and if we are not able to secure positive coverage determinations and reimbursement levels, our business will be materially adversely affected. Third- party payers have in the past disallowed, and may in the future disallow, in whole or in part, requests for reimbursement based on determinations that the member is not eligible for coverage, certain amounts are not reimbursable under plan coverage, were for services provided that were not medically necessary, were redundant or were not coupled with other specified tests or services or additional supporting documentation is necessary. Retroactive adjustments may change amounts realized from third- party payers. We are also subject to claims reviews and / or audits by such payers, including governmental audits of our Medicare claims, and have in the past been required to repay these payers in certain circumstances where a preliminary finding was made that we were incorrectly reimbursed. We may also in the future be required to repay these payers if a finding is made that we were incorrectly reimbursed. In addition, several payers and other entities conduct technology assessments of new medical tests and devices and provide and / or sell the results of their assessments to other parties. These assessments may be used by third- party payers and healthcare providers as grounds to deny coverage for or refuse to use a test or procedure. We have received a negative technology assessment from at least one of these entities and could receive more. **Seeking payer coverage and other approvals is a time- consuming and costly process.** If third- party payers decide not to cover our diagnostic testing services or if they offer inadequate payment amounts, our ability to generate revenue from AlloSure Kidney, AlloMap Heart, AlloSure Heart, **HeartCare,** AlloSure Lung and future solutions could be limited. Payment for diagnostic tests furnished to Medicare beneficiaries is typically made based on a fee schedule set by CMS. In recent years, payments under these fee schedules have decreased and may decrease further. Any third- party payer may stop or lower payment at any time, which could substantially

reduce our revenue. See the risk factor above titled “We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance”. Since each payer makes its own decision as to whether to establish a policy to reimburse for a test, seeking payer coverage and other approvals is a time-consuming and costly process. We cannot be certain that adequate coverage and reimbursement for AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart, or future solutions will be provided in the future by any third-party payer. Reimbursement for AlloSure Kidney, AlloMap Heart and AlloSure Heart comes primarily from Medicare and private third-party payers such as insurance companies and managed care organizations. The reimbursement process can take six months or more to complete depending on the payer and a new LCD through Medicare takes approximately 18 months. See the discussion regarding the Billing Articles under the risk factor above titled “We receive a substantial portion of our revenues from Medicare, and the loss of, or a significant reduction in, reimbursement from Medicare would severely and adversely affect our financial performance”. Coverage policies approving AlloMap Heart have been adopted by many of the largest private payers. Many of the payers with positive coverage policies have also entered into contracts with us to formalize pricing and payment terms. We continue to work with third-party payers to expand and seek such coverage and to appeal denial decisions based on existing and ongoing studies, peer-reviewed publications, support from physician and patient groups and the growing number of AlloMap Heart tests that have been reimbursed by public and private payers. There are no assurances that the current policies will not be modified in the future. If our test is considered on a policy-wide level by major third-party payers, whether at our request or on their own initiative, and our test is determined to be ineligible for coverage and reimbursement by such payers, if we do not submit for Medicare reimbursement for AlloSure Kidney for certain prior or future periods or if the Billing Articles continue to limit Medicare reimbursement for AlloSure Heart or AlloMap Heart, our collection efforts and potential for revenue growth could be adversely impacted. Our Medicare Part B coverage for AlloSure Kidney and AlloMap Heart is included in a formal local coverage decision for molecular diagnostics. However, any change in this coverage decision or other future adverse coverage decisions by CMS, including with respect to coding or as a result of the Billing Articles, could substantially reduce our revenue. Medicare reimbursements currently comprise a significant portion of our revenue. Our current Medicare Part B reimbursement was not set pursuant to a national coverage determination by CMS. Although we believe that coverage is available under Medicare Part B even without such a determination, we currently lack the national coverage certainty afforded by a formal coverage determination by CMS. This means that Medicare contractors, including our California Medicare contractor, currently may continue to develop their own coverage and reimbursement policies with respect to our technology. Until 2016, AlloMap Heart was billed using an unlisted Current Procedural Terminology, or CPT, code, but in 2016, a new CPT Category 1 Multianalyte Assays with Algorithmic Analyses, or MAAA, code was added that specifically describes the test. Further, pursuant to MolDX billing requirements, the AlloMap Heart test also has been assigned a McKesson Diagnostics Z-Code™, which is included on all Medicare claims. If in the future CMS makes a determination not to pay for this code, or for any MAAA codes, this could be harmful to our business, and could have negative spillover implications that prevent or limit coverage by other third-party payers that might mirror aspects of Medicare payment criteria. Since the launch of AlloSure Kidney in October 2016, and at the instruction of the MolDX Program of Palmetto, the test has been billed utilizing an unlisted CPT code. If in the future CMS makes a determination to no longer provide coverage for services billed with an unlisted CPT code, our ability to bill and obtain reimbursement from public and private payers could be negatively impacted. In addition, we received “Z” codes for AlloSure Kidney in order to submit for future Medicare reimbursement. Moreover, there can be no assurance that any of our tests or other offerings currently being promoted or on the market or being leveraged by clinicians or patients without FDA clearance or approval will continue to be allowed without such clearance or approval. We have in the past been, and from time to time in the future may become, involved in lawsuits, claims and proceedings incident to the ordinary course of, or otherwise in connection with, our business. For example, in response to our false advertising suit filed against Natera Inc., or Natera, on April 10, 2019, Natera filed a counterclaim against us on February 18, 2020 in the U. S. District Court for the District of Delaware, or the Court, alleging we made false and misleading claims about the performance capabilities of AlloSure. The trial concluded on March 14, 2022, with the jury finding that Natera violated the Lanham Act by falsely advertising the scientific performance of its Prospera transplant test and awarding us \$44.9 million in damages, comprised of \$21.2 million in compensatory damages and \$23.7 million in punitive damages. In July 2023, the Court upheld and reaffirmed the March 2022 jury verdict but did not uphold the monetary damages awarded by the jury. Both parties have appealed and briefing is ongoing. Our appeal may be unsuccessful or, if it is successful and the damages are upheld, we may be unable to collect any monetary damages. In August 2023, the Court issued an injunction prohibiting Natera from making the claims the jury previously found to be false advertising. On July 19, 2022, the United States Court of Appeals for the Federal Circuit affirmed the Court’s judgment dismissing our patent infringement suit against Natera. In May 2023, we submitted a petition of certiorari to the U. S. Supreme Court for consideration of the patent infringement suit and in October 2023, the U. S. Supreme Court declined to hear our suit. In addition, in response to our patent infringement suit filed against Natera on March 26, 2019, Natera filed suit against us on January 13, 2020 in the Court alleging, among other things, that AlloSure infringes Natera’s U. S. Patent 10, 526, 658. This case was consolidated with our patent infringement suit on February 4, 2020. On March 25, 2020, Natera filed an amendment to the suit alleging, among other things, that AlloSure also infringes Natera’s U. S. Patent 10, 597, 724. The suit seeks a judgment that we have infringed Natera’s patents, an order preliminarily and permanently enjoining us from any further infringement of such patents and unspecified damages. On May 13, 2022, Natera filed two new complaints alleging that AlloSure infringes Natera’s U. S. Patents 10, 655, 180 and 11, 111, 544. These two cases were consolidated with the patent infringement case on June 15, 2022. On May 17, 2022, Natera agreed to dismiss the case alleging infringement of Natera’s U. S. Patent 10, 526, 658. On September 6, 2022, we withdrew our motion to dismiss. On December 11, 2023, the Court dismissed Natera’s U. S. Patent 10, 597, 724. Natera has appealed that decision. On January 26, 2024, following a five-day trial, a jury concluded that we did not infringe Natera’s U. S. Patent 10, 655, 180 but did

infringe Natera's U. S. Patent 11, 111, 544. The jury awarded Natera approximately \$96.3 million in damages based on sales of AlloSure and AlloSeq between September 2021 and August 2023. Natera's U. S. Patent 11, 111, 544 expires in September 2026. We anticipate continued litigation as to whether our current AlloSure process infringes the patent. Natera may also move for injunctive relief. We intend to seek judicial review of the verdict and contest any potential claims of ongoing infringement and any motion for injunctive relief. We intend to defend ourselves these matters vigorously, and we believe that we have good and substantial defenses to the claims alleged in the suits, but there is no guarantee that we will prevail. Furthermore See Note 9 . **Commitments and Contingencies, to the consolidated financial statements included elsewhere in this Annual Report on Form** May 23, 2022, Plumbers & Pipefitters Local Union # 295 Pension Fund filed a federal securities class action in the U. S. District Court for the Northern District of California against us; Reginald Secto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; Marcel Konrad, our former interim Chief Financial Officer and former Senior Vice President of Finance & Accounting; and Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors. The action alleges that we and the individual defendants made materially false and / or misleading statements and / or omissions and that such statements violated Section 10 (b) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and Rule 10b- **K under the 5** promulgated thereunder. The action **caption “ Litigation and Indemnification Obligations ”, which is incorporated herein** also alleges that the individual defendants are liable pursuant to Section 20 (a) of the Exchange Act as controlling persons of our Company. The suit seeks to recover damages caused by **reference** the alleged violations of federal securities laws, along with the plaintiffs' costs incurred in the lawsuit, including their reasonable attorneys' and experts' witness fees and other costs. On August 25, 2022, the court appointed an investor group led by the Oklahoma Police Pension and Retirement System as lead plaintiffs and appointed Saxena White P. A. and Robbins Geller Rudman & Dowd LLP as lead counsels. Plaintiffs filed an amended complaint on November 28, 2022. On January 27, 2023, defendants moved to dismiss all claims and to strike certain allegations in the amended complaint. On May 24, 2023, the court granted our motion to strike and motion to dismiss, dismissing all claims against defendants with leave to amend. On June 28, 2023, plaintiffs filed a second amended complaint against us, Reginald Secto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; and Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors. Under a briefing schedule ordered by the court on June 12, 2023, defendants filed a motion to dismiss and motion to strike the second amended complaint on July 26, 2023, plaintiffs' opposition was filed on August 30, 2023 and defendants' reply was filed on September 22, 2023. The court held oral argument on October 31, 2023. The parties filed a joint status statement with the court on February 15, 2024. We intend to defend ourselves vigorously, and believe that we have good and substantial defenses to the claims alleged in the suit, but there is no guarantee that we will prevail. Additionally, on September 21, 2022, Jeffrey Edelman brought a stockholder derivative action complaint in the U. S. District Court for the Northern District of California, or the Edelman Derivative Action, against us as nominal defendant and Reginald Secto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors; and the other members of our Board of Directors. The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and / or officers of our Company and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14 (a) and 20 (a) of the Exchange Act. The action alleges that the individual defendants are liable pursuant to Section 20 (a) of the Exchange Act as controlling persons of our Company. The suit seeks a declaration that the individual defendants breached their fiduciary duties to us, violated Sections 14 (a) and 20 (a) of the Exchange Act and were unjustly enriched, and also seeks to recover damages sustained by us as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses. In addition, on February 7, 2023, Jaysen Stevenson brought a stockholder derivative action complaint in the U. S. District Court for the Northern District of California, or the Stevenson Derivative Action, against us as nominal defendant and Reginald Secto, our former President, Chief Executive Officer and member of our Board of Directors; Ankur Dhingra, our former Chief Financial Officer; Peter Maag, our former President, former Chief Executive Officer, former Chairman of our Board of Directors and current member of our Board of Directors; and other current and former members of our Board of Directors. The claims and allegations in the Stevenson Derivative Action are substantially similar to those in the Edelman Derivative Action. The plaintiff alleges that the individual defendants breached their fiduciary duties as our directors and / or officers and engaged in insider trading, waste of corporate assets, unjust enrichment and violations of Sections 14 (a) and 20 (a) of the Exchange Act. The suit seeks declaratory relief and to recover alleged damages sustained by us as a result of the alleged violations, along with the plaintiff's costs incurred in the lawsuit, including reasonable attorneys' and experts' fees, costs and expenses. On March 9, 2023, the court consolidated the Edelman Derivative Action and the Stevenson Derivative Action and stayed both actions pursuant to the terms of the stay order in the Edelman Derivative Action. The consolidated derivative action remains stayed. The parties in the Stevenson Derivative Action filed a joint status statement with the court on September 6, 2023, and the parties in the consolidated derivative action filed a joint status statement and administrative motion with the court on February 13, 2024. Additionally, on February 8, 2024, Christian Jacobsen filed a stockholder derivative action complaint in the U. S. District Court for the Northern District of California against us as nominal defendant and Dr. Secto, Mr. Dhingra, Dr. Maag, and other current and former members of our Board of Directors (the “ Jacobsen Derivative Action ”). The plaintiff alleges that the individual defendants breached their fiduciary duties as directors and / or officers of our Company, violated Section 14 (a) of the Exchange Act, are liable for contribution under Sections 10 (b) and 21 (D) of the Exchange Act, engaged in unjust enrichment, waste of corporate assets, aiding and abetting, insider trading, and misappropriation of information, and / or are liable for indemnification. The suit seeks declaratory relief, disgorgement, and to recover alleged damages sustained by us as a result of the alleged violations, along with

plaintiff's costs incurred in the lawsuit, including reasonable attorneys', accountants', and experts' fees, costs, and expenses. The Jacobsen Derivative Action was designated related to the consolidated derivative action. We intend to defend ourselves vigorously, and we believe that we have good and substantial defenses to the claims alleged in the consolidated derivative action and the Jacobsen Derivative Action, but there is no guarantee that we will prevail. Litigation is inherently unpredictable. It is possible that an adverse result in one or more of these possible future events could have a material adverse effect on us, including increased expenses to defend, settle or resolve such litigation. Key elements of our strategy are to discover, develop, validate and commercialize a portfolio of new diagnostic solutions. We cannot be sure that we will be able to successfully complete development of or commercialize any of our planned future solutions, or that they will prove to be capable of reliably being used for organ surveillance in the heart or in other types of organs. Before we can successfully develop and commercialize any of our currently planned or other new diagnostic solutions, we will need to: • conduct substantial research and development; • obtain the necessary testing samples and related data; • conduct clinical validation studies; • expend significant funds; • expand and scale-up our laboratory processes; • expand and train our sales force; • gain acceptance from ordering clinicians at a larger number of transplant centers; • gain acceptance from ordering laboratories associated with transplant centers; and • seek and obtain regulatory clearance or approvals of our new solutions, as required by applicable regulations. **We have included a discussion of a number of anticipated targets in this Annual Report on Form 10-K. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot be certain that we will meet our projected targets and if we do not meet these targets as publicly announced, the commercialization of our diagnostic solutions may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline.** This process involves a high degree of risk and may take up to several years or more. Our test development and commercialization efforts may be delayed or fail for many reasons, including: • failure of the test at the research or development stage; • difficulty in accessing suitable testing samples, especially testing samples with known clinical results; • **lack of clinical validation data to support the effectiveness of the test;** • delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner; **or** • failure to obtain or maintain necessary clearances or approvals to market the test. **In addition, the publication of clinical data in peer-reviewed publications is necessary to promote clinician adoption and favorable reimbursement decisions. Clinicians typically take a significant amount of time to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about AlloSure Kidney, AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung and our future solutions, and demonstrate the clinical benefits of these solutions. If our solutions fail to gain commercial acceptance by patients, clinicians or third-party payers, our business and results of operations would be negatively affected. The administration of clinical and economic utility studies is expensive and demands significant attention from our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our current and future products and patient and digital solutions would suffer and our business would be harmed.** Few research and development projects result in commercial products, and success in early clinical studies often is not replicated in later studies. At any point, we may abandon development of new diagnostic solutions, or we may be required to expend considerable resources repeating clinical trials, which would adversely impact the timing for generating potential revenues from those new diagnostic solutions. In addition, as we develop diagnostic solutions, we will have to make additional investments in our sales and marketing operations, which may be prematurely or unnecessarily incurred if the commercial launch of a test is abandoned or delayed. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study, we would likely abandon the development of the test or test feature that was the subject of the clinical trial, which could harm our business. **If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of additional diagnostic solutions by us may be delayed and, as a result, our business will suffer and our stock price may decline.** From time to time, we expect to estimate and publicly announce the anticipated timing of the accomplishment of various clinical and other product development goals. In addition, we have included a discussion of a number of anticipated targets in this Annual Report on Form 10-K. The actual timing of accomplishment of these targets could vary dramatically compared to our estimates, in some cases for reasons beyond our control. We cannot be certain that we will meet our projected targets and if we do not meet these targets as publicly announced, the commercialization of our diagnostic solutions may be delayed or may not occur at all and, as a result, our business will suffer and our stock price may decline. The field of diagnostic testing in transplantation is evolving. Although there have been few advances in technology relating to organ rejection in transplant recipients, the market for medical diagnostic companies is marked by rapid and substantial technological development and innovations that could make AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~AlloMap Heart, AlloSure Heart~~ and our other products and patient and digital solutions, including those in development, outdated. We must continually innovate, expand and update our test offerings to address unmet needs in monitoring transplant-related conditions. AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~AlloMap Heart, AlloSure Heart~~, and our other products and patient and digital solutions, including those in development, could become obsolete unless we continually innovate, enhance and expand our product offerings to include new clinical applications. If we are unable to demonstrate the effectiveness of AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~or AlloMap Heart, AlloSure Heart,~~ our other products and patient and digital solutions and future diagnostic solutions and tests, if any, compared to new methodologies and technologies, then sales of our tests, products and patient and digital solutions could decline, which would harm our business and financial results. Clinicians and healthcare administrators are traditionally slow to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of

third-party reimbursement. It is critical to the success of our sales efforts that we continue to educate clinicians, administrators and laboratory directors about our testing services, products and patient and digital solutions, and demonstrate the clinical and diagnostic benefits of these services, products and patient and digital solutions. We believe that clinicians, transplant centers and laboratories may not use our services, products and patient and digital solutions unless they determine, based on published peer-reviewed journal articles, the experience of other clinicians or laboratory verification, that our services, products and patient and digital solutions provide accurate, reliable and cost-effective information that is useful in pre-transplant matching and monitoring their post-transplant recipients. Our product kits are sold to hundreds of laboratories, mainly in Europe and the U. S. Laboratories order our products based on the accuracy, speed and cost of the test together with the cost and availability of equipment on which to run the test. Switching to or adopting our products may require the purchase of new and costly testing equipment. To attract new laboratory customers, the performance of our products must provide a performance or cost advantages over similar products sold by our competitors. If clinicians, hospital administrators and laboratories do not adopt and **or** continue to use our tests and products or our future solutions and tests, our business and financial results will suffer. Historically, our financial results **have been**, **including** and we expect that our operating results will continue to be, subject to quarterly fluctuations. Our net income (loss), **have been**, and other **we expect that our** operating results will **continue to** be affected by numerous, **subject to quarterly fluctuations as a result of a variety of** factors, **many of which are outside of our control**, including: **our ability** those listed elsewhere in this “Risk Factors” section. In addition, **to the extent that we continue** successfully market and sell our testing services and products; **our ability to successfully spend considerable amounts on research and development expenditures**, commercialize **commercialization efforts for** new diagnostic solutions; **the amount of our research and development expenditures**; **the timing of cash collections from third-party payers**; **the extent to which our current and future solutions, if any, are eligible for coverage and reimbursement from third-party payers**; **the process of integrating new acquisitions**, and the **their related integration into** associated potential disruption to our business; **changes in coverage and reimbursement or in reimbursement-related laws directly affecting our business**, **we expect** including as a result of the Billing Articles; **our decision to incur costs before achieving any anticipated** continue our Medicare reimbursement submissions for AlloSure Kidney; **our decision to issue future benefits** financial guidance and the terms of such guidance; **any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved or that otherwise may affect our intellectual property position**; **announcements by our competitors of new or competitive products**; **regulatory or legal developments affecting our test or competing products**; **total operating expenses**; and **changes in expectation as to our future financial performance, including financial estimates, publications or research reports by securities analysts**. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance. If the use of **Transplant centers may not adopt** AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung, AlloMap Heart, AlloSure Heart** or any of our other solutions **due to historical practices** is not supported by studies published in peer-reviewed scientific and medical publications, and then periodically supplemented with additional support in peer-reviewed journals, the rate of adoption of our **or due** current and future solutions by clinicians and treatment centers and the rate of reimbursement of our current and future solutions by payers may be negatively affected. Transplant, like all specialties, is based on evidence-based medicine. As a result, laying a strong foundation of evidence and improved clinical utility is essential in the adoption of the tools offered by us. The results of our studies involving AlloSure Kidney, AlloSure Lung, AlloMap Heart and AlloSure Heart have been presented at major medical society congresses and published in peer-reviewed publications in leading medical journals. This continued presence in peer-reviewed publications is necessary to **more** promote clinician adoption and favorable reimbursement **policies associated with** decisions. We believe that peer-reviewed journal articles that provide evidence of the utility of our solutions or the technology underlying AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart and our other **means** products and patient and digital solutions are very important to the commercial success of our solutions. Clinicians typically take a significant amount of time to adopt new products, testing practices and clinical treatments, partly because of perceived liability risks and the uncertainty of third-party reimbursement. It is critical to the success of our sales efforts that we educate a sufficient number of clinicians and administrators about AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart and our future solutions, and demonstrate the clinical benefits of these solutions. Clinicians may not adopt, and third-party payers may not cover or adequately reimburse for, our current and future products and patient and digital solutions unless they determine, based on published peer-reviewed journal articles and the experience of other clinicians, that our diagnostic current and future products and patient and digital solutions provide accurate, reliable and cost-effective information that is useful in monitoring transplant **transplants** recipients and making informed and timely treatment decisions. The administration of clinical and economic utility studies is expensive and demands significant attention from our management team. Data collected from these studies may not be positive or consistent with our existing data, or may not be statistically significant or compelling to the medical community. If the results obtained from our ongoing or future studies are inconsistent with certain results obtained from our previous studies, adoption of our current and future products and patient and digital solutions would suffer and our business would be harmed. While we have had success in generating peer-reviewed publications regarding AlloSure Kidney, AlloSure Lung, AlloMap Heart, and AlloSure Heart, additional peer-reviewed publications regarding AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart and our future products and patient and digital solutions may be limited by many factors, including delays in the completion of, poor design of, or lack of compelling data from clinical studies that would be the subject of the article. If our current and future products and patient and digital solutions or the technology underlying AlloSure Kidney, AlloSure Lung, AlloMap Heart, AlloSure Heart, or our future products and patient and digital solutions do not receive sufficient favorable exposure in peer-reviewed publications, the rate of

clinician adoption and positive reimbursement coverage decisions could be negatively affected. The publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining reimbursement for diagnostic solutions such as ours, and our inability to control when, if ever, results are published may delay or limit our ability to derive sufficient revenue from any product that is the subject of a study. To ensure the success of AlloSure Kidney and future tests based on donor-derived cell-free DNA, or dd-cfDNA, we will need to continue our efforts to complete and publicize research and trials, especially the Kidney Allograft Outcomes AlloSure Registry, or K-OAR, registry study, that provides evidence of the utility of dd-cfDNA and validate AlloSure Kidney as a solution. Due to the historically limited monitoring options and the well-established coverage and reimbursement for biopsies, clinicians are accustomed to monitoring for acute rejection in kidney and heart transplant recipients by utilizing biopsies. Many clinicians use AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung**, ~~AlloMap Heart and AlloSure Heart~~ in parallel with biopsies rather than as an alternative to biopsies. While we do not market AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare or AlloSure Lung**, ~~AlloMap Heart or AlloSure Heart~~ as biopsy alternatives, per se, if treatment center administrators view our test as an alternative to a biopsy but believe they would derive more revenue from the performance of biopsies, such administrators may be motivated to reduce or avoid the use of our test. While biopsies are less common for monitoring kidney transplant patients, there are transplant centers that manage patients with protocol biopsies, which could impact AlloSure Kidney revenue. We cannot provide assurance that our efforts will increase the use of our test by new or existing customers. Our failure to increase the frequency of use of our test by new and existing customers would adversely affect our growth and revenues. **If we are unable to successfully compete with established players in the clinical surveillance of the transplantation field, we may be unable to increase or sustain our revenues or achieve profitability.** Our AlloSure Kidney solution for kidney transplant recipients competes against existing diagnostic tests utilized by pathologists, which involves evaluating biopsy samples to determine the presence or absence of rejection. However, because of the risks and discomforts of the invasive kidney biopsy procedure, as well as the expense and relatively low rate of finding moderate to severe grade rejection, biopsy is not a standard practice for surveillance of transplanted kidneys. Additional competition for kidney surveillance diagnostics currently comes from general, non-specific clinical chemistry tests such as serum creatinine, urine protein, donor specific antibodies, complete blood count, lipid profile and others that are widely ordered by physician offices and routinely performed in clinical reference labs and hospital labs. Our competitors also include companies that are focused on the development and commercialization of molecular diagnostic tests. In the field of post-transplant surveillance, Natera, Eurofins, and Oncocyte, ~~have commercially available molecular diagnostics tests~~. **Other entrants with kitted products have indicated they are entering the market for post-transplant surveillance, including Thermo Fisher, Devyser, Bio-Rad, EuroBio, and Oncocyte.** Competition for our AlloMap Heart solution for heart transplant recipients also comes from biopsies, which generally involve evaluating biopsy samples to determine the presence or absence of rejection. This practice has been the standard of care in the United States for many years, and we will need to continue to educate clinicians, transplant recipients and payers about the various benefits of our test in order to change clinical practice. We expect the competition for pre-transplant typing and post-transplant surveillance to increase as there are numerous established and startup companies in the process of developing products and services for the transplant market which may directly or indirectly compete with our existing pre- and post-transplant solutions, or our development pipeline. Competition from other companies, especially those with an eye toward transitioning to more automated typing processes, could impact our ability to maintain market share and its current margins. For example, QTYPE competes with other quantitative polymerase chain reaction, or PCR, products including products offered by Thermo Fisher Scientific, Inc., or Thermo Fisher, as well as alternatives to PCR such as next generation sequencing, or NGS, typing products. ~~In addition to businesses focused on pre-transplantation such as Thermo Fisher's One Lambda and Immucor, Inc.'s LIFECODES, companies that have not historically focused on transplantation but that possesses existing knowledge of dd-cfDNA technology have indicated they are considering this market.~~ Competition for our patient and digital solutions include various companies that develop application software and operate in the healthcare field. Our competition for patient solutions includes hospital-affiliated pharmacies located on-site at the transplant center and specialty pharmacies that provide transplant-specific care and dispensing services. Our primary competitor for our patient management EMR solution is Phoenix, Epic's transplant application. In addition, other established and emerging healthcare, information technology and service companies may commercialize competitive products including informatics, analysis, integrated genetic tools and services for health and wellness. The field of clinical surveillance of transplantation is evolving. New and well-established companies are devoting substantial resources to the application of molecular diagnostics to the treatment of medical conditions. Some of these companies may elect to develop and market diagnostic solutions in the post-transplant surveillance market. Many of our potential competitors may have greater brand recognition or substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that could be viewed by clinicians and payers as functionally equivalent to our AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung**, ~~AlloMap Heart and AlloSure Heart~~ tests, which could force us to lower the current list price of our test and impact our operating margins and our ability to achieve profitability. If we are unable to compete successfully against current or future competitors, we may be unable to increase market acceptance for and sales of AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung tests, AlloMap Heart, AlloSure Heart** and our products and patient and digital solutions, which could prevent us from increasing or sustaining our revenues or achieving profitability and could cause the market price of our common stock to decline. If we are unable to successfully and continually update our products on a timely basis, our ability to attract and retain customers could be impaired and our competitive position could be harmed. We operate in an environment characterized by rapid development and continuing innovation. We will need to continue to maintain the value of our product offering. To compete successfully, we must continually update our product range and produce continually updated test kits and software. The failure to maintain the quality of our products or inability to keep pace

with this innovation could render our existing or future solutions obsolete or less attractive to lab directors and clinicians. Any failure to anticipate or develop new or enhanced solutions in a timely manner could result in decreased revenue and harm to our business and prospects. If we fail to introduce new or enhanced solutions that meet the needs of our customers, we will lose market share and our business, operating results and prospects will be adversely affected. Our research and development efforts will be hindered if we are not able to acquire or contract with third parties for access to ~~additional~~ tissue and blood samples. Our clinical development relies on our ability to secure access to tissue and blood samples, as well as recipient information, including biopsy results and clinical outcomes from the same patient. Furthermore, the studies through which our future solutions are developed may rely on access to multiple samples from the same recipient over a period of time as opposed to samples at a single point in time or archived samples. We will require additional samples and recipient data for future research, development and validation. Access to recipients and samples on a real-time, or non-archived, basis is limited and often on an exclusive basis, and there is no guarantee that future initiatives will be successful in obtaining and validating additional samples. Additionally, the process of negotiating access to new and archived donor and recipient data and samples is lengthy since it typically involves numerous parties and approval levels to resolve complex issues, such as usage rights, institutional review board approval, recipient consent, privacy rights and informed consent of recipients, publication rights, intellectual property ownership and research parameters. If we are not able to acquire or negotiate access to new and archived donor and recipient data and tissue and blood samples with source institutions, or if other laboratories or our competitors secure access to these samples before us, our ability to research, develop and commercialize future solutions such as AlloSure Kidney will be limited or delayed. ~~If we cannot maintain existing clinical collaborations and enter into new ones, our efforts to commercialize and develop products could be delayed.~~ In the past, we have entered into clinical collaborations with highly regarded academic institutions and leading treatment centers in the transplant field. Our success in the future may depend in part on our ability to enter into agreements with other leading institutions in the transplant field. Securing these agreements can be difficult due to internal and external constraints placed on these organizations. Some organizations may limit the number of collaborations they have with any one company so as to not be perceived as biased or conflicted. Organizations may also have insufficient administrative and related infrastructure to enable collaborations with many companies at once, which can extend the time it takes to develop, negotiate and implement a collaboration. In addition to completing clinical collaborations, publication of clinical data in peer-reviewed journals is a crucial step in commercializing and obtaining coverage and reimbursement for solutions such as ours. Our inability to control when, if ever, results of such studies are published may delay or limit our ability to derive sufficient revenues from any test that may result from a collaboration. ~~with them.~~ We cannot control the amount and timing of our collaborators' resources that will be devoted to performing their responsibilities under our agreements with them. Our collaborators may choose to pursue alternative technologies in preference to those being developed in collaboration with us. The development, validation and commercialization of our potential solutions may be delayed if collaborators fail to fulfill their responsibilities in a timely manner or in accordance with applicable regulatory requirements or if they breach or terminate their collaboration agreements with us. Any issues arising from these arrangements will affect our ability to serve the entire region, and our reputation may suffer even if we subsequently locate new partners, which may permanently affect our business. Disputes with our collaborators could also impair our reputation or result in development delays, decreased revenues and **litigation expenses**. From time to time, we expect to engage in discussions with potential clinical collaborators, which may or may not lead to collaborations. We cannot guarantee that any discussions will result in clinical collaborations or that any clinical studies that may result will be enrolled or completed in a reasonable time frame or with successful outcomes. Once news of discussions regarding possible collaborations becomes known in the medical community, regardless of whether the news is accurate, failure to announce a collaborative agreement or the other entity's announcement of a collaboration with an entity other than us may result in adverse speculation about us, our current and future solutions or our technology, resulting in harm to our reputation and our business. As the volume of the tests that we perform grows, we will need to continue to ramp up our testing capacity, implement increases in scale and related processing, customer service, billing and systems process improvements and expand our internal quality assurance program to support testing on a larger scale. We will also need additional certified laboratory scientists and other scientific and technical personnel to process our tests. We cannot be certain that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available. As additional products are developed, we may need to bring new equipment on-line, implement new systems, technology, controls and procedures and hire personnel with different qualifications. We plan to expand our sales force to support additional products. There is significant competition for qualified, productive sales personnel with advanced sales skills and technical knowledge in our field. Our ability to achieve significant growth in revenue in the future will depend, in large part, on our success in recruiting, training and retaining sufficient qualified sales personnel. The value of AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung**, ~~AlloMap Heart and AlloSure Heart~~ depends, in large part, on our ability to perform AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung**; ~~AlloMap Heart and AlloSure Heart~~ tests on a timely basis and at a high quality standard, and on our reputation for such timeliness and quality. Failure to implement necessary procedures, transition to new equipment or processes or hire new personnel could result in higher costs of processing or an inability to meet market demand in a timely manner. There can be no assurance that we will be able to perform AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung**; ~~AlloMap Heart, AlloSure Heart~~, or our future solutions, if any, on a timely basis at a level consistent with demand, that our efforts to scale our commercial operations will not negatively affect the quality of test results or that we will be successful in responding to the growing complexity of our testing operations. If we encounter difficulty meeting market demand for our current and future solutions, our reputation could be harmed and our future prospects and our business could suffer. In addition, our growth may place a significant strain on our management, operating and financial systems and our sales, marketing and administrative resources. As a result of our growth, our operating costs may escalate even faster than planned, and some of our

internal systems may need to be enhanced or replaced. If we cannot effectively manage our expanding operations and our costs, we may not be able to grow effectively or we may grow at a slower pace, and our business could be adversely affected. From 2022 to 2023 to 2024, our revenue ~~declined~~ **increased** from \$ 321.8 million to \$ 280.3 million, which represents an annual ~~decrease~~ **increase** of 19 (13)%. In the future, our revenue may not grow at all and it may continue to decline. We believe that our future revenue will depend on, among other factors: • the continued usage and acceptance of our current and future solutions; • demand for our testing services, products and patient and digital solutions; • the introduction and acceptance of new or enhanced products or services by us or by competitors; • our ability to maintain reimbursement for AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare and AlloSure Lung**, ~~AlloMap Heart and AlloSure Heart~~ and secure reimbursement for our future solutions ; • **our decision to continue our Medicare reimbursement submissions for AlloSure Kidney; • our decision to issue future financial guidance and the terms of such guidance**; • our ability to anticipate and effectively adapt to developing markets and to rapidly changing technologies; • our ability to attract, retain and motivate qualified personnel; • the initiation, renewal or expiration of significant contracts with our commercial partners; • pricing changes by us, our suppliers or our competitors; and • general economic conditions and other factors. We may not be successful in our efforts to manage any of the foregoing, and any failure to be successful in these efforts could materially and adversely affect revenue growth. You should not consider our past revenue growth to be indicative of future growth. We perform all of our testing services for the U. S. in our laboratory located in Brisbane, California. We do not have redundant laboratory facilities. Brisbane, California is situated on or near earthquake fault lines. Our facility and the equipment we use to perform testing services would be costly to replace and could require substantial lead time to repair or replace if damaged or destroyed. Our facilities may 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 may result in the loss of customers or harm our reputation, and we may be unable to regain those customers in the future. Although we possess insurance for damage to our property and the disruption of our business, we do not have earthquake insurance and thus coverage 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 . **We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage, and, in the event of a major earthquake in our region, our business could suffer significant and uninsured damage and loss** . In order to establish a redundant laboratory facility, we would have to spend considerable time and money securing adequate space, constructing the facility, recruiting and training employees and establishing the additional operational and administrative infrastructure necessary to support a second facility. Additionally, any new clinical laboratory facility opened by us in the U. S. would be required to be certified under the Clinical Laboratory Improvement Amendments of 1988, or CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. We would also be required to secure and maintain state licenses required by several states, including California, Florida, Maryland, New York, Rhode Island and Pennsylvania, which can take a significant amount of time and result in delays in our ability to begin operations at that facility. If we failed to secure any such licenses, we would not be able to process samples from recipients in such states. We also expect that it would be difficult, time- consuming and costly to train, equip and use a third- party to perform tests on our behalf. We could only use another facility with the established state licensures and CLIA certification necessary to perform AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung** ; ~~AlloMap Heart, AlloSure Heart,~~ or future solutions following validation and other required procedures. We cannot be certain that we would be able to find another CLIA- certified facility willing or able to adopt AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare, AlloSure Lung** , ~~AlloMap Heart, AlloSure Heart~~ or future solutions or able to comply with the required quality and regulatory standards, or that this laboratory would be willing or able to perform the tests for us on commercially reasonable terms. There is an increasing focus from certain investors, employees, regulators and other stakeholders concerning corporate responsibility, specifically related to environmental, social and governance, or ESG, factors. Some investors and investor advocacy groups may use these factors to guide investment strategies and, in some cases, investors may choose not to invest in our company if they believe our policies relating to corporate responsibility are inadequate. Third-party providers of corporate responsibility ratings and reports on companies have increased to meet growing investor demand for measurement of corporate responsibility performance, and a variety of organizations currently measure the performance of companies on such ESG topics, and the results of these assessments are widely publicized. Investors, particularly institutional investors, use these ratings to benchmark companies against their peers and if we are perceived as lagging with respect to ESG initiatives, these investors may engage with us to improve ESG disclosures or performance and may also make voting decisions, or take other actions, to hold us and our ~~board~~ **Board** of ~~directors~~ **Directors** accountable. In addition, the criteria by which our corporate responsibility practices are assessed may change, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies with respect to corporate responsibility are inadequate. We may face reputational damage in the event that our corporate responsibility procedures or standards do not meet the standards set by various constituencies . ~~We may face reputational damage in the event our corporate responsibility initiatives or objectives do not meet the standards set by our investors, stockholders, lawmakers, listing exchanges or other constituencies, or if we are unable to achieve an acceptable ESG or sustainability rating from third- party rating services. A low ESG or sustainability rating by a third- party rating service could also result in the exclusion of our common stock from consideration by certain investors who may elect to invest with our competition instead.~~ Ongoing focus on corporate responsibility matters by investors and, **stockholders, lawmakers, listing exchanges or other constituencies** ~~parties as described above~~ may impose additional costs or expose us to new risks. Any failure or perceived failure by us in this regard could have a material adverse effect on our reputation and on our business, share

price, financial condition or results of operations, including the sustainability of our business over time. In addition, **in March 2024**, the SEC **adopted** ~~has announced proposed~~ rules that, among other matters, ~~will~~ establish a framework for reporting of climate-related risks. **However, the SEC voluntarily stayed implementation of the final rules pending completion of judicial review.** To the extent the proposed rules **survive ongoing and possibly additional forthcoming legal challenges, they may** impose additional reporting obligations, **and** we could ~~face~~ **incur** increased costs. ~~Separately, the SEC has also announced that it is scrutinizing existing climate-change related disclosures in public filings, increasing the potential for enforcement if the SEC were to allege our existing climate disclosures are misleading or deficient.~~ Expedited, reliable shipping is essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of recipient samples to our laboratory and enhanced tracking of these recipient samples. Should a carrier encounter delivery performance issues such as loss, damage or destruction of a sample, it may be difficult to replace our patient samples in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our services and increased cost and expense to our business. In addition, any significant increase in shipping rates could adversely affect our operating margins and results of operations. Similarly, strikes, severe weather, natural disasters or other service interruptions, including those affecting delivery services we use would adversely affect our ability to receive and process recipient samples on a timely basis. Our ability to commercialize our testing solutions that we develop is dependent on our relationships with laboratory services providers and their willingness to support our current and future solutions. We rely on third-party laboratory services providers to draw and partially process the patient blood samples that are analyzed in our Brisbane, California laboratory. Our business will suffer if these service providers do not support AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~AlloMap Heart, AlloSure Heart~~ or the other solutions that we may develop. For example, these laboratories may determine that processing the samples for our solutions requires too much additional effort. Additionally, if transplant facilities have relationships with large reference laboratories that will not process and send out our specimens, the clinicians at these facilities may deem ordering our tests outside of these relationships too inconvenient for their patients. A lack of acceptance of our current and future solutions by these service providers could result in lower test volume. As of December 31, ~~2023~~ **2024**, we had cash, cash equivalents and marketable securities of \$ ~~235-260~~ **4-7** million and an accumulated deficit of \$ ~~678-626~~ **3-2** million. We expect capital outlays and operating expenditures to increase over the next several years as we expand our infrastructure, commercial operations and research and development activities. Specifically, we may need to raise additional capital to, among other things: • develop other solutions for clinical surveillance in transplantation; • increase our selling and marketing efforts to drive market adoption and address competitive developments; • expand our clinical laboratory operations; • fund our clinical validation study activities; • expand our research and development activities; • sustain or achieve broader commercialization of AlloSure Kidney, **KidneyCare, AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung; ~~KidneyCare, AlloMap Heart, AlloSure Heart, HeartCare~~, our products and patient and digital solutions or enhancements to those tests, products and patient and digital solutions; • acquire or license products or technologies including through acquisitions; and • finance our capital expenditures and general and administrative expenses. ~~Our present and future funding requirements will depend on many factors, including:~~ • the level of research and development investment required to develop our new solutions; • costs of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights; • our need or decision to acquire or license complementary technologies or acquire complementary businesses; • changes in test development plans needed to address any difficulties in commercialization; • competing technological and market developments; • whether our diagnostic solutions become subject to additional FDA or other regulation; and • changes in regulatory policies or laws that affect our operations. Additional capital, if needed, may not be available on satisfactory terms, or at all, and might include the issuance of equity securities, debt, cash from collaboration agreements or a combination of these. Furthermore, if we raise additional funds by issuing equity securities, dilution to our existing stockholders could result. Any equity securities issued also may provide for rights, preferences or privileges senior to those of holders of our common stock and would result in dilution to our stockholders. If we raise additional funds by issuing debt securities, these debt securities would have rights, preferences and privileges senior to those of holders of our common stock, and the terms of the debt securities issued could impose significant restrictions on our operations. If we raise additional funds through collaborations and licensing arrangements, we might be required to relinquish significant rights to our technologies or our solutions under development, or grant licenses on terms that are not favorable to us, which could lower the economic value of those programs to us. If adequate funds are not available, we may have to scale back our operations or limit our research and development activities, which may cause us to grow at a slower pace, or not at all, and our business could be adversely affected. Our success depends largely on the skills, experience and performance of key members of our executive management team. The efforts of each of these persons will be critical to us as we continue to develop our technologies and testing processes. If we were to lose one or more of these key employees, including due to disease, disability or death, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. We do not currently maintain “key person” insurance on any of our employees. Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians, including geneticists, biostatisticians, engineers, licensed laboratory technicians and chemists. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses, particularly in the San Francisco Bay Area. We also face competition from universities, public and private research institutions and other organizations in recruiting and retaining highly qualified scientific personnel. Moreover, regulation or legislation impacting the workforce, such as the proposed rule published by the Federal Trade Commission which would, if issued, generally prevent employers from entering into non-compete with employees and require employers to rescind existing non-competes, may ~~be~~ lead to increased uncertainty in hiring and competition for talent. In addition, our success depends on our ability to attract and retain laboratory and field personnel with extensive experience in transplant recipient care and surveillance and close relationships with clinicians, pathologists and other

hospital personnel. We may have difficulties locating, recruiting or retaining qualified salespeople, which could cause a delay or decline in the rate of adoption of AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~AlloMap Heart, AlloSure Heart~~ or our future solutions, if any. New hires require training and take time before they achieve full productivity. New employees may not become as productive as we expect, and we may be unable to hire or retain sufficient numbers of qualified individuals. If we are not able to attract and retain the necessary personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our discovery, development, verification and commercialization programs. As part of our business strategy,..... to us, or at all. Undetected errors or defects in our products could result in voluntary corrective actions or agency enforcement actions, including recall of our products, as well as harm our reputation, decrease market acceptance of our products and expose us to product liability or professional liability claims, which could exceed our resources. Our products may contain undetected errors or defects that are not identified until after the products are first introduced. Disruptions or other performance problems with our products, or the perception of disruption or performance problems with our products, may require us to initiate a product recall, and may damage our customers' businesses and harm our reputation. We may also be subject to warranty and liability claims for damages related to errors or defects in our products. A material liability claim, product recall or similar occurrence may cause us to incur significant expense, decrease market acceptance of our products and adversely impact our business and operating results. In addition, the marketing, sale and use of AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~AlloMap Heart, AlloSure Heart~~ and our other products and solutions, or activities related to our research and clinical studies could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect which resulted in the failure to adequately perform the analysis for which it was designed. For example, a defect in one of our diagnostic solutions could lead to a false positive or false negative result, affecting the eventual diagnosis. Any incomplete or inaccurate analysis on the part of our technicians could also affect the reliability of the test results. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming to defend, either of which could materially harm our business or financial condition. We cannot provide assurance that our product liability insurance would adequately protect our assets from the financial impact of defending product liability or professional liability claims or any judgments, fines or settlement costs arising out of any such claims. In addition, any product liability claim brought against us, with or without merit, could increase our product liability insurance rates and prevent us from securing insurance coverage in the future at reasonable coverage levels, or at all. Additionally, any product liability lawsuit could cause injury to our reputation, result in the suspension of our testing pending an investigation into the cause of the alleged failure, or cause current collaborators to terminate existing agreements and potential collaborators to seek other partners, any of which could negatively impact our results of operations. Our relationship with any of our third-party service providers may impair our ability to perform our services. The failure of any of our third-party service providers to adequately perform their service obligations may reduce our revenues and increase our expenses or prevent us from providing our products and services in a timely manner if at all. In addition, our reputation, business and financial performance could be materially harmed if we are unable to, or are perceived as unable to provide test kits and perform reliable services. We rely solely on certain suppliers to supply some of the laboratory instruments and key reagents that we use in the production of our products and / or in the performance of our **tests.** **The failure of these suppliers to perform as expected, or an interruption in our relationship with them, could interfere with our ability to provide our products and** tests. These sole source suppliers include Thermo Fisher, which supplies us with instruments, laboratory reagents and consumables; Roche Molecular Systems, which supplies us with laboratory reagents and consumables; Illumina, Inc., or Illumina, which supplies us with instruments, laboratory reagents and consumables; Becton, Dickinson and Company, and Streck, which supplies us with cell preparation tubes; Beckman Coulter, which provides laboratory reagents and consumables; and Qiagen N. V., which supplies us with a proprietary buffer reagent and reagent kits. We do not have guaranteed supply agreements with Thermo Fisher, Becton, Dickinson and Company or Avantor, which exposes us to the risk that these suppliers may choose to discontinue doing business with us at any time. We periodically forecast our needs to these sole source suppliers and enter into standard purchase orders based on these forecasts. In 2023, we received FDA approval for an updated AlloMap that uses a real-time PCR platform from Roche and we are able to switch to that analytical platform and reduce reliance on the ABI 7900. We believe that there are relatively few suppliers other than Thermo Fisher, Roche, Illumina, Becton, Dickinson and Company and Qiagen N. V. that are currently capable of supplying the instruments, reagents and other supplies necessary for our current products and services. Even if we were to identify secondary suppliers, there can be no assurance that we will be able to enter into agreements with such suppliers on a timely basis on acceptable terms, if at all. If we should encounter delays or difficulties in securing from Thermo Fisher, Becton, Dickinson and Company or Avantor, or Avantor encounters delays or difficulties in securing from Qiagen N. V., including as a result of impacts on their respective businesses due to the ongoing conflict between Ukraine and Russia, the global impact of restrictions and sanctions imposed on Russia, and the Israel- Hamas war, the quality and quantity of reagents, supplies or instruments that we require for our current products and services or other solutions we develop, we may need to reconfigure our test processes, which would result in delays in commercialization or an interruption in sales. Clinicians and customers who order our current products and services rely on the continued and timely availability of our products and services. If we are unable to provide results within a timely manner, clinicians may elect not to use our products or services in the future and our business and operating results could be harmed. As part of our longer-term growth strategy, we intend to target select international markets to grow our presence outside of the U. S. We also currently distribute products in Europe, Canada, Asia, the Middle East, and Central and South America. To promote the growth of our business internationally, we will need to attract additional partners to expand into new markets. Relying on partners for our sales and marketing subjects us to various risks, including: • our partners may fail to commit the necessary resources to develop a market for our products, may spend the majority of their time selling products unrelated to ours, or may be unsuccessful in marketing our products for other reasons; • under certain agreements, our partners'

obligations, including their required level of promotional activities, may be conditioned upon our ability to achieve or maintain a specified level of reimbursement coverage; • agreements with our partners may terminate prematurely due to disagreements or may result in disputes or litigation with our partners; • we may not be able to renew existing partner agreements, or enter into new agreements, on acceptable terms; • our existing relationships with partners may preclude us from entering into additional future arrangements; • our partners may violate local laws or regulations, potentially causing reputational or monetary damage to our business; • our partners may engage in sales practices that are locally acceptable but do not comply with standards required under U. S. laws that apply to us; and • our partners may be negatively affected by the financial instability of, and austerity measures implemented by, the countries in which they operate. If our present or future partners do not perform adequately, or we are unable to enter into agreements in new markets, we may be unable to achieve revenue growth or market acceptance in jurisdictions in which we depend on partners. In addition, conducting international operations subjects us to risks that, generally, we have not faced in the U. S., including: • uncertain or changing regulatory registration and approval processes; • failure by us to obtain regulatory approvals or adequate reimbursement for the use of our current and future solutions in various countries; • competition from companies located in the countries in which we offer our products that may put us at a competitive disadvantage; • financial risks, such as longer accounts receivable payment cycles and difficulties in collecting accounts receivable; • **risks related to our operations in Russia and Iran, including restrictions on our access to banking services, changes in the U. S., EU or other sanctions laws that limit financial transactions or increase or compliance burden and potential legal exposure and counterparty risk;** • logistics and regulations associated with shipping recipient samples, including infrastructure conditions and transportation delays; • limits in our ability to penetrate international markets if we are not able to process solutions locally; • difficulties in managing and staffing international operations and assuring compliance with foreign corrupt practices laws; • potentially adverse tax consequences, including the complexities of foreign value added tax systems, tax inefficiencies related to our corporate structure and restrictions on the repatriation of earnings; • increased financial accounting and reporting burdens and complexities; • multiple, conflicting and changing laws and regulations such as healthcare regulatory requirements and other governmental approvals, permits and licenses; • the imposition of trade barriers such as tariffs, quotas, trade wars, preferential bidding or import or export licensing requirements; • political and economic instability, including interruptions in international relations, wars, terrorism and political unrest, general security concerns, outbreak of disease, boycotts, curtailment of trade and other business restrictions, including the ongoing conflict between Ukraine and Russia, the global impact of restrictions and sanctions imposed on Russia and the Israel- Hamas war; • fluctuations in currency exchange rates; • regulatory and compliance risks that relate to maintaining accurate information and control over activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, its books and records provisions or its anti- bribery provisions, as well as risks associated with other anti- bribery and anti- corruption laws; and • reduced or varied protection for intellectual property rights in some countries. The occurrence of any one of the above could harm our business and, consequently, our revenues and results of operations. Our expanding international operations could be affected by changes in laws, trade regulations, labor and employment regulations, and procedures and actions affecting approval, production, pricing, reimbursement and marketing of our current and future products and solutions, as well as by inter- governmental disputes. ~~Any of these changes could adversely affect our business. Additionally, operating internationally requires significant management attention and financial resources. We cannot be certain that the investment and additional resources required in establishing operations in other countries will produce desired levels of revenue or profitability.~~ In addition, any failure to comply with applicable legal and regulatory obligations could impact us in a variety of ways that include, but are not limited to, significant criminal, civil and administrative penalties, including imprisonment of individuals, fines and penalties, denial of export privileges, seizure of shipments, and restrictions on certain business activities. ~~Also, which the failure to comply with applicable legal and regulatory obligations could result in the disruption of our distribution and sales activities. We are also unable to predict how changing global economic conditions or potential global health concerns will affect our partners, suppliers and distributors. Any negative impact of such matters on our partners, suppliers or distributors may also have an adverse impact on our results of operations or financial condition.~~ Our success expanding internationally will depend, in part, on our ability to develop and implement policies and strategies that are effective in anticipating and managing these and other risks in the countries in which we do business. Failure to manage these and other risks may have a material adverse effect on our operations in any particular country and on our business as a whole. **Disputes with labor unions may adversely affect our ability to operate in our Sweden facility and may impact our financial results. Our production group in Sweden is represented by an IF Metall collective bargaining agreement. Our failure to successfully renegotiate this labor agreement as it expires could lead to work stoppages or other disputes with labor unions. Our manufacturing facility in Sweden is used to support the production, packaging and labeling of our proprietary test kits: Olerup SSP, QTYPE, AlloSeq cfDNA and HCT. Disruptions to our manufacturing facility through various forms of labor disputes could adversely affect us. Any strike, work stoppage, or other dispute with a labor union distracts management from operating the business, may displace employees from ordinary job positions to fill in vacant positions, may affect our reputation, and could materially adversely affect our business, results of operations, and financial condition**. Many of the countries in which we operate, including the U. S. and several of the members of the European Union, or EU, have experienced and continue to experience uncertain economic conditions resulting from global as well as local factors. Our business or financial results may be adversely impacted by these uncertain economic conditions, including: adverse changes in interest rates, foreign currency exchange rates, tax laws or tax rates; **prolonged periods of** increased inflation globally and in the U. S. in particular; liquidity concerns at financial institutions; a potential economic recession; contraction in the availability of credit in the marketplace due to legislation or other economic conditions, which may potentially impair our ability to access the capital markets on terms acceptable to us or at all; and the effects of government initiatives to manage economic conditions. Moreover, disagreement over the federal budget has caused the U. S. federal government to shut down for periods of time. Continued adverse political

conditions or a severe or prolonged economic downturn, such as the global financial crisis, could result in a variety of risks to our business, including a decrease in the demand for our tests and in our ability to raise additional capital when needed on acceptable terms, if at all. **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 or payers may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts, and we may utilize our capital resources sooner than expected.** In addition, we cannot predict how future economic conditions will affect our critical customers, suppliers and distributors and any negative impact on our critical customers, suppliers or distributors may also have an adverse impact on our results of operations or financial condition. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business. ~~Our business could be adversely impacted by inflation. Inflation rates, particularly in the United States, have increased recently to levels not seen in years. We may experience inflationary pressures, primarily in personnel costs and with certain laboratory supplies. We anticipate inflationary impacts on other cost areas in the future. The extent of any future impacts from inflation on our business and our results of operations will be dependent 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. Further, given the complexities of the reimbursement landscape in which we operate, our payors 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.~~ Our effective tax rate may fluctuate and we may incur obligations in tax jurisdictions in excess of amounts that have been accrued. We are subject to income taxes in the United States and various foreign jurisdictions. Our effective tax rate may be lower or higher than experienced in the past due to numerous factors, including a change in the mix of our profitability from country to country, the establishment or release of valuation allowances against our deferred tax assets, and changes in tax laws. In addition, we have recorded gross unrecognized tax benefits in our financial statements that, if recognized, would impact our effective tax rate. We are subject to tax audits in various jurisdictions, including the United States, and tax authorities may disagree with certain positions we have taken and assess additional taxes. There can be no assurance that we will accurately predict the outcomes of these audits, and the actual outcomes could have a material impact on our net income or financial condition. Any of these factors could cause us to experience an effective tax rate significantly different from previous periods or our current expectations, which could have an adverse effect on our business and results of operations. The recognition of deferred tax assets is reduced by a valuation allowance if it is more likely than not that the tax benefits will not be realized. We regularly review our deferred tax assets for recoverability and establish a valuation allowance based on historical income, projected future income, the expected timing of the reversals of existing temporary differences, and the implementation of tax- planning strategies. ~~Our insurance policies are expensive and protect us only from some business risks, which will leave us exposed to significant uninsured liabilities. We do not carry insurance for all categories of risk that our business may encounter. For example, we do not carry earthquake insurance. In the event of a major earthquake in our region, our business could suffer significant and uninsured damage and loss. Some of the policies we currently maintain include general liability, foreign liability, employee benefits liability, property, automobile, umbrella, workers' compensation, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our cash position and results of operations.~~ If we use hazardous materials in a manner that causes injury, we could be liable for damages. Our activities currently require the use of hazardous chemicals. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state and local laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. **We may use third party collaborators to....., decreased revenues and litigation expenses.** Changes in, or interpretations of, accounting rules and regulations could result in unfavorable accounting changes or require us to change our compensation policies. Accounting methods and policies for diagnostic companies, including policies governing revenue recognition, research and development and related expenses and accounting for stock- based compensation, are subject to further review, interpretation and guidance from relevant accounting authorities, including the SEC. Changes to, or interpretations of, accounting methods or policies may require us to reclassify, restate or otherwise change or revise our consolidated financial statements, including those contained in this Annual Report on Form 10- K. In addition, the preparation of our consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the consolidated financial statements, as well as the reported revenue generated and expenses incurred during the reporting periods. Any changes or modifications to the methodology used for determining our estimates, assumptions and forecasts could have a material adverse effect on our business, financial condition and results of operations. Our current or future restructuring plans may not optimize costs and simplify our organizational and corporate structure and may materially impair our business operations. We have previously announced restructuring plans intended to optimize costs and simplify our organizational and corporate structure, and we most recently implemented such plans in January, May and December 2023, **and November and December 2024.** Any additional restructuring efforts may ~~divert management' s attention, increase expenses on a short- term basis and lead to potential issues with employees, customers or suppliers. If we do not complete these activities in a timely manner; do not realize anticipated cost savings, synergies and efficiencies or business disruption occurs during or following such activities; or incur unanticipated charges, our business, financial condition, operating results and cash flows may~~

be materially impaired. Risks Related to Acquisitions, Partnerships and Investments Intangibles, including goodwill, acquired in connection with acquisitions may subsequently be impaired and, if so, could increase our net accumulated deficit. Under United States Generally Accepted Accounting Principles, or U. S. GAAP, we are required to evaluate our goodwill and indefinite- lived intangibles for impairment when events or changes in circumstances indicate the carrying value may not be recoverable; specifically, we are required to evaluate whether the intangible assets and goodwill as a result of an acquisition continue to have a fair value that meets or exceeds the amounts recorded on our balance sheet. We test goodwill and indefinite- lived intangibles for impairment at least annually and more frequently if impairment indicators are present. If the fair values of such assets decline below their carrying value on the balance sheet, we may be required to recognize an impairment charge related to such decline. Under U. S. GAAP, we are also required to evaluate finite- lived intangible assets, which are long- lived assets, for indicators of possible impairment when events or changes in circumstances indicate the carrying amount of the intangible asset may not be recoverable. Finite- lived intangible assets are intangible assets that we are amortizing over their estimated useful lives. If recoverability is in question, we would then compare the carrying amounts of the intangible assets with the future net undiscounted cash flows expected to be generated by such asset. Should an impairment exist, the impairment loss would be measured based on the excess carrying value of the intangible asset over the asset' s fair value determined using discounted estimates of future cash flows. Lower than expected revenue growth, a trend of weaker than anticipated financial performance, a decline in our market capitalization for a sustained period of time, unfavorable changes in market or economic and industry conditions all could significantly impact our impairment analysis. If we determine an impairment exists, we may be required to recognize further impairment charges that, if incurred, could have a material adverse effect on our financial condition and results of operations. As part of our business strategy, we may pursue acquisitions of complementary businesses and assets, as well as technology licensing arrangements to expand our existing know- how, expertise and intellectual property in other fields, including for the development of other commercial tests. We also may pursue strategic alliances that leverage our core technology and industry experience to expand our test offerings or distribution. The identification of suitable acquisition candidates can be difficult, time- consuming and costly, and we may not successfully complete acquisitions that we target in the future. Risks we may face in connection with acquisitions include: • diversion of management time and focus from operating our business to addressing acquisition integration challenges; • reduction of available cash reserves, assumption of debt or dilutive issuances of equity securities due to payment of consideration; • coordination of research and development and sales and marketing functions; • integration of product and service offerings; • expectations for acquired technology or research and development may prove unsuccessful; • inability to retain key personnel from the acquired company; • financial reporting, revenue recognition or other financial control deficiencies of or arising from the acquired company that we do not adequately address and that cause our reported results to be incorrect or delayed; • liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violations of laws, commercial disputes, tax liabilities and other known and unknown liabilities; • litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties; • integrating a global workforce of the acquired company into our business; • obtaining the approval of minority shareholders to complete an acquisition; and • commercialization of new products being developed by the acquired company. Our failure to address these risks or other problems encountered in connection with our past or future acquisitions and investments could cause us to fail to realize the anticipated benefits of these acquisitions or investments, cause us to incur unanticipated liabilities, and harm our business generally. There is also a risk that future acquisitions will result in the incurrence of debt, contingent liabilities, amortization expenses, incremental operating expenses or the write- off of goodwill and other intangible assets, any of which could harm our business and results of operations. We may not identify or complete these transactions in a timely manner, on a cost- effective basis, or at all, and we may not realize the anticipated benefits of any acquisition, technology license, strategic alliance or joint venture. To finance any acquisitions, we may choose to issue shares of our common stock as consideration, which would dilute your interest in us. If the price of our common stock is low or volatile, we may not be able to acquire other companies using our stock as consideration. Alternatively, it may be necessary for us to raise additional funds for acquisitions through public or private financings. Additional funds may not be available on terms that are favorable to us, or at all. We may not be able to achieve the anticipated strategic benefits from our acquisition of ~~Otrr, Complete Transplant Management, or Otrr, or XynManagement, Inc., or XynManagement, TransChart, MedActionPlan, or the Transplant Pharmacy, or TTP, HLA Data Systems, MediGO, or any other businesses or assets that we may acquire.~~ The integration of any businesses or assets we may acquire will be a time- consuming process. The integration process will require substantial management time and attention, which may divert attention and resources from other important areas, including our existing business. In addition, we may not be able to fully realize the anticipated strategic benefits of any such combination or integration and any other businesses or assets we have or may acquire, which includes, with respect to Otrr, the complementary Otrr software, with respect to XynManagement, XynQAPI, TransChart and MedActionPlan, as well as TTP, HLA Data Systems, and MediGO' s services and technologies, and in each case the benefits of any significant cross- selling opportunities. If we are not able to achieve the anticipated strategic benefits of any such combination, it could adversely affect our business, financial condition and results of operations, and could adversely affect the market price of our common stock if the anticipated financial and strategic benefits of the acquisition are not realized as rapidly as, or to the extent anticipated by investors and analysts. Failure to achieve these anticipated benefits could result in increased costs and decreases in future revenue and / or net income following the acquisition. Our License and Commercialization Agreement with Illumina may not result in material benefits to our business. Under the License and Commercialization Agreement, or the License Agreement, with Illumina, we are obligated to complete timely development and commercialization of future products, including meeting certain commercialization milestones. The failure to meet any such milestones could result in the loss of exclusivity for the affected licensed products. Additionally, ~~we agreed to minimum purchase commitments of finished products and raw materials from Illumina and~~ we are required to pay royalties in the mid- single to low- double digits

on sales of future commercialized products. We cannot make any assurances that our efforts under the License Agreement will be successful. As a result, we may not be able to fully realize the anticipated strategic benefits of the License Agreement. If we fail to successfully execute on the License Agreement, we may not realize the benefits expected from the transaction and our business may be harmed. Risks Related to Billing and Reimbursement Billing for clinical laboratory testing services is complex. In cases where we do not have a contract in place requiring the payment of a fixed fee per test, we perform tests in advance of payment and without certainty as to the outcome of the billing process. In cases where we do receive a fixed fee per test, we may still have disputes over pricing and billing. We receive payment from individual recipients and from a variety of payers, such as commercial insurance carriers and governmental programs, primarily Medicare. Each payer typically has different billing requirements. Among the factors complicating our billing of third- party payers are: • disputes among payers regarding which party is responsible for payment; • disparity in coverage among various payers; • different process, information and billing requirements among payers; and • incorrect or missing billing information, which is required to be provided by the prescribing clinician. ~~See the discussion of the Billing Articles under the risk factor above titled “Health insurers and other third- party payers may decide to revoke coverage of our existing test, decide not to cover our future solutions or may provide inadequate reimbursement, which could jeopardize our commercial prospects”.~~ Additionally, from time to time, payers change processes that may affect timely payment. For example, some commercial payers have instituted prior authorization requirements before our testing is performed. These changes may result in uneven cash flow or impact the timing of revenue recognized with these payers. With respect to payments received from governmental programs, factors such as a prolonged government shutdown could cause significant regulatory delays or could result in attempts to reduce payments made to us by federal government healthcare programs. In addition, payers may refuse to ultimately make payment if their processes and requirements have not been met on a timely basis. In addition, we are subject to and expect to continue to be subject to one or more audits under the CMS Recovery Audit Contractor, or RAC, program, the CMS Targeted Probe and Educate, or TPE, program, the Unified Program Integrity Contractors, or UPIC, program and other federal and state audits. Following two rounds of TPE audit in 2022 in which AlloSure Kidney and AlloSure Heart claims were reviewed and denied, Noridian informed us in the first quarter of 2023 it was making a referral to CMS given disagreement as to the interpretation of the applicable LCDs. We appealed claims which had a basis for appeal. Ultimately, 100 % of claims which were appealed were resolved in our favor. We have also met with CMS to discuss the difference in interpretation and intend to continue this dialogue regarding our position that the Noridian interpretation is inconsistent with the LCD, MoIDX’ s and Noridian’ s prior associated responses to public comments, and medical necessity. In addition, in the second quarter of 2023, we received a record request from UPIC. UPIC has the authority to implement Medicare payment suspensions during the pendency of an audit and the ability to refer billing matters to other regulatory agencies. In the third quarter of 2023, the UPIC provided us with notice that we had received Medicare payments in error, resulting in an overpayment of \$ 38, 975. 02. The UPIC further stated that going forward it wished to support our efforts to remedy the billing issues and it would continue to monitor our Medicare claim submission patterns. We have appealed the denied claims consistent with our statutory rights. **In the first quarter of 2025, we received an additional UPIC records request.** We expect further intensification of the regulatory environment surrounding the healthcare industry, as third-party firms engaged by CMS and others conduct extensive pre- and post- payment audits of claims data as well as medical and other records in order to identify improper payments to healthcare providers under the Medicare and Medicaid programs. We could be forced to expend considerable resources responding to these audits or other inquiries. These billing complexities, and the resulting uncertainty in obtaining payment for AlloSure Kidney, AlloMap Heart, AlloSure Heart, **HeartCare and AlloSure Lung** and future solutions, as well as the results of Noridian’ s referral to CMS and any audits or inquiries evaluating our services create a risk of further regulatory or enforcement action from these or other regulatory agencies, or that our claims are denied or that any historical reimbursement of such claims is subject to forfeiture and could negatively affect our revenue, cash flows and profitability. The pricing and reimbursement environment may change in the future and become more challenging as a result of any of several possible regulatory developments, including policies advanced by the U. S. government, new healthcare legislation or fiscal challenges faced by government health administration authorities. Specifically, there have been a number of legislative and regulatory proposals and initiatives to change the healthcare system in ways that could affect our ability to profitably sell any diagnostic products we may develop and commercialize. Some of these proposed and implemented reforms could result in reduced reimbursement rates for our diagnostic products from governmental agencies or other third-party payers, which would adversely affect our business strategy, operations and financial results. For example, as a result of the Patient Protection and Affordable Care Act of 2010 (as amended by the Health Care and Education Reconciliation Act of 2010), or collectively, the Affordable Care Act, substantial changes have been made and may continue to be made to the current system for paying for healthcare in the U. S., including changes made in order to extend medical benefits to those who currently lack insurance coverage. The Affordable Care Act also provided that payments under the Medicare CLFS were to receive a negative 1. 75 % annual adjustment through 2015. Although we have not been subject to such adjustment in the past, we cannot be certain that the claims administrators will not attempt to apply this adjustment in the future. Among other things, the Affordable Care Act includes payment reductions to Medicare Advantage plans. These cuts have been mitigated in part by a CMS demonstration program that expired in 2015. We cannot be assured that future cuts would be mitigated by CMS. Any reductions in payment to Medicare Advantage plans could materially impact coverage and reimbursement for AlloMap Heart. In addition to the Affordable Care Act, various healthcare reform proposals have also emerged from federal and state governments. For example, in February 2012, the U. S. Congress passed the “ Middle Class Tax Relief and Job Creation Act of 2012 ”, which in part reduced the potential future cost- based increases to the Medicare CLFS by 2 %. **PAMA The Protecting Access to Medicare Act of 2014** introduced a multi- year phase in of a new payment system for services paid under the CLFS. Under this new system, beginning in 2017 laboratories began reporting to CMS the payment rates paid to the laboratories by commercial third-party payers including Medicare and Medicaid managed care plans, for each test and the volume of each test performed. CMS

began using the reported data to set new payment rates under the CLFS in 2018. For most tests, rates will only be adjusted every three years. For newly developed tests that are considered to be “ advanced diagnostic lab tests, ” the Medicare payment rate will be the actual list price offered to third- party payers for the first three quarters that the tests are offered, subject to later adjustment. CMS will establish subsequent payment rates using the commercial third- party payer data reported for those tests. PAMA includes a substantial new payment system for clinical laboratory tests under the CLFS. Under PAMA, laboratories that receive the majority of their Medicare revenues from payments made under the CLFS report initially and then on a subsequent three- year basis thereafter (or annually for advanced diagnostic laboratory tests), private payer payment rates and volumes for their tests. The PAMA rules use the rates and volumes reported by laboratories to develop Medicare payment rates for the tests equal to the volume- weighted median of the private payer payment rates for the tests. There have been public announcements by **President Trump and** members of the U. S. Congress regarding plans to repeal and replace ~~the Affordable Care Act, and the Biden administration has announced plans to expand~~ the Affordable Care Act. We cannot predict the ultimate form or timing of any repeal, replacement or expansion of the Affordable Care Act or the effect such repeal, replacement or expansion would have on our business. Regardless of the impact of any ~~or~~ repeal, replacement or expansion of the Affordable Care Act on us, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government- adopted reform measures could decrease the amount of reimbursement available from governmental and other third- party payers. On April 1, 2013, cuts to the federal budget resulting from sequestration were implemented, requiring a 2 % cut in Medicare payment for all services, including AlloSure Kidney and AlloMap Heart, and is expected to remain in effect through at least 2025. Federal budgetary limitations and changes in healthcare policy, such as the creation of broad limits for diagnostic products or requirements that Medicare patients pay for portions of clinical laboratory tests or services received, could substantially diminish the sale, or inhibit the utilization, of AlloSure Kidney, AlloMap Heart, AlloSure Heart, **HeartCare and AlloSure Lung** and our future diagnostic solutions, increase costs, divert management’ s attention and adversely affect our ability to generate revenue and achieve profitability. In addition to the Affordable Care Act, there will continue to be proposals by legislators at both the federal and state levels, regulators and third- party payers to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our current and future solutions or the amounts of reimbursement available for our current and future solutions from governmental agencies or third- party payers. While in general it is difficult to predict specifically what effects the Affordable Care Act or any future healthcare reform legislation or policies will have on our business, current and future healthcare reform legislation and policies could have a material adverse effect on our business and financial condition. In December 2020, the U. S. Congress passed the Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2019, or the Immuno Bill. The Immuno Bill extends Medicare’ s Part B coverage of immunosuppressive drugs for kidney transplant recipients beyond the current three- year limit, allowing patients to more easily maintain access to their treatment and prevent graft failure, costly dialysis treatments and retransplantation. While the Immuno Bill will help improve the long- term outcomes of transplant patients, future policies advanced by the U. S. government, new healthcare legislation or fiscal challenges faced by government health administration authorities could result in changes to the Immuno Bill and Medicare’ s coverage of immunosuppressive drugs for kidney transplant recipients in the future.

**Risks Related to the Healthcare Regulatory Environment** We are subject to the CLIA, a federal law that regulates clinical laboratories that perform testing on specimens taken from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. If our laboratory is out of compliance with the CLIA requirements, we may be subject to sanctions such as suspension, limitation or revocation of our CLIA certificate, as well as a direct plan of correction, state on- site monitoring, civil money penalties, civil injunctive suit or criminal penalties. We must maintain the CLIA compliance and certification to be eligible to bill for services provided to Medicare beneficiaries. If we were to be found to be out of compliance with the CLIA program requirements and subjected to sanction, our business could be materially harmed. Licensure is also required for our laboratory under California law in order to conduct testing. California laws establish standards for day- to- day operation of our clinical laboratory, including the training and skills required of personnel and quality control. Moreover, several states, including New York, require that we hold licenses to test specimens from patients residing in those states. Other states have similar requirements or may adopt similar requirements in the future. In addition to our California certifications, we currently hold licenses in Florida, Maryland, New York, Pennsylvania and Rhode Island. The loss of any of these state certifications would impact our ability to provide services in those states, which could negatively affect our business. Finally, we may be subject to regulation in foreign jurisdictions where we offer our test. Failure to maintain certification in those states or countries where it is required could prevent us from testing samples from those states or countries, could lead to the suspension or loss of licenses, certificates or authorizations, and could have an adverse effect on our business. We were inspected as part of the customary College of American Pathologists audit and recertified in **March 2022-2024** as a result of passing that inspection. We expect the next regular inspection under the CLIA to occur in **2024-2026**. If we were to lose our CLIA accreditation or California license, whether as a result of a revocation, suspension or limitation, we would no longer be able to perform **AlloSure Kidney, AlloMap Heart, AlloSure Kidney Heart, HeartCare, or AlloSure Lung Heart**, which would limit our revenues and materially 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, which could also have a material adverse effect on our business. The FDA has traditionally chosen not to exercise its authority to regulate laboratory developed tests, or LDTs, because it believes that laboratories certified as high complexity under the CLIA, such as ours, have demonstrated expertise and ability in test procedures and analysis. However, beginning in September 2006, the FDA issued draft guidance on a subset of LDTs known as “ in vitro diagnostic multivariate index assays, ” or IVDMIAs. We applied for, and obtained in August 2008, 510 (k) clearance for AlloMap Heart for marketing and sale as a test to aid in the identification of recipients with a low probability of moderate or severe rejection. A 510 (k) submission is a premarketing submission made to the FDA. Clearance may be granted by the FDA if it finds the device or test provides satisfactory evidence pertaining to the claimed

intended uses and indications for the device or test. In October 2023, the FDA proposed a new policy under which the FDA intends to provide greater oversight of LDTs, through a phase- out of its general enforcement discretion approach to LDTs. In connection with this, the FDA proposed a rule that would amend its regulations to make explicit that in vitro diagnostic products are devices under the Federal Food, Drug and Cosmetic Act. There is no assurance whether, or when, this proposed policy and / or rule will be adopted or as to the content of any policies or rules eventually adopted. Any future rulemaking, guidance, or other oversight of LDTs and clinical laboratories that develop and perform them, if and when finalized, may affect the sales of our products and how customers use our products, and may require us to change our business model in order to maintain compliance with these laws. **A similar situation may occur if Congress decides to enable newly proposed regulations, such as the updated Verifying Accurate Leading- edge IVCT Development Act of 2021. There is no assurance whether, or when, this proposed policy and / or rule will be adopted or as to the content of any policies or rule that may eventually be adopted. For AlloSure Kidney and other similar testing solutions, if required by the FDA or if new laws are enacted we may be required to conduct additional analytical studies and clinical trials to demonstrate clinical validity and safety and effectiveness of our tests, and submit to the FDA a premarket approval application, or PMA, or 510 (k) premarket notification application. We would need to obtain FDA approval or clearance for any existing tests currently offered as LDTs, and subsequent to commercialization of any new tests. There can be no assurance that any of our tests or additional uses of our tests for which we seek clearance or approval in the future will be cleared or approved on a timely basis, or at all, and there can be no assurance that labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our current and future tests. Moreover, any new FDA or regulatory requirements could complicate our compliance efforts.** While we believe that we are currently in material compliance with applicable laws and regulations relating to our LDTs, we cannot be certain that the FDA or other regulatory agencies would agree with our determination. A determination that we have violated these laws, or a public announcement that we are being investigated for possible violation of these laws, could hurt our business and our reputation. If we are required to conduct additional analytical studies and clinical trials prior to marketing our solutions under development, those trials could lead to delays or a failure to obtain necessary regulatory approvals and harm our ability to be profitable. If the FDA or the U. S. Congress ~~decide~~ **decides** to regulate LDTs and other future solutions under development as medical devices, we could be required to conduct additional premarket analytical studies and clinical testing subsequent to continued commercialization in the case of AlloSure LDTs and / or conduct premarket clinical and analytical testing prior to submitting a regulatory application for commercial sales for future products not yet developed. If we are required to conduct premarket analytical studies and clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of analytical or clinical testing could significantly increase our development costs and delay test commercialization and also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient blood or tissue samples or insufficient data regarding the associated clinical outcomes. We may find it necessary to engage contract research organizations to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials and reduce our control over such activities. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, applicable regulatory requirements, or for other reasons, our clinical trials may have to be extended, delayed or terminated. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our solutions under development and our ability to be profitable. Any test for which we obtain regulatory clearance will be subject to extensive ongoing regulatory requirements, and we may be subject to penalties if we or our contractors or commercial partners fail to comply with regulatory requirements or if we experience unanticipated problems with our products. AlloSure Kidney, **AlloMap Heart, AlloSure Heart, HeartCare,** AlloSure Lung, ~~AlloMap Heart, AlloSure Heart~~, and our other products and solutions, along with the manufacturing processes, packaging, labeling, distribution, import, export, and advertising and promotional activities for such products and solutions, are or will be subject to continual requirements of, and review by, CMS, state licensing agencies, the FDA and comparable regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, requirements relating to quality control, quality assurance and corresponding maintenance of records and documents, requirements relating to product labeling, advertising, promotion, recordkeeping and adverse event reporting. Regulatory clearance of a test or device may be subject to limitations by the regulatory body as to the indicated uses for which the product may be marketed or to other conditions of approval. For example, we are exploring utilization of AlloMap Heart in areas that could be considered outside the scope of our current labeling. Broader uses would require FDA clearance as well as changes to the labeling. In addition, clearance may contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the test or device. Discovery of previously- unknown problems with our current or future solutions, or failure to comply with regulatory requirements, may result in actions such as: • restrictions on operations of our laboratory; • restrictions on manufacturing processes; • restrictions on marketing of a test; • warning or untitled letters; • withdrawal of the test from the market; • refusal to approve applications or supplements to approved applications that we may submit; • fines, restitution or disgorgement of profits or revenue; • suspension, limitation or withdrawal of regulatory clearances; • exclusion from participation in U. S. federal or state healthcare programs, such as Medicare and Medicaid; • refusal to permit the import or export of our products; • product seizure; • injunctions; and • imposition of civil or criminal penalties. The clinical laboratory testing industry is highly regulated, and there can be no assurance that the regulatory environment in which we operate will not change significantly and adversely in the future. Our arrangements with customers may expose us to broadly applicable fraud and abuse and other laws and regulations that may restrict the financial arrangements and relationships through which we

market, sell and distribute our products and services. Our employees, consultants, principal investigators, advisors and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements. In addition to the CLIA regulation, other federal and state healthcare laws and regulations that may affect our ability to conduct business, include, without limitation:

- federal and state laws and regulations regarding billing and claims payment applicable to clinical laboratories and / or regulatory agencies enforcing those laws and regulations;
- federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented to the government, claims for payment from Medicare, Medicaid or other third-party payers that are false or fraudulent, or making a false statement material to a false or fraudulent claim;
- the federal Anti-Kickback Statute, which constrains our marketing practices, educational programs, pricing policies, and relationships with healthcare providers or other entities, by prohibiting, among other things, knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce or reward, or in return for, either the referral of an individual or the purchase or recommendation of an item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs;
- the federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services, including clinical laboratory services, reimbursed by Medicare if the physician (or a member of the physician's family);
- has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information; HIPAA also created criminal liability for knowingly and willfully falsifying or concealing a material fact or making a materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;
- state laws regarding prohibitions on fee-splitting;
- the federal healthcare program exclusion statute; and
- state and foreign law equivalents of each of the above federal laws and regulations, such as anti-kickback, false claims, and self-referral laws, which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge under one or more of such laws. Any action brought against us for violation of these 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. We may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments, with potential liability under the federal False Claims Act, including mandatory treble damages and significant per-claim penalties. We previously received a civil investigative demand, or CID, from the United States Department of Justice, or DOJ, requesting that we produce certain documents in connection with a False Claims Act investigation being conducted by the DOJ regarding certain business practices related to our kidney testing and phlebotomy services, and a subpoena from the SEC in relation to an investigation by the SEC in respect of matters similar to those identified in the CID, as well as certain of our accounting and public reporting practices. On September 25, 2023, we reported that by letter dated September 19, 2023, we were notified by the staff of the SEC that the SEC has concluded its investigation as to our company and does not intend to recommend an enforcement action by the SEC against us. We also previously received an information request from a state regulatory agency. The state regulatory agency later requested that we submit an application for state licensure for certain specimen processing activities. We are in the process of applying for that license. We previously received a request for information from a separate state regulatory agency and we may receive additional requests for information from the DOJ or other regulatory and governmental agencies regarding similar or related subject matters. We do not believe that the CID, the prior SEC subpoena, or the state regulatory agency information request ~~raise~~ **raises** or raised any issues regarding the safety or clinical utility of any of our products or services and are cooperating fully with the investigations and the request for information. Although we remain committed to compliance with all applicable laws and regulations, we cannot predict the outcome of the DOJ investigation or any other requests or investigations that may arise in the future regarding these or other subject matters. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other laws and regulations that apply to us, we may be subject to penalties, including significant criminal, civil, and administrative penalties, damages, fines, imprisonment for individuals, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, recall or seizure of products, total or partial suspension of production, denial or withdrawal of pre-marketing product approvals, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, if any governmental body, such as the DOJ or SEC, determines that we have not complied with applicable securities or other laws, such governmental body could initiate a proceeding against us, which may ultimately lead to significant penalties and other relief assessed against us, including monetary fines. We may expend significant financial and managerial resources in connection with responding to the CID and other information requests. Any of the foregoing consequences could seriously harm our business and our financial results. In addition, we have implemented and strive to continuously develop, implement and improve compliance policies and procedures intended to train our sales, billing, marketing and other personnel regarding compliance with state and federal laws applicable to our business. Our efforts to implement appropriate monitoring of compliance with such policies and procedures are likewise ongoing. We may need to supplement and amend our current policies and procedures and implement additional policies and procedures in the future. In addition, despite our compliance policies and procedures, and related training and monitoring, we may experience situations in which employees may fail to fully adhere to our policies and procedures. Such failures may subject us to administrative, civil, and criminal actions, penalties, damages, fines, exclusion from participation in federal healthcare

programs, refunding of payments received by us and curtailment of our operations. Foreign governments may impose reimbursement standards, which may adversely affect our future profitability. When we market our products and our solutions under development in foreign jurisdictions, we are subject to rules and regulations in those jurisdictions. In some foreign countries, including countries in the EU, the reimbursement of our current and future solutions is subject to governmental control. In these countries, reimbursement negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a test candidate. If reimbursement of our future solutions in any jurisdiction is unavailable or limited in scope or amount, or if reimbursement rates are set at unsatisfactory levels, we may be unable to, or decide not to, market our test in that jurisdiction.

**Risks Related to Our Intellectual Property** Our ability to compete and to achieve and maintain profitability depends on our ability to protect our proprietary discoveries and technologies. We currently rely on a combination of patents, copyrights, trademarks, trade secrets, confidentiality agreements and license agreements to protect our intellectual property rights. ~~Our patent position for AlloMap Heart is based on issued patents and patent applications disclosing identification of genes differentially expressed between activated and quiescent leukocytes and demonstration of correlation between gene expression patterns and specific clinical states and outcomes.~~ As of December 31, 2023 ~~2024~~, we had ~~10~~ **seven** issued U. S. patents related to ~~transplant rejection and autoimmunity~~. Among those, we have one issued U. S. patent covering ~~methods of diagnosing transplant rejection~~ **and using all 11 informative genes measured in AlloMap Heart, which will expire in March 2024. We have four additional patents covering additional genes or gene variants for diagnosing transplant rejection or autoimmune disease, which will expire between April-October 2024-2025 and September 2029-May 2035. In addition, we had three U. S. patents related to organ function recovery and allograft preservation, which will expire between July 2038 and June 2041.** Our patents and the patents we exclusively license from others may be successfully challenged by third parties as being invalid or unenforceable. For example, in September 2021, the Court in the patent infringement case against Natera ruled that three of the patents we asserted against Natera are invalid. The Court's finding does not have any impact on our ability to continue providing AlloSure. This ruling may limit our ability to prevent Natera and other competitors and third parties from developing and marketing products similar to ours and we may not be able to prevent Natera and others from developing or selling products that are covered by our products or technologies without payment to us. In addition, our exclusive license agreement with Stanford that previously covered certain patents related to diagnostic and predictive technologies terminated in October 2023. Third parties may independently develop similar or competing technology that avoids the patents we own or exclusively license. We cannot be certain that the steps we have taken will prevent the misappropriation and use of our intellectual property, particularly in foreign countries where the laws may not protect our proprietary rights as fully as in the United States. The extent to which the patent rights of life sciences companies effectively protect their products and technologies is often highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the proper scope of allowable claims of patents held by such companies has emerged to date in the United States. Various courts, including the U. S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostic solutions or genomic diagnostics. This evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents. Changes in either the patent laws or interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. Patent applications in the United States and many foreign jurisdictions are not published until at least 18 months after filing, and it is possible for a patent application filed in the United States to be maintained in secrecy until a patent is issued on the application. In addition, publications in the scientific literature often lag behind actual discoveries. We therefore cannot be certain that others have not filed patent applications that cover inventions that are the subject of pending applications that we own or exclusively license or that we or our licensors ~~;~~ **were** first to file. Our competitors may have filed, and may in the future file, patent applications covering technology that is similar to or the same as our technology. Any such patent application may have priority over patent applications that we own or exclusively license and, if a patent issues on such patent application, we could be required to obtain a license to such patent in order to carry on our business. If another party has filed a United States patent application covering an invention that is similar to, or the same as, an invention that we own or license, we or our licensors may have to participate in an interference or other proceeding in the U. S. Patent and Trademark Office or a court to determine priority of invention in the United States for pre-AIA applications and patents. We or our licensors may have to participate in a derivation proceeding to resolve disputes relating to inventorship. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in our inability to obtain or retain any United States patent rights with respect to such invention. We may face intellectual property infringement claims that could be time-consuming and costly to defend and could result in our loss of significant rights and the assessment of treble damages. We may in the future receive offers to license patents or notices of claims of infringement, misappropriation or misuse of other parties' proprietary rights. We may also initiate claims to defend our intellectual property. Intellectual property litigation, regardless of outcome, is unpredictable, expensive and time-consuming, could divert management's attention from our business and have a material negative effect on our business, operating results or financial condition. If there is a successful claim of infringement against us, we may be required to pay substantial damages (including treble damages if we were to be found to have willfully infringed a third-party's patent) to the party claiming infringement, develop non-infringing technology, stop selling our test or using technology that contains the allegedly infringing intellectual property or enter into royalty or license agreements that may not be available on acceptable or commercially practical terms, if at all. Our failure to develop non-infringing technologies or license the proprietary rights on a timely basis could harm our business. In addition, revising our current or future solutions to exclude any infringing technologies would require us to re-validate the test, which would be costly and time-consuming. Also, we may be unaware of pending patent applications that relate to our current or future solutions. Parties making infringement claims on future issued patents may be able to obtain an injunction that would prevent us from selling our current or future solutions or using technology that contains

the allegedly infringing intellectual property, which could harm our business. See Note 9, Commitments and Contingencies, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K under the caption risk factor above titled “We are and could become subject to legal proceedings that could be time-consuming, result in costly litigation and Indemnification Obligations” settlements / judgments, require significant amounts of management attention and result in the diversion of significant operational resources, which could adversely affect our business is incorporated herein by reference, financial condition and results of operations” for a discussion of our recently completed and ongoing litigation with Natera. We may be required to take further action to maintain and protect our intellectual property rights against third parties. In the event we determine that a party is infringing our intellectual property rights, we may try to negotiate a license arrangement with such party or we may determine to initiate a lawsuit against such party. The process of negotiating a license with a third party can be lengthy, and may take months or even years in some circumstances. In addition, it is possible that third parties who we believe are infringing our intellectual property rights are unwilling to license our intellectual property from us on terms we can accept, or at all. See Note 9, Commitments and Contingencies, to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K under the caption risk factor above titled “Litigation and Indemnification Obligations” could become subject to legal proceedings that could be time-consuming, result in costly litigation with Natera, and settlements / judgments, require significant amounts of management attention and result in the diversion of significant operational resources, which could adversely affect our business is incorporated herein by reference, for a discussion of our recently completed and ongoing litigation with Natera. The decision to commence litigation over infringement of a patent is complex and may lead to several risks to us, including the following, among others: • the time, significant expense and distraction to management of managing such litigation; • the uncertainty of litigation and its potential outcomes; • the possibility that in the course of such litigation, the defendant may challenge the validity of our patents, which could result in a re-examination or post grant review of our patents and the possibility that the claims in our patents may be limited in scope or invalidated altogether; • the potential that the defendant may successfully persuade a court that their technology or products do not infringe our intellectual property rights; • the impact of such litigation on other licensing relationships we have or seek to establish, including the timing of renewing or entering into such relationships, as applicable, as well as the terms of such relationships; • the potential that a defendant may assert counterclaims against us; and • adverse publicity to us or harm to relationships we have with customers or others. If we are unable to protect or enforce our intellectual property rights effectively in all major markets, our business would be harmed. Filing, prosecuting, defending and enforcing patents on all of our technologies and solutions throughout the world would be prohibitively expensive. As a result, we seek to protect our proprietary position by filing patent applications in the U. S. and in select foreign jurisdictions and cannot guarantee that we will obtain the patent protection necessary to protect our competitive position in all major markets. Competitors may use our technologies or solutions in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export infringing products to territories where we have patent protection but where enforcement is not as strong as that in the U. S. These products may compete with our current and future products in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or the marketing of competing products in violation of our proprietary rights generally. Further, the legal systems of certain countries make it difficult or impossible to obtain patent protection for diagnostic solutions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and could divert our efforts and attention from other aspects of our business. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for some of our technologies and solutions, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we cannot be certain that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized disclosure is difficult and we do not know whether the procedures we have followed to prevent such disclosure are, or will be, adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U. S. may be less willing or unwilling to protect trade secrets. If any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to, or independently developed by, a competitor, our competitive position would be harmed. If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest, and our business may be adversely affected. AlloMap, AlloSure, Olerup SSP, QTYPE, Ottr and CareDx are registered trademarks of our company in the United States. Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This process can be expensive, particularly

for a company of our size, and time-consuming. In addition, in an infringement proceeding, a court may decide that a trademark of ours is not valid or is unenforceable, or may refuse to stop the other party from using the trademark at issue. We may not be able to protect our rights to these and other trademarks and trade names which we need to build name recognition by potential partners or customers in our markets of interest. Over the long-term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may be subject to claims by third parties that we or our employees have wrongfully used or disclosed alleged trade secrets or misappropriated intellectual property, or claiming ownership of what we view as our own intellectual property. As is commonplace in our industry, we employ individuals who were previously employed at other diagnostics, medical device, life sciences or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees do not use the proprietary information of others in the course of their work for us and no claims against us are currently pending, we may be subject to claims that these employees have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. We may also be forced to bring claims against third parties or defend against third-party claims in order to determine the ownership of our intellectual property. An adverse result in the prosecution or defense of any such claims could require us to pay substantial monetary damages and could result in the loss of valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against these claims, litigation could result in substantial costs and be a distraction to management. We license technology from third parties necessary to develop and commercialize our products. On May 4, 2018, we entered into the License Agreement with Illumina, which provides us with worldwide distribution, development and commercialization rights to Illumina's NGS product line for use in transplantation diagnostic testing. These NGS products include: AlloSeq Tx, a high-resolution HLA typing solution, AlloSeq cfDNA, our surveillance solution designed to measure dd-cfDNA in blood to detect active rejection in transplant recipients, and AlloSeq HCT, an NGS solution for chimerism testing for stem cell transplant recipients. In April 2020, we entered into a license agreement with Cornell University pursuant to which we were granted exclusive rights to three patents and two patent applications covering methods and technology for measurement of gene expression in urine to diagnose kidney transplant rejection. In June 2021, we entered into a strategic agreement, which was amended in April 2022, with OrganX to develop clinical decision support tools across the transplant patient journey. Together, we and OrganX will develop advanced analytics that integrate AlloSure with large transplant databases to provide clinical data solutions. This partnership delivers the next level of innovation by incorporating a variety of clinical inputs to create a universal composite scoring system. In March 2023, we entered into a license and collaboration agreement with a private entity pursuant to which we were granted an irrevocable, non-transferable right to commercialize their proprietary software, iBox, for the predictive analysis of post-transplantation kidney allograft loss in the field of transplantation for a period of four years with exclusive rights in the United States. Our rights to use these and other licensed technologies, data and materials and to employ the inventions claimed in licensed patents are subject to the continuation of and our compliance with the terms of the applicable licenses. Termination of the license could prevent us from producing or selling some or all of our products. Failure of a licensor to abide by the terms of a license or to prevent infringement by third parties could also harm our business and negatively impact our market position. Risks Related to Cybersecurity and Data Privacy Security breaches, loss of data and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation. We store sensitive intellectual property and other proprietary business information, including that of our customers, payers and collaboration partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems and cloud-based data center systems. These applications and data encompass a wide variety of business critical information, including research and development information, commercial information and business and financial information. We work with a third-party billing software to collect and store sensitive data, including legally-obtained-protected health information, credit card information and personally identifiable information about our customers, payers, recipients and collaboration partners. A data breach or loss of data could have a material adverse effect on our operations, including the potential for material fines and business interruption. We are highly dependent on information technology networks and systems, including the Internet, to securely process, transmit and store our critical information. Security breaches of this infrastructure, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches, can create system disruptions, shutdowns or unauthorized disclosure or modification of confidential information. The secure processing, storage, maintenance and transmission of this critical information are vital to our operations and business strategy, and we devote significant resources to protecting such information. Although we take measures to protect sensitive information from unauthorized access or disclosure, our information technology and infrastructure may be vulnerable to attacks by hackers or viruses or breached due to employee error, malfeasance or other disruptions. In addition, we may face increased cybersecurity risks due to our reliance on internet technology, which may create additional opportunities for cybercriminals to exploit vulnerabilities. While we maintain monitoring practices and protections for our information technology to reduce these risks and test our systems on an ongoing basis for any potential threats, there can be no assurance that these efforts will prevent a cyber-attack or other security breach. Third parties have attempted, and may in the future attempt, to fraudulently induce employees, contractors or consumers into disclosing sensitive information such as user names, passwords or other information or otherwise compromise the security of our internal networks, electronic systems and / or physical facilities in order to gain access to our data or our critical information, which could result in significant legal and financial exposure. ~~We have experienced cybersecurity incidents and expect that we will continue to be subject to cybersecurity attacks in the future. In addition, a contractor or other third party with whom we do business, as well as parties with which we do not do business, may attempt to circumvent our security measures or obtain such information, and may purposefully or inadvertently cause a breach involving sensitive information.~~ While we still continue to evaluate and implement additional protective measures to reduce the risk and

detect cyber incidents, cyberattacks are becoming more sophisticated and frequent and the techniques used in such attacks change rapidly. Despite our cybersecurity measures (including employee and third-party training regarding phishing, malware, and other cyber risks, monitoring of networks and systems and maintenance of back up of protective systems), which are continuously reviewed and upgraded, our information technology networks and infrastructure may still be vulnerable to damage, disruptions or shut downs due to attack by hackers or breaches, phishing scams, ransomware, systems failures, computer viruses, employee errors or other malfeasance. A security breach or privacy violation that leads to disclosure or modification of or prevents access to consumer information (including personally identifiable information or protected health information) could harm our reputation, compel us to comply with disparate state breach notification laws, require us to verify the correctness of database contents and otherwise subject us to liability under laws that protect personal data, resulting in increased costs or loss of revenue. If we are unable to prevent such security breaches or privacy violations or implement satisfactory remedial measures, our operations could be disrupted, and we may suffer loss of reputation, financial loss and other regulatory penalties because of lost or misappropriated information, including sensitive consumer data. In addition, these breaches and other inappropriate access can be difficult to detect, and any delay in identifying them may lead to increased harm of the type described above. Any such breach or interruption could compromise our networks or those of our third-party service providers, and the information stored there could be inaccessible or could be accessed by unauthorized parties, publicly disclosed, lost or stolen. Any such interruption in access, improper access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, such as ~~the Health Insurance Portability and Accountability Act of 1996, or~~ HIPAA, and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to perform tests, provide test results, bill our payers or patients, process claims and appeals, provide customer assistance services, conduct research and development activities, collect, process and prepare company financial information, provide information about our current and future products and solutions and other patient and clinician education and outreach efforts through our website, and manage the administrative aspects of our business, any of which could damage our reputation and adversely affect our business. Any such breach could also result in the compromise of our trade secrets and other proprietary information, which could adversely affect our competitive position. We have insurance coverage in place for certain potential liabilities and costs relating to service interruptions, data corruption, cybersecurity risks, data security incidents and / or network security breaches, but this insurance is limited in amount, subject to a deductible, and may not be adequate to cover us for all costs arising from these incidents. Furthermore, in the future such insurance may not be available on commercially reasonable terms, or at all. In addition, the interpretation and application of consumer, health-related, privacy and data protection laws in the U. S., Europe and elsewhere are often uncertain, contradictory and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in government-imposed fines or orders requiring that we change our practices, which could adversely affect our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. For example, ~~the California Consumer Privacy Act, or the CCPA,~~ took effect on January 1, 2020 and requires, among other things, covered companies to provide disclosures to California consumers concerning the collection and sale of personal information, and will give such consumers the right to opt-out of certain sales of personal information. ~~The California Privacy Rights Act, or the CPRA,~~ which took effect in January 2023, amended the CCPA, and also created a new state agency that has authority to implement and enforce the CCPA and the CPRA. The CCPA and the CPRA may increase our compliance costs and potential liability, and we cannot yet predict the impact of the amendments to the CCPA on our business. Additionally, state legislation continues to be a driving force behind the changing privacy law landscape in the United States. For example, Virginia passed the Consumer Data Protection Act, Colorado passed the Colorado Privacy Act, Utah passed the Consumer Privacy Act, and Connecticut passed the Connecticut Data Privacy Act, all of which became effective in 2023. Further, Delaware, Indiana, Iowa, Montana, Oregon, Tennessee and Texas also adopted privacy laws, which take effect from July 1, 2024 through 2026. Internationally, the General Data Protection Regulation, or the GDPR, took effect in May 2018 within ~~the European Economic Area, or the EEA,~~ and many EEA jurisdictions have also adopted their own data privacy and protection laws in addition to the GDPR. Furthermore, other international jurisdictions, including Singapore, South Korea, China, Brazil, Mexico and Australia, have also implemented laws relating to data privacy and protection. Risks Related to Our Common Stock Fluctuations in our operating results may lead to fluctuations, including declines, in the share price for our common stock. In ~~2023~~ **2024**, our closing stock price ranged from \$ ~~47.90-56~~ **47.90-56** to \$ ~~17-33.61-99~~ **17-33.61-99** per share. Our operating results and our share price may fluctuate from period to period due to a variety of factors, including: • demand by clinicians and recipients for our current and future solutions, if any; • coverage and reimbursement decisions by third-party payers and announcements of those decisions; • clinical trial results and publication of results in peer-reviewed journals or ~~the their~~ presentation at medical conferences; • the inclusion or exclusion of our current and future solutions in large clinical trials conducted by others; • new or less expensive tests and services or new technology introduced or offered by our competitors or us; • the level of our development activity conducted for new solutions, and our success in commercializing these developments; • our ability to efficiently integrate the business of new acquisitions; • the level of our spending on test commercialization efforts, licensing and acquisition initiatives, clinical trials, and internal research and development; • changes in the regulatory environment, including any announcement from the FDA regarding its decisions in regulating our activities; • changes in recommendations of securities analysts or lack of analyst coverage; • failure to meet analyst expectations regarding our operating results; • additions or departures of key personnel; • public health emergencies; • share repurchases completed by us; and • general market conditions. Variations in the timing of our future revenues and expenses could also cause significant fluctuations in our operating results from period to period and may result in unanticipated earning shortfalls or losses. In addition, national stock exchanges, and in particular the market for life science companies, have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to the operating

performance of those companies. Moreover, we may be subject to additional securities class action litigation as a result of volatility in the price of our common stock, which could result in substantial costs and diversion of management's attention and resources and could harm our stock price, business, prospects, results of operations and financial condition. Our common stock is currently traded on the Nasdaq Global Market, but we can provide no assurances that there will be active trading on that market or on any other market in the future. If there is no active market or if the volume of trading is limited, holders of our common stock may have difficulty selling their shares. The market price of our common stock has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this Annual Report on Form 10-K, factors that could cause fluctuations in the market price of our common stock include the following:

- price and volume fluctuations in the overall stock market from time to time;
- volatility in the market prices and trading volumes of life sciences stocks;
- changes in operating performance and stock market valuations of other life sciences companies generally, or those in our industry in particular;
- sales of shares of our common stock by us or our stockholders;
- entering into financing or other arrangements with rights or terms senior to the interests of common stockholders;
- failure of securities analysts to maintain coverage of us, changes in financial estimates by securities analysts who follow our company, or our failure to meet these estimates or the expectations of investors;
- the financial projections we may provide to the public, any changes in those projections or failure to meet those projections;
- announcements by us or our competitors of new products or services;
- the public's reaction to our press releases, other public announcements and filings with the SEC;
- rumors and market speculation involving us or other companies in our industry;
- actual or anticipated changes in our operating results or fluctuations in our operating results;
- actual or anticipated developments in our business, our competitors' businesses or the competitive landscape generally;
- litigation involving us, our industry or both, or investigations by regulators into our operations or those of our competitors;
- developments or disputes concerning our intellectual property or other proprietary rights;
- announced or completed acquisitions of businesses or technologies by us or our competitors;
- new laws or regulations or new interpretations of existing laws or regulations applicable to our business;
- changes in accounting standards, policies, guidelines, interpretations or principles;
- any significant change in our management;
- our prior decision to withdraw our revenue guidance for fiscal 2023;
- our decision to issue future financial guidance and the terms of such guidance; and
- general economic conditions and slow or negative growth of our markets.

If our principal stockholders, executive officers and directors choose to act together, they may be able to control our management and operations, which may prevent us from taking actions that may be favorable to you. Our executive officers, directors and holders of 5% or more of our outstanding common stock (based on the most recent public filings), and entities affiliated with them, beneficially own in the aggregate approximately ~~66.36~~ **21**% of our common stock as of February ~~26, 2024~~ **2025**. These stockholders, acting together, will have the ability to exert substantial influence over all matters requiring approval by our stockholders, including the election and removal of directors and any proposed merger, consolidation or sale of all or substantially all of our assets. In addition, they could dictate the management of our business and affairs. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control of us or impeding a merger or consolidation, takeover or other business combination that could be favorable to you. Sales of substantial amounts of our common stock in the public markets, or sales of our common stock by our executive officers and directors under Rule 10b5-1 plans, could adversely affect the market price of our common stock. Sales of a substantial number of shares of our common stock in the public market, or the perception that such sales could occur, could adversely affect the market price of our common stock and may make it more difficult for you to sell your common stock at a time and price that you deem appropriate. In addition, our executive officers and directors have and may adopt written plans, known as "Rule 10b5-1 Plans," under which they will contract with a broker to sell shares of our common stock on a periodic basis to diversify their assets and investments. Sales made by our executive officers and directors pursuant to Rule 10b5-1, regardless of the amount of such sales, could adversely affect the market price of our common stock. We do not expect to pay dividends in the foreseeable future. As a result, you must rely on stock appreciation for any return on your investment. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Any payment of cash dividends will also depend on our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our ~~board~~ **Board** of ~~directors~~ **Directors**. Accordingly, you will have to rely on capital appreciation, if any, to earn a return on your investment in our common stock. We may elect to repurchase shares of our common stock, which might limit our ability to pursue other growth opportunities. On December 3, 2022, our ~~board~~ **Board** of ~~directors~~ **Directors** authorized a stock repurchase program, whereby we may purchase up to \$ 50 million in shares of our common stock over a period of up to two years, commencing on December 8, 2022, or the Repurchase Program. The Repurchase Program may be carried out at the discretion of a committee of our ~~board~~ **Board** of ~~directors~~ **Directors** through open market purchases, one or more Rule 10b5-1 trading plans and block trades and in privately negotiated transactions. Any repurchase of shares of our common stock under the Repurchase Program will depend on several factors, including, but not limited to, results of operations, capital requirements, financial conditions, available capital from operations or other sources, including debt, and the market price of our common stock. In addition, on August 16, 2022, the United States enacted the Inflation Reduction Act of 2022, which, among other things, imposes an excise tax of 1% tax on the fair market value of net stock repurchases made after December 31, 2022. Therefore, there is no assurance with respect to the amount, price or timing of any such repurchases. We may elect to retain all future earnings for the operation and expansion of our business, rather than repurchasing shares of our common stock. During the year ended December 31, ~~2023~~ **2024**, we purchased an aggregate of ~~2,555,500~~ **942,997** shares of our common stock under the Repurchase Program for an aggregate purchase price of \$ ~~27.0~~ **5** million. ~~The As of December 31, 2023, \$ 21.9 million remained available for future repurchases under the Repurchase Program was renewed on February 20, 2025 where we may purchase up to \$ 50 million in shares of our common stock over a period of up to two years, commencing on February 20, 2025.~~ In the event we make any additional stock repurchases in the future, our ability to finance any material expansion of our business, including through

acquisitions, investments or increased capital spending, or to fund our operations, may be limited. In addition, any repurchases we may make in the future may not prove to be at optimal prices. Our ~~board~~ **Board** of ~~directors~~ **Directors** may modify or amend the Repurchase Program, or adopt a new stock repurchase program, at any time at its discretion without stockholder approval. If we are unable to substantially utilize our net operating loss carryforwards, our financial results could be harmed. Section 382 of the U. S. Internal Revenue Code of 1986, as amended, generally limits the ability of a corporation that undergoes an “ ownership change ” to utilize its net operating loss carry- forwards, or NOLs, and certain other tax attributes against any taxable income in taxable periods after the ownership change. The amount of taxable income in each taxable year after the ownership change that may be offset by pre- change NOLs and certain other pre- change tax attributes is generally equal to the product of (a) the fair market value of the corporation ’ s outstanding shares (or, in the case of a foreign corporation, the fair market value of items treated as connected with the conduct of a trade or business in the United States) immediately prior to the ownership change and (b) the long- term tax exempt rate (i. e., a rate of interest established by the U. S. Internal Revenue Service, or IRS, that fluctuates from month to month). In general, an “ ownership change ” occurs whenever the percentage of the shares of a corporation owned, directly or indirectly, by “ 5- percent shareholders ” (within the meaning of Section 382 of the Internal Revenue Code of 1986, as amended) increases by more than 50 percentage points over the lowest percentage of the shares of such corporation owned, directly or indirectly, by such “ 5- percent shareholders ” at any time over the preceding three years. Based on a review of our equity transactions since inception, a portion of our NOLs have been limited due to the equity financings that we have completed. Future equity transactions may result in further substantial annual limitations on the utilization of our NOLs due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions. Limitations imposed on our ability to utilize NOLs could cause U. S. federal and state income taxes to be paid earlier than would be paid if such limitations were not in effect and could cause such NOLs to expire unused, in each case reducing or eliminating the benefit of such NOLs. Furthermore, we may not be able to generate sufficient taxable income to utilize our NOLs before they expire. If any of these events occur, we may not derive some or all of the expected benefits from our NOLs. ~~We have identified material weaknesses in our internal control over financial reporting as of December 31, 2022, which were not remediated at December 31, 2023. If we are unable to remediate these material weaknesses and maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner.~~ Effective internal control over financial reporting is necessary for us to provide reasonable assurance regarding the preparation and fair presentation of published consolidated financial statements in accordance with accounting principles generally accepted in the United States. ~~As described under Item 9A “ In connection with the preparation of our....., 2023: • General Information Technology Controls . We did not design and maintain effective general information technology controls, or GITCs, for information systems and applications that are relevant to the preparation of the consolidated financial statements. Specifically, we did not design and maintain: (i) sufficient user access controls to ensure appropriate segregation of duties, logical access controls to prevent unauthorized user access and adequately restrict user and privileged access to financial applications, programs and data to appropriate Company personnel; (ii) program change management controls to ensure that information technology, or IT, program and data changes affecting financial IT applications and underlying accounting records are identified, tested, authorized and implemented appropriately with appropriate segregation of duties; and (iii) computer and network operations controls to ensure that batch and interface jobs are monitored and privileges are appropriately granted, authorized and monitored. As a result, business process controls (automated and manual) that are dependent on the ineffective GITCs, or that rely on data produced from systems impacted by the ineffective GITCs, are also deemed ineffective, which affects substantially all financial statement account balances and disclosures. • Purchase Order Approval Workflow. We did not design and maintain effective process- level control activities related to procurement to ensure appropriate approval of purchase orders, which could affect the amount and classification of costs capitalized or expensed. • Committee of Sponsoring Organizations of the Treadway Commission (COSO) Framework. We did not fully maintain components of the COSO framework, including elements of the control environment, information and communication, and control activities and monitoring activities components, relating to: (i) sufficiency of competent personnel to perform internal control activities and support the achievement of our internal control objectives; (ii) enforcing accountability of personnel for the performance of their internal control responsibilities across the organization in the pursuit of objectives; (iii) designing and maintaining general control activities over technology to support the achievement of our internal control objectives; (iv) performing control activities in accordance with established policies in a timely manner; and (v) performing sufficient reviews of information to assess its relevance, accuracy, and completeness in supporting the internal control components. As such, our management concluded that we did not have an ~~and Procedures ”~~ adequate process in place to complete its assessment of the design and operating effectiveness of internal control over financial reporting in a timely manner. These material weaknesses have not been remediated as of the date of this Annual Report on Form 10- K. ~~In connection with the preparation of our consolidated financial statements as of December 31, 2024~~ **2022** and for the year then ended, we identified a material ~~weakness~~ **weaknesses** in our internal control over financial reporting ~~, which were not remediated at~~. This material weakness was identified in connection with the preparation of our consolidated financial statements for the fiscal year ended December 31, ~~2022~~ **2023** and has not been remediated. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. ~~As Our management concluded that we had the following material weaknesses as of December 31, 2023: • General Information Technology . Our management has been engaged in developing and implementing remediation plans to address the material weaknesses--~~ **weakness** described above. However, the material ~~weaknesses--~~ **weakness** will not be fully remediated until management can demonstrate the full effectiveness of controls over a sufficient period of time, and we can give no assurance on the success of such measures or the outcome of our assessment of these measures at this time. If the steps we take to remediate the material ~~weaknesses--~~ **weakness** are ineffective, ~~these--~~ **the**~~

material ~~weaknesses~~ **weakness** could result in material misstatements to our annual or interim consolidated financial statements that might not be prevented or detected on a timely basis, or in delayed filings of our required periodic reports. This might lead to investors losing confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be adversely affected, and we could become subject to litigation or investigations by The Nasdaq Stock Market LLC, the SEC or other regulatory authorities, which could require additional financial and management resources. Furthermore, if we identify any new material weaknesses in the future, any such newly identified material weakness could limit our ability to prevent or detect a misstatement of our accounts or disclosures that could result in a material misstatement of our annual or interim financial statements. In such case, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting and our stock price may decline as a result. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate our existing material ~~weaknesses~~ **weakness** or avoid potential future material weaknesses. Our organizational documents and Delaware law make a takeover of our company more difficult, which may prevent certain changes in control and limit the market price of our common stock. Our certificate of incorporation and bylaws and Section 203 of the General Corporation Law of the State of Delaware, or Section 203, contain provisions that may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. These provisions include: • our ~~board~~ **Board** of ~~directors~~ **Directors** is authorized, without prior stockholder approval, to create and issue preferred stock which could be used to implement anti- takeover devices; • advance notice is required for director nominations or for proposals that can be acted upon at stockholder meetings; • our ~~board~~ **Board** of ~~directors~~ **Directors** is currently classified such that not all members of our board are elected at one time, which may make it more difficult for a person who acquires control of a majority of our outstanding voting stock to replace all or a majority of our directors; • stockholder action by written consent is prohibited; • special meetings of the stockholders may be called only by the chairman of our ~~board~~ **Board** of ~~directors~~ **Directors**, a majority of our ~~board~~ **Board** of ~~directors~~ **Directors** or by our chief executive officer or president (if at such time we have no chief executive officer); and • stockholders are not permitted to cumulate their votes for the election of directors. In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control. These provisions also could discourage proxy contests and make it more difficult for you and other stockholders to elect directors and take other corporate actions. The existence of these provisions could limit the price that investors might be willing to pay in the future for shares of our common stock. Some provisions in our certificate of incorporation and bylaws may deter third parties from acquiring us, which may limit the market price of our common stock. Our amended and restated bylaws designate the federal district courts of the United States of America as the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act ~~of 1933, as amended~~, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, employees or agents. Our amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act ~~of 1933, as amended~~. This provision does not apply to claims brought pursuant to the Securities Exchange Act ~~of 1934, as amended~~, or the rules and regulations promulgated thereunder, or any other claim for which the U. S. federal courts have exclusive jurisdiction. Any person or entity holding, owning or otherwise acquiring any interest in any security of our company shall be deemed to have notice of and consented to this provision. The enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws has been challenged in legal proceedings and there is uncertainty as to whether a court would enforce such provisions. In addition, investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. This choice- of- forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, employees or agents, which may discourage such lawsuits against us and such persons. In addition, a stockholder that is unable to bring a claim in the judicial forum of its choosing may be required to incur additional costs in the pursuit of actions which are subject to this exclusive forum provision. Alternatively, if a court were to find this provision of our amended and restated bylaws inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business, financial condition or operating results. General Risk Factors We incur costs and demands upon management as a result of complying with the laws and regulations affecting public companies in the U. S., which may adversely affect our operating results. As a public company listed in the U. S., we incur significant additional legal, accounting and other expenses. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and The Nasdaq Stock Market LLC, may increase legal and financial compliance costs and make some activities more time- consuming. These laws, regulations and standards are subject to varying interpretations, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. We invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management' s time and attention from revenue- generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, if we fail to comply with these laws, regulations and standards, it might also be more difficult for us to obtain certain types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage.

The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our ~~board~~ **Board of directors-Directors**, on committees of our ~~board~~ **Board of directors-Directors** or as members of senior management. If equity research analysts do not publish research or reports about our business, or if they issue unfavorable commentary or downgrade our common stock, the price of our common stock could decline. The trading market for our common stock relies in part on the research and reports that equity research analysts publish about us and our business. We do not control these analysts or the content and opinions included in their reports. Securities analysts may elect not to provide research coverage of our common stock and a lack of research coverage may adversely affect the market price of our common stock. The price of our stock could decline if one or more equity research analysts downgrade our stock or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business. If one or more equity research analysts cease coverage of our company, we could lose visibility in the market, which in turn could cause our stock price to decline. Our financial controls and procedures may not be sufficient to ensure timely and reliable reporting of financial information, which could materially harm our stock price, exchange listing and our ability to finance our operations. We are required to comply with the Sarbanes-Oxley Act of 2002 and the related rules and regulations of the SEC, including expanded disclosures and accelerated reporting requirements and more complex accounting rules. Compliance with Section 404 of the Sarbanes-Oxley Act, or Section 404, and other requirements will increase our costs and require additional management resources. Pursuant to Section 404, we are required to, among other things, file a report by our management on our internal control over financial reporting, including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We are continuing to implement and update new finance and accounting systems as we grow our business and organization and to satisfy internal control and reporting requirements. Despite our efforts, there is a risk that neither we nor our independent registered public accounting firm will be able to conclude that our internal control over financial reporting is effective as required by Section 404. This could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our consolidated financial statements. The effectiveness of our controls and procedures may in the future be limited by a variety of factors, including: • faulty human judgment and simple errors, omissions or mistakes; • fraudulent action of an individual or collusion of two or more people; • inappropriate management override of procedures; and • the possibility that any enhancements to controls and procedures may still not be adequate to assure timely and accurate financial information. If we are unable to complete the required Section 404 assessment as to the adequacy of our internal control over financial reporting or otherwise fail to maintain or implement effective controls and procedures for financial reporting, we could be unable to accurately and timely report our financial position, results of operations, and cash flows or key operating metrics, which could result in late filings of our annual and quarterly reports under the ~~Securities Exchange Act of 1934, as amended~~, restatements of our consolidated financial statements or other corrective disclosures, a decline in our stock price, suspension or delisting of our common stock from the Nasdaq Global Market, SEC investigations, civil or criminal sanctions, an inability to access the capital and commercial lending markets, defaults under our debt and other agreements or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity. Techniques employed by short sellers may drive down the market price of our common stock. Short selling is the practice of selling securities that the seller does not own, but rather has borrowed from a third-party with the intention of buying identical securities back at a later date to return to the lender. The short seller hopes to profit from a decline in the value of the securities between the sale of the borrowed securities and the purchase of the replacement shares, as the short seller expects to pay less in that purchase than it received in the sale. As it is in the short seller's best interests for the price of the stock to decline, many short sellers publish, or arrange for the publication of, negative opinions regarding the relevant issuer and its business prospects in order to create negative market momentum and generate profits for themselves after selling a stock short. These short attacks have, in the past, led to selling of shares in the market. We believe that our securities have in the past been, and may continue to be, the subject of short selling. Reports and information have been published about us that we believe are mischaracterized or incorrect, and which have in the past been followed by a decline in our stock price. It is not clear what additional effects the negative publicity will have on us, if any, other than potentially affecting the market price of our common stock. If we continue to be the subject of unfavorable allegations, we may have to expend a significant amount of resources to investigate such allegations and / or defend ourselves. While we would strongly defend against any such short seller attacks, we may be constrained in the manner in which we can proceed against the relevant short seller by applicable state law or issues of commercial confidentiality. Such a situation could be costly and time-consuming, and could be distracting for our management team. Additionally, such allegations against us could negatively impact our business operations and stockholders' equity, and the value of any investment in our stock could be reduced. ~~The impact of the Russian invasion of Ukraine and the Israel-Hamas war on the global economy, energy supplies and raw materials is uncertain, but may prove to negatively impact our business and operations. The short and long-term implications of Russia's invasion of Ukraine and the Israel-Hamas war are difficult to predict at this time. We continue to monitor any adverse impact that the outbreak of war in Ukraine, the subsequent institution of sanctions against Russia by the United States and several European and Asian countries, and the Israel-Hamas war may have on the global economy in general, on our business and operations and on the businesses and operations of our suppliers and customers. For example, a prolonged conflict in Ukraine or Israel may result in increased inflation, escalating energy prices and constrained availability, and thus increasing costs of raw materials. We will continue to monitor these fluid situations and develop contingency plans as necessary to address any disruptions to our business operations as they develop. To the extent the wars in Ukraine or Israel may adversely affect our business as discussed above, it may also have the effect of heightening many of the other risks described herein. Such risks include, but are not limited to, adverse effects on macroeconomic conditions, including inflation, rising interest rates and a potential economic recession; disruptions to our global technology infrastructure, including through cyberattack, ransom attack, or cyber-intrusion; adverse changes in international trade policies and relations; our ability to maintain or increase our product prices; disruptions in global supply chains; our exposure to foreign currency fluctuations; and constraints, volatility, or~~

disruption in the capital markets, any of which could negatively affect our business and financial condition.