PRECIPIO, INC.

Annual Report on Form 10-K

For the Fiscal Year Ended December 31, 2025

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

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the fiscal year ended December 31, 2025

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the transition period from _____ to _____

Commission File Number: 001-36439

PRECIPIO, INC.
(Exact name of registrant as specified in its charter)

Delaware	**91-1789357**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
4 Science Park, New Haven, CT	**06511**
(Address of principal executive offices)	**(Zip Code)**

(203) 787-7888
(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.01 par value per share	PRPO	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: None

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based on the last reported closing price per share of Common Stock as reported on the Nasdaq Capital Market on the last business day of the registrant's most recently completed second quarter was approximately $15.2 million.

As of March 23, 2026, the number of shares of common stock outstanding was 1,783,682.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant's definitive Proxy Statement for the Annual Meeting of Stockholders (the "2026 Proxy Statement") is incorporated by reference in Part III of this Form 10-K to the extent stated herein. The 2026 Proxy Statement, or an amendment to this Form 10-K, will be filed with the SEC within 120 days after December 31, 2025. Except with respect to information specifically incorporated by reference in this Form 10-K, the Proxy Statement is not deemed to be filed as a part hereof.

PRECIPIO, INC.
Annual Report on Form 10-K
For the Year Ended December 31, 2025

INDEX

PART I.

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report"), including the sections entitled "Risk Factors" "Management's Discussion & Analysis of Financial Condition and Results of Operations" and "Our Business" contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, which statements involve substantial risks and uncertainties. These statements are based on management's current views, assumptions or beliefs of future events and financial performance and are subject to uncertainty and changes in circumstances. Readers of this report should understand that these statements are not guarantees of performance or results. Many factors could affect our actual financial results and cause them to vary materially from the expectations contained in the forward-looking statements. These factors include, among other things: our expected revenue, income (loss), receivables, operating expenses, the effects of a cyberattack on us or our operations, supplier pricing, availability and prices of raw materials, insurance reimbursements, product pricing, foreign currency exchange rates, sources of funding operations and acquisitions, our ability to raise funds, sufficiency of available liquidity, future interest and inflation costs, future economic circumstances, business strategy, industry conditions and key trends, our ability to execute our operating plans, the success of our cost savings initiatives, competitive environment and related market conditions, our ability to comply with the listing requirements of the Nasdaq Capital Market, expected financial and other benefits from our organizational restructuring activities, geopolitical uncertainties including the ongoing Russia and Ukraine conflict and the Israel-Hamas war, actions of governments and regulatory factors affecting our business, projections of future earnings, revenues, synergies, accretion or other financial items, any statements of the plans, strategies and objectives of management for future operations, retaining key employees and other risks as described in our reports filed with the Securities and Exchange Commission (the "SEC"). In some cases these statements are identifiable through the use of words such as "anticipate," "believe," "estimate," "expect," "intend," "plan," "project," "target," "can," "could," "may," "should," "will," "would" or the negative of such terms and other similar expressions. Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include, among other, the following:

- the progress, timing and amount of expenses associated with our development and commercialization activities;
- our plans and ability to develop and commercialize new products and services, and make improvements to our existing products and services;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our ability or the amount of time it will take to achieve successful reimbursement of our existing and future products and services from third-party payors, such as commercial insurance companies and health maintenance organizations, and government insurance programs, such as Medicare and Medicaid;
- changes in government and third-party payer regulations, reimbursement, or coverage policies or other future reforms in the United States (U.S.) healthcare system (or in the interpretation of current regulations), new insurance or payment systems, including state, regional or private insurance cooperatives (e.g., health insurance exchanges) affecting governmental and third-party coverage or reimbursement for commercial laboratory testing, including the impact of the U.S. Protecting Access to Medicare Act of 2014;
- loss or suspension of a license or imposition of fines or penalties under, or future changes in, or interpretations of applicable licensing laws or regulations regarding the operation of clinical laboratories, the development and commercialization of laboratory-developed tests (LDTs), and the delivery of clinical laboratory test results, including, but not limited to, the U.S. Clinical Laboratory Improvement Act of 1967, the U.S. Clinical Laboratory Improvement Amendments of 1988, the European Union In Vitro Diagnostics Regulation, and similar laws and regulations in jurisdictions in which we conduct business;
- the accuracy of our estimates of the size and characteristics of the markets that may be addressed by our products;
- the success of any nonclinical studies or clinical trials that we may conduct, and any other studies or trials we may conduct;

- our intention to seek, and our ability to establish, strategic collaborations or partnerships for the development or sale of our products and the effectiveness of such collaborations or partnerships;
- our expectations as to future financial performance, expense levels and liquidity sources;
- our anticipated cash needs and our estimates regarding our capital requirements and our needs for additional financing, as well as our ability to obtain such additional financing on reasonable terms;
- our ability to compete with other companies that are or may be developing or selling products that are competitive with our products;
- our ability to build a sales force to market our products and services, and anticipated increases in our sales and marketing costs due to an expansion in our sales force and marketing activities;
- the rate and degree of market acceptance of our products;
- termination, loss, delay, reduction in scope, or increased costs of contracts;
- regulatory developments in the United States and foreign countries;
- increased U.S. trade tariffs and resulting trade disputes with other countries;
- federal and state regulatory requirements, including potential United States Food and Drug Administration regulation of our products or future products;
- anticipated trends and challenges in our potential markets;
- our ability to attract and retain key personnel;
- our expectations related to the use of our cash reserves;
- the impact of new laws and regulations or amendments to existing laws and regulations;
- risks associated with the impact of global conflicts on the economy and supply chain;
- risks associated with the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, economic sanctions and economic slowdowns or recessions or public health pandemics;
- developments and projections relating to our competitors and our industry;
- our expectations regarding the period during which we qualify as a "smaller reporting company" as defined by Rule 12b-2 of the Exchange Act (we will remain a smaller reporting company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million); and
- our estimates and expectations regarding cash and expense levels, future revenue, capital requirements and needs for additional financing, including our expected use of proceeds from our public offerings, and liquidity sources.

You are cautioned not to place undue reliance on these forward-looking statements. The forward-looking statements we make are not guarantees of future performance and are subject to various assumptions, risks and other factors that could cause actual results to differ materially from those suggested by these forward-looking statements. Actual results may differ materially from those suggested by these forward-looking statements for a number of reasons, including those described in Item 1A, "Risk Factors," and other factors identified by cautionary language used elsewhere in this Annual Report.

We expressly disclaim any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

The following discussion should be read together with our financial statements and related notes contained in this Annual Report. Results for the year ended December 31, 2025 are not necessarily indicative of results that may be attained in the future.

Solely for convenience, trademarks and tradenames referred to in this Annual Report on Form 10-K appear (after the first usage) without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or that the applicable owner will not assert its rights, to these trademarks and tradenames.

Item 1. Business

We are a healthcare biotechnology company with a mission to battle the systemic problem of disease misdiagnosis, by focusing on improving cancer diagnostics, particularly, hematologic malignancies. Our objective is to enhance diagnostic accuracy and accessibility while building a sustainable business model that supports ongoing innovation. We aim to achieve this through a combination of clinical laboratory services and proprietary diagnostic product development. By integrating diagnostic services with product development, our service business doubles as a self-funded research and development ("R&D") unit, enabling us to achieve rapid and cost-efficient innovation rather than being a major cost center for us.

This unique integrated operating structure is the foundation of our approach to research, development, and product commercialization. Unlike other companies that rely primarily on stand-alone research facilities or external clinical validation programs, our clinical laboratory operations enables our R&D team to evaluate, refine, and validate diagnostic products in the course of routine clinical testing activities, and at incremental cost. Through these activities, we generate clinical data, operational experience, and specimen access that support ongoing assay development and product improvement. While these activities are initially conducted to provide diagnostic services to patients and their healthcare providers, they also contribute to product development and validation processes.

Our Structure (Two Divisions):

We have a single operating segment but operate two business divisions that are complementary to each other:

Pathology Services Division

Our pathology services division provides specialized cancer diagnostic testing services to physicians, hospitals, and laboratories. This division generates revenue and supports the development of our expertise in oncology diagnostics.

The pathology services division delivers specialized diagnostic testing focused primarily on hematologic cancers. Services include molecular diagnostics, cytogenetics, and related advanced laboratory analyses performed for healthcare providers and institutions. We receive patient samples (blood and biopsies) sent in from clinics and hospitals, and conduct a diagnostic analysis, ultimately providing a pathology report that informs the physician about the nature of the disease the patient has.

The pathology services division operates two full laboratories that include all the equipment, personnel, and work processes required to receive patient samples daily, and deliver clinical results to the physicians under the proper compliance umbrella.

This division provides:

- An internal clinical environment to develop, test and validate all new products before going to market.
- Recurring diagnostic service revenue.
- Direct engagement with clinicians and patient testing needs.
- Operational experience that informs diagnostic development activities.

While reimbursement levels and testing volumes may vary, we view this division as an important foundation for both current operations and future product development.

Products Division

The products division develops and commercializes proprietary assays designed for use by clinical laboratories. These products allow the Company to expand its reach by enabling other laboratories to benefit from the diagnostic products developed by the Company while building scalable diagnostic solutions.

We believe this dual structure provides a unique model for R&D development of clinically applicable products, while delivering operational stability and supporting innovation and future growth. Furthermore, it provides us with substantial competitive advantages in terms of the economics of product development and time to market.

The products division focuses on developing proprietary diagnostic assays and kits intended for use by other clinical laboratories. These products are designed to improve testing accessibility and laboratory workflow efficiency while enabling broader market reach without requiring us to perform all testing internally.

Key elements of this division include:

- Assay development and validation.
- Manufacturing and commercialization of diagnostic kits.
- Distribution through laboratory partners and commercial channels.

Product revenues may offer greater scalability than traditional laboratory services, although adoption depends on regulatory, reimbursement, and market factors.

Integrated R&D Model: Relationship Between Pathology and Products Divisions

As described above, our pathology services division operates fully equipped clinical laboratories staffed with specialized personnel, as well as the infrastructure necessary to perform complex diagnostic testing. These operations provide access to instrumentation, technical expertise, and clinical workflows that support the development, evaluation, and refinement of the diagnostic products. In addition, our clinical testing activities provide access, where appropriate and consistent with regulatory and ethical requirements, to patient specimens that are critical for assay development, validation, and performance assessment. Such specimens, particularly fresh clinical samples relevant to hematologic malignancies, are extremely difficult and costly for product-focused organizations to obtain in sufficient quantity or condition through external channels.

As a technology innovator, this model provides us with a significant set of competitive advantages. First, the ongoing access to patient specimens removes a significant challenge faced by other manufacturers, both from a cost, as well as from an ability to even procure these samples.

Second, the immediate access to this entire infrastructure, coupled with daily feedback from clinicians, gives us time-to-market advantage in being able to respond to both new scientific publications, as well as market demand, in developing new products.

This integrated operating model allows us to leverage existing revenue-generating laboratory infrastructure to support research and development activities, which reduces development costs and timelines compared to approaches that rely solely on dedicated research facilities or external clinical partnerships. It also enables us to respond quickly to emerging scientific developments by developing new assays or refining existing tests as clinically appropriate. This becomes a key competitive advantage in a constantly-evolving field, by enabling the company to be the first to deliver to the market the most updated, clinically-relevant products.

This integrated approach allows us to:

- Evaluate clinical needs through direct laboratory operations.
- Validate assays using operational experience.
- Refine products based on clinician and laboratory feedback.
- Leverage clinical samples from the pathology services divisions to develop new assays at a lower cost and faster timeline to go to market.

We believe this model may improve alignment between product development and clinical market demand.

Growth Strategy

Our growth strategy includes several key components:

- Expansion of Proprietary Diagnostic Products: Increasing commercialization of diagnostic assay kits through partnerships, distribution channels, and broader laboratory adoption.
- Sustained Pathology Services Operations: Maintaining and expanding diagnostic testing services to support revenue generation, clinical engagement, and operational expertise.

- Regulatory and Reimbursement Progress: Pursuing appropriate regulatory clearances and reimbursement coverage to support market adoption.
- Operational Efficiency and Scale: Improving laboratory and manufacturing efficiencies while managing costs to support long-term financial performance.

Execution of this strategy is subject to various risks, including market competition, reimbursement dynamics, regulatory developments, and operational factors as further set out in the Risk Factors.

Industry

We believe there is a significant problem of misdiagnosis across numerous disease states (particularly in blood-related cancers) due to an inefficient and commoditized industry. We believe that the diagnostic industry focuses primarily on competitive pricing and test turnaround times, at the expense of quality and accuracy. Increasingly complex disease states are met with eroding specialization rather than increased subspecialized expertise. According to a study conducted by the National Coalition of Health, this results in blood cancer misdiagnosis rates as high as 28%, failing to meet the needs of physicians, patients and the healthcare system as a whole. New technologies offer improved accuracy; however, many are either inaccessible or are not economically practical for clinical use. Despite much publicity of the industry transitioning from fee-per-service to value-based payments, this transition has not yet occurred in diagnostics. When a patient is misdiagnosed, physicians often end up administering incorrect treatments, creating adverse effects rather than improving outcomes. We believe that insurance providers, Medicare and Medicaid waste valuable dollars on the application of incorrect treatments and can incur substantial downstream costs. According to a report by Pinnacle Health, the estimated cost of misdiagnosis within the healthcare system is $100 billion annually. Most importantly, however, patients pay the ultimate price of misdiagnosis with increased morbidity and mortality. Developing diagnostic products that increase accuracy, while also providing improved workflow and economic outcomes to laboratories is key to addressing this problem and delivering better diagnostic care.

Market

Our market is the United States domestic oncology market where we participate as a commercial diagnostic laboratory and market our products. The oncology total available market, is currently estimated to exceed $116 billion by 2034, with an estimated compound annual growth rate exceeding 5%. We also provide new technologies to the oncology diagnostic laboratory market in the form of HemeScreen and IV-Cell product offerings. The diagnostics product market is estimated to have annual revenues exceeding $56 billion by 2030. The annual growth rate of each market segment is estimated at 5%. Successful deployment within the United States will be closely followed by international marketing where the same product opportunities exist for our products.

From our New Haven, Connecticut commercial lab, we currently provide diagnostic blood cancer testing services to oncology practices in over 20 states. Building on our commercial laboratory expertise, we have developed several impactful diagnostic technologies that are more cost effective than current industry alternatives, which reduces the diagnostic testing time and improves efficiencies to perform such tests. We anticipate gaining a share of the oncology diagnostic product market as commercial diagnostic laboratories and oncology practices adopt these new cost effective technologies.

Our Technologies

Our strategy is to develop, manufacture and sell multiple technologies that we expect to be adopted by laboratories. Since we operate a clinical laboratory, we have access to patient samples that can, in parallel to the clinical work we conduct, be utilized to develop these new technologies. Since its inception, our R&D team has developed two products that are offered in the market, and we continue to develop a robust pipeline of products we expect to launch in the future. The following is a description of the two products currently on the market:

1. *HemeScreen™*

The ongoing introduction of new, genetic-based targeted therapies have made molecular testing a mainstream and essential component of the diagnostic process. World Health Organization (WHO) and The National Comprehensive Cancer Network® (NCCN) guidelines have delineated the testing requirements of several specific genetic markers that are required during the diagnostic workup based on the patient's disease state.

The current products on the market largely offer two types of solutions for genetic testing. One of those solutions is single-gene testing products via various testing modalities; the other solution is broad, next generation sequencing ("NGS") panels that typically range from 50 to >500 genes in one panel. There are benefits and drawbacks to both current product options. While the single-gene products are focused, a lab requires multiple different products to address the clinical testing needs; using multiple products requires the purchase of multiple products and multiple testing machines, requiring the lab to spend substantial capital expenditures; a complex lab workflow; the splitting of a sample; all resulting in poor economics. Poor economics of an assay require the laboratory to batch samples, resulting in lengthy turnaround time to provide results to patients, and impacting patient care. Conversely, NGS, although providing broad gene coverage, is cumbersome and expensive to operate, thus resulting in lengthy test turnaround time, and is costly to the payors who are reluctant to pay for the testing of 50 genes, when only 5 are defined as medically necessary.

A small panel targeted approach that operates on a single, low-cost, and easy-to-operate platform should be considered an attractive solution that provides the clinician with the answers they need while maintaining a simple, cost-effective workflow and economic model within the laboratory. HemeScreen utilizes an inexpensive RT-PCR (reverse transcription polymerase chain reaction). HemeScreen is a set of disease-specific reagents that provide a simple workflow, is easy to use, and create attractive economics to the lab, resulting in their ability to reduce batches and provide faster test turnaround time. Our customers that utilize HemeScreen have demonstrated a reduction in test turnaround time of 2 weeks to 2 days, and have also improved their financial outcome through this cost-effective technology.

The first panel developed using HemeScreen technology was our Myeloproliferative Neoplasms panel. We have since added Acute Myeloid Leukemia, Chronic Lymphocytic Leukemia, Cytopenia, and BCR-ABL panels, evolving HemeScreen into a "suite" of robust genetic diagnostic panels, and we released a number of panels during 2024 such as BCR-ABL1 and Bloodhound MPN assays. These assays provide lower limits of detection compared to their HemeScreen predecessors and provide quantitative results. These assays were also released with complementary analysis software (BHAS) for rapid data analysis to further streamline laboratory workflows.

We own pending U.S. and European patent applications on our proprietary panels. Our technology enables testing to be completed in one rapid scanning process. The HemeScreen panels test for the presence of various mutations. In developing HemeScreen, we focused on improving the economics of providing blood cancer diagnostic tests and reducing laboratory technician time consumed in the testing process. By using our HemeScreen media, laboratories can:

1. Avoid the cost of multiple platforms and test all the genes on one single platform;
2. Reduce the threshold of expertise required to perform these tests;
3. Reduce the batch requirements for the test and to subsequently significantly reduce the turnaround time for patient results;
4. Provide improved clinical service to physicians; and
5. Yield significant revenue to the laboratory.

2. IV-Cell™

The cytogenetics laboratory workflow of bone marrow and peripheral blood samples suffers from an inherent flaw. The flaw stems from the requirement of the oncologist to provide their clinical suspicion, which determines the pathway of diagnosis, and guides the laboratory in the testing to be conducted, intended to confirm/rule out the oncologist's clinical suspicion.

When a laboratory receives a sample, the cytogenetics laboratory must immediately set up the sample for cell culturing. Faced with four different options of cell lineages for culturing – myeloid, B-cell, T-cell, and Plasma – current products on the market limit the laboratory to select only one cell lineage to culture. This selection is typically based solely

on the clinical suspicion provided; hence, if the clinical suspicion is incorrect, the laboratory will have cultured the wrong cell lineage, potentially arriving at a false negative result. Our data shows this occurs in approximately 40% of patient cases, creating a substantial driver of misdiagnoses.

IV-Cell is a proprietary cell culture media that addresses the problem of diagnostic mistakes through the process of selective culturing. IV-Cell is a universal media that enables simultaneous culturing of all four hematopoietic cell lineages. Developed by Precipio, the culturing technology ensures that the laboratory is able to obtain sufficient information through other test modalities, thereby not relying solely on clinical suspicion, in order to ultimately select the correct cell lineage for culturing and evaluation.

IV-Cell was validated in our laboratory in parallel with existing commercially available reagents and has successfully demonstrated superior results compared to MarrowMax. Subsequently, IV-Cell has been used at our laboratory for the past few years on more than 1,000 clinical specimens, producing more precise diagnostic results.

The IV-Cell technology and media can be purchased via a direct supply contract, whereby we are contracted with a manufacturer (under license and non-disclosure) to produce the media.

Competition

Our principal competition in clinical pathology services comes largely from two groups. The first group consists of companies that specialize in oncology and offer directly competing services to our diagnostic services. These companies provide a high level of service focused on oncology and offer their services to oncologists and pathology departments within hospitals. Competitors in this group include NeoGenomics Laboratories, Inc., also known as NeoGenomics or Neo, GenPath Diagnostics and Inform Diagnostics. The second group consists of large commercial companies that offer a wide variety of laboratory tests ranging from simple chemistry tests to complex genetic testing. Competitors in this group include LabCorp (NYSE: LH) and Quest Diagnostics (NYSE: DGX). Within the liquid biopsy market, our competitors include Foundation Medicine and Guardant Health.

For the Products division, our competitors include various reagent manufacturers who produce various products that compete with our products.

Many of the companies against which we may compete have significantly greater financial resources and expertise than we do in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel as well as in acquiring technologies complementary to, or necessary for, our programs. Our competitors also may obtain Food and Drug Administration ("FDA") or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market.

Single gene vs. NGS (Next Generation Sequencing) concept

Molecular tests have become part of standard of care for the diagnostic of cancer biopsies. Genes are interrogated in search of mutations that can help explain the cause of cancer; indicate the severity of the cancer (prognosis); and provide guidance as to which targeted therapies may be applicable and therefore more effective for a specific patient.

The NCCN and WHO outline various genes that are required in the workup of various disease entities (typically 5-10 tests per disease entity), and as a result of that, companies have developed testing reagents for those specific genes. For example, for the evaluation of MPN (one of Precipio's HemeScreen panels), the gene JAK2 is required to be tested. There are numerous competitors such as Qiagen, BioRad, Ipsogen, Cepheid, Asuragen, Abbott, Entrogen and others that have developed a testing assay for the mutation analysis of the JAK2 gene. These are called single-gene testing assays. If a lab wishes to test the required genes, they will typically need to purchase multiple machines (a substantial capital investment that can exceed $1 million), purchase multiple single-gene assays from different manufacturers, and set up multiple work flows, etc. This creates a complex and inefficient workflow.

On the other end of the spectrum are companies that have developed NGS panels for molecular analysis. NGS is a robust, broad ranging technology that enables a lab to test for tens, hundreds, and even thousands of genes in one test. Companies such as Life Technologies, Illumina, Roche, Natera, PerkinElmer, BioRad, Qiagen and many others have developed machines and assays that can test hundreds of genes simultaneously. While this technology is extremely robust, there are a few challenges to NGS, including, but not limited to:

1. Operability – this is a complex technology that requires a high level of lab competency and an advanced level of staff sophistication and training;
2. Cost – running NGS testing is expensive; the machines can cost millions of dollars; reagents are expensive, and the staff to run these tests are highly paid; and
3. Reimbursement – Conversely, given that the clinical requirements for genetic testing typically range from 5-10 genes, and these panels can run 50 – 500 genes, payers are reluctant to pay the high cost of these panels given that the vast majority of the information provided may not have clinical relevance.

Precipio's HemeScreen panels were designed to meet the clinical requirements outlined in the guidelines, while creating a low cost, easy to operate testing technology that results in a simplified workflow. Our panels:

1. Typically range from 4-7 genes (matching the clinical requirements);
2. Are all run on one, inexpensive machine (an RT-PCR, which costs between $30-75k);
3. Require very basic laboratory training and can be run by any lab tech with limited training; and
4. Have attractive economics that provide attractive margins to laboratories who decide to use only RUO assays.

IV-Cell competition

As described in the section above, the cytogenetics workup requires the selection and evaluation of a cell lineage within 4 potential cell lineages. All other competitors have a set of products that include a "base media" that is used for culturing, plus a set of various mitogens that are mixed into the base media in order to stimulate the specific cell lineage in question. Competitors include Gibco, Irvine Scientific, Capricorn Scientific, Sigma-Aldrich, Euroclone and others.

Precipio's IV-Cell is, to our knowledge, based on publicly available information, the only known media that has an all-in-one product that includes a base media plus all necessary mitogens, enabling the simultaneous culturing of all 4 cell lineages.

Competitive Advantage

Our competitive advantage is derived from our ability to identify real-world clinical challenges in the laboratory; develop technology-based solutions to those challenges; test them within our lab on real clinical samples; and then commercialize the technology and bring it to market. Our model gives us a unique capability to ensure that the finished product is relevant, reliable, and workable within the laboratory workflow. Furthermore, given the hands-on experience we have as first-users of our own products, we have unparalleled experience, insight, and expertise required to support our customers and help them maximize the value of our technologies that they use.

As cancer diagnostic testing continues to evolve, laboratory testing has become extremely complex, requiring even greater diagnostic precision, attention to process and a more appropriate evaluation. Our organizational structure enables management and R&D resources to efficiently focus on laboratory economics (time and material); the delivery of complex results (technical processing); and proprietary analysis (gather data, considerations, determination and information presentation) for the physician - all ultimately leading to minimizing misdiagnoses and better patient care. Embedding R&D personnel into a collaborative workflow within our clinical laboratory operations results in a very cost effective development environment enabling identification of issues, the isolation of causes and the creation of proprietary product solutions to mitigate misdiagnoses.

Government Regulation

The healthcare industry is subject to extensive regulation by a number of governmental entities at the federal, state and local level. Laws and regulations in the healthcare industry are extremely complex and, in many instances, the

industry does not have the benefit of significant regulatory or judicial interpretation. For example, the U.S. federal transparency requirements under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act ("PPACA") including the provision commonly referred to as the Physician Payments Sunshine Act, and its implementing regulations, which requires applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to Center for Medicare and Medicaid Services ("CMS"), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other licensed health care practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members.

Our business is impacted not only by those laws and regulations that are directly applicable to us but also by certain laws and regulations that are applicable to our payers, vendors and referral sources. While our management believes we are in compliance with all of the existing laws and regulations applicable to us, such laws and regulations are subject to rapid change and often are uncertain in their application and enforcement. Further, to the extent we engage in new business initiatives, we must continue to evaluate whether new laws and regulations are applicable to us. There can be no assurance that we will not be subject to scrutiny or challenge under one or more of these laws or that any enforcement actions would not be successful. Any such challenge, whether or not successful, could have a material adverse effect upon our business and consolidated financial statements.

Our current active laboratory certifications can be found on http://www.precipiodx.com/accreditations.html. The laboratory operations are governed by Standard Operating Procedure manuals, ("SOPs"), which detail each aspect of the laboratory environment including the work flow, quality control, maintenance, and safety. These SOPs are reviewed and approved annually and signed off by the laboratory manager and medical director.

Among the various federal and state laws and regulations that may govern or impact our current and planned operations are the following:

Reimbursement

This section is relevant to our clinical pathology services; our products are sold and invoiced directly (or via distributors) to customers who pay for the products, so there are no reimbursement issues. For our laboratory services, as blood-related cancers are more likely to be developed later in life, the largest insurance provider is Medicare, which constituted approximately 32% of our patients' cases during the year ended December 31, 2025. Non-Medicare patients are typically insured by private insurance companies who provide patient coverage and pay for patients' health-related costs. These private insurance companies will often adjust their rates according to the insurance rates annually published by the CMS. We, and other providers, typically bill according to the codes relevant to the tests we conduct.

Medicare and Medicaid Reimbursement

Many of the services that we provide are reimbursed by Medicare and state Medicaid programs and are therefore subject to extensive government regulation.

Medicare is a federally funded program that provides health insurance coverage for qualified persons age 65 or older, some disabled persons, and persons with end-stage renal disease and persons with Lou Gehrig's disease. Medicaid programs are jointly funded by the federal and state governments and are administered by states under approved plans.

Medicaid provides medical benefits to eligible people with limited income and resources and people with disabilities, among others. Although the federal government establishes general guidelines for the Medicaid program, each state sets its own guidelines regarding eligibility and covered services. Some individuals, known as "dual eligibles", may be eligible for benefits under both Medicare and a state Medicaid program. Reimbursement under the Medicare and Medicaid programs is contingent on the satisfaction of numerous rules and regulations, including those requiring certification and/or licensure. Congress often enacts legislation that affects the reimbursement rates under government healthcare programs.

Approximately 40% of our revenue for the year ended December 31, 2025 was derived directly from Medicare, Medicaid or other government-sponsored healthcare programs. Also, we indirectly provide services to beneficiaries of Medicare, Medicaid and other government-sponsored healthcare programs through managed care entities. Should there be material changes to federal or state reimbursement methodologies, regulations or policies, our direct reimbursements from government-sponsored healthcare programs, as well as service fees that relate indirectly to such reimbursements, could be adversely affected.

Healthcare Reform

In recent years, federal and state governments have considered and enacted policy changes designed to reform the healthcare industry. The most prominent of these healthcare reform efforts, the PPACA, has resulted in sweeping changes to the U.S. system for the delivery and financing of health care. As currently structured, the PPACA increases the number of persons covered under government programs and private insurance; furnishes economic incentives for measurable improvements in health care quality outcomes; promotes a more integrated health care delivery system and the creation of new health care delivery. It is unclear how other healthcare reform measures of the Trump administration or other efforts, if any, to challenge, repeal or replace the PPACA will impact our business.

U.S. Food and Drug Administration Regulation

Medical devices are subject to extensive regulation by the FDA. The FDA regulates, among other things, the research, design, development, preclinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, marketing authorization, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- requesting or requiring recalls, withdrawals, or administrative detention or seizure of products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for marketing authorization or new products or modified products; or
- criminal prosecution.

Currently, we offer our products as RUO products. An RUO product is one that is not intended for clinical diagnostic use and must be labeled “For Research Use Only. Not for use in diagnostic procedures.” Products that are intended for research use only and are properly labeled as RUO are exempt from compliance with the requirements of the FDA applicable to medical devices. A product labeled RUO but intended to be used diagnostically may be viewed by the FDA as adulterated or misbranded and is subject to FDA enforcement activities. The FDA may consider the totality of the circumstances surrounding distribution and use of an RUO product, including how the product is marketed, when determining its intended use. In November 2013, the FDA issued a guidance document entitled “Distribution of In Vitro Diagnostic Products Labeled for Research Use Only or Investigational Use Only” (“RUO Guidance”), which highlights the FDA’s interpretation that distribution of RUO products with any labeling, advertising or promotion that suggests that clinical laboratories can validate the test through their own procedures and subsequently offer it for clinical diagnostic use as a laboratory developed test is in conflict with RUO status. The RUO Guidance further articulates the FDA’s position that any assistance offered in performing clinical validation or verification, or similar specialized technical support, to clinical laboratories, conflicts with RUO status.

Additionally, our laboratories offer testing utilizing our LDTs. Historically, it has been the FDA’s position that it has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the FDA’s requirements for medical devices, such as the FDA’s requirements pertaining to marketing

authorization, establishment registration, device listing, the Quality System Regulation (as of February 2, 2026, the Quality Management System Regulation), and other post-market controls.

On April 29, 2024, FDA published a final rule that, if implemented, would have amended FDA's regulatory definition of in vitro diagnostics to include LDTs and phased out the agency's longstanding enforcement discretion for most LDTs over a planned multi-stage implementation period. The rule would have subjected many LDTs to premarket review and device regulatory requirements.

Subsequently, in March 2025, a federal district court in American Clinical Laboratory Association v. FDA and Association for Molecular Pathology v. FDA vacated the April 29, 2024 final rule on the basis that FDA lacked statutory authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act. In September 2025, FDA published a rule restoring the regulatory text governing LDTs to the pre-2024 status quo. As a result, the April 2024 final rule is no longer in effect, and there are currently no FDA-imposed device-style premarket requirements or staged compliance deadlines applicable solely because a laboratory develops and uses an LDT.

Accordingly, LDTs continue to be regulated primarily under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA") and related CMS authorities as laboratory services, and FDA generally continues to exercise enforcement discretion with respect to LDTs. The regulatory framework for LDT oversight remains uncertain, and future actions by FDA, CMS, or Congress or subsequent litigation could alter the applicable requirements or enforcement posture. If FDA, CMS, or Congress adopts new requirements governing LDTs, compliance with such requirements could require significant additional investments in regulatory, quality, clinical validation, operational, and administrative infrastructure and could adversely affect our business, results of operations, financial condition, and prospects.

If the FDA were to determine that certain tests offered by us as LDTs or products offered by us as RUO products are subject to regulation as medical devices for any reason, including new rules, policies or guidance, or due to changes in statute, our tests or products may become subject to extensive FDA requirements. If required, the regulatory marketing authorization process required to market our current or future tests or products as medical devices in the United States may involve, among other things, successfully completing additional clinical validations and submitting to and obtaining clearance, authorization or approval from the FDA. Furthermore, any future legislative proposals, if enacted, could create new or different regulatory and compliance burdens on us and could have a negative effect on our ability to keep products on the market or develop new products. We are actively monitoring developments, assessing the impact on our operations, and evaluating compliance strategies, including potential FDA submissions and resource allocation for regulatory changes.

European Union Regulation

Our products are regulated as in-vitro diagnostic devices in the European Union ("EU") and are subject to the In-Vitro Diagnostic Devices Regulation (EU) 2017/746 ("IVDR"), which became fully applicable in all EU Member States on May 26, 2022. The IVDR introduced more stringent requirements than the previous In Vitro Diagnostics Directive 98/79/EC ("IVDD"), including enhanced clinical evidence, post-market surveillance, and increased scrutiny by notified bodies for most device classes.

Under the IVDR's transitional provisions, devices for which a declaration of conformity was drawn up prior to May 26, 2022 under the IVDD and which require Notified Body involvement the IVDR may continue to be placed on the EU and Northern Ireland markets until December 31, 2028, assuming a Class C risk classification. This is contingent on the devices with post-market surveillance, vigilance, and registration requirements under the IVDR, and provided the manufacturer submits a formal application to an IVDR-designated notified body by May 26, 2026 and concludes a written agreement with that notified body by September 26, 2026. Failure to meet either of these deadlines would result in the loss of transitional protection on that date. HemeScreen qualifies for these transitional provisions by virtue of its registration and sale in Northern Ireland, which follows EU medical device rules under the Windsor Framework.

There is no certainty regarding the timing or outcome of notified body conformity assessments under the IVDR. The transition to IVDR continues to present regulatory, operational, and financial challenges, including potential delays in obtaining notified body certification and increased compliance costs. We are actively monitoring regulatory developments and have taken steps to transition our products to IVDR compliance, including engagement with notified

bodies and implementation of enhanced post-market surveillance measures. For more information about how the transitional provisions may impact our business, see "Risk Factors - *Changes to the UK regulations may require additional review of our devices and there is a risk our devices may not be compliant with any revised UK regulations*" in Item 1A of this Annual Report.

The United Kingdom formally left the EU on January 31, 2020. In respect of medical devices, since the end of the Brexit transition period on January 1, 2021, medical devices must be registered with the Medicines and Healthcare products Regulatory Agency, or MHRA, before being placed on the market in Great Britain. If a manufacturer of a device placed on the market in Great Britain is established outside the United Kingdom, the manufacturer must appoint a UK Responsible Person with a registered place of business in the United Kingdom to act on the manufacturer's behalf with respect to certain regulatory obligations, including device registration.

CE marked devices and in vitro diagnostic medical devices, or IVDs, that comply with applicable EU legislation may continue to be placed on the Great Britain market until June 30, 2030, at the latest, subject to compliance with applicable registration and post market requirements. Thereafter, devices and IVDs placed on the Great Britain market will generally be required to bear a UK Conformity Assessed, or UKCA, mark, unless otherwise permitted under applicable reliance or transitional mechanisms. Manufacturers may elect to use the UKCA mark on a voluntary basis prior to such date. UKCA marking is not recognized in the EU.

The EU regulatory framework for medical devices continues to apply in Northern Ireland under the Windsor Framework. Medical devices placed on the market in Northern Ireland may bear either a CE mark or a CE UK(NI) marking, although devices bearing the CE UK(NI) marking are not accepted on the EU market.

Following a public consultation, the UK government is implementing changes to UK medical devices legislation. The first such legislation came into force on June 16, 2025 and introduced revised post market surveillance requirements for medical devices in Great Britain intended to improve traceability and incident monitoring. The UK government has also indicated that further legislation is expected to revise pre-market requirements for devices and IVDs placed on the Great Britain market. Proposed reforms include a potential international reliance framework that could facilitate market access for certain devices previously authorized by comparable regulators. The scope, timing, and final requirements of these reforms remain subject to further legislation and regulatory guidance.

Research and Development Expenses

For the years ended December 31, 2025 and 2024, we recorded $1.6 million and $1.3 million, respectively, of research and development expenses. More information regarding our research and development activities can be found in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" under Item 7 of this Annual Report.

Human Capital

Employees.

As of March 9, 2026, Precipio employed sixty-one (61) employees on a full-time basis and ten (10) employees as part-time. Of the total full-time and part-time employees, ten (10) were in Finance, General and Administration, forty-four (44) were in laboratory and production, ten (10) were in Sales and Marketing, two (2) were in Customer Service and Support and five (5) were in Research & Development.

All of our employees are based in the U.S. and a majority are based in Connecticut. None of our employees are represented by a labor union or covered by a collective bargaining agreement, and we believe our relationship with our employees is good.

Career Development and Growth.

We emphasize employee development and training. We invest in our employees by providing development opportunities, and the necessary resources to support their success, including coaching, management and leadership training, presentation workshops and paid conference attendance. The diversity of our employees and their skillsets also offer a unique opportunity for us to learn from each other's experiences.

Compensation and Benefits.

Our human capital management strategies, initiatives, and outcomes are reviewed on a regular basis with our Board's Governance Committee as well as Compensation Committee to help align with our overall business strategies. Our competitive compensation programs are designed to align the compensation of our employees with our performance and to provide the proper incentives to attract, retain and motivate employees. The aim is to structure our compensation programs to balance incentive earnings for both short-term and long-term performance.

We are committed to providing comprehensive benefits and some examples of the benefits we offer are: medical insurance including prescription drug benefits, dental insurance, vision insurance, accident insurance, life insurance, disability insurance, health savings accounts, flexible spending accounts and access to mental health support. We also enable our employees to take unlimited personal time off and have put in place enhanced parental leave benefits.

Employee Engagement.

We conduct confidential employee engagement surveys to obtain feedback on a variety of topics, including culture, values, diversity and inclusion, career development, employee satisfaction and tenure, and execution of our company strategy. These survey results are reviewed by our executive team so that we can continue to increase employee satisfaction and improve the well-being of our employees. We are also committed to communication and transparency, using multiple forums and channels to allow for the sharing of appropriate, timely information to all employees. We focus our employee communications on continual engagement, providing updates on our business, technology, and workforce, including learning opportunities. We believe our management team has the experience necessary to effectively execute our strategy and advance our product and technology leadership.

Inclusion Efforts.

We strive to create a culture in which all employees feel heard, respected, and valued. We are committed to creating and maintaining an inclusive and safe work environment. As we grow and mature, we look forward to establishing programs that infuse inclusivity within the business, identify barriers that impact recruitment, development and retention of underrepresented employees, identify educational content, communicate the value and impact of inclusivity on goals and objectives, all while continuing to focus on hiring diverse talent at all levels of the Company. Our ability to innovate and meet people's needs is strongest when all voices are heard and valued.

Code of Business Conduct and Ethics.

We are committed to conducting business in accordance with the highest ethical standards and applicable laws. We maintain, and all of our employees are expected to adhere to our Code of Business Conduct and Ethics, (the "Code of Conduct"), which serves as the foundation of our core values that drive our culture. All of our employees complete training and education on a range of important topics related to our Code of Conduct, and they must certify they understand and comply with the expectations contained in the Code of Conduct. We also maintain an anonymous hotline for employees to report concerns regarding violations of the Code of Conduct.

The full text of our Code of Business Conduct and Ethics is posted on the investor relations page of our website at https://www.precipiodx.com/investors/corporate-governance/.

We intend to satisfy any disclosure requirements under Item 5.05 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code of Business Conduct and Ethics by posting such information on our website, at the Internet address and location specified above.

Information about our Executive Officers.

Our executive officers, their ages as of March 1, 2026 and their respective positions are as follows:

Ilan Danieli, Chief Executive Officer, age 54

Mr. Danieli was the founder of Precipio Diagnostics LLC and was the Chief Executive Officer of Precipio Diagnostics LLC since 2011. Mr. Danieli assumed the role of Chief Executive Officer of Precipio, Inc. at the time of a June 2017 merger transaction with Transgenomic, Inc. (the "Merger"). With over 20 years managing small and medium-size companies, some of his previous experiences include serving as COO of Osiris, a publicly-traded company based in New York City with operations in the US, Canada, Europe and Asia, VP of Operations for Laurus Capital Management, a multi- billion-dollar hedge fund, and in various other entrepreneurial ventures. Ilan holds an MBA from the Darden School at the University of Virginia, and a BA in Economics from Bar-Ilan University in Israel.

Matthew Gage, Chief Financial Officer, age 59

Mr. Gage was appointed Interim Chief Financial Officer of Precipio, Inc. effective March 21, 2022 and promoted to Chief Financial Officer effective July 1, 2023 without any change to his compensation or stock awards. Mr. Gage previously served as Director of Financial Reporting and Analysis of Precipio, Inc., upon joining the Company in June 2017 following its acquisition of Transgenomic Inc., where he was Director of Financial Reporting and Analysis since 2014. Mr. Gage has over 30 years of experience in corporate finance, 25 years of which being with publicly traded companies. Mr. Gage holds a Bachelor of Science Degree in Business Administration from Bryant University.

Ahmed Zaki Sabet, Chief Operating Officer, age 40

Mr. Sabet has been with Precipio since co-founding the Company in 2011 and currently serves as the Chief Operating Officer. Mr. Sabet holds over 17 years of experience in laboratory management spanning all fields of reference laboratory operations primarily focusing on cancer diagnostics. Prior to Precipio, Mr. Sabet has served as a consultant with the College of American Pathologists (CAP) and assisted several diagnostic companies in setting up their specialized cancer testing operations. Mr. Sabet holds a Bachelor of Science degree in Biomedical Engineering from the New Jersey Institute of Technology.

Dr. Ayman Mohamed, Chief Technology Officer, age 41

Dr. Mohamed has been with Precipio since co-founding the Company in 2011, and currently serves as the Chief Technology Officer, as well as the laboratory's Technical Director. In this dual role, Dr. Mohamed is responsible for the entire process from conceptualization and invention of proprietary technologies, through design and development, economic cost analysis and modeling, testing and validation; and finally, the technical implementation of the technologies for clinical use in the Company's laboratories. Dr. Mohamed has been responsible for the development and introduction of ground-breaking products such as IV-Cell™ and HemeScreen. Prior to joining the Company, Dr. Mohamed served in various technical and research positions in both commercial diagnostic companies as well as academic centers such as Yale University. Dr. Mohamed holds an MD and a Masters in Human Genetics from the University of Alexandria, Egypt.

Environmental, Social, and Governance

As our business continues to grow and develop, we recognize the importance of making responsible business decisions for the benefit of all of our stakeholders, including our stockholders, customers, employees, partners, the communities in which we work and live, as well as the planet. To that end, we published our Environmental, Social, and Governance (ESG) Report in February 2023, which is available on our website, and expect to continue reporting on our progress to our various stakeholders.

As part of our commitment to responsible business practices, we integrate ESG principles into our corporate strategy. Our ESG efforts focus on corporate governance, environmental responsibility, and human capital management.

Environmental: We actively reduce waste by implementing office-wide recycling and minimizing paper usage. We continue to explore further sustainability initiatives to reduce our environmental footprint.

Social: Our workforce reflects a commitment to diversity, with a focus on gender, ethnicity, and cultural inclusion. We invest in professional development through annual performance reviews and targeted training programs. Additionally, we support community engagement through partnerships such as the Salvation Army's "Adopt-A-Family" program.

Governance: Our Board of Directors maintains independence, with three key committees—Audit, Compensation, and Nominating & Corporate Governance—ensuring oversight and accountability. Employees adhere to a robust Code of Business Conduct and Ethics, with an anonymous Ethics Hotline for reporting concerns.

Our ESG report, available on our website, details our commitments and progress. We will continue evaluating and reporting on ESG risks and improvements over time.

Climate Change

We are committed to operating our business in an environmentally sustainable manner, meaning developing and producing products in a resource efficient way while limiting our environmental impact in the most material areas of greenhouse gas emissions, energy use, waste, and water.

For more information about how climate change impacts our business, see "Risk factors – Global climate change could negatively affect our business" in Item 1A of this Annual Report.

Compliance with Environmental Laws

We believe we are in compliance with current environmental protection requirements that apply to us or our business. Costs attributable to environmental compliance are not currently material.

Intellectual Property

The Company has filed U.S. and European patent applications for its proprietary HemeScreen technology, reinforcing our commitment to innovation in diagnostic solutions. In addition to patent protection, we have also registered trademarks to safeguard our brand identity and ensure the distinctiveness of our products in the marketplace. This combination of patent and trademark applications reflects our ongoing efforts to protect and commercialize our intellectual property, strengthen our market position, and drive long-term value. We continue to invest in research and development to expand our portfolio of proprietary technologies.

Privacy Laws

We are subject to U.S. federal, state, and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. For example, at the federal level, in addition to HIPAA, failing to take appropriate steps to keep consumers' personal information secure may constitute unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission (FTC) Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business and the cost of available tools to improve security and reduce vulnerabilities

Certain U.S. state laws also govern the privacy and security of personal information. For example, California enacted the California Consumer Privacy Act, or CCPA, which, effective January 1, 2023, created new individual privacy rights for California consumers (as defined in the law) and placed increased privacy and security obligations on entities

handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. While there is currently an exception for protected health information that is subject to HIPAA, as currently written, the CCPA may impact our business activities. Further, the California Privacy Rights Act, or CPRA, took effect on January 1, 2023, and amended the CCPA by creating additional obligations with respect to processing and storing personal information. These additional obligations have included expanding consumers' rights with respect to certain categories of sensitive personal information and establishing the California Privacy Protection Agency to enforce the CCPA.

Similar laws have been passed in numerous other states. Other states have proposed new privacy laws which, if enacted, may add additional complexity, variation in requirements, restrictions and potential legal risk, require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data and could result in increased compliance costs and/or changes in business practices and policies. The existence of comprehensive privacy laws in different states in the country would make our compliance obligations more complex and costly and may increase the likelihood that we may be subject to enforcement actions or otherwise incur liability for noncompliance. There are also states that are specifically regulating health information. For example, Washington's My Health My Data Act, which became effective on March 31, 2024, regulates the collection and sharing of health information and has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. In addition, other states have proposed and/or passed legislation that regulates the privacy and/or security of certain specific types of information. For example, a small number of states have passed laws that regulate biometric data specifically.

In Europe, with respect to the collection and processing of personal data relating to the EU, European Economic Area ("EEA") and United Kingdom ("UK"), we are subject to the EU General Data Protection Regulation (EU GDPR), the UK General Data Protection Regulation (UK GDPR), as well as applicable data protection laws in effect in the Member States of the EEA and in the UK (including the UK Data Protection Act 2018) which govern the processing of personal data in connection with (i) the marketing or offering of our goods or services to individuals in the UK and EEA; (ii) the monitoring of their behavior so long as this takes place in the EEA/UK (for example, through cookies and other tracking tools), or (iii) the activities of any establishments we may set up in the UK or any EEA Member State (e.g. branches, subsidiaries or any significant sales representative presence). The UK's data protection regime is independent from but aligned to the EU's data protection regime. In this Annual Report on Form 10-K, references to "GDPR" encompasses both the EU GDPR and UK GDPR, unless specified otherwise. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requiring additional disclosures to individuals regarding data processing activities, requiring that safeguards are implemented to protect the security and confidentiality of personal data, limiting retention periods for personal data, creating mandatory data breach notification requirements in certain circumstances, and requiring that certain measures (including contractual requirements) are put in place when engaging third-party service providers. The GDPR also imposes strict rules on the transfer of personal data to countries outside of the UK and EEA that do not ensure an adequate level of protection, including the United States in certain circumstances, unless derogation exists or a valid GDPR transfer mechanism (for example, the European Commission approved Standard Contractual Clauses (SCCs) and the UK International Data Transfer Agreement or Addendum (UK IDTA) have been put in place, and transfer impact assessments conducted). Failure to comply with the requirements of the GDPR and the related national data protection laws of the EEA Member States and the UK may result in fines up to €20 million (17.5 million for the UK GDPR) or 4% of a company's global annual revenues for the preceding financial year, whichever is higher. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

Corporate History

Precipio, Inc. was incorporated in Delaware on March 6, 1997. Our principal office is located at 4 Science Park, New Haven, Connecticut 06511.

Our internet address is www.precipiodx.com. Information found on our website is not incorporated by reference into this report and should not be considered as part of this report. We make available free of charge through our website

our SEC filings, including exhibits and amendments to these reports, furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. You can review our electronically filed reports and other information that we file with the SEC on the SEC's website at http://www.sec.gov.

Item 1A. Risk Factors

The following risks and uncertainties, together with all other information in this Annual Report on Form 10-K, including our consolidated financial statements and related notes, should be considered carefully. Any of the risk factors we describe below could adversely affect our business, financial condition or results of operations, and could cause the market price of our common stock to fluctuate or decline.

Summary of Risk Factors

- There is substantial doubt about our ability to continue as a going concern.
- Our ability to expand our business may depend on access to additional capital.
- We are subject to concentrations of revenue risk and concentrations of credit risk in accounts receivable.
- We may become subject to costly litigation, which could adversely affect our business, financial condition and results of operations.
- Failure to Comply with Insider Trading Regulations and Policies Could Result in Significant Legal and Reputational Consequences.
- The commercial success of our products, including those we are developing, will depend upon the degree of market acceptance of these products among physicians, patients, health care payers and the medical community and on our ability to successfully market our products.
- If we cannot compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability.
- We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results.
- International expansion of our business could expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.
- Changes to the UK medical device regulatory framework could require additional compliance measures and affect our ability to market our products in Great Britain.
- Unfavorable U.S. or global economic conditions and conflicts could adversely affect our business, financial condition or results of operations.
- Global climate change could negatively affect our business.
- We depend upon a limited number of key personnel, and if we are not able to retain them or recruit additional qualified personnel, the execution of our strategy, management of our business and commercialization of our product candidates could be delayed or negatively impacted.
- We will need to increase the size of our organization, and we may experience difficulties in managing growth.
- We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities and retain the proper talent to execute on our sales and marketing strategy, we may not be able to generate product revenue.
- We need to ensure strong product performance and reliability to maintain and grow our business.
- We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

- Cybersecurity risks could compromise our information and expose us to liability, which may harm our ability to operate effectively and may cause our business and reputation to suffer.
- Our ability to use net operating loss carryforwards to offset future taxable income for U.S. federal tax purposes is subject to limitation and risk that could further limit our ability to utilize our net operating losses.
- The testing, manufacturing and marketing of diagnostics entails an inherent risk of product liability and personal injury claims.
- All of our diagnostic technology development and our clinical services are performed at two laboratories, and in the event either or both of these facilities were to be affected by a termination of the lease or a man-made or natural disaster, our operations could be severely impaired.
- An impairment in the carrying value of our intangible assets could negatively affect our results of operations.
- Governmental payers and health care plans have taken steps to control costs.
- Changes in payer mix could have a material adverse impact on our net sales and profitability.
- Our laboratories require ongoing CLIA certification and we cannot guarantee that our laboratories will pass all future certification inspections.
- Our products that we sell as research use only products and/or that we offer as laboratory developed tests could become subject to government regulations requiring marketing authorization, and the marketing authorization and maintenance process for such products may be expensive, time-consuming and uncertain in both timing and outcome.
- Failure to comply with HIPAA could be costly.
- Our failure to comply with any applicable government laws and regulations or otherwise respond to claims relating to improper handling, storage or disposal of hazardous chemicals that we use may adversely affect our results of operations.
- We may become subject to the Anti-Kickback Statute, Stark Law, False Claims Act, Civil Monetary Penalties Law and may be subject to analogous provisions of applicable state laws and could face substantial penalties if we fail to comply with such laws.
- The use of artificial intelligence in diagnostic or laboratory applications may subject us to additional regulatory and liability risks.
- We cannot be certain that measures taken to protect our intellectual property will be effective.
- The price of our common stock may fluctuate significantly, which could negatively affect us and holders of our common stock.
- The price of our stock may be vulnerable to manipulation.
- If we cannot continue to satisfy Nasdaq listing maintenance requirements and other rules, our securities may be delisted, which could negatively impact the price of our securities.
- Increased costs associated with corporate governance compliance may significantly impact our results of operations.
- We have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock.
- If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume could decline.
- The issuance of our common stock to creditors or litigants may cause significant dilution to our stockholders and cause the price of our common stock to fall.
- Improper timing of equity awards could result in regulatory scrutiny and reputational harm.
- Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

- We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

Risks Related to Our Business and Strategy

There is substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has issued an opinion on our consolidated financial statements included in this Annual Report on Form 10-K that states that the consolidated financial statements were prepared assuming we will continue as a going concern. Our consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America applicable for a going concern, which assume that we will realize our assets and discharge our liabilities in the ordinary course of business. We have incurred substantial operating losses and have typically used cash in our operating activities for the past few years. For the year ended December 31, 2025, the Company had an operating loss of $1.2 million and net cash provided by operating activities of $0.7 million. As of December 31, 2025, the Company had an accumulated deficit of $102.8 million and working capital of $2.3 million. Our consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that may be necessary should we be unable to continue as a going concern. We also cannot be certain that additional financing, if needed, will be available on acceptable terms, or at all, and our failure to raise capital when needed could limit our ability to continue our operations. There remains substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the date the consolidated financial statements were issued.

To date, we have experienced negative cash flow from development of our diagnostic technology, as well as from the costs associated with establishing a laboratory and building a sales force to market our products and services. We expect to incur net losses through at least the first half of 2026 as we further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will increase due to the additional costs associated with market development activities and expanding our staff to sell and support our products. Our ability to achieve or, if achieved, sustain profitability is based on numerous factors, many of which are beyond our control, including the market acceptance of our products, competitive product development and our market penetration and margins. We may never be able to generate sufficient revenue to achieve or, if achieved, sustain profitability.

Because of the numerous risks and uncertainties associated with further development and commercialization of our diagnostic technology and any future tests, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the development and commercialization of tests in the medical diagnostic industry. We may never successfully commercialize our diagnostic technology or any future tests, and our business may fail.

Our ability to expand our business may depend on access to additional capital.

As of December 31, 2025, we had cash of $2.6 million and working capital of $2.3 million. Although we have recently generated positive operating cash flow, our future liquidity will depend on our ability to sustain or improve operating performance and manage working capital. We may have to raise significant additional capital or obtain additional credit in the future to fund our operations, fund growth initiatives, respond to changes in reimbursement or regulatory requirements, pursue strategic opportunities, or address unforeseen events. The failure to raise significant capital, or obtain credit when needed, on acceptable terms, could have a material adverse effect on our business, prospects, financial condition and results of operations, and we may not be able to continue our business as currently contemplated or may be required to seek protection under United States federal bankruptcy law.

Our future capital requirements will depend on numerous factors, including revenue growth, reimbursement trends, regulatory developments, investment in commercialization activities, working capital needs, and potential strategic initiatives. While we have historically relied on equity and debt financings to fund operations, we may seek additional financing in the future. There can be no assurance that such financing will be available on favorable terms, or at all.

If we are unable to maintain positive operating performance or obtain additional capital when needed, we may be required to delay or scale back certain growth initiatives, product development efforts or strategic plans.

We have incurred losses since inception and, although recent results reflect improvement, we may incur losses in future periods. Our ability to achieve and sustain profitability depends on a number of factors, many of which are beyond our control, including market acceptance of our products, competitive dynamics, reimbursement levels, regulatory requirements and operating efficiency. There can be no assurance that we will achieve or sustain profitability in future periods.

We are subject to concentrations of revenue risk and concentrations of credit risk in accounts receivable.

We have had several customers who, from time to time, have individually represented 10% or more of our total revenue, or whose accounts receivable balances individually represented 10% or more of our total accounts receivable.

For the years ended December 31, 2025 and 2024, one customer individually represented 26% and 17% of our total revenue, respectively. We expect to maintain ongoing relationships with our customers, however, the loss of, or significant decrease in demand from, any of our top customers could have a material adverse effect on our business, results of operations and financial condition.

At December 31, 2025, we had three customers who each individually represented more than 10% of our total accounts receivable. Collectively they accounted for approximately 56% of our total accounts receivable. At December 31, 2024, one customer accounted for approximately 29% of our total accounts receivable. The business risks associated with this concentration, including increased credit risks for these and other customers and the possibility of related credit loss write-offs, could negatively affect our margins and profits. Additionally, the loss of any of our top customers, whether through competition or consolidation, or a disruption in sales to such a customer, could result in a decrease of the Company's future sales, earnings and cash flows. Generally, we do not require collateral or other securities to support our accounts receivable and while we are directly affected by the financial condition of our customers, management does not believe significant credit risks exist at December 31, 2025.

We may become subject to costly litigation, which could adversely affect our business, financial condition and results of operations.

Due to the nature of our business and our history of insufficient capital resources to pay our obligations on a timely basis, we may be subject to a variety of regulatory investigations, claims, lawsuits and other proceedings in the ordinary course of our business. The results of these legal proceedings cannot be predicted with certainty due to the uncertainty inherent in litigation, including the effects of discovery of new evidence or advancement of new legal theories, the difficulty of predicting decisions of judges and juries and the possibility that decisions may be reversed on appeal. Such litigation has been, and in the future, could be, costly, time-consuming and distracting to management, result in a diversion of resources and could materially adversely affect our business, financial condition and operating results.

In addition, we may settle some litigation through the issuance of equity securities which may result in significant dilution to our stockholders.

For more information related to this risk factor, see Legal Proceedings under Item 3 in this Annual Report.

Failure to Comply with Insider Trading Regulations and Policies Could Result in Significant Legal and Reputational Consequences.

Precipio, Inc. is subject to federal and state securities laws, including regulations prohibiting insider trading. Any failure by our directors, officers, employees, or affiliates to comply with these laws and our internal policies could lead to civil and criminal penalties, regulatory scrutiny, and reputational harm that could negatively impact our business, financial condition, and stockholder value. To mitigate these risks, the Company has implemented a comprehensive Insider Trading Policy, which: prohibits trading in the Company's securities while in possession of material nonpublic information; restricts trading by directors, executive officers, and designated employees during blackout periods that typically

commence 15 days before the end of each fiscal quarter and continue until two full trading days after earnings are publicly disclosed; requires pre-clearance of trades for directors, officers, and certain employees to prevent inadvertent violations; bans hedging, pledging, short sales, and speculative transactions involving the Company's stock; and establishes procedures for Rule 10b5-1 trading plans to allow compliant trading activity.

Despite these safeguards, there can be no assurance that insider trading violations will not occur. Any breach of these laws or our policy—whether intentional or inadvertent—could lead to regulatory investigations, shareholder litigation, and significant financial and reputational damage to the Company and the individuals involved.

For additional details, refer to our Insider Trading Policy, which is filed as Exhibit 19.1 to this Form 10-K.

The information required by Item 408(a) regarding insider trading plans is incorporated by reference to the Company's definitive proxy statement to be filed within 120 days of our fiscal year-end.

The commercial success of our diagnostic products, including those we are developing, will depend upon the degree of market acceptance of these products among physicians, patients, health care payers and the medical community and on our ability to successfully market our products.

Our products may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits for us. Our ability to achieve commercial market acceptance for our existing and future products will depend on several factors, including:

- our ability to convince the medical community of the clinical utility of our products and their potential advantages over existing diagnostics technology;
- the willingness of physicians and patients to utilize our products; and
- the agreement by commercial third-party payers and government payers to reimburse our products, the scope and amount of which will affect patients' willingness or ability to pay for our products and will likely heavily influence physicians' decisions to recommend our products.

In addition, physicians may rely on guidelines issued by industry groups, such as the NCCN, medical societies, such as the College of American Pathologists ("CAP"), or other key oncology-related organizations before utilizing any diagnostic test.

We believe that publications of scientific and medical results in peer-reviewed journals and presentations at leading conferences are critical to the broad adoption of our products. Publication in leading medical journals is subject to a peer-review process, and peer reviewers may not consider the results of studies involving our products sufficiently novel or worthy of publication. The failure to be listed in physician guidelines or to be published in peer-reviewed journals could limit the adoption of our products. Failure to achieve widespread market acceptance of our products would materially harm our business, financial condition, and results of operations.

If we cannot compete successfully with our competitors, including new entrants in the market, we may be unable to increase or sustain our revenue or achieve and sustain profitability.

The medical diagnostic industry is intensely competitive and characterized by rapid technological progress. We face significant competition from competitors ranging in size from diversified global companies with significant research and development resources to small, specialized firms whose narrower product lines may allow them to be more effective in deploying related PCR technology in the genetic diagnostic industry. Our closest competitors fall largely into three groups, the first consisting of companies that specialize in oncology and offer directly competing services to our diagnostic services, the second offering their services to oncologists and pathology departments within hospitals, and the third consisting of large commercial companies that offer a wide variety of laboratory tests that range from simple chemistry tests to complex genetic testing. The technologies associated with the molecular diagnostics industry are evolving rapidly and there is intense competition within such industry. Certain molecular diagnostics companies have established technologies that may be competitive to our diagnostic product candidates and any future tests that we develop. Some of these tests may use different approaches or means to obtain diagnostic results, which could be more effective or

less expensive than our tests for similar indications. Moreover, these and other future competitors have or may have considerably greater resources than we do in terms of technology, sales, marketing, commercialization and capital resources. These competitors may have substantial advantages over us in terms of research and development expertise, experience in clinical studies, experience in regulatory issues, brand name exposure and expertise in sales and marketing as well as in operating central laboratory services. Many of these organizations have financial, marketing and human resources greater than ours; therefore, there can be no assurance that we can successfully compete with present or potential competitors or that such competition will not have a materially adverse effect on our business, financial position or results of operations.

We believe that many of our competitors spend significantly more on research and development-related activities than we do. Our competitors may discover new diagnostic tools or develop existing technologies to compete with our diagnostic technology. Our commercial opportunities will be reduced or eliminated if these competing products are more effective, are more convenient or are less expensive than our product candidates.

We may not be able to develop new products or enhance the capabilities of our systems to keep pace with rapidly changing technology and customer requirements, which could have a material adverse effect on our business and operating results.

Our success depends on our ability to develop new products and applications for our diagnostic technology in existing and new markets, while improving the performance and cost-effectiveness of our systems. New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future products and systems. Existing or future markets for our products, as well as potential markets for our diagnostic product candidates, are characterized by rapid technological change and innovation. It is critical to our success that we anticipate changes in technology and customer requirements and successfully introduce new, enhanced and competitive technologies to meet our customers' and prospective customers' needs on a timely and cost-effective basis. At the same time, however, we must carefully manage the introduction of new products. If customers believe that such products will offer enhanced features or be sold for a more attractive price, they may delay purchases until such products are available. We may also have excess or obsolete inventory of older products as we transition to new products and our experience in managing product transitions is very limited. If we do not successfully innovate and introduce new technology into our product lines or effectively manage the transitions to new product offerings, our revenues and results of operations will be adversely impacted.

Competitors may respond more quickly and effectively than we do to new or changing opportunities, technologies, standards or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies.

International expansion of our business could expose us to business, regulatory, political, operational, financial and economic risks associated with doing business outside of the United States.

When cleared, authorized or approved, we and our collaborators may market, sell, and distribute our products and services outside of the United States, and our business would be subject to risks associated with doing business outside of the United States, including an increase in our expenses and diversion of our management's attention from the development of future products and services. Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including:

- multiple, conflicting and changing laws and regulations such as privacy, security and data use regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, anticorruption laws, regulatory requirements, reimbursement or payer regimes and other governmental;
- approvals, permits and licenses;
- failure by us, our collaborators or our distributors to obtain regulatory clearance, authorization or approval for the use of our products and services in various countries;
- additional potentially relevant third-party patent rights;

- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property rights throughout the world;
- difficulties in staffing and managing foreign operations, including repatriating foreign earned profits;
- complexities associated with managing multiple payer reimbursement regimes, government payers or patient self-pay systems;
- difficulties in negotiating favorable reimbursement negotiations with governmental authorities;
- logistics and regulations associated with shipping samples, including infrastructure conditions and transportation delays;
- limits in our ability to penetrate international markets if we are not able to conduct our clinical diagnostic services locally;
- financial risks, such as longer payment cycles, difficulty collecting accounts receivable, the impact of local and regional financial crises on demand and payment for our products and services and exposure to foreign currency exchange rate fluctuations;
- international regulations and license requirements that may restrict foreign investment in and operation of the internet, IT infrastructure, data centers and other sectors, and international transfers of data;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, and outbreak of disease;
- boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the Foreign Corrupt Practices Act of 1977, or FCPA, its books and records provisions, or its anti-bribery provisions or laws similar to the FCPA in other jurisdictions in which we may in the future operate, such as the United Kingdom's Bribery Act of 2010 and anti-bribery requirements of member states in the EU.

Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

The sales of our products in the EU and the UK are regulated through a process that either requires self-certification or certification by a notified body in order to affix a CE mark. Such processes are uncertain, particularly in light of changes to the regulatory framework in the EU and UK. There may be a risk of delay in placing such products on the market and, once on the market, a risk of review and challenges to certain certified statuses.

On May 12, 2022, we received CE-IVD marking for our HemeScreen® reagents in the EU in accordance with the requirements of the EU In Vitro Diagnostic Directive ("IVDD") (Directive 98/79/EC). The EU In Vitro Diagnostic Regulation ("IVDR") (Regulation (EU) 2017/746) came into effect on May 26, 2022 and replaced the IVDD.

Because our CE marking was obtained under the IVDD by self-declaration without notified body involvement, and because our HemeScreen® products require notified body involvement in the conformity assessment procedure under the IVDR, we qualify for the transitional provisions under Article 110(3) of the IVDR, as introduced for self-declared devices by Regulation (EU) 2022/112 and further amended by Regulation (EU) 2024/1860. These provisions allow devices for which a declaration of conformity was drawn up prior to May 26, 2022 under the IVDD and which require notified body involvement in the conformity assessment procedure under the IVDR to continue to be placed on the EU and Northern Ireland markets until December 31, 2028, assuming a Class C risk classification under the IVDR, provided that certain conditions are met on a continuing basis. These conditions include: continued compliance with the IVDD; no significant changes to the design or intended purpose of the device; maintenance of a quality management system in accordance with Article 10(8) of the IVDR, which was required to be in place by May 26, 2025; and compliance with IVDR requirements for post-market surveillance, vigilance, and registration of economic operators and devices.

To maintain eligibility for this transitional period beyond May 26, 2026, we must submit a formal application for conformity assessment to an IVDR-designated notified body by that date, and must conclude a written agreement with a notified body by September 26, 2026. Failure to meet either of these deadlines would result in the transitional protection lapsing on the relevant date, regardless of whether the transition period would otherwise have continued until December 31, 2028. These are firm regulatory deadlines and we are actively working to meet them.

Our HemeScreen® products will in any event require full recertification under the IVDR to remain on the EU and Northern Ireland markets beyond the applicable transition deadline. This will require evaluation by an EU-designated notified body to confirm whether our products meet the general safety and performance requirements of the IVDR. There is no guarantee that a notified body will determine our products comply with such requirements. The number of notified bodies currently designated under the IVDR remains limited, and there is currently a significant shortage of notified body capacity to assess the volume of devices requiring certification under the IVDR. We cannot assure that our ability to market HemeScreen® reagents in the EU and Northern Ireland will not be interrupted in the future. Any such interruption could negatively impact our business and operating results.

Changes to the UK regulations may require additional review of our devices and there is a risk our devices may not be compliant with any revised UK regulations.

Our products are subject to evolving regulatory requirements in Great Britain, Northern Ireland and the EU. In Great Britain, medical devices are subject to MHRA registration requirements, and manufacturers established outside the United Kingdom must appoint a UK Responsible Person to satisfy certain regulatory obligations. In addition, the UK government is continuing to implement changes to its medical devices regime, including revised post market surveillance requirements and potential future changes to pre market authorization requirements and reliance mechanisms.

In Northern Ireland, EU medical device rules continue to apply under the Windsor Framework. In addition, our ability to continue placing certain products on the EU and Northern Ireland markets during the IVDR transition period depends on satisfaction of specific legal and procedural conditions. For devices qualifying under the IVDR transitional provisions, including, as applicable, devices for which a declaration of conformity was drawn up prior to May 26, 2022 under the IVDD and that require Notified Body involvement under the IVDR, continued market access is contingent on ongoing compliance with applicable post market surveillance, vigilance, and registration requirements, timely submission of a formal application to an IVDR designated notified body by May 26, 2026, and execution of a written agreement with such notified body by September 26, 2026. If these conditions are not met, the applicable transitional protection would cease.

Compliance with these evolving requirements may require significant additional operational, quality, clinical, technical, and regulatory resources. Any delay in obtaining, maintaining, or renewing required registrations, certifications, notified body arrangements, or other regulatory authorizations, any adverse change in applicable reliance mechanisms or transitional provisions, or any failure to comply with applicable post market obligations could delay or prevent our ability to market our products in Great Britain, Northern Ireland or the EU, disrupt commercialization, increase costs, and materially adversely affect our business, financial condition, and results of operations

Unfavorable U.S. or global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and financial markets. A severe or prolonged economic downturn or increase in inflation rates, or increased U.S. trade tariffs and trade disputes with other countries, could result in a variety of risks to our business, including weakened demand for our products and services and our ability to raise additional capital when needed on favorable terms, if at all. A weak declining or inflationary economy, or increased U.S. trade tariffs, could also strain our collaborators and suppliers, possibly resulting in supply disruption, or cause delays in their payments to us.

The continuing worldwide macroeconomic and geopolitical uncertainty, as well as existing tariffs and trade wars, may adversely affect our business and prospects, both domestically and internationally. Continued concerns about the systemic impact of potential recession and geopolitical issues, including wars and terrorism, have contributed to increased market volatility and uncertainty for economic growth in the world. Our business and results of operations may be adversely impacted by changes in macroeconomic conditions, including inflation, bank failures, rising interest rates, and availability of capital markets. Economic uncertainty, an increase in unemployment rates, as well as an increase in health insurance premiums, co-payments and deductibles may result in cost-conscious consumers making fewer trips to their physicians and specialists, which in turn would adversely affect demand for our products and procedures. Furthermore,

governments and other third-party payors around the world facing tightening budgets could move to further reduce the reimbursement rates or the scope of coverage offered, which could adversely affect sales of our products.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect the Company's current and projected business operations and its financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the Company, the financial institutions with which we have or may enter into credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions with which we have or may enter into financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to other working capital sources and/or delays, inability or reductions in our ability to enter into new credit facilities or access other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in any credit agreements or credit arrangements; or
- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements.

In addition, investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws and otherwise have a material adverse impact on our business.

Failure to obtain and retain new customers, the loss of existing customers or material contracts, or a reduction in services or tests ordered or specimens submitted by existing customers, or the inability to retain existing and/or create new relationships with health systems could impact our ability to successfully grow its business.

To maintain and grow our business, we need to obtain and retain new customers and business partners. In addition, a reduction in tests ordered or specimens submitted by existing customers, a decrease in demand for our services from existing customers, or the loss of existing contracts, without offsetting growth in its customer base, could impact our ability to successfully grow its business and could have a material adverse effect on our revenues and profitability. Our failure to successfully compete with our competitors could result in the loss of existing customers, an inability to gain new customers, and reduced or stagnant growth of our business.

Global climate change could negatively affect our business.

Increased public awareness and concern regarding global climate change will likely result in more regional and/or national requirements to reduce or mitigate the effects of greenhouse gas emissions. In addition, our stockholders and customers also expect us to reduce our greenhouse gas emissions. There continues to be a lack of consistent climate legislation, which creates economic and regulatory uncertainty. Any future regulations aimed at mitigating climate change may negatively impact the prices of raw materials and energy as well as the demand for certain of our customer's products which could in turn impact demand for our products and impact our results of operations. The costs of compliance and any changes to our operations mandated by new or amended laws, may be significant. We may also face unexpected delays in obtaining permits and approvals required by such laws in connection with our manufacturing facilities, which would hinder our operation of these facilities. Furthermore, any violations of these laws may result in substantial fines and penalties, remediation costs, third party damages, or a suspension or cessation of our operations.

We also face physical and transition risks from climate change. The manifestations of climate change, such as extreme weather conditions or more frequent extreme weather events, including wildfires, flooding, water stress and extreme heat, could disrupt our operations, damage our facilities, disrupt our supply chain, impact the availability and cost of materials needed for manufacturing or increase insurance and other operating costs. As a result, severe weather events or natural disasters could result in a prolonged disruption to our operations or operations of our customers or suppliers, which could have a material adverse effect on our operating results, cash flows or financial condition.

We may be impacted by economic and supply disruptions associated with events beyond our control, such as war, including the current conflicts between Russia and Ukraine and between Israel and Hamas, acts of terror, political unrest, public health concerns, labor disputes or natural disasters.

The operations of our suppliers and customers, could be disrupted by events beyond our control, such as war, acts of terror, political unrest, public health concerns, labor disputes, or severe weather conditions or natural disasters. In addition, our operations could be adversely affected as a result of other disruptions at our facilities due to fire, electrical blackouts, power losses, telecommunications failures or other similar effects. Any such disruption could cause delays in the production and distribution of our products and the loss of sales and customers. We may not be insured against all such potential losses and, if insured, the insurance proceeds that we receive may not adequately compensate us for all of our losses. Such losses could lead to an increase in the deductibles or cost of insurance for those facilities, a reduction of insurance available to us, or the unavailability of insurance on terms that are acceptable to us.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

We operate mainly in the United States but may sell our products in other countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. Similarly, changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, during the prior Trump

administration, increased tariffs were implemented on goods imported into the U.S., particularly from China, Canada, and Mexico.

The current U.S. administration has threatened to continue to broadly impose tariffs, which could lead to corresponding punitive actions by the countries with which the U.S. trades. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. Political tensions as a result of trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations. We will continue to monitor global capital markets and assessing the potential impact of these factors on our business.

Additionally, severe or prolonged economic downturn or additional global financial crises could result in a variety of risks to our business, including weakened demand for any product candidates we develop or our ability to raise additional capital when needed on acceptable terms, if at all. For example, on October 1, 2025, the U.S. federal government entered a shutdown suspending services deemed non-essential as a result of the failure by Congress to enact regular appropriations for the 2026 fiscal year. If the shutdown continues for a prolonged period of time, it could result in increased uncertainty and volatility in the global economy and financial markets which could have a material adverse effect on our business. Weak economic conditions or significant uncertainty regarding the stability of financial markets related to stock market volatility, inflation, recession, changes in tariffs or other trade restrictions, trade agreements, trade wars or governmental fiscal, monetary and tax policies, among others, could adversely impact our business, financial condition and operating results.

We depend upon a limited number of key personnel, and if we are not able to retain them or recruit additional qualified personnel, the execution of our strategy, management of our business and commercialization of our product candidates could be delayed or negatively impacted.

Our success is largely dependent upon the continued contributions of our officers and employees. Our success also depends in part on our ability to attract and retain highly qualified scientific, commercial and administrative personnel. In order to pursue our test development and commercialization strategies, we will need to attract and hire additional personnel with specialized experience in a number of disciplines, including assay development, laboratory and clinical operations, sales and marketing, billing and reimbursement. There is intense competition for personnel in the fields in which we operate. If we are unable to attract new employees and retain existing employees, the development and commercialization of our product candidates and any future tests could be delayed or negatively impacted. If any of them becomes unable or unwilling to continue in their respective positions, and we are unable to find suitable replacements, our business and financial results could be materially negatively affected. If we are unable to hire and retain employees capable of performing at a high-level, or if mitigation measures we may take to respond to a decrease in labor availability, such as overtime and third-party outsourcing, have unintended negative effects, our business could be adversely affected. A sustained labor shortage, lack of skilled labor, increased turnover or labor cost inflation as a result of general macroeconomic factors could lead to increased costs, such as increased overtime to meet demand and increased wage rates to attract and retain employees, which could negatively affect our ability to efficiently operate our manufacturing and distribution facilities and overall business and have other adverse effects on our results of operations and financial condition.

We will need to increase the size of our organization, and we may experience difficulties in managing growth.

We are a small company with 61 full-time employees and 10 part-time employees as of March 9, 2026. Future growth will impose significant added responsibilities on members of management, including the need to identify, attract, retain, motivate and integrate highly skilled personnel. We may increase the number of employees in the future depending on the progress of our development of diagnostic technology. Our future financial performance and our ability to

commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to:

- integrate additional management, administrative, manufacturing and regulatory personnel;
- maintain sufficient administrative, accounting and management information systems and controls; and
- hire and train additional qualified personnel.

Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our current or future product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our current or future diagnostic products and product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

We may not be able to accomplish these tasks, and our failure to accomplish any of them could harm our financial results.

We currently have limited experience in marketing products. If we are unable to establish marketing and sales capabilities and retain the proper talent to execute on our sales and marketing strategy, we may not be able to generate product revenue.

We have limited experience in marketing our products and services. We intend to continue to develop our in-house marketing capabilities and sales force, which will require significant capital expenditures, management resources and time. We will have to compete with other companies to recruit, hire, train and retain marketing and sales personnel.

If we are unable to further grow our internal sales, marketing and distribution capabilities, we may pursue collaborative arrangements regarding the sales and marketing of our product candidates or future products. However, we may not be able to establish or maintain such collaborative arrangements, or if we are able to do so, they may not have effective sales forces. Any revenue we receive will depend upon the efforts of such third parties, which may not be successful. We may have little or no control over the marketing and sales efforts of such third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We also face competition in our search for third parties to assist us with the sales and marketing efforts of our product candidates.

We need to ensure strong product performance and reliability to maintain and grow our business.

We need to maintain and continuously improve the performance and reliability of our diagnostic tests to achieve our profitability objectives. Poor product performance and reliability could lead to customer dissatisfaction, adversely affect our reputation and revenues, and increase our service and distribution costs and working capital requirements. Our diagnostic tests may contain errors or defects, and while we have made efforts to test them extensively, we cannot assure that our current diagnostic tests, or those developed in the future, will not have performance problems. Performance issues with our diagnostic tests will increase our costs in the near-term and accordingly adversely affect our business, financial condition and results of operations.

We are subject to stringent and changing laws, regulations and standards, and contractual obligations relating to privacy, data protection, and data security. The actual or perceived failure to comply with such obligations could lead to government enforcement actions (which could include civil or criminal penalties), fines and sanctions, private litigation and/or adverse publicity and could negatively affect our operating results and business.

We are subject to U.S. federal, state, and foreign data protection laws and regulations, such as laws and regulations that address privacy and data security. For additional details on our US and EU/UK GDPR compliance obligations, see the "*Privacy Laws*" sub-section in the Business section of this Annual Report on Form 10-K.

In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. For example, at the federal level, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its respective implementing regulations, imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. In addition, certain state laws govern privacy and security of personal information, including health information specifically. These various privacy and security laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products. State laws are changing rapidly and there are discussions in the U.S. Congress of new comprehensive federal data privacy laws to which we could become subject to, if enacted.

In Europe, with respect to the collection and processing of personal data from the UK and EEA, we are subject to stringent data protection obligations under the GDPR and other applicable data protection laws which require significant compliance effort and will increase our costs. These obligations include strict rules on transferring personal data to countries outside of the UK and EEA that do not ensure an adequate level of protection, including in certain circumstances, the U.S. Any inability to transfer personal data from the UK or EEA to the U.S. or to our service providers outside these regions may impede our operations and may adversely affect our business and financial position. Failure to comply with GDPR obligations could expose us to substantial fines, regulatory scrutiny, private legal claims, and reputational harm. Following the UK's exit from the EU (Brexit) there will be increasing scope for divergence in application, interpretation and enforcement of the data protection laws between these jurisdictions which present additional risk. The UK has introduced the Data (Use and Access) Bill into its legislative process, which, if enacted, may alter the UK's data protection regime and potentially threaten its adequacy decision from the European Commission—a development that could complicate cross-border data flows and increase compliance burdens. The uncertainty surrounding future UK data protection laws and their interaction with those of the EEA may add legal risk, operational complexity, and additional cost to our privacy and security compliance programs, potentially requiring us to implement different compliance measures for the UK and EEA.

With respect to the collection and processing of personal data in the UK and EEA, we are subject to stringent data protection obligations under the GDPR and other applicable laws. These include strict rules on transferring personal data outside these jurisdictions to countries, such as the United States, that may not be deemed to provide an adequate level of protection. Any inability to lawfully transfer personal data from the UK or EEA to the United States or our service providers outside these regions could disrupt our operations, increase compliance costs, and adversely affect our business and financial position. Failure to comply with GDPR obligations could expose us to substantial fines, regulatory scrutiny, private legal claims, and reputational harm. Following Brexit, diverging legal frameworks between the UK and the EU present additional risks. The UK has introduced the Data (Use and Access) Bill, which, if enacted, may alter the UK's data protection regime and potentially threaten its adequacy decision from the European Commission—a development that could complicate cross-border data flows and increase compliance burdens. The uncertainty surrounding future UK data protection laws and their interaction with the EEA framework may add legal risk, operational complexity, and additional costs to our privacy and security compliance programs, potentially requiring different compliance measures for the UK and EEA.

All of these evolving compliance and operational requirements impose significant costs, such as costs related to organizational changes, implementing additional protection technologies, training employees and engaging consultants and legal advisors, which are likely to increase over time. In addition, such requirements may require us to modify our data processing practices and policies, utilize management's time and/or divert resources from other initiatives and projects. Any failure or perceived failure by us to comply with any applicable federal, state or foreign laws and regulations relating to data privacy and security could result in damage to our reputation, as well as proceedings or litigation by governmental agencies or other third parties, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, injunctions, penalties or judgments. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our use of new and evolving technologies, such as artificial intelligence, may present risks and challenges that can impact our business, including by posing cybersecurity and other risks to our confidential and/or proprietary information, including personal information, and as a result we may be exposed to reputational harm and liability.

We may use and integrate artificial intelligence into our business processes. Use of this technology presents risks and challenges that could affect our business. If we enable or use solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability.

The rapid evolution of artificial intelligence will require the application of significant resources to design, develop, test and maintain such systems to help ensure that artificial intelligence is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. Our vendors may in turn incorporate artificial intelligence tools into their offerings, and the providers of these artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Cybersecurity risks could compromise our information and expose us to liability, which may harm our ability to operate effectively and may cause our business and reputation to suffer.

Cybersecurity refers to the combination of technologies, processes and procedures established to protect information technology systems and data from unauthorized access, misuse, attack, or damage. We rely on our information systems to provide security for processing, transmission and storage of confidential information and personal information about our patients, customers and personnel and rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies, data breaches or cybersecurity incidents. We also rely on our employees and consultants to safeguard their security credentials and follow our policies and procedures regarding use and access of computers and other devices that may contain our sensitive information. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyberattacks and any such attacks could result in losses described above, as well as disputes with physicians, patients and our partners, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third-parties to prevent or mitigate cybersecurity incidents, data breaches or improper access to, misuse of, or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such cybersecurity incidents, data breaches or other adverse events, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business.

Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, intentional or inadvertent wrongful conduct by insider employees or vendors, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful ransomware, malware, denial-of-service attacks, social engineering fraud (including phishing attacks) or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. The regulatory environment surrounding information security and privacy is increasingly demanding, with the frequent imposition of new and changing requirements. Compliance with changes in privacy and information security laws and with rapidly evolving industry standards may result in our incurring significant expense due to increased investment in technology and the development of new operational processes.

We maintain our information technology systems with safeguards designed to protect against cyberattacks including passive intrusion protection, firewalls and virus detection software. However, these safeguards do not ensure that a significant cyberattack could not occur. Although we have taken steps to protect the security of our information

systems and the data maintained in those systems, it is possible that our safety and security measures will not prevent the systems' improper functioning or damage or the improper access or disclosure of personally identifiable information such as in the event of cyberattacks.

Security incidents, including physical or electronic break-ins, computer viruses, attacks by hackers and similar cybersecurity incidents, and data breaches, can create system disruptions or shutdowns or the unauthorized disclosure of, access to, or misuse of confidential information. If personal information or protected health information is improperly accessed, tampered with, misused or disclosed as a result of a cybersecurity incident or data breach, we may incur significant costs to notify impacted stakeholders (including affected individuals, investors and regulators) and mitigate potential harm to affected individuals, and we may be subject to sanctions and civil or criminal penalties if we are found to be in violation of the privacy or security rules under HIPAA or other similar federal or state laws protecting confidential personal information. In addition, a cybersecurity incident, data breach of or other adverse event affecting our information systems could damage our reputation, subject us to liability claims or regulatory penalties for compromised personal information and could have a material adverse effect on our business, financial condition and results of operations. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our privacy and data security obligations. Further, although we maintain cyber liability insurance, this insurance may not provide adequate coverage against potential liabilities related to any experienced cybersecurity incident or data breach. Cybersecurity incidents could result in operational disruption, regulatory investigations, required notifications and remediation, litigation, fines, reputational harm, or financial costs that could materially adversely affect our business, financial condition, results of operations, or prospects.

We recently reported that we experienced a cybersecurity incident involving unauthorized access to an employee's cloud-based storage account that may have resulted in access to certain personally identifiable information and protected health information of individuals, which we publicly disclosed in January 2026. In response, we initiated an investigation, engaged third-party cybersecurity specialists, secured the impacted account, notified law enforcement authorities, and are conducting a review of the potentially affected data. The event remains under investigation, and we continue to assess the scope and potential impacts of the incident, including any regulatory, legal, or financial implications. While we have taken mitigation steps, there can be no assurance that similar incidents will not occur in the future or that additional impacts from this or related incidents will not be identified.

Changes in tax law could adversely affect our business and financial condition.

U.S. federal, state and local and non-U.S. tax laws are subject to change through legislative, administrative and judicial actions. Changes to tax laws or regulations, or changes in interpretations of existing laws (which changes may have retroactive effect), could increase our tax liability, reduce available tax benefits, or otherwise adversely affect our financial condition and results of operations.

For example, the One Big Beautiful Bill Act ("OBBBA"), signed into law on July 4, 2025, made significant changes to U.S. federal tax law, including modifications to the treatment of research and development expenditures under Section 174 of the Internal Revenue Code. Under prior law, research and development expenses were required to be capitalized and amortized. The OBBBA permits certain taxpayers, beginning in taxable years after December 31, 2024, to elect to immediately deduct qualifying U.S.-based research and development expenditures, while also providing mechanisms to accelerate deductions of previously capitalized amounts. The application and interpretation of these provisions may affect our cash flow and effective tax rate.

In addition, changes in tax policy, including the potential expiration or modification of provisions enacted under prior tax reform legislation, the imposition of new income or non-income taxes (such as payroll, sales, use, value-added, digital or other taxes), or changes in international tax rules, could increase our compliance costs or overall tax burden. As we expand our business activities, including internationally, our exposure to tax law changes may increase. Any such changes could materially adversely affect our financial condition and results of operations.

Our ability to use net operating loss carryforwards to offset future taxable income for U.S. federal tax purposes is subject to limitation and risk that could further limit our ability to utilize our net operating losses.

As of December 31, 2025, we had approximately $81 million of federal net operating losses, ("NOLs"). Approximately $28 million of the federal NOLs will expire at various dates beginning in 2036 through 2037 if not utilized, while the remaining amount will have an indefinite life. As of December 31, 2025, we had approximately $2.7 million of state NOLs. The state NOLs expire on various dates. Under current law, federal NOLs generated in taxable years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such federal NOLs may be limited to 80% of our taxable income annually for tax years beginning after December 31, 2020. NOLs generated prior to December 31, 2017, however, have a 20-year carryforward period, but are not subject to the 80% limitation.

Under U.S. federal income tax law, a corporation's ability to utilize its NOLs to offset future taxable income may be significantly limited if it experiences an "ownership change" as defined in Section 382 of the Internal Revenue Code of 1986, as amended. In general, an ownership change will occur if there is a cumulative change in a corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period, including changes in ownership arising from new issuances of stock. A corporation that experiences an ownership change will generally be subject to an annual limitation on the use of its pre-ownership change NOLs equal to the value of the corporation immediately before the ownership change, multiplied by the long-term tax-exempt rate (subject to certain adjustments). Our ability to use NOLs to reduce future taxable income and liabilities may be subject to annual limitations as a result of ownership changes that may occur in the future. Furthermore, our ability to utilize NOLs of companies that we have acquired or may acquire in the future may be subject to similar limitations. There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs by federal or state taxing authorities or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to reduce future income tax liabilities. For these reasons, we may not be able to utilize a material portion of the NOLs, even if we attain profitability, which could potentially result in increased future tax liability to us and could adversely affect our operating results and financial condition.

The testing, manufacturing and marketing of diagnostics entails an inherent risk of product liability and personal injury claims.

To date, we have experienced no product liability or personal injury claims, but any such claims arising in the future could have a material adverse effect on our business, financial condition and results of operations. Potential product liability or personal injury claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of our policy or limited by other claims under our umbrella insurance policy. Additionally, our existing

insurance may not be renewed by us at a cost and level of coverage comparable to that presently in effect, if at all. In the event that we are held liable for a claim against which we are not insured or for damages exceeding the limits of our insurance coverage, such claim could have a material adverse effect on our cash flow and thus potentially a materially adverse effect on our business, financial condition and results of operations.

All of our diagnostic technology development and our clinical services are performed at two laboratories, and in the event either or both of these facilities were to be affected by a termination of the lease or a man-made or natural disaster, our operations could be severely impaired.

Our laboratory and research and development facilities located in New Haven, Connecticut and Omaha, Nebraska house development teams that collaborate on new products and services. The Company's laboratories in both New Haven, Connecticut and Omaha, Nebraska are CLIA compliant and provide essential blood cancer diagnostics to office-based oncologists in many states nationwide. Despite precautions taken by us, any future natural or man-made disaster at these laboratories, such as a fire, earthquake or terrorist activity, could cause substantial delays in our operations, damage or destroy our equipment and testing samples or cause us to incur additional expenses.

In addition, we are leasing the facilities where our laboratories operate. We are currently in compliance with all and any lease obligations, but should the leases terminate for any reason, or if at any time either of the laboratories is moved due to conditions outside our control, it could cause substantial delay in our diagnostics operations, damage or destroy our equipment and biological samples or cause us to incur additional expenses. In the event of an extended shutdown of either laboratory, we may be unable to perform our services in a timely manner or at all and therefore would be unable to operate in a commercially competitive manner. This could harm our operating results and financial condition.

Further, if we have to use a substitute laboratory in the event our facilities are shut down, we could only use another facility with established state licensure and accreditation under CLIA. We may not be able to find another CLIA-certified facility and comply with applicable procedures, or find any such laboratory that would be willing to perform the tests for us on commercially reasonable terms. Additionally, any new laboratory opened by us would be subject to recertification under CLIA and licensure by various states, which would take a significant amount of time and result in delays in our ability to continue our operations.

An impairment in the carrying value of our intangible assets could negatively affect our results of operations.

A significant portion of our assets are intangible assets which are reviewed at least annually for impairment. If we do not realize our business plan, our intangible assets may become impaired resulting in an impairment loss in our results of operations.

Reimbursement and Regulatory Risks Relating to Our Business

Governmental payers and health care plans have taken steps to control costs, which could negatively affect our business.

Third-party payers, including private insurers and governmental entities, have implemented and will continue to implement measures to control the cost, utilization, and delivery of healthcare services, including products and services we offer. These changes have adversely affected and may in the future adversely affect coverage for our services. We also believe that healthcare professionals may not use our services if third-party payers do not provide adequate coverage and reimbursement for them. These changes in federal, state, local, and third-party payer regulations or policies may decrease our revenues and adversely affect our results of operations and our financial condition. Occasionally, legislative pauses and changes impact our products that are reimbursed under the Medicare Physician Fee Schedule ("MPFS"), or the Clinical Laboratory Fee Schedule ("CLFS"). Further, CMS and state Medicaid agencies may adopt regulations and policies that change, limit or exclude coverage for our products and services.

We expect that efforts to contain costs will continue and that coverage and reimbursement for our products and services may be impacted. These efforts, including changes in law or regulations that may occur in the future, may each

individually or collectively have a material adverse impact on our business, results of operations, financial condition, and prospects.

Changes in payer mix could have a material adverse impact on our net sales and profitability.

Testing services are billed to physicians, patients, government payers such as Medicare, and insurance companies. Tests may be billed to different payers depending on a particular patient's medical insurance coverage. Government payers have increased their efforts to control the cost, utilization and delivery of health care services as well as reimbursement for laboratory testing services. Further reductions of reimbursement for Medicare and Medicaid services or changes in policy regarding coverage of tests or other requirements for payment, such as prior authorization or a physician or qualified practitioner's signature on test requisitions, may be implemented from time to time. Reimbursement for the laboratory services component of our business is also subject to statutory and regulatory reduction. Reductions in the reimbursement rates and changes in payment policies of other third party payers may occur as well. Such changes in the past have resulted in reduced payments as well as added costs and have decreased test utilization for the clinical laboratory industry by adding more complex new regulatory and administrative requirements. As a result, increases in the percentage of services billed to government payers could have an adverse impact on our net sales.

Our laboratories require ongoing CLIA certification, and we cannot guarantee that our laboratories will pass all future certification inspections.

CLIA extended federal oversight to virtually all clinical laboratories by requiring that they be certified by the federal government or by a federally-approved accreditation agency. CLIA requires that all clinical laboratories meet quality assurance, quality control and personnel standards. Laboratories must also undergo proficiency testing and are subject to inspections.

The sanctions for failure to comply with CLIA requirements include suspension, revocation or limitation of a laboratory's CLIA certificate, which is necessary to conduct business, cancellation or suspension of the laboratory's approval to receive Medicare and/or Medicaid reimbursement, as well as significant fines and/or criminal penalties. The loss or suspension of a CLIA certification, imposition of a fine or other penalties, or future changes to CLIA or regulations (or interpretation of the law or regulations) could have a material adverse effect on us.

We believe that we are in compliance with all applicable laboratory requirements, but no assurances can be given that our laboratories will pass all future certification inspections.

Our products that we sell as research use only products and/or that we offer as laboratory developed tests could become subject to government regulations requiring marketing authorization, and the marketing authorization and maintenance process for such products may be expensive, time-consuming and uncertain in both timing and outcome.

A number of our products are currently, and in the future will be, labeled and sold as research use only (RUO) products. Even though our products are labeled and sold as RUO products, the United States Food and Drug Administration (FDA) could question whether our products are intended for research use only. For example, in August 2021, we were contacted by the FDA regarding HemeScreen, and we have subsequently revised the labeling for HemeScreen. Should the FDA disagree with our conclusion that our products are intended for research use only or deem our sales, marketing and promotional efforts as being inconsistent with RUO products, our products could be subject to government regulation as diagnostic products. Diagnostic products are regulated as medical devices by the FDA and may require marketing authorization through clearance following the 510(k) premarket notification process, authorization following a request for de novo classification or premarket approval from the FDA, in each case prior to marketing. Obtaining the requisite marketing authorizations can be expensive and may involve considerable delay. Moreover, if the FDA believed we inappropriately labeled our products as RUO products, it could allege that we had misbranded or adulterated our RUO products. If the FDA asserts that our RUO products are subject to marketing authorization, or that our RUO products are adulterated or misbranded, our business, financial condition or results of operations could be adversely affected.

Additionally, our CLIA laboratory offers testing utilizing our laboratory-developed tests (LDTs). Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs

to comply with the FDA's requirements for medical devices, such as the FDA's requirements pertaining to marketing authorization, establishment registration, device listing, the Quality System Regulation, and other post-market controls. However, at various points in recent years, the FDA has stated it intends to end its policy of enforcement discretion and to actively regulate LDTs.

On April 29, 2024, the U.S. Food and Drug Administration ("FDA") published a final rule that, if implemented, would have amended FDA's regulatory definition of in vitro diagnostics to include laboratory developed tests ("LDTs") and phased out the agency's longstanding enforcement discretion for most LDTs over a planned multi-stage implementation period. The rule would have subjected many LDTs to premarket review and device regulatory requirements.

Subsequently, in March 2025, a federal district court in American Clinical Laboratory Association v. FDA and Association for Molecular Pathology v. FDA vacated the April 29, 2024 final rule on the basis that FDA lacked statutory authority to regulate LDTs as medical devices under the Federal Food, Drug, and Cosmetic Act. In September 2025, FDA published a rule restoring the regulatory text governing LDTs to the pre-2024 status quo. As a result, the April 2024 final rule is no longer in effect, and there are currently no FDA-imposed device-style premarket requirements or staged compliance deadlines applicable solely because a laboratory develops and uses an LDT.

If the FDA were to determine that certain tests offered by us as LDTs are no longer eligible for enforcement discretion for any reason, including new rules, policies or guidance, or due to changes in statute, our test may become subject to extensive FDA requirements and our business, financial condition or results of operations may be adversely affected. If required, the regulatory marketing authorization process required to bring our current or future LDTs into compliance may involve, among other things, successfully completing additional clinical validations and submitting to and obtaining clearance, authorization or approval from the FDA. Furthermore, pending legislative proposals, if enacted, could create new or different regulatory and compliance burdens on us and could have a negative effect on our ability to keep products on the market or develop new products, which could have a material effect on our business.

In the event that the FDA requires marketing authorization of our LDTs in the future, the FDA may not ultimately grant any clearance, authorization or approval requested by us in a timely manner, may limit our indication in a way that is not commercially desirable, or refuse to provide such marketing authorization at all. In addition, if the FDA inspects our laboratory in relation to the marketing of any FDA-authorized test, any enforcement action the FDA takes might not be limited to the FDA-authorized test carried by us and could encompass our other testing services.

Failure to comply with HIPAA could be costly.

HIPAA and associated regulations protect the privacy and security of certain patient health information and establish standards for electronic health care transactions in the United States. These privacy regulations establish federal standards regarding the uses and disclosures of protected health information. Our laboratories are subject to HIPAA and its associated regulations. If we fail to comply with these laws and regulations we could suffer civil and criminal penalties, fines, exclusion from participation in governmental health care programs and the loss of various licenses, certificates and authorizations necessary to operate our patient testing business. We could also incur liabilities from third party claims. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation of HIPAA.

Our failure to comply with any applicable government laws and regulations or otherwise respond to claims relating to improper handling, storage or disposal of hazardous chemicals that we use may adversely affect our results of operations.

Our research and development and commercial activities involve the controlled use of hazardous materials and chemicals. We are subject to federal, state, local and international laws and regulations governing the use, storage, handling and disposal of hazardous materials and waste products. If we fail to comply with applicable laws or regulations, we could be required to pay penalties or be held liable for any damages that result and this liability could exceed our financial resources. We cannot be certain that accidental contamination or injury will not occur. Any such accident could damage our research and manufacturing facilities and operations, resulting in delays and increased costs.

We may become subject to the Anti-Kickback Statute, Stark Law, False Claims Act, Civil Monetary Penalties Law and may be subject to analogous provisions of applicable state laws and could face substantial penalties if we fail to comply with such laws.

There are several federal laws addressing fraud and abuse that apply to businesses that receive reimbursement from a federal health care program. There are also a number of similar state laws covering fraud and abuse with respect to, for example, private payers, self-pay and insurance. Currently, we receive a substantial percentage of our revenue from private payers and from Medicare. Accordingly, our business is subject to federal fraud and abuse laws, such as the Anti-Kickback Statute, the Stark Law, the False Claims Act, the Civil Monetary Penalties Law and other similar laws. Moreover, we are already subject to similar state laws. We believe we have operated, and intend to continue to operate, our business in compliance with these laws. However, these laws are subject to modification and changes in interpretation, and are enforced by authorities vested with broad discretion. Federal and state enforcement entities have significantly increased their scrutiny of healthcare companies and providers which has led to investigations, prosecutions, convictions and large settlements. We continually monitor developments in this area. If these laws are interpreted in a manner contrary to our interpretation or are reinterpreted or amended, or if new legislation is enacted with respect to healthcare fraud and abuse, illegal remuneration, or similar issues, we may be required to restructure our affected operations to maintain compliance with applicable law. There can be no assurances that any such restructuring will be possible or, if possible, would not have a material adverse effect on our results of operations, financial position, or cash flows.

Anti-Kickback Statute

A federal law commonly referred to as the "Anti-Kickback Statute" prohibits the knowing and willful offer, payment, solicitation or receipt of remuneration, directly or indirectly, in return for the referral of patients or arranging for the referral of patients, or in return for the recommendation, arrangement, purchase, lease or order of items or services that are covered, in whole or in part, by a federal healthcare program such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value such as gifts, discounts, rebates, waiver of payments or providing anything at less than its fair market value. The PPACA amended the intent requirement of the Anti-Kickback Statute such that a person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate the statute. Further, the PPACA now provides that claims submitted in violation of the Anti-Kickback Statute constitute false or fraudulent claims for purposes of the federal False Claims Act ("FCA"), including the failure to timely return an overpayment. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties. Many states have adopted similar prohibitions against kickbacks and other practices that are intended to influence the purchase, lease or ordering of healthcare items and services reimbursed by a governmental health program or state Medicaid program. Some of these state prohibitions apply to remuneration for referrals of healthcare items or services reimbursed by any third-party payer, including commercial payers and self-pay patients.

Stark Law

Section 1877 of the Social Security Act, or the Stark Law, prohibits a physician from referring a patient to an entity for certain "designated health services" reimbursable by Medicare if the physician (or close family members) has a financial relationship with that entity, including an ownership or investment interest, a loan or debt relationship or a compensation relationship, unless an exception to the Stark Law is fully satisfied. The designated health services covered by the law include, among others, laboratory and imaging services. Some states have self-referral laws similar to the Stark Law for Medicaid claims and commercial claims.

Violation of the Stark Law may result in prohibition of payment for services rendered, a refund of any Medicare payments for services that resulted from an unlawful referral, civil monetary penalties for specified infractions, criminal penalties, and potential exclusion from participation in government healthcare programs, and potential false claims liability. The repayment provisions in the Stark Law are not dependent on the parties having an improper intent; rather, the Stark Law is a strict liability statute and any violation is subject to repayment of all amounts arising out of tainted referrals. If physician self-referral laws are interpreted differently or if other legislative restrictions are issued, we could

incur significant sanctions and loss of revenues, or we could have to change our arrangements and operations in a way that could have a material adverse effect on our business, prospects, damage to our reputation, results of operations and financial condition.

False Claims Act

The FCA prohibits providers from, among other things, (1) knowingly presenting or causing to be presented, claims for payments from the Medicare, Medicaid or other federal healthcare programs that are false or fraudulent; (2) knowingly making, using or causing to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the federal government; or (3) knowingly making, using or causing to be made or used, a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The "qui tam" or "whistleblower" provisions of the FCA allow private individuals to bring actions under the FCA on behalf of the government. These private parties are entitled to share in any amounts recovered by the government, and, as a result, the number of "whistleblower" lawsuits that have been filed against providers has increased significantly in recent years. Defendants found to be liable under the FCA may be required to pay three times the actual damages sustained by the government, plus civil penalties for each separate false claim.

There are many potential bases for liability under the FCA. The government has used the FCA to prosecute Medicare and other government healthcare program fraud such as coding errors, billing for services not provided, and providing care that is not medically necessary or that is substandard in quality. The PPACA also provides that claims submitted in connection with patient referrals that result from violations of the Anti-Kickback Statute constitute false claims for the purpose of the FCA, and some courts have held that a violation of the Stark law can result in FCA liability, as well. In addition, a number of states have adopted their own false claims and whistleblower provisions whereby a private party may file a civil lawsuit in state court. We are required to provide information to our employees and certain contractors about state and federal false claims laws and whistleblower provisions and protections.

Civil Monetary Penalties Law

The Civil Monetary Penalties Law prohibits, among other things, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person or entity knows or should know is likely to influence the beneficiary's selection of a particular provider or supplier of items or services reimbursable by a federal or state healthcare program. This broad provision applies to many kinds of inducements or benefits provided to patients, including complimentary items, services or transportation that are of more than a nominal value. This law could affect how we have to structure our operations and activities.

The use of artificial intelligence in diagnostic or laboratory applications may subject us to additional regulatory and liability risks.

The integration of artificial intelligence or machine learning technologies into diagnostic or laboratory workflows may subject us to additional regulatory oversight, including potential review by the U.S. Food and Drug Administration or other regulatory authorities. Regulatory standards applicable to AI-enabled medical technologies continue to evolve and may require additional validation, documentation, or monitoring. AI-based tools may be subject to increased scrutiny regarding accuracy, bias, and clinical reliability. If AI-enabled outputs are determined to be inaccurate or unreliable, we could face liability claims, regulatory enforcement, reputational harm, or limitations on our ability to market such tools.

Intellectual Property Risks Related to Our Business

We cannot be certain that measures taken to protect our intellectual property will be effective.

We rely upon patents, trade secrets, copyrights and trademarks, as well as non-disclosure agreements and other contractual confidentiality provisions to protect our confidential and proprietary information for which we are not seeking patent protection for various reasons. Such measures, however, may not provide adequate protection for our trade secrets

or other proprietary information. If such measures do not protect our rights, third parties could use our technology and our ability to compete in the market would be reduced. Our intellectual property portfolio with respect to certain aspects of our technology and product candidates is at an early stage. We own pending patent applications in the United States and Europe directed to our HemeScreen test. We cannot be certain that these pending applications will issue as patents.

If any of our owned patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned patents. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patents and patent applications at a reasonable cost or in a timely manner. Disruptions at the United States Patent and Trademark Office (USPTO) or other government agencies may also slow the time necessary for patent applications to be reviewed by the USPTO, which could adversely affect our patent portfolio. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in any of our owned or pending patent applications, or that we were the first to file for patent protection of such inventions.

We depend on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling some of our products.

We may enter into license agreements with third parties for certain licensed technologies that are, or may become, relevant to the products we market, or plan to market. In addition, we may elect to license third party intellectual property to further our business objectives and/or as needed for freedom to operate for our products. We may not own the patents, patent applications or other intellectual property rights that are the subject of the license agreements we enter into. Our rights to use these technologies and employ the inventions claimed in the licensed patents, patent applications and other intellectual property rights are or will be subject to the continuation of and compliance with the terms of those licenses.

We might not be able to obtain licenses to technology or other intellectual property rights that we require. Even if such licenses are obtainable, they may not be available at a reasonable cost or multiple licenses may be needed for the same product (e.g., stacked royalties). We could therefore incur substantial costs related to royalty payments for licenses obtained from third parties, which could negatively affect our gross margins. Further, we could encounter delays in product introductions, or interruptions in product sales, as we develop alternative methods or products.

In some cases, we do not or may not control the prosecution, maintenance, or filing of the patents or patent applications to which we hold licenses, or the enforcement of these patents against third parties. As a result, we cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position may be harmed.

In addition to the protection afforded by patents, we rely upon trade secret protection, know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our contractors, collaborators, scientific advisors, employees and consultants and invention assignment agreements with our consultants and employees. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. The assignment of intellectual property rights under these agreements may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. In addition, we may not be able to prevent the unauthorized disclosure or use of our technical know-how or other trade secrets by the parties to these agreements despite the existence of confidentiality agreements and other contractual restrictions. Monitoring unauthorized uses and disclosures is difficult and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the contractors, collaborators, scientific advisors, employees and consultants who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation. As a result, we could lose our trade secrets. Enforcing a claim against a third party that illegally obtained and is using our trade secrets, like patent litigation, is expensive and time-consuming and the outcome is unpredictable.

Moreover, our trade secrets could otherwise become known or be independently discovered by our competitors or other third parties. Competitors and other third parties could purchase our product candidates and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If our trade secrets are not adequately protected or sufficient to provide an advantage over our competitors, our competitive position could be adversely affected, as could our business. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate, we may have insufficient recourse against third parties for misappropriating our trade secrets.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. If we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. 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. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Third-party claims of intellectual property infringement, misappropriation or other violations may prevent or delay our product discovery and development efforts and have a material adverse effect on our business.

Our commercial success depends in part on our avoiding infringement, misappropriation and other violations of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the diagnostic industries. In addition, administrative proceedings for challenging patents,

including interference, reexamination proceedings, *inter partes* review, and post grant review before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions bring uncertainty to the possibility of challenge to our patents in the future. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the diagnostic industry expands and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. Patents issued in the U.S. by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be third-party patents of which we are currently unaware with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products or product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our technologies or product candidates, including processes for manufacture or methods of use, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. Even if we obtained such a license, it may only be non-exclusive, which would permit third parties to use the same intellectual property and compete with us. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, we may be unable to commercialize our product candidates or such efforts may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our products or product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of

the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market earlier than would otherwise have been the case, which would have a material adverse effect on our business.

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

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

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes to the patent law in the U.S. and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other diagnostic companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the diagnostic industry involve both technological and legal complexity, and is therefore costly, time-consuming and inherently uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. For example, in the case, *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. In addition, the case *Amgen Inc. v. Sanofi* affects the way antibody claims are examined and litigated. We cannot predict how future decisions by the courts, the Congress or the USPTO may impact the value of our patents.

In addition, a European Unified Patent Court (UPC) came into force in June 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for member states of the EU. This could enable third parties to seek revocation of a European patent in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. If our pending European patent application issues, and if we obtain other such patents and applications in the future, any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and products. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce or defend the validity of any European patents we may obtain. We may decide to opt out from the UPC any future European patent applications that we may file and any patents we may obtain. If certain formalities and requirements are not met, however, such European patents and patent applications could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our pending European patent application and future European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. For example, third parties that have been introduced to or have benefited from our inventions may attempt to replicate or reverse engineer our products and circumvent ownership of our inventions. In addition, we may face claims that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

We have limited foreign intellectual property rights and may not be able to protect our intellectual property rights throughout the world.

We have limited intellectual property rights outside the United States and do not have any issued patents in foreign jurisdictions. Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products. In addition, if we obtain foreign patent protection in the future, competitors may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from 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, and may require a compulsory license to, patents, trade secrets and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products against third parties in violation of our proprietary rights generally. The initiation of proceedings by third parties to challenge the scope or validity of any patent rights we may obtain in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Proceedings to enforce any patent rights we may obtain in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put any patent rights we may obtain at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

•others may be able to make products that are similar to our product candidates or utilize similar technology but that are not covered by the claims of the patents that we hold rights to;

•we, or our licensors or collaborators, might not have been the first to invent or the first to file patent applications covering certain of our or their inventions;

•others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned intellectual property rights;

•it is possible that our current or future pending owned patent applications will not lead to issued patents;

•issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;

•our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in the US;

•we may not develop additional proprietary technologies that are patentable;

•the patents of others may harm our business; and

•we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations and prospects

Risks Related to Our Common Stock

The price of our common stock may fluctuate significantly, which could negatively affect us and holders of our common stock.

There has been, and continues to be, a limited public market for our common stock, and an active trading market for our common stock has not and may never develop or, if developed, be sustained. The trading price of our common stock may be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our common stock to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their shares of our common stock and may otherwise negatively affect the liquidity of our common stock. In addition, the stock market in general has experienced price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Companies that experience significant volatility in the market price of their securities are sometimes subject to securities class action litigation, and we could in the future be subject to such claims. Such a claim could also divert the time and attention of our management.

The price of our stock may be vulnerable to manipulation.

We believe our common stock has been the subject of significant short-selling by certain market participants. Short sales are transactions in which a market participant sells a security that it does not own. To complete the transaction, the market participant must borrow the security to make delivery to the buyer. The market participant is then obligated to replace the security borrowed by purchasing the security at the market price at the time of required replacement. If the price at the time of replacement is lower than the price at which the security was originally sold by the market participant, then the market participant will realize a gain on the transaction. Thus, it is in the market participant's interest for the market price of the underlying security to decline as much as possible during the period prior to the time of replacement.

Because our unrestricted public float has been small relative to other issuers, previous short selling efforts have impacted, and may in the future continue to impact, the value of our stock in an extreme and volatile manner to our detriment and the detriment of our stockholders. Efforts by certain market participants to manipulate the price of our common stock for their personal financial gain may cause our stockholders to lose a portion of their investment, may make it more difficult for us to raise equity capital when needed without significantly diluting existing stockholders, and may reduce demand from new investors to purchase shares of our stock.

If we cannot continue to satisfy Nasdaq listing maintenance requirements and other rules, our securities may be delisted, which could negatively impact the price of our securities.

Although our common stock is listed on The Nasdaq Capital Market ("Nasdaq"), we may be unable to continue to satisfy the listing maintenance requirements and rules. If we are unable to satisfy Nasdaq's criteria for maintaining our listing, our securities could be subject to delisting.

If Nasdaq were to delist our securities, we could face significant consequences, including:

- a limited availability for market quotations for our securities;
- reduced liquidity with respect to our securities;
- a determination that our common stock is a "penny stock," which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading;
- activity in the secondary trading market for our common stock;
- reduced or limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities or obtain additional financing in the future.

In addition, we would no longer be subject to Nasdaq rules, including rules requiring us to have a certain number of independent directors and to meet other corporate governance standards.

Increased costs associated with corporate governance compliance may significantly impact our results of operations.

As a public company, we incur significant legal, accounting, and other expenses due to our compliance with regulations and disclosure obligations applicable to us, including compliance with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, as well as rules implemented by the SEC, and Nasdaq. The SEC and other regulators have continued to adopt new rules and regulations and make additional changes to existing regulations that require our compliance. In July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that have required the SEC to adopt additional rules and regulations in these areas. Stockholder activism, the current political environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact, in ways we cannot currently anticipate, the manner in which we operate our business. Our management and other personnel devote a substantial amount of time to these compliance programs and monitoring of public company reporting obligations, and as a result of the new corporate governance and executive compensation related rules, regulations, and guidelines prompted by the Dodd-Frank Act, and further regulations and disclosure obligations expected in the future, we will likely need to devote additional time and costs to comply with such compliance programs and rules. These rules and regulations will cause us to incur significant legal and financial compliance costs and will make some activities more time-consuming and costly.

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in our periodic reports that we file with the SEC under Section 404 of the Sarbanes-Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. If we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common stock could decline.

We are required to comply with certain of the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, which requires management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of our internal control over financial reporting. This assessment needs to include the disclosure of any material weaknesses in our internal control over financial reporting identified by our management or our independent registered public accounting firm. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting or if we are unable to complete our evaluation, testing, and any required remediation in a timely fashion, we will be unable to assert that our internal control over financial reporting is effective.

These developments could make it more difficult for us to retain qualified members of our Board of Directors, or qualified executive officers. We are presently evaluating and monitoring regulatory developments and cannot estimate the timing or magnitude of additional costs we may incur as a result. To the extent these costs are significant, our general and administrative expenses are likely to increase.

Our internal control over financial reporting and our disclosure controls and procedures may not prevent all possible errors that could occur.

The Sarbanes-Oxley Act requires that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that

are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls that we develop may become inadequate, and weaknesses in our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls could adversely affect the results of periodic management evaluations and annual independent registered public accounting firm attestation reports regarding the effectiveness of our internal control over financial reporting, which we may be required to include in our periodic reports that we file with the SEC under Section 404 of the Sarbanes-Oxley Act, and could harm our operating results, cause us to fail to meet our reporting obligations, or result in a restatement of our prior period financial statements. If we are not able to demonstrate compliance with the Sarbanes-Oxley Act, that our internal control over financial reporting is perceived as inadequate, or that we are unable to produce timely or accurate financial statements, investors may lose confidence in our operating results, and the price of our common stock could decline.

We have not paid dividends on our common stock in the past and do not expect to pay dividends on our common stock for the foreseeable future. Any return on investment may be limited to the value of our common stock.

No cash dividends have been paid on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor's investment will only occur if our stock price appreciates. Investors in our common stock should not rely on an investment in our company if they require dividend income.

We may be at an increased risk of securities class action litigation.

Historically, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology stocks, such as ours, have experienced significant stock price volatility in recent years. If we were to be sued, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If securities or industry analysts do not publish research or reports about our business, or if they change their recommendations regarding our stock adversely, our stock price and trading volume 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. The price of our common stock could decline if one or more equity research analysts downgrade our common stock or if they issue other unfavorable commentary or cease publishing reports about us or our business.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our diagnostic technologies or current or future development programs.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or current or future product candidates or to grant licenses on terms that may not be favorable

to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates, delay our pursuit of potential in-licenses or acquisitions or grant rights to develop and market current or future product candidates that we would otherwise prefer to develop and market ourselves.

The issuance of our common stock to creditors or litigants may cause significant dilution to our stockholders and cause the price of our common stock to fall.

We may seek to settle outstanding obligations to vendors, debtholders or litigants in any litigation through the issuance of our common stock or other security to such persons. Such issuances may cause significant dilution to our stockholders and cause the price of our common stock to fall.

Improper timing of equity awards could result in regulatory scrutiny and reputational harm.

We grant stock options and other equity-based awards to executives and employees as part of our compensation program. The timing of these grants is subject to SEC disclosure rules under Item 402(x), which require transparency regarding whether awards are made in proximity to the release of material nonpublic information. While we maintain policies to ensure that equity grants are not made during blackout periods or near material announcements, there can be no assurance that all grants will be perceived as free from opportunistic timing concerns. If the timing of option grants were ever questioned by regulators, investors, or other stakeholders, we could face SEC or other regulatory scrutiny, leading to potential enforcement actions; shareholder litigation alleging improper stock option practices and reputational damage, which could negatively impact investor confidence and stock performance. To mitigate these risks, we have adopted strict governance procedures, requiring that equity grants be (i) approved by the Compensation Committee on pre-scheduled dates (ii) will not be issued four trading days before or after material disclosures and be subject to internal review to ensure compliance with SEC regulations. Despite these safeguards, if regulatory agencies or investors perceive equity awards as improperly timed, the Company's financial condition and stockholder value could be negatively affected.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

As widely reported, global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability, current macroeconomic conditions, currency exchange rates, and volatile financial markets. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

Our amended and restated bylaws, as amended, designate specific courts in as the exclusive forum for certain litigation that may be initiated by the Company's stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

Pursuant to our amended and restated bylaws, as amended (the "bylaws"), unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for state law claims for (1) any derivative action or proceeding brought on our behalf; (2) any action or proceeding asserting a claim

of breach of a fiduciary duty owed by any current or former director, officer or other employee or agent of ours to us or our stockholders or debtholders, (3) any action asserting a claim against us or any director or officer or other employee of ours arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or the bylaws (in each case, as they may be amended from time to time), (4) any action asserting a claim against us or any current or former director or officer or other employee or agent of ours governed by the internal affairs doctrine or (5) any action asserting an "internal corporate claim" as that term is defined in Section 115 of the General Corporation Law of the State of Delaware (the "Delaware Forum Provision"); provided, however, that the Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. Our amended and restated bylaws further provide that unless we consent in writing to the selection of an alternative forum, that in the event that the Court of Chancery of the State of Delaware lacks jurisdiction over any such action or proceeding, the sole and exclusive forum for such action or proceeding shall be another state or federal court located within the State of Delaware; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the U.S. federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims. Additionally, these forum selection clauses may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage the filing of lawsuits against us and our directors, officers and employees, even though an action, if successful, might benefit our stockholders. In addition, while the Delaware Supreme Court and other states courts have upheld the validity of federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court, there is uncertainty as to whether other courts will enforce our forum provision. If our forum provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. Forum provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware and the federal district courts of the United States may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be

located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and our bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a requirement that special meetings of stockholders be called only by the chairman of the board, board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office, or our chief executive officer;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than a majority of the shares then entitled to vote generally for the election of directors; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law ("DGCL"), which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These antitakeover provisions and other provisions in our fourth amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

We are a "smaller reporting company," and the reduced disclosure requirements applicable to smaller reporting companies may make our common stock less attractive to investors.

We are a smaller reporting company under Rule 12b-2 of the Exchange Act. For so long as we remain a smaller reporting company, we are permitted and plan to rely on exemptions from certain disclosure requirements, including reduced disclosure obligations regarding executive compensation. These exemptions and reduced disclosures in our SEC filings due to our status as a smaller reporting company also mean our auditors are not required to audit our internal control over financial reporting and may make it harder for investors to analyze our results of operations and financial prospects. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common

stock and our common stock prices may be more volatile. We will remain a smaller reporting company until our public float exceeds $250 million or our annual revenues exceed $100 million with a public float greater than $700 million.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

The Company is committed to protecting the confidentiality, integrity, and availability of its information systems and the data they contain from cybersecurity threats. The Company recognizes that cybersecurity is a dynamic and evolving area of risk that requires ongoing assessment, management, and oversight. Third parties are also incorporated into our approach to cybersecurity. We engage third-party services to conduct evaluations of our security controls, whether through penetration testing, independent audits, cybersecurity maturity assessments or consulting on best practices to address current and new challenges. These evaluations include testing both the design and operational effectiveness of security controls.

Risk management and strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with an IT consultant who reports to our IT Manager and Chief Operating Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with IT and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage consultants, or other third parties in connection with our risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards. We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

We recently reported that we experienced a cybersecurity incident involving unauthorized access to an employee’s cloud-based storage account that may have resulted in access to certain personally identifiable information and protected health information of individuals, which we publicly disclosed in January 2026. In response, we initiated an investigation, engaged third-party cybersecurity specialists, secured the impacted account, notified law enforcement authorities, and are conducting a review of the potentially affected data. The event remains under investigation, and we continue to assess the scope and potential impacts of the incident, including any regulatory, legal, or financial implications. While we have taken mitigation steps, there can be no assurance that similar incidents will not occur in the future or that additional impacts from this or related incidents will not be identified.

For additional information regarding risks from cybersecurity threats, please refer to Item 1A, "Risk Factors," in this annual report on Form 10-K.

Governance

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its risk oversight function directly as a whole, as well as through the audit committee.

Our Chief Operating Officer is primarily responsible to assess and manage our material risks from cybersecurity threats with assistance from third-party service providers.

Our Chief Operating Officer oversees our cybersecurity policies and processes, including those described in "Risk Management and Strategy" above. The cybersecurity risk management program includes tools and activities to prevent, detect, and analyze current and emerging cybersecurity threats, and plans and strategies to address threats and incidents.

Our Chief Financial Officer and IT consultant provide periodic briefings to the audit committee regarding our company's cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. Our audit committee provides regular updates to the board of directors on such reports.

Item 2. Properties

We currently lease approximately 15,298 square feet of laboratory and office space in New Haven, Connecticut, which we occupy under leases expiring in February 2030 with annual rental payments between $0.4 million and $0.6 million. We also lease approximately 6,808 square feet of laboratory space in Omaha, Nebraska, which we occupy under a lease expiring in July 2030 with annual rental payments of $0.1 million. We believe that these facilities are adequate to meet our current and planned needs. We believe that if additional space is needed in the future, we could find alternate space at competitive market rates as needed.

Item 3. Legal Proceedings

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not limited to, matters such as licensure, accreditation, government healthcare program participation requirement, reimbursement for patient services and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers.

Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation, as well as regulatory actions unknown or unasserted at this time.

The outcome of legal proceedings and claims brought against us are subject to significant uncertainty. If one or more of these legal matters were resolved against us in the same reporting period for amounts in excess of management's expectations, our financial statements for such reporting period could be materially and adversely affected. In general, the resolution of a legal matter resolved against us, could also prevent us from offering our services or products to others, could be material to our financial condition or cash flows, or both, or could otherwise adversely affect our operating results.

From time to time, the Company is involved in legal proceedings related to matters, which are incidental to our business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business, but, regardless of

the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

During the year ended December 31, 2025, we were involved in a legal proceeding brought by a former employee before the court in San Antonio, Texas alleging unfair dismissal where the former employee seeks monetary damages. The matter was resolved in 2025 through a settlement agreement. The settlement was reached without any admission of liability and is not material to the Company's financial statements. Accordingly, the matter is considered closed.

For a fulsome discussion of legal proceedings, see Note 8 – "Commitment and Contingencies" in the notes to the consolidated financial statements included elsewhere in this Annual Report on Form 10-K. This discussion is incorporated herein by reference.

Item 4. Mine Safety Disclosures

Not Applicable.

PART II

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

Market Information. Since June 30, 2017, our common stock has traded on the Nasdaq Capital Market under the symbol "PRPO."

Performance Graph. We are a smaller reporting company, as defined by Rule 12b-2 of the Exchange Act, and are not required to provide the information required under this item.

Holders. At March 23, 2026, there were 1,783,682 shares of our common stock outstanding and approximately 33 holders of record.

Dividends. No cash dividends have been paid on our common stock. We expect that any income received from operations will be devoted to our future operations and growth. We do not expect to pay cash dividends on our common stock in the near future. Payment of dividends would depend upon our profitability at the time, cash available for those dividends, and other factors as our board of directors may consider relevant. If we do not pay dividends, our common stock may be less valuable because a return on an investor's investment will only occur if our stock price appreciates. Investors in our common stock should not rely on an investment in our company if they require dividend income and should not purchase our common stock with the expectation of receiving cash dividends.

Issuer Purchases of Equity Securities. We made no purchases of our common stock during the year ended December 31, 2025. Therefore, tabular disclosure is not presented.

Recent Sales of Unregistered Securities. None.

Item 6. [Reserved]

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

Forward-Looking Information

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis and set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the section titled "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a healthcare biotechnology company focused on improving cancer diagnostics. The Company's objective is to enhance diagnostic accuracy and accessibility while building a sustainable business model that supports ongoing innovation. The Company can achieve this through a combination of clinical laboratory services and proprietary diagnostic product development. By integrating diagnostic services with product development, the Company's service business doubles as a self-funded research and development (R&D) unit, enabling the Company to achieve rapid and cost-efficient innovation, rather than being a major cost center of the Company.

This unique integrated operating structure is the foundation of the Company's approach to research, development, and product commercialization. Unlike companies that rely primarily on stand-alone research facilities or external clinical validation programs, the Company's clinical laboratory operations enables its R&D team to evaluate, refine, and validate

diagnostic products in the course of routine clinical testing activities, and at minimal incremental cost. Through these activities, the Company generates clinical data, operational experience, and specimen access that support ongoing assay development and product improvement. While these activities are initially conducted to provide diagnostic services to patients and their healthcare providers, they also contribute to product development and validation processes.

Precipio has a single operating segment but operates two business divisions that are complementary to each other. The Company's pathology services division provides specialized cancer diagnostic testing services to physicians, hospitals, and laboratories. This division generates revenue and supports the development of the Company's expertise in oncology diagnostics. The pathology services division delivers specialized diagnostic testing focused primarily on hematologic cancers and operates a full laboratory that includes all the equipment, personnel, and work processes required to receive patient samples daily, and deliver clinical results to the physicians under the proper compliance umbrella, while also generating profitable revenue to the company. While reimbursement levels and testing volumes may vary, the Company views this division as an important foundation for both current operations and future product development.

The Company's product division develops and commercializes proprietary diagnostic assay kits designed for use by clinical laboratories. These products allow the Company to expand its reach by enabling other laboratories to benefit from the diagnostic products developed by the Company, while building scalable diagnostic solutions. The Company believes this dual structure provides a unique model for R&D development of clinically applicable products, while delivering operational stability and supporting innovation and future growth. Furthermore, it provides the Company with substantial competitive advantages in terms of the economics of product development, and time to market. The products division focuses on developing proprietary diagnostic assays and kits intended for use by other clinical laboratories. These products are designed to improve testing accessibility and laboratory workflow efficiency while enabling broader market reach without requiring Precipio to perform all testing internally. Product revenues may offer greater scalability than traditional laboratory services, although adoption depends on regulatory, reimbursement, and market factors.

To deliver our strategy, we have structured our organization to develop diagnostic products, including our laboratory and research and development ("R&D") facilities located in New Haven, Connecticut and Omaha, Nebraska, respectively, which house teams that collaborate on the development of new products and services. We operate clinical laboratory improvement amendment ("CLIA") laboratories in both New Haven, Connecticut and Omaha, Nebraska where we provide essential blood cancer diagnostics to office-based oncologists in many states nationwide. To deliver on our strategy of mitigating misdiagnoses we rely heavily on our CLIA laboratories to support R&D beta-testing of the products we develop, in a clinical environment.

Our operating structure promotes the harnessing of our proprietary technology and genetic diagnostic expertise to bring to market our robust pipeline of innovative solutions designed to address the root causes of misdiagnoses.

Going Concern

The consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America ("GAAP") applicable for a going concern, which assume that we will realize our assets and discharge our liabilities in the ordinary course of business. We have incurred substantial operating losses and have typically used cash in our operating activities for the past several years. For the year ended December 31, 2025, we had an operating loss of $1.2 million and net cash provided by operating activities of $0.7 million. As of December 31, 2025, we had an accumulated deficit of $102.8 million and working capital of $2.3 million. Our ability to continue as a going concern over the next twelve months from the date the consolidated financial statements were issued is dependent upon a combination of achieving our business plan, including generating additional revenue and avoiding potential business disruption due to the macroeconomic environment and geopolitical instability, and raising additional financing, if needed, to meet our debt obligations and paying liabilities arising from normal business operations when they come due.

There remains substantial doubt about our ability to continue as a going concern for the next twelve months from the date the consolidated financial statements were available to be issued. There can be no assurance that we will be able to successfully achieve our initiatives summarized above in order to continue as a going concern. The accompanying financial statements have been prepared assuming we will continue as a going concern and do not include any adjustments

that might result should we be unable to continue as a going concern as a result of the outcome of this uncertainty. See "Risk Factors – There is substantial doubt about our ability to continue as a going concern".

Results of Operations for the Years Ended December 31, 2025 and 2024

Net Sales. Net sales were as follows:

	Dollars in Thousands			
	Year Ended December 31,		Change	
	2025	2024	$	%
Service revenue, net, less allowance for credit loss	$ 21,309	$ 15,921	$ 5,388	34 %
Product revenue	2,740	2,611	129	5 %
Net Sales	$ 24,049	$ 18,532	$ 5,517	30 %

Net sales for the year ended December 31, 2025 were $24.0 million, an increase of $5.5 million, as compared to the same period in 2024. During the year ended December 31, 2025, patient diagnostic service revenue increased $5.4 million as compared to the same period in 2024. This increase was due to a greater number of cases processed in the current year period. We processed 15,470 cases during the year ended December 31, 2025 as compared to 11,894 cases during the same period in 2024, or a 30% increase in cases. Product revenue increased by $0.1 million for the year ended December 31, 2025 as compared to the same period in 2024.

Cost of Sales. Cost of sales includes material and supply costs, including shipping, for the patient tests performed, costs related to products and other direct costs (primarily personnel costs, pathologist interpretation costs and rent) associated with the operations of our laboratory. Cost of sales increased by $2.4 million for the year ended December 31, 2025 as compared to the same period in 2024. The majority of the increase related to increases in reagents, operating supplies, personnel costs and pathologist interpretation costs all due to the increase in the number of cases processed, as discussed above.

Gross Profit. Gross profit and gross margins were as follows:

	Dollars in Thousands			
	Year Ended December 31,		Change	
	2025	2024	$	%
Gross Profit	$ 10,706	$ 7,559	3,147	42
Gross Margin	45%	41%		

Gross margin was 45% and 41% of total net sales, for the years ended December 31, 2025 and 2024, respectively, and the gross profit was approximately $10.7 million and $7.6 million during the years ended December 31, 2025 and 2024, respectively. Gross profit increased during the year ended December 31, 2025, as compared to the prior year period, as a result of increases in case volume and revenue. We operate a fully staffed CLIA and CAP certified clinical pathology and molecular laboratory. As such, it is necessary to maintain appropriate staffing levels to provide industry standard laboratory processing and reporting to ordering physicians. An increase in case volume will enable our laboratory to yield economies of scale and to leverage fixed expenses.

Operating Expenses. Operating expenses primarily consist of personnel costs, professional fees, travel costs, facility costs, stock-based compensation costs and depreciation and amortization. Our operating expenses increased by $0.1 million to $11.9 million for the year ended December 31, 2025 as compared to $11.8 million for the year ended December 31, 2024. For the year ended December 31, 2025: (1) general and administrative expenses remained flat which included an increase of $0.1 million in personnel costs offset by a decrease of $0.1 million in legal and professional fees, (2) sales and marketing expenses increased by $0.1 million due to an increase in professional fees, (3) research and development expenses increased by $0.3 million due to an increase in personnel costs and operating supplies, and (4) stock-based compensation decreased by $0.3 million.

Other (Expense) Income. We recorded net other income of $0.8 million for the year ended December 31, 2025 which included income of $0.1 million from the gain on settlement of liabilities, income of $0.8 million from the receipt of Employee Retention Credits (as defined below), and net interest expense of $0.1 million. During the year ended December 31, 2024, we recorded net other expense of $0.1 million which was related to net interest expense.

Liquidity and Capital Resources

Our working capital positions at December 31, 2025 and 2024 were as follows (in thousands):

	December 31, 2025	December 31, 2024	Change
Current assets (including cash of $2,651 and $1,389 respectively)	$ 6,039	$ 3,451	$ 2,588
Current liabilities	3,752	4,271	(519)
Working capital	$ 2,287	$ (820)	$ 3,107

During the year ended December 31, 2025, we received net cash proceeds of approximately $1.3 million from the exercise of 444,444 warrants, which resulted in the issuance of 242,562 shares of common stock of the Company.

Also, during the year ended December 31, 2025, we received $0.8 million related to refundable Employee Retention Credits that it had applied for.

Analysis of Cash Flows - Years Ended December 31, 2025 and 2024

The following table summarizes our net cash flow activity (in thousands):

	Dollars in Thousands		
	Year Ended December 31,		
	2025	2024	Change
Net cash provided by operating activities	$ 685	$ 439	$ 246
Net cash used in investing activities	(326)	(223)	(103)
Net cash provided by (used in) financing activities	903	(329)	1,232
Net change in cash	$ 1,262	$ (113)	$ 1,375

Net Change in Cash. Cash increased by $1.3 million during the year ended December 31, 2025 and decreased by $0.1 million during the year ended December 31, 2024.

Cash Flows Provided by (Used in) Operating Activities. The cash flows provided by operating activities of $0.7 million during the year ended December 31, 2025 included an increase in accounts payable of $0.5 million, an increase in deferred revenues of $0.1 million, and non-cash adjustments of $3.2 million. These were partially offset by a net loss of $0.4 million, an increase in accounts receivables of $1.4 million, an increase in inventories of $0.2 million, a decrease in operating lease liabilities of $0.2 million and a decrease in accrued expenses of $0.9 million. The non-cash adjustments included $0.2 million for the change in provision for credit losses. We routinely provide a reserve for credit losses as a result of having limited in-network payer contracts. The other non-cash adjustments to net loss of approximately $3.0 million include, among other things, depreciation and amortization, and stock-based compensation. The cash flows provided by operating activities of approximately $0.4 million during the year ended December 31, 2024 included a decrease in accounts receivables of $0.4 million, a decrease in other assets of $0.3 million, an increase in accrued expenses of $1.0 million, an increase in deferred revenue of $0.1 million and non-cash adjustments of $3.4 million. These were partially offset by a net loss of $4.3 million, an increase in inventories of $0.3 million, and a decrease in operating lease liabilities of $0.2 million.

Cash Flows Used In Investing Activities. Cash flows used in investing activities were $0.3 million and $0.2 million for the years ended December 31, 2025 and 2024, respectively, resulting from purchases of property and equipment.

Cash Flows Provided by (Used in) Financing Activities. Cash flows provided by financing activities totaled $0.9 million for the year ended December 31, 2025, which included $1.3 million in proceeds from the exercise of warrants and $0.1 million in proceeds from the exercise of stock options. These were partially offset by $0.5 million in payments on our long-term debt and finance lease obligations. Cash flows used in financing activities totaled $0.3 million for the year ended December 31, 2024, which included $0.7 million in payments on our long-term debt and finance lease obligations. These were partially offset by $0.3 million of proceeds from debt and $0.1 million of proceeds from the issuance of common stock.

At each of December 31, 2025 and December 31, 2024, other than certain purchase commitments, we did not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources. The purchase commitments are mostly for laboratory reagents used in our normal operating business. See Note 8 – "Commitments and Contingencies" to our consolidated financial statements appearing elsewhere in this report for further discussion.

Contractual Obligations and Commitments

At December 31, 2025, our contractual obligations and other commitments were as follows:

	Payments Due By Period				
(in thousands)	Total	Less Than 1 Year	1-3 Years	3-5 Years	More than 5 Years
Long term debt[1]	$ 87	$ 35	$ 52	$ —	$ —
Finance lease obligations[2]	1,201	300	507	315	79
Operating lease obligations[2]	3,273	648	1,446	1,086	93
Purchase obligations[3]	3,080	2,290	316	316	158
	$ 7,641	$ 3,273	$ 2,321	$ 1,717	$ 330

(1) Total payments include $83,000 in principal and $4,000 in interest. See Note 5 - "Long-Term Debt" to our accompanying consolidated financial statements included with this Annual Report on Form 10-K.
(2) See Note 7 - "Leases" to our accompanying consolidated financial statements included with this Annual Report on Form 10-K.
(3) These amounts represent purchase commitments, including all open purchase orders See Note 8 – "Commitments and Contingencies" to our accompanying consolidated financial statements included with this Annual Report on Form 10-K.

Critical Accounting Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires the Company's management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statement and the reported amounts of revenues and expenses during the reporting period.

Making estimates requires management to exercise significant judgment. It is at least reasonably possible that the estimate of the effect of a condition, situation or set of circumstances that existed at the date of the financial statements, which management considered in formulating its estimate, could change in the near term due to one or more future confirming events.

We believe that the following critical accounting estimates are particularly subject to management's judgment and could materially affect our financial condition and results of operations:

● Assumptions used in the Black-Scholes pricing model for valuation of stock option awards, such as expected volatility, risk-free interest rate, expected term and expected dividends.

● Assumptions used in the recording of allowances for credit losses and contractual allowances, including customer creditworthiness, market conditions, and trends in healthcare and insurance practices.

Management also regularly makes estimates related to the recoverability of long-lived assets; the fair values and useful lives of intangible assets acquired in business combinations; and income taxes. The Company bases its estimates on historical experience and on various assumptions that are believed to be reasonable, the results of which form the basis for the amounts recorded in the consolidated financial statements. As appropriate, the Company obtains reports from third-party valuation experts to inform and support estimates related to fair value measurements.

For additional information on critical accounting estimates, see Note 2 to the consolidated Financial Statements, "Summary of Significant Accounting Policies," in Part II, Item 8, of this Annual Report on Form 10-K.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09—Income Taxes (Topic 740)—Improvements to Income Tax Disclosures ("ASU 2023-09") which amends the Codification to enhance the transparency and decision usefulness of income tax disclosures. ASU 2023-09 requires additional disaggregation of the reconciliation between the statutory and effective tax rate for an entity and of income taxes paid, both of which are disclosures required by current GAAP. The amendments improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid disaggregated by jurisdiction. The amendments in ASU 2023-09 apply to all entities that are subject to Topic 740, Income Taxes. For public business entities, the amendments in ASU 2023-09 are effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company has adopted this standard with retrospective application in the 2025 annual financial statements and have included the additional disclosures in Note 9 - Income Taxes.

Recent Accounting Pronouncements Not Yet Adopted

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income (Topic 220): Expense Disaggregation Disclosures (ASU 2024-03"). This update requires entities to disaggregate operating expenses into specific categories, such as purchases of inventory, compensation, depreciation, and amortization, to provide enhanced transparency into the nature and function of expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the impact of this standard on its financial statement presentation and disclosures.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides a practical expedient related to the estimation of expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under Topic 606, including those assets acquired in a business combination. The practical expedient permits all entities to assume that current conditions as of the balance sheet date do not change for the remaining life of the asset. This ASU is effective for fiscal years beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. The Company is currently evaluating the impact of adopting this standard on its consolidated financial statements and disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles — Goodwill and Other — Internal-use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software,* which eliminates the previous stage-based model for capitalizing software costs and replaces it with a principles-based framework. This new guidance is designed to be more adaptable to modern, agile software development methods, clarifying when an entity should capitalize software costs based on a "probable-to-complete" threshold. This ASU is effective for fiscal years beginning after December 15, 2027, and interim reporting periods within those annual reporting periods, and may be applied using a prospective, modified, or retrospective transition approach. The Company is currently evaluating the impact of adopting this standard on its consolidated financial statements and disclosures.

Other Developments

Change Healthcare

Change Healthcare ("CHC"), a subsidiary of UnitedHealth Group, experienced a cybersecurity breach in February 2024 which resulted in the temporary shut-down of some of its systems. Precipio uses CHC to process its billings for pathology services. Thus, when CHC shut down its business operations our pathology billings were halted. Our ability to process billings, accept payer remittances, process medical and billing benefit notices, bill secondary insurers, as well as patients, and communicate with commercial payers was severely impacted. Starting shortly after the breach, we redirected a significant amount of our internal resources to internally handle the billing services that CHC was no longer delivering. This resulted in billing and cash reimbursement delays during the year ended December 31, 2024.

Along with the delays in billing and cash reimbursements, we incurred approximately $0.3 million of expenses during the year ended December 31, 2024, as we incurred lost collections and used alternative methods for claims processing. CHC established a Temporary Funding Assistance Program to help bridge the gap in short-term cash flow needs for its customers affected by the disruption of its services due to the cyberattack. On October 28, 2024, we received a notice from CHC stating that they had restored the connectivity of their systems. During the year ended December 31, 2024, we received approximately $1.1 million from CHC through this program.

During the year ended December 31, 2025, we made approximately $0.9 million in repayments to CHC and wrote off another $0.1 million. See Note 6 – "Accrued Expenses and Other Current Liabilities" for further discussion.

Employee Retention Credit (ERC)

On March 27, 2020, the U.S. government enacted the CARES Act. Under the provisions of the CARES Act, and its subsequent extensions, we became eligible to apply for a refundable Employee Retention Credit (the "ERC"), subject to certain criteria, which could be used to offset payroll tax liabilities.

In November 2022, we submitted an ERC claim totaling approximately $1.5 million. During the year ended December 31, 2025, we received payments totaling approximately $0.8 million. We recorded this amount as other income in the condensed consolidated statements of operations.

We retain all rights to pursue and receive the remaining balance of approximately $0.7 million and are actively evaluating the likelihood and timing of any additional disbursements. We have not waived any claims to the unpaid portion of the ERC and are taking reasonable steps to secure the remaining balance. However, there can be no assurance as to the timing, amount, or certainty of receipt of additional funds, and we will continue to assess the collectability of the remaining claim in accordance with applicable accounting standards.

The $0.8 million ERC refund and the $0.1 million CHC write-off discussed above are non-recurring items and, as a result of these non-recurring items, we recorded approximately $0.9 million of other income in the consolidated statements of operations.

One Big Beautiful Bill Act of 2025

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted in the United States. The OBBBA includes significant changes to federal tax law and other regulatory provisions that may impact us. We are currently assessing the impact of the OBBBA on our business, outlook, and financial statements.

Impact of Inflation

Inflationary factors, such as increases in our cost of goods, labor, or other operating expenses, may adversely affect our operating results. While it is difficult to accurately measure the impact of inflation due to the imprecise nature

of the estimates required, we do not believe inflation had a material effect on our financial condition or results of operations during the years ended December 31, 2025 and 2024. We cannot assure you, however, that we will be able to increase the prices of our products or reduce our operating expenses in an amount sufficient to offset the effects future inflationary pressures may have on our gross margin. Accordingly, we cannot assure you that our financial condition and results of operations will not be materially impacted by inflation in the future.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Item 8. Financial Statements and Supplementary Data

Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors of
Precipio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Precipio, Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Critical Audit Matters

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

Assessment of the estimation for collections over diagnostic testing for which revenue is recognized.

Description of Matter
As described in Note 2 to the financial statements, the Company records its service revenues from diagnostic testing net of contractual and collection allowances that are estimated based on historical trends and anticipated reimbursement from third party payers. As of December 31, 2025, the Company recognized gross revenue of approximately $53.5 million along with contractual allowances of approximately $29.2 million and collection allowances of approximately $0.2 million. The net revenue figure of approximately $24.0 million is recorded as net sales on the consolidated statements of operations.

The principal considerations for our determination that performing procedures over revenue recognition relating to the service revenue is a critical audit matter are based on the significant judgments by management in estimating the amount to be recognized as revenue as well as the effort and complexity in assessing audit evidence in performing procedures to evaluate the amount recognized. The calculation involves estimating adjustments to gross revenue based upon sales mix and third-party contractual terms,such as Medicare rates or variations of Medicare rates.

How We Addressed the Matter
We obtained an understanding of the design of controls in place over the Company's process to calculate the various allowances. Our audit procedures included the evaluation of significant inputs through the evaluation of the Company's retrospective analysis of allowances as compared to actual payments received, evaluation of estimates based on historical collections by payer, and performance of analytical procedures and sensitivity analyses over the Company's significant inputs to assess the Company's ability to accurately estimate the allowances. We also tested the underlying data used in management's calculations for accuracy and completeness, which included detail testing of the service revenue.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2016 (such date takes into account the acquisition of the attest business of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

New Haven, CT
March 30, 2026

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of
Precipio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Precipio, Inc. (the "Company") as of December 31, 2024, the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has a significant working capital deficiency, has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

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

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

Marcum LLP

We served as the Company's auditor from 2016 through 2025.

New Haven, CT
March 27, 2025, except for Note 9, as to which the date is March 30, 2026

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2025 and 2024
(Dollars in thousands, except share data)

	2025	2024
ASSETS		
CURRENT ASSETS:		
Cash	$ 2,651	$ 1,389
Accounts receivable (net of allowance for credit losses of $1,045 and $995, respectively)	1,984	799
Inventories	935	724
Other current assets	469	539
Total current assets	6,039	3,451
PROPERTY AND EQUIPMENT, NET	729	719
OTHER ASSETS:		
Finance lease right-of-use assets, net	998	517
Operating lease right-of-use assets, net	2,565	395
Intangibles, net	10,919	11,869
Other assets	67	45
Total assets	$ 21,317	$ 16,996
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt, less debt issuance costs	$ 30	$ 297
Current maturities of finance lease liabilities	209	124
Current maturities of operating lease liabilities	410	201
Accounts payable	1,131	618
Accrued expenses	1,690	2,799
Deferred revenue	282	232
Total current liabilities	3,752	4,271
LONG TERM LIABILITIES:		
Long-term debt, less current maturities and debt issuance costs	47	77
Finance lease liabilities, less current maturities	751	348
Operating lease liabilities, less current maturities	2,206	206
Total liabilities	6,756	4,902
COMMITMENTS AND CONTINGENCIES (Note 8)		
STOCKHOLDERS' EQUITY:		
Preferred stock - $0.01 par value, 15,000,000 shares authorized at December 31, 2025 and December 31, 2024, 47 shares issued and outstanding at December 31, 2025 and December 31, 2024, liquidation preference of $135 at December 31, 2025	—	—
Common stock, $0.01 par value, 150,000,000 shares authorized at December 31, 2025 and December 31, 2024, 1,780,899 and 1,493,639 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	18	15
Additional paid-in capital	117,346	114,519
Accumulated deficit	(102,803)	(102,440)
Total stockholders' equity	14,561	12,094
Total liabilities and stockholders' equity	$ 21,317	$ 16,996

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2025 and 2024
(Dollars in thousands, except per share data)

	2025	2024
SALES:		
Service revenue, net	$ 21,506	$ 15,965
Product revenue	2,740	2,611
Revenue, net of contractual allowances and adjustments	24,246	18,576
Adjustment for allowance for credit losses	(197)	(44)
Net sales	24,049	18,532
COST OF SALES:		
Cost of service revenue	12,088	9,643
Cost of product revenue	1,255	1,330
Total cost of sales	13,343	10,973
Gross profit	10,706	7,559
OPERATING EXPENSES:		
Operating expenses	11,908	11,775
OPERATING LOSS	(1,202)	(4,216)
OTHER INCOME (EXPENSE):		
Interest expense, net	(73)	(74)
Gain on settlement of liability	143	—
Employee Retention Credit	789	—
Other expense	(20)	—
Total other income (expense)	839	(74)
LOSS BEFORE INCOME TAXES	(363)	(4,290)
INCOME TAX EXPENSE	–	—
NET LOSS	$ (363)	$ (4,290)
Net loss per common share:		
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.23)	$ (2.93)
BASIC AND DILUTED WEIGHTED-AVERAGE SHARES OF COMMON STOCK OUTSTANDING	1,605,080	1,465,518

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2025 and 2024
(Dollars in thousands)

	Preferred Stock		Common Stock		Additional		
	Outstanding Shares	Par Value	Outstanding Shares	Par Value	Paid-in Capital	Accumulated Deficit	Total Precipio, Inc.
Balance, January 1, 2024	47	$ —	1,420,125	$ 14	$ 112,565	$ (98,150)	$ 14,429
Net loss	—	—	—	—	—	(4,290)	(4,290)
Issuance of common stock in connection with at the market offering, net of issuance costs	—	—	11,822	—	78	—	78
Issuance of common stock for Board fees and consulting services	—	—	61,692	1	385	—	386
Non-cash stock-based compensation in connection with stock options	—	—	—	—	1,491	—	1,491
Balance, December 31, 2024	47	$ —	1,493,639	$ 15	$ 114,519	$ (102,440)	$ 12,094
Net loss	—	—	—	—	—	(363)	(363)
Proceeds upon issuance of common stock from exercise of warrants	—	—	242,562	3	1,258	—	1,261
Proceeds upon issuance of common stock from exercise of stock options	—	—	15,279	—	119	—	119
Issuance of common stock for Board fees and consulting services	—	—	29,419	—	241	—	241
Non-cash stock-based compensation in connection with stock options	—	—	—	—	1,209	—	1,209
Balance, December 31, 2025	47	$ —	1,780,899	$ 18	$ 117,346	$ (102,803)	$ 14,561

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2025 and 2024
(Dollars in thousands)

	Year Ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (363)	$ (4,290)
Adjustments to reconcile net loss to net cash flows provided by operating activities:		
Depreciation and amortization	1,245	1,199
Amortization of operating lease right-of-use asset	319	217
Amortization of finance lease right-of-use asset	188	97
Amortization of deferred financing costs, debt discounts and debt premiums	3	3
Gain on settlement of liability	(143)	—
Stock-based compensation	1,209	1,491
Value of stock issued in payment of Board fees and consulting services	241	386
Provision for credit losses	177	64
Derecognition of finance lease right-of-use asset and liability	(4)	2
Derecognition of operating lease right-of-use asset and liability	(38)	—
Loss on disposal of asset	20	—
Changes in operating assets and liabilities:		
Accounts receivable	(1,362)	438
Inventories	(211)	(340)
Other assets	48	303
Accounts payable	513	(10)
Operating lease liabilities	(241)	(218)
Deferred revenue	50	122
Accrued expenses	(966)	975
Net cash provided by operating activities	685	439
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(326)	(223)
Net cash used in investing activities	(326)	(223)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on finance lease obligations	(157)	(92)
Deposits on finance lease right-of-use assets	(20)	(28)
Issuance of common stock, net of issuance costs	—	78
Proceeds from exercise of warrants	1,261	—
Proceeds from exercise of stock options	119	—
Proceeds from debt	—	250
Principal payments on long-term debt	(300)	(537)
Net cash flows provided by (used in) financing activities	903	(329)
NET CHANGE IN CASH	1,262	(113)
CASH AT BEGINNING OF PERIOD	1,389	1,502
CASH AT END OF PERIOD	$ 2,651	$ 1,389

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS - continued
For the Years Ended December 31, 2025 and 2024
(Dollars in thousands)

	Year Ended December 31,	
	2025	2024
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid during the period for interest	$ 100	$ 85
SUPPLEMENTAL DISCLOSURE OF CONSULTING SERVICES OR ANY OTHER NON-CASH COMMON STOCK RELATED ACTIVITY		
Purchases of equipment financed through accounts payable	—	6
Prepaid insurance financed with loan	—	317
Operating lease right-of-use assets obtained in exchange for operating lease obligations	2,489	—
Finance lease right-of-use assets obtained in exchange for finance lease obligations	649	414

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
For the Years Ended December 31, 2025 and 2024

1. BUSINESS DESCRIPTION

Business Description.

Precipio, Inc., and its subsidiaries, (collectively, "we", "us", "our", the "Company" or "Precipio") is a healthcare biotechnology company focused on improving cancer diagnostics. The Company's objective is to enhance diagnostic accuracy and accessibility while building a sustainable business model that supports ongoing innovation. The Company can achieve this through a combination of clinical laboratory services and proprietary diagnostic product development. By integrating diagnostic services with product development, the Company's service business doubles as a self-funded research and development (R&D) unit, enabling the Company to achieve rapid and cost-efficient innovation rather than being a major cost center of the Company.

This unique integrated operating structure is the foundation of the Company's approach to research, development, and product commercialization. Unlike companies that rely primarily on stand-alone research facilities or external clinical validation programs, the Company's clinical laboratory operations enables its R&D team to evaluate, refine, and validate diagnostic products in the course of routine clinical testing activities, and at minimal incremental cost. Through these activities, the Company generates clinical data, operational experience, and specimen access that support ongoing assay development and product improvement. While these activities are initially conducted to provide diagnostic services to patients and their healthcare providers, they also contribute to product development and validation processes.

Precipio has a single operating segment but operates two business divisions that are complementary to each other. The Company's pathology services division provides specialized cancer diagnostic testing services to physicians, hospitals, and laboratories. This division generates revenue and supports the development of the Company's expertise in oncology diagnostics. The pathology services division delivers specialized diagnostic testing focused primarily on hematologic cancers and operates a full laboratory that includes all the equipment, personnel, and work processes required to receive patient samples daily, and deliver clinical results to the physicians under the proper compliance umbrella, while also generating profitable revenue to the company. While reimbursement levels and testing volumes may vary, the Company views this division as an important foundation for both current operations and future product development.

The Company's product division develops and commercializes proprietary diagnostic assay kits designed for use by clinical laboratories. These products allow the Company to expand its reach by enabling other laboratories to benefit from the diagnostic products developed by the Company, while building scalable diagnostic solutions. The Company believes this dual structure provides a unique model for R&D development of clinically applicable products, while delivering operational stability and supporting innovation and future growth. Furthermore, it provides the Company with substantial competitive advantages in terms of the economics of product development, and time to market. The products division focuses on developing proprietary diagnostic assays and kits intended for use by other clinical laboratories. These products are designed to improve testing accessibility and laboratory workflow efficiency while enabling broader market reach without requiring Precipio to perform all testing internally. Product revenues may offer greater scalability than traditional laboratory services, although adoption depends on regulatory, reimbursement, and market factors.

To deliver our strategy, we have structured our organization to develop diagnostic products, including our laboratory and research and development ("R&D") facilities located in New Haven, Connecticut and Omaha, Nebraska, respectively, which house teams that collaborate on the development of new products and services. We operate clinical laboratory improvement amendment ("CLIA") laboratories in both New Haven, Connecticut and Omaha, Nebraska where we provide essential blood cancer diagnostics to office-based oncologists in many states nationwide. To deliver on our strategy of mitigating misdiagnoses we rely heavily on our CLIA laboratories to support R&D beta-testing of the products we develop, in a clinical environment.

Our operating structure promotes the harnessing of our proprietary technology and genetic diagnostic expertise to bring to market our robust pipeline of innovative solutions designed to address the root causes of misdiagnoses.

Going Concern.

The consolidated financial statements have been prepared using accounting principles generally accepted in the United States of America ("GAAP") applicable for a going concern, which assume that the Company will realize its assets and discharge its liabilities in the ordinary course of business and do not include any adjustments that might result should the Company be unable to continue as a going concern. The Company has incurred substantial operating losses and has typically used cash in its operating activities for the past several years. For the year ended December 31, 2025, the Company had an operating loss of $1.2 million and net cash provided by operating activities of $0.7 million. As of December 31, 2025, the Company had an accumulated deficit of $102.8 million and working capital of $2.3 million. The Company's ability to continue as a going concern, over the next twelve months from the date of issuance of these consolidated financial statements in this Annual Report on Form 10-K, is dependent upon a combination of achieving its business plan, including generating additional revenue and avoiding potential business disruption due to the macroeconomic environment and geopolitical instability, and raising additional financing, if needed, to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

There remains substantial doubt about the Company's ability to continue as a going concern for the next twelve months from the date these consolidated financial statements were issued. There can be no assurance that the Company will be able to successfully achieve its initiatives summarized above in order to continue as a going concern over the next twelve months from the date of issuance of this Annual Report Form 10-K. The accompanying financial statements have been prepared assuming the Company will continue as a going concern over the next twelve months from the date of issuance of this Annual Report Form 10-K.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation.

The consolidated financial statements include the accounts of Precipio, Inc. and our wholly owned subsidiaries. All inter-company balances and transactions have been eliminated in consolidation.

Use of Estimates.

The preparation of the consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of net sales and expenses during the reporting period. The most significant estimates and assumptions with regard to these consolidated financial statements relate to the allowance for credit losses, assumptions used within the fair value of debt and equity transactions and contractual allowances. These assumptions require considerable judgment by management. Actual results could differ from the estimates and assumptions used in preparing these consolidated financial statements.

Risks and Uncertainties.

Certain risks and uncertainties are inherent in our day-to-day operations and in the process of preparing our financial statements. The more significant of those risks are presented below and throughout the notes to the consolidated financial statements.

The Company operates in the healthcare industry which is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not necessarily limited to, matters such as licensure, accreditation, government healthcare program participation requirements, reimbursement for patient services, and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers. Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws

and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation as well as regulatory actions unknown or unasserted at this time.

Fair Value.

Unless otherwise specified, book value approximates fair value. Our common stock warrant liabilities are recorded at fair value. See Note 11 – "Fair Value" for additional information.

Other Current Assets.

Other current assets of $0.5 million as of December 31, 2025 include prepaid insurance of approximately $0.3 million and prepaid and other assets of $0.2 million. Other current assets of $0.5 million as of December 31, 2024 include prepaid insurance of $0.3 million and prepaid and other assets of $0.2 million.

Concentrations of Risk.

From time to time, we may maintain a cash position with financial institutions in amounts that exceed Federal Deposit Insurance Corporation insured limits of up to $250,000 per depositor per financial institution. We have not experienced any losses on such accounts as of December 31, 2025.

Service companies in the health care industry typically grant credit without collateral to patients. The majority of these patients are insured under third-party insurance agreements. The services provided by the Company are routinely billed utilizing the Current Procedural Terminology (CPT) code set designed to communicate uniform information about medical services and procedures among physicians, coders, patients, accreditation organizations, and payers for administrative, financial, and analytical purposes. CPT codes are currently identified by the Centers for Medicare and Medicaid Services and third-party payers. The Company utilizes CPT codes for Pathology and Laboratory Services contained within codes 80000-89398.

Inventories.

Inventories consist of laboratory supplies and diagnostic assay kits and are valued at cost (determined on an average cost basis, which approximates the first-in, first-out method) or net realizable value, whichever is lower. We evaluate inventory for items that are slow moving or obsolete and record an appropriate reserve for obsolescence if needed. The allowance for slow moving or obsolete inventory was zero at December 31, 2025 and 2024, respectively.

Property and Equipment, net.

Property and equipment are carried at cost, net of accumulated depreciation and amortization. Expenditures for maintenance and repairs are expensed as incurred. Depreciation and amortization are computed by the straight-line method over the estimated useful lives of the related assets as follows:

Furniture and fixtures	5 to 7 years
Leasehold improvements	Lesser of useful life or lease term
Laboratory equipment	3 to 10 years
Computer equipment and software	3 to 7 years

For assets sold or otherwise disposed of, the cost and related accumulated depreciation and amortization are removed from the accounts, and any related gain or loss is reflected in operations for the period. Expenditures for major betterments that extend the useful lives of property and equipment are capitalized.

Intangible Assets.

We review our amortizable long-lived assets for impairment annually or whenever events indicate that the carrying amount of the asset (group) may not be recoverable. An impairment loss may be needed if the sum of the future

undiscounted cash flows is less than the carrying amount of the asset (group). The amount of the loss would be determined by comparing the fair value of the asset to the carrying amount of the asset (group). There were no impairment charges on our amortizable long-lived assets during the years ended December 31, 2025 and 2024.

Debt Issuance Costs

Debt issuance costs are being amortized over the lives of the related financings on a basis that approximates the effective interest method. Costs are presented as a reduction of the related debt in the accompanying balance sheets. The amortization expense recorded was less than $0.1 million for the years ended December 31, 2025 and 2024, respectively. See Note 5 – "Long Term Debt" for further discussion.

Stock-Based Compensation.

All stock-based awards to date have exercise prices equal to the market price of our common stock on the date of grant and have ten-year contractual terms. Stock-based compensation cost is based on the fair value of the portion of stock-based awards that is ultimately expected to vest. The Company utilizes the Black-Scholes or other option pricing models for determining the estimated fair value for stock-based awards. As of December 31, 2025 unvested awards with time-based vesting had vesting periods of up to four years from the date of grant. As of December 31, 2025 and 2024, the Company had unvested awards with market-condition vesting of 30,000 and zero, respectively. No awards outstanding at December 31, 2025 and 2024, respectively, are subject to performance vesting conditions.

Net Sales Recognition.

Revenue recognition occurs when a customer obtains control of the promised goods and service. Revenue assigned to the goods and services reflects the consideration which the Company expects to receive in exchange for those goods and services.

The Company derives its revenues from diagnostic testing - histology, flow cytometry, cytology and molecular testing; clinical research from bio-pharma customers, state and federal grant programs; biomarker testing from bio-pharma customers and from other product sales including revenues from equipment leases and reagent sales associated with our HSRR program. All sources of revenue are recorded net of accruals for estimated chargebacks, rebates, cash discounts, other allowances, and returns. Due to differences in the substance of these revenue types, the transactions require, and the Company utilizes, different revenue recognition policies for each. See more detailed information on revenue in Note 13 – Sales Service Revenue, Net And Accounts Receivable.

The Company recognizes revenue utilizing the five-step framework of ASC 606. Control of the laboratory testing services is transferred to the customer at a point in time. As such, the Company recognizes revenue for diagnostic testing at a point in time based on the delivery method (web-portal access or fax) for a patient's laboratory report. Diagnostic testing service revenue is reported at the estimated net realizable amounts from patients, third-party payers and others for services rendered, including retroactive adjustment under reimbursement agreements with third-party payers. Provisions for third-party payer settlements are provided in the period in which the related services are rendered and adjusted in the future periods, as final settlements are determined. For clinical research and biomarker services, the Company utilizes an "effort based" method of assessing performance and measures progress towards satisfaction of the performance obligation based upon the delivery of results per the contract. Control of reagents and other diagnostic products are transferred to the customer at a point in time and, as such, the Company recognizes these revenues at a point in time based on the delivery method. When we receive payment in advance, we initially defer the revenue and recognize it when we deliver the service.

Taxes collected from customers and remitted to government agencies for specific net sales producing transactions are recorded net with no effect on the statements of operations.

Accounts Receivable

Accounts Receivable result from diagnostic services provided to self-pay and insured patients, project based testing services and clinical research. The payment for services provided by the Company are generally due within 30 days

from the invoice date. Accounts receivable are reduced by an allowance for credit losses. In evaluating the collectability of accounts receivable, the Company analyzes and identifies trends for each of its sources of revenue to estimate the appropriate allowance for credit losses. For receivables associated with self-pay patients, including patients with insurance and a deductible and copayment, the Company records an allowance for credit losses in the period of services on the basis of past experience of patients unable or unwilling to pay for service fee for which they are financially responsible. For receivables associated with services provided to patients with third-party coverage, the Company analyzes contractually due amounts and provides an allowance, if necessary. The difference between the standard rates and the amounts actually collected after all reasonable collection efforts have been exhausted is charged against the allowance for credit losses.

Presentation of Insurance Claims and Related Insurance Recoveries.

The Company accounts for its insurance claims and related insurance recoveries at their gross values as standards for health care entities do not allow the Company to net insurance recoveries against the related claim liabilities. There were no insurance claims or insurance recoveries recorded during the years ended December 31, 2025 and 2024.

Advertising Costs.

Advertising costs are expensed as incurred and are included in operating expenses on the consolidated statements of operations. Advertising costs charged to operations were approximately $0.1 million in 2025 and 2024, respectively.

Research and Development Costs.

All costs associated with internal research and development are expensed as incurred. These costs include salaries and employee related expenses, operating supplies and facility-related expenses. Research and development costs charged to operations totaled $1.6 million and $1.3 million for the years ended December 31, 2025 and 2024, respectively.

Income Taxes.

Deferred tax assets and liabilities are determined based on the differences between the financial reporting and tax basis of assets and liabilities at each balance sheet date using tax rates expected to be in effect in the year the differences are expected to reverse. The effect on the deferred tax assets and liabilities of a change in tax rates is recognized in the period when the change in tax rates is enacted.

A valuation allowance is established when it is determined that it is more likely than not that some portion or all of the deferred tax assets will not be realized. A full valuation allowance has been applied against the Company's net deferred tax assets as of December 31, 2025 and 2024, due to projected losses and because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets.

Management's conclusions regarding uncertain tax positions may be subject to review and adjustment at a later date based upon ongoing analysis of, or changes in tax laws, regulations and interpretations thereof as well as other factors. The Company's policy is to record interest and penalties directly related to income taxes as income tax expense in the accompanying consolidated statements of operations, of which there was none for the years ended December 31, 2025 and 2024.

Common Stock Warrants.

The Company classifies the issuance of common stock warrants as equity any contracts that (i) require physical settlement or net-stock settlement or (ii) gives the Company a choice of net-cash settlement or settlement in its own stocks (physical settlement or net-stock settlement). The Company classifies as assets or liabilities any contracts that (i) require net-cash settlement (including a requirement to net-cash settle the contract if an event occurs and if that event is outside of the Company's control), or (ii) gives the counterparty a choice of net-cash settlement or settlement in stock (physical settlement or net-stock settlement).

Historically, certain of our issued warrants to purchase common stock did not qualify to be treated as equity and accordingly, were recorded as a liability ("Common Stock Warrant Liability"). We are required to present these instruments at fair value at each reporting date and any changes in fair values are recorded as an adjustment to earnings.

Consolidation of Variable Interest Entities.

We evaluate any entity in which we are involved to determine if the entity is a VIE and if so, whether we hold a variable interest and are the primary beneficiary. We consolidate VIEs that are subject to assessment when we are deemed to be the primary beneficiary of the VIE. The process for determining whether we are the primary beneficiary of the VIE is to conclude whether we are a party to the VIE holding a variable interest that meets both of the following criteria: (1) has the power to make decisions that most significantly affect the economic performance of the VIE, and (2) has the obligation to absorb losses or the right to receive benefits that in either case could potentially be significant to the VIE.

Loss Per Share.

Basic loss per share is calculated based on the weighted-average number of common shares outstanding during each period. Diluted loss per share includes shares issuable upon exercise of outstanding stock options, warrants or conversion rights that have exercise or conversion prices below the market value of our common stock. Options, warrants and conversion rights pertaining to 375,181 and 754,251 shares of our common stock have been excluded from the computation of diluted loss per share at December 31, 2025 and 2024, respectively, because the effect is anti-dilutive due to the net loss.

The following table summarizes the outstanding securities not included in the computation of diluted net loss per share:

	December 31,	
	2025	2024
Stock options	359,306	303,932
Warrants	10,000	444,444
Preferred stock	5,875	5,875
Total	375,181	754,251

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU 2023-09—Income Taxes (Topic 740)—Improvements to Income Tax Disclosures ("ASU 2023-09") which amends the Codification to enhance the transparency and decision usefulness of income tax disclosures. ASU 2023-09 requires additional disaggregation of the reconciliation between the statutory and effective tax rate for an entity and of income taxes paid, both of which are disclosures required by current GAAP. The amendments improve the transparency of income tax disclosures by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) income taxes paid to be disaggregated by jurisdiction. The amendments in ASU 2023-09 apply to all entities that are subject to Topic 740, Income Taxes. For public business entities, the amendments in ASU 2023-09 are effective for annual periods beginning after December 15, 2024, with early adoption permitted. The Company has adopted this standard with retrospective application in the 2025 annual financial statements and have included the additional disclosures in Note 9 - Income Taxes.

Recent Accounting Pronouncements Not Yet Adopted.

In November 2024, the FASB issued ASU 2024-03, Income Statement—Reporting Comprehensive Income (Topic 220): Expense Disaggregation Disclosures (ASU 2024-03"). This update requires entities to disaggregate operating expenses into specific categories, such as purchases of inventory, compensation, depreciation, and amortization, to provide enhanced transparency into the nature and function of expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, with early adoption permitted. ASU 2024-03 may be applied retrospectively or prospectively. The Company is currently evaluating the impact of this standard on its financial statement presentation and disclosures.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments — Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides a practical expedient related to the estimation of expected credit losses for current accounts receivable and current contract assets arising from transactions accounted for under Topic 606, including those assets acquired in a business combination. The practical expedient permits all entities to assume that current conditions as of the balance sheet date do not change for the remaining life of the asset. This ASU is effective for fiscal years beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. The Company is currently evaluating the impact of adopting this standard on its consolidated financial statements and disclosures.

In September 2025, the FASB issued ASU 2025-06, *Intangibles — Goodwill and Other — Internal-use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software,* which eliminates the previous stage-based model for capitalizing software costs and replaces it with a principles-based framework. This new guidance is designed to be more adaptable to modern, agile software development methods, clarifying when an entity should capitalize software costs based on a "probable-to-complete" threshold. This ASU is effective for fiscal years beginning after December 15, 2027, and interim reporting periods within those annual reporting periods, and may be applied using a prospective, modified, or retrospective transition approach. The Company is currently evaluating the impact of adopting this standard on its consolidated financial statements and disclosures.

3. PROPERTY AND EQUIPMENT, NET

A summary of property and equipment at December 31, 2025 and 2024 is as follows:

	2025	2024
Furniture and fixtures and leasehold improvements	$ 26	$ 34
Laboratory equipment	1,233	1,017
Computer equipment and laboratory software	1,309	1,209
Construction in process	27	86
	2,595	2,346
Less—accumulated depreciation and amortization	(1,866)	(1,627)
Total	$ 729	$ 719

Depreciation expense was approximately $0.3 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively.

4. INTANGIBLES

Intangible assets consist of the following:

	Dollars in Thousands December 31, 2025		
	Cost	Accumulated Amortization	Net Book Value
Technology	$ 18,990	$ 8,071	$ 10,919

	Dollars in Thousands December 31, 2024		
	Cost	Accumulated Amortization	Net Book Value
Technology	$ 18,990	$ 7,121	$ 11,869

	Estimated Useful Life	
Technology	20	years

Amortization expense for intangible assets was $1.0 million during the years ended December 31, 2025 and 2024, respectively. Amortization expense for intangible assets is expected to be $1.0 million for each of the years ending December 31, 2026, 2027, 2028, 2029 and 2030, respectively.

5. LONG-TERM DEBT

Long-term debt consists of the following:

	Dollars in Thousands	
	December 31, 2025	December 31, 2024
Connecticut Department of Economic and Community Development (DECD)	$ 83	$ 115
DECD debt issuance costs	(6)	(9)
Financed insurance loan	—	177
Business loan agreement	—	91
Total long-term debt	77	374
Current portion of long-term debt	(30)	(297)
Long-term debt, net of current maturities	$ 47	$ 77

Department of Economic and Community Development

On January 8, 2018, the Company entered into an agreement with DECD by which the Company received a loan of $300,000 secured by substantially all of the Company's assets (the "DECD 2018 Loan"). The DECD 2018 Loan is a ten-year loan due on December 31, 2027 and includes interest paid monthly at 3.25%. The maturity date of the DECD 2018 Loan was extended to May 31, 2028 and the modification did not have a material impact on the Company's cash flows.

Debt issuance costs associated with the DECD 2018 Loan were approximately $31.0 thousand. Amortization of the debt issuance cost was approximately $3.0 thousand and $3.0 thousand for the years ended December 31, 2025 and 2024, respectively. Net debt issuance costs were approximately $6.0 thousand and $9.0 thousand at December 31, 2025 and 2024, respectively, and are presented as a reduction of the related debt in the accompanying consolidated balance sheets. Amortization for each of the next two years is expected to be approximately $3.0 thousand.

Financed Insurance Loan.

The Company finances certain of its insurance premiums (the "Financed Insurance Loans"). In July 2024, the Company financed $0.3 million with a 9.99% interest rate and made payments on a monthly basis through June 2025. As of December 31, 2025 and 2024, the Financed Insurance Loan's outstanding balance of zero and $0.2 million, respectively, was included in current maturities of long-term debt in the Company's consolidated balance sheets. A corresponding prepaid asset was included in other current assets in the Company's consolidated balance sheets.

Business Loan Agreement.

On May 1, 2024, the Company entered into a Business Loan and Security Agreement (the "Loan Agreement") with Altbanq Lending LLC, pursuant to which the Company obtained a loan in the principal amount of $250,000 (the "Secured Loan"). According to the Loan Agreement, the Company granted the lender a continuing security interest in certain collateral (as defined in the Loan Agreement). Furthermore, the Company's Chief Executive Officer provided a personal guaranty for the Secured Loan. The Secured Loan has a term of one year and an interest rate of 20%, such that pursuant to the Loan Agreement, the Company is obligated to pay the Lender fifty-two payments of $5,769 on a weekly basis and the total sum of the Secured Loan and interest (not including any fees) is equal to a total repayment amount of $300,000 ("the Repayment Amount"). If the Company defaulted on payments then a default fee of $15,000 shall be payable to the lender. As of the date hereof, the Repayment Amount was paid in full and the Company did not default on any payments

As of December 31, 2025 and December 31, 2024, the outstanding balance of zero and $0.1 million, respectively, under the Loan Agreement, was included in current maturities of long-term debt in the Company's consolidated balance sheets.

The aggregate future maturities required on gross long-term debt at December 31, 2025 are as follows:

	2026	2027	2028	Total
DECD loan	$ 33	$ 34	$ 16	$ 83

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES.

Accrued expenses at December 31, 2025 and 2024 are as follows:

(dollars in thousands)	December 31, 2025	December 31, 2024
Accrued expenses	$ 402	$ 595
Accrued compensation	977	955
Accrued franchise, property and sales and use taxes	209	173
CHC temporary funding assistance	83	1,057
Accrued interest	19	19
	$ 1,690	$ 2,799

The Company uses Change Healthcare ("CHC"), a healthcare technology company owned by UnitedHealth Group, to process some of its patient claims billings. In February 2024, CHC announced that it had experienced a cyberattack and as a result had to temporarily shut down some of its information technology systems. This system shut down caused delays in billing and reimbursement processes to CHC's customers and, as a result, CHC established a Temporary Funding Assistance Program to help bridge the gap in short-term cash flow needs for customers affected by the disruption of its services due to the cyberattack. Funding distributed through this program is interest free and has no other fees or costs associated with it.

During the year ended December 31, 2024, the Company received approximately $1.1 million through CHC's Temporary Assistance Program. On October 28, 2024, the Company received a notice from CHC stating that they have restored the connectivity of their systems and are requesting repayment of the funds the Company received through the Temporary Assistance Program. The repayment date contained in the notice was January 2, 2025.

During the year ended December 31, 2025, we made approximately $0.9 million in repayments to CHC and wrote off another $0.1 million, leaving a balance of approximately $0.1 million as of December 31, 2025. In January 2026, the Company paid the remaining amount due and as of the issuance of this Annual Report on Form 10-K there was no amount due to CHC.

7. LEASES

The Company leases administrative facilities and laboratory equipment through operating lease agreements. In addition we rent various equipment used in our diagnostic lab and in our administrative offices through finance lease arrangements. Our operating leases include both lease (e.g., fixed payments including rent) and non-lease components (e.g., common area or other maintenance costs). The facility leases include one or more options to renew, from 1 to 5 years or more. The exercise of lease renewal options is typically at our sole discretion, therefore, the renewals to extend the lease terms are not included in our right-of-use ("ROU") assets and lease liabilities as they are not reasonably certain of exercise. We regularly evaluate the renewal options and, when they are reasonably certain of exercise, we include the renewal period in our lease term. As our leases do not provide an implicit rate, we use our collateralized incremental borrowing rate based on the information available at the lease commencement date in determining the present value of the lease payments.

Operating leases result in the recognition of ROU assets and lease liabilities on the balance sheet. ROU assets represent our right to use the leased asset for the lease term and lease liabilities represent our obligation to make lease payments. Operating lease ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. Lease expense is recognized on a straight-line basis over the lease term. Leases with an initial term of 12 months or less are not recorded on the balance sheet. The primary leases we enter into with initial terms of 12 months or less are for equipment.

The Company also recognizes ROU assets from finance leases in connection with its HSRR program. For certain customers in the HSRR program, the Company leases diagnostic testing equipment and then subleases the equipment to the customer. Finance lease ROU assets and finance lease liabilities are recognized at the lease commencement date, and at the sublease commencement date the finance lease ROU asset is derecognized and is recorded as cost of sales in the consolidated statements of operations. There were no derecognized finance lease ROU assets related to the HSRR program for the years ended December 31, 2025 and 2024. Where Precipio is the lessor, customers lease diagnostic testing equipment from the Company with the transfer of ownership to the customer at the end of the lease term at no additional cost. For these contracts, the Company accounts for the arrangements as sales-type leases. The lease asset for sales-type leases is the net investment in leased asset, which is recorded once the finance lease ROU asset is derecognized and a related gain or loss is noted. The net investment in leased assets was zero and less than $0.1 million as of December 31, 2025 and 2024, respectively, and is included in other current assets and other assets in our consolidated balance sheets.

The balance sheet presentation of our operating and finance leases is as follows:

(dollars in thousands)

Classification on the Consolidated Balance Sheet	December 31, 2025	December 31, 2024
Assets:		
Operating lease right-of-use assets, net	$ 2,565	$ 395
Finance lease right-of-use assets, net	998	517
Total lease assets	$ 3,563	$ 912
Liabilities:		
Current:		
Current maturities of operating lease liabilities	$ 410	$ 201
Current maturities of finance lease liabilities	209	124
Noncurrent:		
Operating lease liabilities, less current maturities	2,206	206
Finance lease liabilities, less current maturities	751	348
Total lease liabilities	$ 3,576	$ 879

As of December 31, 2025, the estimated future minimum lease payments, excluding non-lease components, are as follows:

(dollars in thousands)	Operating Leases	Finance Leases	Total
	December 31, 2025	December 31, 2025	December 31, 2025
2026	$ 648	$ 300	$ 948
2027	701	274	975
2028	745	234	979
2029	787	186	973
2030	299	129	428
Thereafter	93	78	171
Total lease obligations	3,273	1,201	4,474
Less: Amount representing interest	(657)	(241)	(898)
Present value of net minimum lease obligations	2,616	960	3,576
Less, current portion	(410)	(209)	(619)
Long term portion	$ 2,206	$ 751	$ 2,957

Other information as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Weighted-average remaining lease term (years):		
Operating leases	4.6	1.9
Finance leases	4.5	4.4
Weighted-average discount rate:		
Operating leases	10.00%	8.00%
Finance leases	10.70%	11.20%

During the years ended December 31, 2025 and 2024, operating cash flows from operating leases were $0.2 million, respectively, and operating lease ROU assets obtained in exchange for operating lease liabilities were $2.5 million and zero, respectively.

Operating Lease Costs

Operating lease costs were $0.3 million and $0.2 million during the years ended December 31, 2025 and 2024, respectively. These costs are primarily related to long-term operating leases for the Company's facilities and laboratory equipment. Short-term and variable lease costs were less than $0.1 million for the years ended December 31, 2025 and 2024, respectively.

Finance Lease Costs

Finance lease amortization and interest expenses are included in the consolidated statements of operations for the years ended December 31, 2025 and 2024. The balances within these accounts are approximately $0.3 million and $0.1 million, respectively.

8. COMMITMENTS AND CONTINGENCIES

PURCHASE COMMITMENTS

The Company has entered into purchase commitments for reagents from suppliers. Some of these agreements run through 2031. The Company and the suppliers will true up the amounts on an annual basis. The future minimum purchase commitments under these and other purchase agreements are as follows:

Years ending December 31,	(dollars in thousands)
2026	$ 2,290
2027	158
2028	158
2029	158
2030	158
Thereafter	158
	$ 3,080

LITIGATIONS

The Company is involved in legal proceedings related to matters, which are incidental to its business. Also, the Company is delinquent on the payment of outstanding accounts payable for certain vendors and suppliers who have taken or have threatened to take legal action to collect such outstanding amounts. See below for a discussion on these matters.

CPA Global provides us with certain patent management services. On February 6, 2017, CPA Global claimed that we owe approximately $0.2 million for certain patent maintenance services rendered. CPA Global has not filed claims against us in connection with this allegation. A liability of less than $0.1 million has been recorded and is reflected in accounts payable within the accompanying consolidated balance sheets at December 31, 2025 and 2024.

During the year ended December 31, 2025, the Company was involved in a legal proceeding brought by a former employee before the court in San Antonio, Texas, alleging unfair dismissal and seeking monetary damages. The matter was resolved in 2025 through a settlement agreement. The settlement was reached without any admission of liability and is not material to the Company's financial statements. Accordingly, the matter is considered closed.

LEGAL AND REGULATORY ENVIRONMENT

The healthcare industry is subject to numerous laws and regulations of federal, state and local governments. These laws and regulations include, but are not limited to, matters such as licensure, accreditation, government healthcare program participation requirement, reimbursement for patient services and Medicare and Medicaid fraud and abuse. Government activity has increased with respect to investigations and allegations concerning possible violations of fraud and abuse statutes and regulations by healthcare providers.

Violations of these laws and regulations could result in expulsion from government healthcare programs together with the imposition of significant fines and penalties, as well as significant repayments for patient services previously billed. Management believes that the Company is in compliance with fraud and abuse regulations, as well as other applicable government laws and regulations. While no material regulatory inquiries have been made, compliance with such laws and regulations can be subject to future government review and interpretation, as well as regulatory actions unknown or unasserted at this time.

9. INCOME TAXES

Net loss before income tax expense for the years ended December 31, 2025 and 2024 is as follows:

	Dollars in Thousands	
	2025	2024
U.S. Operations	$ (363)	$ (4,290)
Total	$ (363)	$ (4,290)

The income tax expense consists of the following for the years ended December 31, 2025 and 2024.

	Dollars in Thousands	
	2025	2024
Federal:		
Current	$ —	$ —
Deferred	—	—
Total Federal	$ —	$ —
State:		
Current	$ —	$ —
Deferred	—	—
Total State	$ —	$ —
Foreign:		
Current	$ —	$ —
Deferred	—	—
Total Foreign	$ —	$ —
Total Tax Provision	$ —	$ —

The Company's provision for income taxes for the years ended December 31, 2025 and December 31, 2024 relates to income taxes in states and other jurisdictions and differs from the amounts determined by applying the statutory federal income tax rate to the loss before income taxes for the following reasons:

	Dollars in Thousands			
	2025		2024	
	$	%	$	%
US Federal Statutory Tax Rate	(76)	21%	(901)	21%
State and Local Income Taxes—net of Federal Income Tax Effect *	(16)	4%	(175)	4%
Foreign Tax Effects				
Other foreign jurisdictions	—	0%	—	0%
Effect of changes in tax laws or rates enacted in the current period				
Other	(17)	5%	(53)	1%
Effect of Cross-Border Tax Laws				
Other	—	0%	—	0%
Tax Credits				
Research and development credits	(120)	33%	(204)	5%
Foreign tax credits	—	0%	—	0%
Changes in valuation allowances	(2,243)	618%	1,274	(30)%
Nontaxable or Nondeductible Items				
Public company expense	56	(15)%	44	(1)%
Incentive stock options	2,400	(661)%	—	0%
Other	16	(4)%	15	0%
Changes in unrecognized tax benefits	—	0%	—	0%

Other Adjustments				
Other	—	0%	—	0%
Effective Tax Rate	—	—	—	—

*State taxes in New Jersey and Florida made up the majority (greater than 50%) of the tax effect in this category.

The following table presents the components of income taxes paid, net of refunds.

	Dollars in Thousands 2025
Federal	$ -
State	$ -
Total	$ -

Deferred income taxes reflect the net effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The Company's net deferred tax assets relate primarily to its net operating loss carryforwards, allowance for credit losses and stock-based compensation, partially offset by property and equipment and intangible assets. The Company has recorded a full valuation allowance to offset the net deferred tax assets, as it is more likely than not that the Company will not realize future benefits associated with these net deferred tax assets at December 31, 2025 and 2024.

At December 31, 2025 and 2024, the Company had net deferred tax assets of $19.0 million and $21.2 million, respectively, against which a full valuation allowance has been recorded. The increase in the valuation allowance for the years ended December 31, 2025 is a decrease of $2.2 million resulting from a change in the tax treatment of stock-based compensation. The change required a decrease in the deferred tax asset resulting from the cumulative effect related to the tax treatment of incentive stock options as opposed to non-qualified stock options. This change is offset by an adjustment to the valuation allowance. In 2024, there was an increase of $1.3 million resulting from additional net operating losses generated in the year. The deferred tax liabilities associated with the book versus tax basis difference of intangible assets are the result of an asset step-up pursuant to a June 2017 merger transaction (the "Merger"). Significant components of the Company's net deferred tax assets at December 31, 2025 and 2024 are as follows:

	Dollars in Thousands	
	2025	2024
Deferred tax assets:		
Net operating loss and credit carryforwards	$ 20,419	$ 19,748
Allowance for credit losses	265	249
Stock-based compensation	586	2,659
Other	164	458
Gross deferred tax assets	21,434	23,114
Deferred tax liabilities:		
Property and equipment	(398)	(233)
Intangible assets	(2,072)	(1,673)
Other	—	—
Gross deferred tax liabilities	(2,470)	(1,906)
Net deferred tax assets	18,964	21,208
Less valuation allowance	(18,964)	(21,208)
Net deferred liability	$ —	$ —

The Company had available gross federal net operating loss ("NOL") carryforwards of approximately $81 million, and state NOL carryforwards of $2.7 million as of December 31, 2025. Approximately $28 million of the federal NOLs will expire at various dates beginning in 2036 through 2037 if not utilized, while the remaining amount will have an indefinite life. After passage of the Tax Cuts and Jobs Act of 2017, federal loss NOL carryforwards arising in taxable

years beginning after December 31, 2017 have an unlimited carryforward period; however, such losses can only offset 80% of taxable income in any one year. Included in the total NOLs for 2025 are $53 million of federal losses that fall under these rules. State NOLs expire on various dates. Section 382 of the Internal Revenue Code, and similar state regulations, contain provisions that may limit the NOL carryforwards available to be used to offset income in any given year upon the occurrence of certain events, including changes in the ownership interests of significant stockholders. In the event of a cumulative change in ownership in excess of 50% over a three-year period, the amount of the NOL carryforwards that the Company may utilize in any one year may be limited. The Company reduced its tax attributes (NOLs and tax credits) and generated a limitation on utilization of such attributes resulting from the Merger.

At December 31, 2025, and as a result of the limitations under Section 382 of the Internal Revenue Code, the Company had a total of unused federal tax net operating loss carryforwards with expiration dates as follows:

	Dollars in Thousands
	2025
2036	$ 14,277
2037	13,641
Unlimited life	53,010
Total Federal	$ 80,928

The Company has adopted guidance on accounting for uncertainty in income taxes which clarified the accounting for income taxes by prescribing the minimum threshold a tax position is required to meet before being recognized in the financial statements as well as guidance on de-recognition, measurement, classification and disclosure of tax positions. There are no material uncertain tax positions that would require recognition in the financial statements. The Company is obligated to file income tax returns in the U.S. federal jurisdiction and various U.S. states. Since the Company had losses in the past, all prior years that generated NOLs are open and subject to audit examination in relation to the NOL generated from those years. During the year ended December 31, 2022, the IRS completed an exam of the Company's 2019 tax year, which resulted in a change to the NOL carryforward. Our evaluation of uncertain tax positions was performed for the tax years open to examination.

10. STOCKHOLDERS' EQUITY

Common Stock

Pursuant to our Third Amended and Restated Certificate of Incorporation, as amended, we currently have 150,000,000 shares of common stock authorized for issuance. On December 20, 2018, the Company's shareholders approved the proposal to authorize the Company's Board of Directors to, in its discretion, amend the Company's Third Amended and Restated Certificate of Incorporation to increase the total number of authorized shares of common stock from 150,000,000 shares to 250,000,000 shares. The Company has not yet implemented this increase.

During the years ended December 31, 2025 and 2024, the Company issued 15,279 and zero shares of its common stock, respectively, in connection with the exercise of 15,279 and zero stock options, respectively. The stock option exercises resulted in net cash proceeds to the Company of $0.1 million and zero during the years ended December 31, 2025 and 2024, respectively.

During the years ended December 31, 2025 and 2024, the Company issued 29,419 and 61,692 shares of its common stock, respectively, in connection with Board fees and consulting services of approximately $0.2 million and $0.4 million, respectively.

At The Market Offering Agreement

AGP 2023 Sales Agreement

On April 14, 2023, the Company entered into the AGP 2023 Sales Agreement, in an "at the market offering" (as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended) of the shares of common stock. AGP will be entitled to a commission at a fixed rate of 3.0% of the gross proceeds from each sale of shares of Common Stock pursuant to the AGP 2023 Sales Agreement.

The sale of our shares of Common Stock to or through AGP, pursuant to the AGP 2023 Sales Agreement, are made pursuant to the 2023 Registration Statement on Form S-3 (File No. 333-271277), filed by the Company with the SEC on April 14, 2023, as amended by Amendment No. 1 filed by the Company with the SEC on April 25, 2023, and declared effective on April 27, 2023, for an aggregate offering price of up to $5.8 million.

On April 8, 2024, we filed a prospectus supplement (the "April 2024 Prospectus Supplement") to our prospectus dated April 25, 2023 registering the offer and sale of up to $1,061,478 of shares of our common stock.

During the year ended December 31, 2025, there were no sales of common stock pursuant to the AGP 2023 Sales Agreement. During the year ended December 31, 2024, we received net proceeds of $0.1 million, from the sale of 11,822 shares of common stock pursuant to the AGP 2023 Sales Agreement.

The Company terminated the AGP 2023 Sales Agreement effective September 2, 2025. Following the termination of the AGP 2023 Sales Agreement, the Company may not offer or sell any additional shares of common stock under the AGP 2023 Sales Agreement. As of the date of issuance of this Annual Report on Form 10-K, we have received an aggregate of $0.1 million in net proceeds, after issuance costs of approximately $2 thousand, from the sales of 11,847 shares of common stock through AGP.

Preferred Stock

The Company's Board of Directors is authorized to issue up to 15,000,000 shares of preferred stock in one or more series, from time to time, with such designations, powers, preferences and rights and such qualifications, limitations and restrictions as may be provided in a resolution or resolutions adopted by the Board of Directors. The authority of the Board of Directors includes, but is not limited to, the determination or fixing of the following with respect to shares of such class or any series thereof: (i) the number of shares; (ii) the dividend rate, whether dividends shall be cumulative and, if so, from which date; (iii) whether shares are to be redeemable and, if so, the terms and amount of any sinking fund providing for the purchase or redemption of such shares; (iv) whether shares shall be convertible and, if so, the terms and provisions thereof; (v) what restrictions are to apply, if any, on the issue or reissue of any additional preferred stock; and (vi) whether shares have voting rights. The preferred stock may be issued with a preference over the common stock as to the payment of dividends. We have no current plans to issue any additional preferred stock. Classes of stock such as the preferred stock may be used, in certain circumstances, to create voting impediments on extraordinary corporate transactions or to frustrate persons seeking to effect a merger or otherwise to gain control of the Company. For the foregoing reasons, any additional preferred stock issued by the Company could have an adverse effect on the rights of the holders of the common stock.

Series B Preferred Stock

The Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock ("Series B Preferred Stock") with the State of Delaware, which designates 6,900 shares of our preferred stock as Series B Preferred Stock. The Series B Preferred Stock has a stated value of $1,000 per share and a par value of $0.01 per share. The Series B Preferred Stock includes a beneficial ownership blocker but has no dividend rights (except to the extent dividends are also paid on the common stock). On August 28, 2017, the Company completed an underwritten public offering consisting of the Company's Series B Preferred Stock and warrants.

The conversion price of the Series B Preferred Stock contains a down round feature. The Company will recognize the effect of the down round feature when it is triggered. At that time, the effect would be treated as a deemed dividend and as a reduction of income available to common shareholders in our basic earnings per share calculation.

There were no conversions of Series B Preferred Stock during the years ended December 31, 2025 and 2024, respectively. At December 31, 2025 and 2024, the Company had 6,900 shares of Series B designated and issued and 47 shares of Series B outstanding. Based on the stated value of $1,000 per share and a conversion price of $8.00 per share, the outstanding shares of Series B Preferred Stock at December 31, 2025 were convertible into 5,875 shares of common stock.

Liquidation Preferences

The following is the liquidation preferences for the Company's preferred stock;

Upon any liquidation, dissolution or winding-up of the Corporation, whether voluntary or involuntary, the holders shall be entitled to receive out of the assets of the Corporation an amount equal to the par value, plus any accrued and unpaid dividends thereon, for each share of Preferred Stock before any distribution or payment shall be made to the holders of the Common Stock, and if the assets of the Corporation shall be insufficient to pay in full such amounts, then the entire assets to be distributed to the holders shall be ratably distributed among the holders in accordance with the respective amounts that would be payable on such shares. If all amounts were paid in full; and thereafter, the holders shall be entitled to receive out of the assets, whether capital or surplus, of the Corporation the same amount that a holder of Common Stock would receive if the Preferred Stock were fully converted to Common Stock which amount shall be paid pari passu with all holders of Common Stock.

Common Stock Warrants

The following represents a summary of the warrants outstanding as of December 31, 2025:

	Issue Year	Expiration	Underlying Shares		Exercise Price
Warrants					
(1)	2025	February 2027	10,000	$	60.00

(1) These warrants were issued to a consultant in connection with services performed.

During the years ended December 31, 2025 and 2024, zero and 15,091 warrants expired. These warrants had been issued in connection with transactions which were completed in 2019.

RDO Common Warrants. In connection with the Registered Direct Offering in June 2023, the Company issued 444,444 warrants to purchase up to 444,444 shares of common stock (the "RDO Common Warrants"). The RDO Common Warrants are exercisable beginning six months after the date of issuance, have an exercise price of $12.60 per share, and will expire December 12, 2028.

During the year ended December 31, 2025, the Company amended the warrant agreements with certain RDO Common Warrant holders giving the holders the right, at their discretion, to exercise their remaining outstanding warrants in a cashless manner.

During the year ended December 31, 2025, 444,444 RDO Common Warrants were exercised for 242,562 shares of our common stock. The Company received net proceeds of approximately $1.3 million from these exercises. The intrinsic value of the warrants exercised during the year ended December 31, 2025 was $3.4 million.

Deemed Dividends

Certain of our preferred stock and warrant issuances contain down round provisions which require us to recognize the effect of the down round feature when it is triggered. That effect is treated as a dividend and as a reduction of income available to common shareholders in basic earnings per share.

There were no deemed dividends recorded during the years ended December 31, 2025 and 2024.

11. FAIR VALUE

FASB guidance on fair value measurements, which defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements for our financial assets and liabilities, as well as for other assets and liabilities that are carried at fair value on a recurring basis in our consolidated financial statements.

FASB guidance establishes a three-level fair value hierarchy based upon the assumptions (inputs) used to price assets or liabilities. The three levels of inputs used to measure fair value are as follows:

Level 1—Unadjusted quoted prices in active markets for identical assets or liabilities;

Level 2—Observable inputs other than those included in Level 1, such as quoted prices for similar assets and liabilities in active markets or quoted prices for identical assets or liabilities in inactive markets; and

Level 3—Unobservable inputs reflecting our own assumptions and best estimate of what inputs market participants would use in pricing the asset or liability.

Common Stock Warrant Liabilities.

Certain of our issued or outstanding warrants to purchase shares of common stock do not qualify to be treated as equity and, accordingly, are recorded as a liability. We are required to record these instruments at fair value at each reporting date and changes are recorded as a non-cash adjustment to earnings. The gains or losses included in earnings are reported in other income (expense) in our consolidated statement of operations.

Bridge Note Warrant Liabilities

During 2019 and 2018, the Company issued warrants in connection with the issuance of convertible notes. All of these warrants issuances were classified as warrant liabilities (the “Bridge Note Warrant Liabilities”).

The Bridge Note Warrant Liabilities are considered Level 3 financial instruments and were valued using the Black Scholes model. During the year ended December 31, 2024, the last remaining warrants related to Bridge Note Warrant Liabilities expired and thus at December 31, 2025 and 2024, respectively, there were no warrant liabilities to be valued.

During the year ended December 31, 2024, the change in the fair value of the warrant liabilities measured using significant unobservable inputs (Level 3) was zero.

12. EQUITY INCENTIVE PLAN

The Company currently issues stock awards under its 2017 Stock Option and Incentive Plan, as amended (the "2017 Plan") which will expire on June 5, 2027. The shares authorized for issuance under the 2017 Plan were 395,380 at December 31, 2025 of which 18,234 were available for future grant. The shares authorized under the 2017 Plan are subject to annual increases on January 1 by 5% of the number of shares of common stock issued and outstanding on the immediately preceding December 31, or such lessor number of shares determined by the Company’s Board of Directors or Compensation Committee. During the year ended December 31, 2025, the shares authorized for issuance increased by 74,681 shares.

The Plan is administered by the Compensation Committee of the Board of Directors (the “Committee”), which has the authority to set the number, exercise price, term and vesting provisions of the awards granted under the Plan, subject to the terms thereof. Either incentive or non-qualified stock options may be granted to employees of the Company, but only non-qualified stock options may be granted to non-employee directors and advisors. However, in either case, the Plan requires that stock options must be granted at exercise prices not less than the fair market value of the common stock

on the date of the grant. Options issued under the plan vest over periods as determined by the Committee and expire 10 years after the date the option was granted.

Stock Options.

The Company accounts for all stock-based compensation payments to employees and directors, including grants of employee stock options, at fair value at the date of grant and expenses the benefit in operating expense in the consolidated statements of operations over the service period of the awards. The Company records the expense for stock-based compensation awards subject to performance-based milestone vesting over the remaining service period when management determines that achievement of the milestone is probable based on the expected satisfaction of the performance conditions as of the reporting date. The Company records the expense for stock-based compensation awards subject to market-condition vesting over a derived service period which is calculated at the grant date. The fair value of each stock option granted is estimated on the date of grant using the Black-Scholes or other option pricing models, which requires various assumptions including estimating stock price volatility, expected life of the stock option, risk free interest rate and estimated forfeiture rate.

During the year ended December 31, 2025, the Company granted stock options to purchase up to 89,000 shares of common stock at a weighted average exercise price of $6.90. The stock options granted have either time-based or market-condition vesting.

The awards with time-based vesting have periods of up to four years and had grant date fair values between $5.24 and $17.56. The fair value was calculated using the Black-Scholes option pricing model and used the follow assumptions: risk free interest rates of 3.82% to 4.65%, based on the U.S. Treasury yield in effect at the time of grant; expected life of five to six years; and volatility of 121% to 128% based on historical volatility of the Company's common stock over a time that is consistent with the expected life of the option.

The awards with market-condition vesting have a derived service period of 1.6 years and had a grant date fair value of $5.70. The fair value was calculated using a Monte Carlo Simulation and used the following assumptions: risk free interest rate of 4.67%; remaining term of ten years; and volatility of 121%.

On August 30, 2024, the Company's board of directors (the "Board") approved a one-time stock option repricing (the "Option Repricing"), effective August 31, 2024 (the "Effective Date"). The Option Repricing was undertaken in accordance with, and as permitted by the 2017 Plan. The Option Repricing applies to all Relevant Options (as defined below) granted pursuant to the 2017 Plan that were held by employees, including executive officers and non-employee directors of the Board, to the extent such options had an exercise price in excess of $6.56, the closing price per share of the Company's Common Stock as reported on The Nasdaq Stock Market on August 30, 2024. "Relevant Options" means all outstanding eligible stock options granted to eligible employees, service providers and non-employee directors of the board of the Company before and including December 31, 2022. As of the Effective Date, all such options were repriced such that the exercise price per share was reduced to $6.56, provided that the original exercise price will apply to stock option exercises during a one year retention period. Under the terms of the Option Repricing, if prior to the first anniversary of the Effective Date (except following a change of control), a Relevant Option is exercised or employment/services are terminated by the Company with cause or voluntarily by the option holder, the option holder will be required to pay the original exercise price of the Relevant Option. If the employment/services of an option holder is terminated by the Company without cause prior to the first anniversary of the Effective Date, the option holder will retain the benefit of the reduced exercise price. The Option Repricing does not change the number of shares, the vesting schedule, or the expiration date of the Relevant Options.

Out of the Company's approximately 304,000 total outstanding options on the Effective Date, approximately 177,000 were repriced. The Board approved the Option Repricing after careful consideration of various alternatives and the recommendation of the compensation committee of the Board that the repricing was fair, just, and reasonable to the Company and its stockholders. Management determined that the Option Repricing represented a modification of the impacted awards and calculated incremental compensation cost of approximately $0.5 million resulting from the modification. The incremental expense was recognized over 1.4 years.

The following table summarizes stock option activity under our plans during the year ended December 31, 2025:

	Number of Options	Weighted-Average Exercise Price
Outstanding at January 1, 2025	303,932	$ 7.18
Granted	89,000	6.90
Exercised	(15,279)	7.78
Forfeited	(18,347)	6.30
Outstanding at December 31, 2025	359,306	$ 7.13
Exercisable at December 31, 2025	237,830	$ 7.28

As of December 31, 2025, there were 307,087 options that were vested or expected to vest with an aggregate intrinsic value of less than $4.8 million and a remaining weighted average contractual life of 6.2 years.

During the year ended December 31, 2024, there were 76,987 options granted with a weighted average exercise price of $5.01 and 5,799 options forfeited with a weighted average exercise price of $17.31.

Restricted Stock Awards.

Restricted stock awards are subject to vesting restrictions. If a grantee's service with the Company is terminated prior to vesting of the restricted stock, all unvested shares shall be forfeited and returned to the Company. Upon vesting, the restricted stock award shall no longer be deemed restricted.

There were no restricted stock awards granted during the years ended December 31, 2025 and December 31, 2024, respectively. As of December 31, 2025 and 2024, respectively, there were no unvested restricted stock awards.

Stock Compensation.

During the years ended December 31, 2025 and 2024, we recorded compensation expense for all stock awards of $1.2 million and $1.5 million, respectively, within operating expense in the accompanying statements of operations. The 2025 and 2024 expense included approximately $0.3 million and $0.2 million, respectively, of expense related to the Option Repricing. As of December 31, 2025, the unrecognized compensation expense related to unvested stock awards was $0.6 million, which is expected to be recognized over a weighted-average period of 2.3 years.

13. SALES SERVICE REVENUE, NET AND ACCOUNTS RECEIVABLE

ASC Topic 606, "Revenue from contracts with customers"

The Company follows the guidance of ASC 606 for the recognition of revenue from contracts with customers to transfer goods and services. The Company performed a comprehensive review of its existing revenue arrangements following the five-step model:

Step 1: Identification of the contract with the customer. Sub-steps include determining the customer in a contract, initial contract identification and determining if multiple contracts should be combined and accounted for as a single transaction.

Step 2: Identify the performance obligation in the contract. Sub-steps include identifying the promised goods and services in the contract and identifying which performance obligations within the contract are distinct.

Step 3: Determine the transaction price. Sub-steps include variable consideration, constraining estimates of variable consideration, the existence of a significant financing component in the contract, noncash consideration and consideration payable to a customer.

Step 4: Allocate transaction price. Sub-steps include assessing the amount of consideration to which the Company expects to be entitled in exchange for transferring the promised goods or services to the customer.

Step 5: Satisfaction of performance obligations. Sub-steps include ascertaining the point in time when an asset is transferred to the customer and when the customer obtains control of the asset upon which time the Company recognizes revenue.

Nature of Contracts and Customers

The Company's contracts and related performance obligations are similar for its customers and the sales process for all customers starts upon the receipt of requisition forms from the customers for patient diagnostic testing and the execution of contracts for biomarker testing and clinical research. Payment terms for the services provided are 30 days, unless separately negotiated.

Diagnostic testing

Control of the laboratory testing services is transferred to the customer at a point in time. As such, the Company recognizes revenue for laboratory testing services at a point in time based on the delivery method (web-portal access or fax) for the patient's laboratory report, per the contract.

Clinical research grants

Control of the clinical research services are transferred to the customer over time. The Company will recognize revenue utilizing the "effort based" method, measuring its progress toward complete satisfaction of the performance obligation.

Biomarker testing and clinical project services

Control of the biomarker testing and clinical project services are transferred to the customer over time. The Company utilizes an "effort based" method of assessing performance and measures progress towards satisfaction of the performance obligation based upon the delivery of results.

The Company generates revenue from the provision of diagnostic testing provided to patients, biomarker testing provided to bio-pharma customers and clinical research grants funded by both bio-pharma customers and government health programs.

Reagents and other diagnostic products

Control of reagents and other diagnostic products are transferred to the customer at a point in time and, as such, the Company recognizes these revenues at a point in time based on the delivery method. These revenues include revenues from reagent sets for our HSRR program and other product sales and are included in other revenue in our consolidated statements of operations.

Disaggregation of Revenues by Transaction Type

We operate in one business segment and, therefore, the results of our operations are reported on a consolidated basis for purposes of segment reporting, consistent with internal management reporting. Service revenue, net for the years ended December 31, 2025 and 2024 was as follows:

(dollars in thousands)	For the Year Ended December 31, Diagnostic Testing	
	2025	2024
Medicaid	$ 48	$ 42
Medicare	9,613	6,355
Self-pay	21	36
Third party payers	11,700	9,483
Contract diagnostics and other	124	49
Service revenue, net	$ 21,506	$ 15,965

Revenue from the Medicare and Medicaid programs account for a portion of the Company's patient diagnostic service revenue. Laws and regulations governing those programs are extremely complex and subject to interpretation. As a result, there is at least a reasonable possibility that recorded estimates will change by a material amount in the near term.

Revenue Recognition

Revenue is recognized when a customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price using the expected value method based on historical experience. The Company does not typically enter arrangements where multiple contracts can be combined as the terms regarding services are generally found within a single agreement/requisition form. The Company derives its revenues from the following types of transactions: diagnostic testing ("Diagnostic"), revenues from the Company's ICP technology and bio-pharma projects encompassing genetic diagnostics (collectively "Biomarker"), revenues from clinical research grants from state and federal research programs and diagnostic product sales, including revenues from equipment leases and reagent sales associated with our HSRR program.

Deferred revenue

Deferred revenue, or unearned revenue, refers to advance payments for products or services that are to be delivered in the future. The Company records such prepayment of unearned revenue as a liability, as revenue that has not yet been earned, but represents products or services that are owed to a customer. As the product or service is delivered over time, the Company recognizes the appropriate amount of revenue from deferred revenue. As of December 31, 2025 and 2024, the deferred revenue was $0.3 million and $0.2 million, respectively.

Contractual Allowances and Adjustments

We are reimbursed by payers for services we provide. Payments for services covered by payers average less than billed charges. We monitor revenue and receivables from payers and record an estimated contractual allowance for certain revenue and receivable balances as of the revenue recognition date to properly account for anticipated differences between amounts estimated in our billing system and amounts ultimately reimbursed by payers. Accordingly, the total revenue and receivables reported in our consolidated financial statements are recorded at the amounts expected to be received from these payers. For service revenue, the contractual allowance is estimated based on several criteria, including unbilled claims, historical trends based on actual claims paid, current contract and reimbursement terms and changes in customer base and payer/product mix. The billing functions for the remaining portion of our revenue are contracted and fixed fees for specific services and are recorded without an allowance for contractual discounts. The following table presents our revenues initially recognized for each associated payer class during the years ended December 31, 2025 and 2024.

(dollars in thousands)	For the Year Ended December 31,					
	Gross Revenues		Contractual Allowances and adjustments		Revenues, net of Contractual Allowances and adjustments	
	2025	2024	2025	2024	2025	2024
Medicaid	$ 48	$ 42	$ —	$ —	$ 48	$ 42
Medicare	9,612	6,355	—	—	9,613	6,355
Self-pay	21	36	—	—	21	36
Third party payers	40,946	32,691	(29,246)	(23,208)	11,700	9,483
Contract diagnostics and other	124	49	—	—	124	49
	50,751	39,173	(29,246)	(23,208)	21,506	15,965
Product	2,741	2,611	—	—	2,740	2,611
	$ 53,492	$ 41,784	$ (29,246)	$ (23,208)	$ 24,246	$ 18,576

Allowance for Credit Losses

The Company provides for a general allowance for collectability of services when recording net sales. The Company has adopted the policy of recognizing net sales to the extent it expects to collect that amount. Reference FASB 954-605-45-5 and ASU 2011-07, Health Care Entities: Presentation and Disclosure of Patient Service Revenue, Provision for Credit Loss, and the Allowance for Credit Losses. The change in the allowance for credit losses is directly related to the increase in patient service revenues. The following table presents our reported revenues net of the collection allowance and adjustments for the years ended December 31, 2025 and 2024.

	For the Year Ended December 31,					
(dollars in thousands)	Revenues, net of Contractual Allowances and adjustments		Allowances for credit losses		Total	
	2025	2024	2025	2024	2025	2024
Medicaid	$ 48	$ 42	$ 31	$ 1	$ 79	$ 43
Medicare	9,613	6,355	(95)	(129)	9,518	6,226
Self-pay	21	36	(1)	(4)	20	32
Third party payers	11,700	9,483	(132)	88	11,568	9,571
Contract diagnostics and other	124	49	—	—	124	49
	21,506	15,965	(197)	(44)	21,309	15,921
Product	2,740	2,611	—	—	2,740	2,611
	$ 24,246	$ 18,576	$ (197)	$ (44)	$ 24,049	$ 18,532

Costs to Obtain or Fulfill a Customer Contract

Sales commissions are expensed when incurred because the amortization period would have been one year or less. These costs are recorded in operating expenses in the consolidated statements of operations.

Shipping and handling costs are comprised of inbound and outbound freight and associated labor. The Company accounts for shipping and handling activities related to contracts with customers as fulfillment costs which are included in cost of sales in the consolidated statements of operations.

Accounts Receivable

The Company has provided an allowance for potential credit losses, which has been determined based on management's industry experience. The Company grants credit without collateral to its patients, most of who are insured under third party payer agreements.

The following summarizes the mix of receivables as of December 31, 2025 and 2024:

(dollars in thousands)	December 31, 2025	December 31, 2024
Medicaid	$ 19	$ (12)
Medicare	1,838	1,086
Self-pay	16	13
Third party payers	859	530
Contract diagnostic services, product and other	297	177
	$ 3,029	$ 1,794
Less allowance for credit losses	(1,045)	(995)
Accounts receivable, net	$ 1,984	$ 799

The following table presents the roll-forward of the allowance for credit losses for the years ended December 31, 2025 and 2024.

(dollars in thousands)	Year Ended December 31, 2025	2024
Balance, January 1	$ (995)	$ (2,572)
Provision for credit losses:		
Medicaid	31	1
Medicare	(95)	(129)
Self-pay	(1)	(4)
Third party payers	(132)	88
	(197)	(44)
Credit loss income (expense)	20	(20)
Total charges	(177)	(64)
Write-offs	127	1,641
Balance, December 31	$ (1,045)	$ (995)

Customer Revenue and Accounts Receivable Concentration

Customer revenue and accounts receivable concentration amounted to the following for the identified periods.

	Net sales		Accounts receivable, as of	
	Year Ended December 31,			
	2025	2024	December 31, 2025	December 31, 2024
Customer A	26 %	17 %	34 %	29 %
Customer B	*	*	12 %	*
Customer C	*	*	10 %	*

* represents less than 10%

14. SEGMENT REPORTING

The Company's chief operating decision maker (CODM) is its Chief Executive Officer. The Company has no segment managers who are held accountable by the CODM for operations, operating results, and planning for levels or components below the consolidated unit level. Accordingly, the Company has determined it has a single operating segment.

The CODM uses consolidated net loss for purposes of allocating resources and assessing segment performance, including monitoring actual results versus historical periods. Cost of revenue and operating expenses are considered significant segment expenses that are regularly provided to the CODM and included within consolidated net loss. The measure of segment assets is the total assets on the Company's consolidated balance sheets. Capital expenditures are reported on a consolidated basis on the Company's consolidated statements of cash flows. The following table includes the Company's segment revenue, significant segment expenses, and other segment items to reconcile to net loss.

	Dollars in Thousands	
	Year Ended December 31,	
	2025	2024
Net sales	$ 24,049	$ 18,532
Less expense (income):		
Cost of sales	13,343	10,973
Operating expenses (1)	11,908	11,775
Other segment expense (income) (2)	(839)	74
Net loss	$ (363)	$ (4,290)

(1) Operating expenses include sales and marketing expenses, general and administrative expenses, research and development expenses and stock-based compensation.

(2) Other segment items include interest income, interest expense, gain on write-off of liability and other income.

15. EMPLOYEE RETENTION CREDIT

On March 27, 2020, the U.S. government enacted the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). Under the provisions of the CARES Act, and the subsequent extensions, the Company became eligible to apply for a refundable Employee Retention Credit (the "ERC") subject to certain criteria, which could be used to offset payroll tax liabilities.

In November 2022, the Company submitted an ERC claim totaling approximately $1.5 million. During the year ended December 31, 2025, the Company received payments for part of the ERC claim totaling approximately $0.8 million. The Company recorded this as other income in the consolidated statements of operations.

The Company retains all rights to pursue and receive the remaining balance of approximately $0.7 million and is actively evaluating the likelihood and timing of any additional disbursements. The Company has not waived any claims to the unpaid portion of the ERC and is taking reasonable steps to secure the remaining balance. However, there can be no assurance as to the timing, amount, or certainty of receipt of additional funds, and the Company will continue to assess the collectability of the remaining claim in accordance with applicable accounting standards.

16. SUBSEQUENT EVENTS

The Company has evaluated events and transactions subsequent to December 31, 2025 through the date the consolidated financial statements were issued. There are no other events to report other than what has been disclosed in the consolidated financial statements.

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

None.

Item 9A. Controls and Procedures

(a) ***Evaluation of Disclosure Controls and Procedures***

We maintain a system of disclosure controls and procedures that are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in the Commission's rules and forms, and to ensure that such information is accumulated and communicated to our management, including our Chief Executive Officer and our Chief Financial Officer, or persons performing similar functions, as appropriate, to allow timely decisions regarding required disclosure.

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) ("Disclosure Controls") will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the Company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected. We monitor our Disclosure Controls and make modifications as necessary; our intent in this regard is that the Disclosure Controls will be modified as systems change and as conditions warrant.

An evaluation of the effectiveness of the design and operation of our Disclosure Controls was performed as of the end of the period covered by this Report. This evaluation was performed under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer. Based on this evaluation, we concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of December 31, 2025.

(b) ***Management's Report on Internal Control Over Financial Reporting***

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act). In order to evaluate the effectiveness of internal control over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act of 2002, our management, with the participation of our principal executive officer and principal financial officer has conducted an assessment, including testing, using the criteria in Internal Control – Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission ("*COSO*") (2013). Our system of internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. This assessment included review of the documentation of controls, evaluation of the design effectiveness of controls, testing of the operating effectiveness of controls and a conclusion on this evaluation.

Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

(c) ***Changes in internal control over financial reporting***

Based on management's evaluation, there were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2025, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

As a smaller reporting company, the Company is not required to include in this Annual Report a report on the effectiveness of internal control over financial reporting by the Company's independent registered public accounting firm.

Item 9B. Other Information

(a) None.

(b) During the fourth quarter of the fiscal year ended December 31, 2025, no director or "officer" as defined in Rule 16a-1(f) under the Exchange Act adopted or terminated any Rule 10b5-1 trading plan or arrangements or any non-Rule 10b5-1 trading plan or arrangements, in both cases as defined in Item 408(a) of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

Part III

Item 10. Directors, Executive Officers and Corporate Governance

We intend to file with the Securities and Exchange Commission a definitive Proxy Statement, which we refer to herein as the 2026 Proxy Statement, not later than 120 days after the close of the fiscal year ended December 31, 2025. The information required by this item is incorporated herein by reference to the 2026 Proxy Statement. The information required by this item related to the executive officers can be found in the section captioned "Executive Officers of the Registrant" under Part I, "Item 1. Our Business" of this Annual Report on Form 10-K, and is also incorporated herein by reference.

Item 11. Executive Compensation

The information required by this item (excluding the information under the heading "Pay Versus Performance") is incorporated herein by reference to the 2026 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2025.

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

The information required by this item is incorporated herein by reference to the 2026 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2025.

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

The information required by this item is incorporated herein by reference to the 2026 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2025.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to the 2026 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2025.

Our independent public accounting firm is CBIZ CPAs, P.C., New Haven, CT. PCAOB Auditor ID 199.

Part IV

Item 15. Exhibits and Financial Statement Schedules

(a) The following documents are filed as part of this report:

1 Financial Statements. The following financial statements of the Registrant are included in response to Item 8 of this report:

Report of Independent Registered Public Accounting Firm.

Consolidated Balance Sheets of the Registrant and Subsidiary as of December 31, 2025 and 2024.

Consolidated Statements of Operations of the Registrant and Subsidiary for the years ended December 31, 2025 and 2024.

Consolidated Statements of Stockholders' Equity of the Registrant and Subsidiary for the years ended December 31, 2025 and 2024.

Consolidated Statements of Cash Flows of the Registrant and Subsidiary for the years ended December 31, 2025 and 2024.

Notes to Consolidated Financial Statements of the Registrant and Subsidiary.

2 Financial Statement Schedules.

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the financial statements.

3 Exhibits. The following exhibits are filed as required by Item 15(a)(3) of this report. Exhibit numbers refer to the paragraph numbers under Item 601 of Regulation S-K:

2.1 Agreement and Plan of Merger, dated October 12, 2016 by and among Transgenomic, Inc., New Haven Labs Inc. and Precipio Diagnostics, LLC (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on October 13, 2016).
2.2 First Amendment to Agreement and Plan of Merger, dated as of February 3, 2017 by and among Transgenomic, Inc., New Haven Labs Inc. and Precipio Diagnostics, LLC (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on February 2, 2017).
2.3 Second Amendment to Agreement and Plan of Merger, dated as of June 27, 2017 by and among Transgenomic, Inc., New Haven Labs Inc. and Precipio Diagnostics, LLC (incorporated by reference to Exhibit 2.1 of the Company's Form 8-K filed on June 30, 2017).
3.1 Third Amended and Restated Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 of the Company's 8-K filed on June 30, 2017).
3.2 Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the Company's Form 8-K filed on June 30, 2017).
3.3 Certificate of Elimination (incorporated by reference to Exhibit 3.3 of the Company's Form 8-K filed on June 30, 2017).
3.4 Certificate of Designation for Series B Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on August 31, 2017).
3.5 Certificate of Designation for Series C Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on November 6, 2017).
3.6 Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation, dated April 25, 2019 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on April 26, 2019).

3.7	Certificate of Amendment to the Third Amended and Restated Certificate of Incorporation, dated September 21, 2023 (incorporated by reference to Exhibit 3.1 of the Company's Form 8-K filed on September 21, 2023).
4.1	Form of Certificate of the Company's Common Stock (incorporated by reference to Exhibit 4 of the Company's Registration Statement on Form S-1 (Registration No. 333-32174) filed on March 10, 2000).
4.2	Description of Securities of the Registrant (incorporated by reference to Exhibit 4.7 of the Company's Form 10-K filed on March 27, 2020).
10.1†	Amended and Restated 2017 Stock Option and Incentive Plan (incorporated by reference to Annex B of the Company's Definitive Proxy Statement on Schedule 14A filed on April 29, 2021).
10.2†	Form of Non-Qualified Stock Option Agreement for Non-Employee Directors (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on June 28, 2017).
10.3†	Form of Non-Qualified Stock Option Agreement for Company Employees (incorporated by reference to Exhibit 10.3 of the Company's Form 8-K filed on June 28, 2017).
10.4†	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.4 of the Company's Form 8-K filed on June 28, 2017).
10.5#	Amended and Restated Pathology Services Agreement, dated March 21, 2017, by and between the Company and Yale University (incorporated by reference to Exhibit 10.1 of the Company's Form 8-K/A filed on July 31, 2017).
10.6	Lease, dated July 11, 2017, by and between the Company and Science Park Development Corporation (incorporated by reference to Exhibit 10.2 of the Company's Form 8K/A filed on July 31, 2017).
10.7†	Employment Agreement dated August 7, 2018 between the Company and Ilan Danieli (incorporated by reference to Exhibit 10.1(a) to the Company's Form 8-K filed on August 9, 2018).
10.8†	Employment Agreement dated August 7, 2018 between the Company and Ahmed Zaki Sabet (incorporated by reference to Exhibit 10.1(c) to the Company's Form 8-K filed on August 9, 2018).
10.9†	Employment Agreement dated August 7, 2018 between the Company and Ayman Mohamed (incorporated by reference to Exhibit 10.1(e) to the Company's Form 8-K filed on August 9, 2018).
10.10†	Payroll and Position Change Notice dated March 21, 2022 between the Company and Matthew Gage (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on March 21, 2022).
10.11	Securities Purchase Agreement, dated June 8, 2023, by and between Precipio, Inc. and the Purchaser (incorporated by reference to the Company's Current Report on Form 8-K filed on June 12, 2023).
10.12	Business Loan and Security Agreement dated May 1, 2024 by and between the Company and Altbanq Lending LLC (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed on May 6, 2024).
10.13	Form of Notice of Stock Option Repricing (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed on November 6, 2024).
19.1	Precipio, Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 of the Company's Form 10-K filed on March 27, 2025).
21.1	Subsidiaries of the Company.
23.1	Consent of CBIZ CPAs P.C.
23.2	Consent of Marcum LLP.
31.1	Certification of Principal Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
31.2	Certification of Principal Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, as amended.
32.1*	Certification of Principal Executive Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
32.2*	Certification of Principal Financial Officer, pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, as amended.
97.1†	Compensation Recovery Policy (incorporated by reference to Exhibit 97.1 to the Company's Form 10-K filed on March 29, 2024).
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document

101.PRE XBRL Taxonomy Extension Presentation Linkbase Document

104 Cover Page Interactive Data File - the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.

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* This certification is not deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933 or the Securities Exchange Act of 1934, except to the extent that the Registrant specifically incorporates it by reference.

\# Confidential treatment has been requested or granted for certain information contained in this exhibit. Such information has been omitted and filed separately with the Securities and Exchange Commission.

† Indicates a management contract or any compensatory plan, contract or arrangement.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized on this 30th day of March 2026.

Precipio, Inc.

By: /s/ ILAN DANIELI
Ilan Danieli,
Chief Executive Officer (Principal Executive Officer)

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Ilan Danieli **Ilan Danieli**	Director and Chief Executive Officer (Principal Executive Officer)	March 30, 2026
/s/ Matthew Gage **Matthew Gage**	Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2026
/s/ Richard Sandberg **Richard Sandberg**	Chairman of the Board of Directors	March 30, 2026
/s/ Kathleen LaPorte **Kathleen LaPorte**	Director	March 30, 2026
/s/ Ronald Andrews **Ronald Andrews**	Director	March 30, 2026
/s/ Jeffrey Cossman, M.D. **Jeffrey Cossman, M.D.**	Director	March 30, 2026
/s/ David Cohen **David Cohen**	Director	March 30, 2026
/s/ Christina Valauri **Christina Valauri**	Director	March 30, 2026

Management Team

Ilan Danieli
Chief Executive Officer

Matthew Gage
Chief financial Officer

Ahmed Zaki Sabet
Chief Operating Officer

Ayman Mohamed, MD
Chief Technology Officer

Miri Chiko-Radomski
Chief Legal Counsel and People Officer

Board of Directors

Richard Sandberg
Chief Executive Officer, Resolys Bio

Kathy Laport
Independent Consultant

Ron A. Andrews
Board of Trustees, Wofford College

David S. Cohen
Chief Operating Officer, Standard Oil of Connecticut

Jeffrey Cossman, MD
Board Member

Ilan Danieli
Chief Executive Officer, Precipio

Christina Valauri
Chief Executive Officer, Sagestone Advisory

Annual Meeting of Stockholders

The Annual Meeting of Stockholders will be held at 10:00 AM, EST on June 15, 2026, virtually via live webcast at:
https://www.virtualshareholdermeeting.com/PRPO2026

Independent Auditors

CBIZ CPAs, P.C.

Investor Inquiries

investors@precipiodx.com

Stock Listing

NASDAQ: PRPO

Transfer Agent

Equiniti Trust Company, LLC,
1110 Centre Pointe Curve, #101
St. Paul, MN 55120
1.800.468.9716

SEC Form 10-K

A copy of our Form 10-K for the fiscal year ending December 31, 2025, filed with the Securities and Exchange Commission (SEC) is available free of charge on the SEC's website at www.sec.gov or from the company's investor relations department by emailing investors@precipiodx.com or sending a written request to Precipio's investor relations department at:

Investor Relations
Precipio Inc.
4 Science Park, 3rd Floor
New Haven, CT 06511