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, 2022

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 $23.3 million.

As of March 28, 2023, the number of shares of common stock outstanding was 23,353,893.

DOCUMENTS INCORPORATED BY REFERENCE

The Registrant's definitive Proxy Statement for the Annual Meeting of Stockholders (the "2023 Proxy Statement") is incorporated by reference in Part III of this Form 10-K to the extent stated herein. The 2023 Proxy Statement, or an amendment to this Form 10-K, will be filed with the SEC within 120 days after December 31, 2022. 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.

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PRECIPIO, INC.
Annual Report on Form 10-K
For the Year Ended December 31, 2022

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: the expected or potential impact of the novel coronavirus ("COVID-19") pandemic which is highly uncertain and will depend on future developments, our expected revenue, income (loss), receivables, operating expenses, 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 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, expected financial and other benefits from our organizational restructuring activities, 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;
- 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;
- 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;

- risks associated with the COVID-19 pandemic, which may adversely impact our workforce, global supply chain, business, preclinical studies, clinical trials and financial results;
- our expectations related to the use of our cash reserves;
- the impact of new laws and regulations or amendments to existing laws and regulations;
- developments and projections relating to our competitors and our industry; 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, 2022 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. Our Business

Business Description

Precipio, Inc., and its subsidiaries, (collectively, "we", "us", "our", the "Company" or "Precipio") is a healthcare biotechnology company focused on cancer diagnostics. Our mission is to address the pervasive problem of cancer misdiagnoses by developing solutions to mitigate the root causes of this problem in the form of diagnostic products, reagents and services. Misdiagnoses are caused by numerous factors, among them outdated diagnostic technologies, lack of subspecialized expertise, and sub-optimal laboratory processes that are needed in today's diagnostic cancer testing in order to provide accurate, rapid, and resource-effective results to treat patients. We focus on blood related cancers which represent some of the most complex cancers to diagnose, and are prone to some of the highest rates of misdiagnosis; industry studies estimate 1 in 5 blood-cancer patients are misdiagnosed. As cancer diagnostic testing has evolved from a cellular to a molecular/genetic-based approach, laboratory testing has become extremely complex, requiring even greater diagnostic precision, attention to process and a more appropriate evaluation of the abundance of genetic data to effectively gather, consider, analyze and present information for the physician for patient treatment.

We develop and sell diagnostic products, reagents and services that improve the accuracy and efficiency of diagnostics, and lead to fewer misdiagnoses. We believe that our products and services impact patient outcomes by providing more accurate diagnostic results than current industry accepted practices that better inform the selection of appropriate therapeutic options. Furthermore, we believe that better patient outcomes have a positive impact on healthcare expenses as a result of fewer misdiagnoses. We believe our platform delivers better diagnostic accuracy than industry peers because of the technologies, workflow processes and experience we have developed. We market our technologies to other laboratories; additionally, we also operate our own laboratory, focused on delivering specialized diagnostic services to physicians and their patients to better ensure they receive accurate results leading to fewer misdiagnoses and promoting cost savings. Better Diagnostic Results – Better Patient Outcome – Lower Healthcare Expenditures.

To deliver our strategy, we have structured our organization in order to drive development of diagnostic products. In our laboratory and R&D facilities located in New Haven, Connecticut and Omaha, Nebraska, our development teams work to develop, test, and ultimately run new products and services in a clinical setting. We operate CLIA (Clinical Laboratory Improvement Amendments), laboratories in both the New Haven, Connecticut and Omaha, Nebraska locations providing essential blood cancer diagnostics to office-based oncologists in many states nationwide.

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, ("TAT"), 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 $750 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, ("TAM"), is estimated to exceed $20 billion in 2023, 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 $14 billion by 2025. 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. WHO (World Health Organization) and NCCN (The National Comprehensive Cancer Network®) 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 offer two solutions for genetic testing. One of those solutions is single-gene testing products via various testing modalities; the other solution is broad, NGS (Next Generation Sequencing) 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 TAT; 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 TAT. Our customers that utilize HemeScreen have demonstrated a reduction in TAT 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 (MPN) panel. We have since added Acute Myeloid Leukemia (AML), Chronic Lymphocytic Leukemia (CLL), Cytopenia, and BCR-

ABL panels, evolving HemeScreen into a "suite" of robust genetic diagnostic panels, and we expect the release of additional diagnostic panels during 2023.

We own a provisional patent application 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 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 superior diagnostic results.

We are marketing this technology by providing major laboratories with access to the media. 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.

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.

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.
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:

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

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 "cocktailed" 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 the only 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 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 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 CMS, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations extend to include transfers of value made to certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and anesthesiologist assistants, and certified-nurse midwives).

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 constitutes approximately 40% of our patients' cases. 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 Center for Medicare and Medicaid Services, ("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, 2022 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 Biden administration or other efforts, if any, to challenge, repeal or replace the PPACA will impact our business.

U.S. Food and Drug Administration Regulation

We offer our products as research use only (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 U.S. Food and Drug Administration (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 CLIA laboratories offer testing utilizing our laboratory developed tests (LDTs). LDTs are defined by the FDA to be tests that are designed, developed, and used within a single laboratory. The FDA takes the position that it has authority to regulate LDTs as medical devices, and historically, 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. However, the FDA has stated it intends to end its policy of enforcement discretion and to actively regulate LDTs. For example, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Regulatory Oversight of Laboratory Developed Tests (LDTs)", that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The draft guidance documents have not been finalized. In January 2017, the FDA issued a "Discussion Paper on Laboratory Developed Tests (LDTs)," which includes a possible approach to LDT oversight that is intended to advance public discussion on the topic. Additionally, legislative proposals continue to be discussed. Such proposals would implement differing approaches to the regulation of LDTs, including in certain instances to require marketing authorization from the FDA. In early 2023, the FDA has also indicated that the agency was looking at rulemaking for diagnostics reform.

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.

European Union Regulation

Our products are regulated as in-vitro diagnostic devices in the European Union (EU) and will therefore be subject to the requirements of the In-Vitro Diagnostic Devices Regulation (EU) 2017/746, ("IVDR"). The IVDR became fully applicable in all EU Member States on May 26, 2022 (therefore not including the UK). The IVDR introduced more stringent requirements than the previous EU In Vitro Diagnostics Directive 98/79/EC, ("IVDD"). For an in-vitro diagnostic device to be placed on the market in the EU, a CE mark demonstrating conformance with the applicable regulations is required. The CE mark confirms that the device meets the general safety and performance requirements under the IVDR (or, previously, the essential requirements under the IVDD). For the lowest risk class devices, the manufacturer can conduct a self-assessment of its device against the requirements and issue a declaration of conformity confirming that the device is compliant. For all other devices, a conformity assessment procedure must be undertaken by an independent notified body to assess the compliance of the device with the applicable requirements.

In accordance with the transitional provisions in the IVDR, devices placed on the EU market prior to 26 May 2022 in accordance with the IVDD (except for Class A, non-sterile devices which must conform with the IVDR requirements since May 26, 2022) may continue to be supplied until a certain date (ranging from May 2025 to May 2027) which will depend on the risk class of the device, provided that manufacturers comply with the IVDR requirements relating to post-market surveillance, market surveillance, vigilance and registration of economic operators and devices. After the applicable date, all devices must be certified under the IVDR in order to be marketed in the EU.

Research and Development Expenses

For the years ended December 31, 2022 and 2021, we recorded $1.7 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 15, 2023, Precipio employed fifty-five (53) employees on a full-time basis and three (3) employees as part-time. Of the total, eleven (11) were in Finance, General and Administration, twenty-one (21) were in laboratory and production, fifteen (15) were in Sales and Marketing, four (4) 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 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 abilities.

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.

Diversity & Inclusion ("D&I").

We strive to create a culture in which all employees feel heard, respected, and valued. We are committed to creating and maintaining a diverse, inclusive and safe work environment. As we grow and mature, we look forward to establishing programs that infuse D&I within the business, identify barriers that impact recruitment, development and retention of underrepresented employees, identify educational content, communicate the value and impact of D&I 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.

Executive Officers of the Registrant

Our executive officers, their ages as of March 15, 2023 and their respective positions are as follows:

Ilan Danieli, Chief Executive Officer, age 51

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 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, Interim Chief Financial Officer, age 56

Mr. Gage was appointed Interim Chief Financial Officer of Precipio, Inc. effective March 21, 2022. Mr. Gage served as Director of Financial Reporting and Analysis of Precipio, Inc. since 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 company finance, 25 years of which being with publicly traded companies. Mr. Gage holds a Bachelor of Science Degree in Business Administration from Bryant University.

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 ESG Report in February 2023, which is available on our website, and expect to continue reporting on our progress to our various stakeholders.

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 provisional patent applications for its proprietary HemeScreen technology.

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 Securities and Exchange Commission, ("SEC"), filings, including exhibits, 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 web site 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.
- We may require significant additional financing to sustain our operations and without it we will not be able to continue operations.
- We may need to raise substantial additional capital to commercialize our diagnostic technology, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts or force us to restrict or cease operations.
- We have incurred losses since our inception and expect to incur losses for the foreseeable future. We cannot be certain that we will achieve or sustain profitability.
- We are subject to concentrations of revenue risk and concentrations of credit risk in accounts receivable.
- We have been, and may continue to be, subject to costly litigation.
- 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.
- We face risks related to health pandemics and other widespread outbreaks of contagious disease, including the novel coronavirus, COVID-19, which could significantly disrupt our operations and impact our financial 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.
- Unfavorable U.S. or global economic conditions 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.
- 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.
- 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 sale or issuance of our common stock to Alliance Global Partners may cause significant dilution and the sale of the shares of common stock acquired by Alliance Global Partners, or the perception that such sales may occur, could cause the price of our common stock to fall.
- 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.

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 used cash in our operating activities for the past few years. For the year ended December 31, 2022, the Company had a net loss of $12.2 million and net cash used in operating activities of $7.7 million. As of December 31, 2022, the Company had an accumulated deficit of $92.3 million and working capital of $1.3 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 2023 as we further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will continue to 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.

We may require significant additional financing to sustain our operations and without it we will not be able to continue operations.

At December 31, 2022, we had working capital of $1.3 million. For the year ended December 31, 2022, we had an operating cash flow deficit of $7.7 million and a net loss of $12.2 million. We do not currently have sufficient financial resources to fund our operations or those of our subsidiaries. Therefore, we need additional funds to continue these operations.

Our primary sources of funds to meet our liquidity and capital requirements include cash on hand, funds generated from operations, funding pursuant to a sales agreement with A.G.P./Alliance Global Partners ("AGP") and possible sales of certain receivables under our receivable factoring agreement.

To facilitate ongoing operations and product development, on April 2, 2021, the Company entered into a sales agreement with AGP, pursuant to which we may offer and sell our common stock, par value $0.01 per share (the "Common Stock") (the "Shares"), having aggregate sales proceeds of up to $22.0 million, to or through AGP, as sales agent (the "AGP Sales Agreement"), from time to time, in an "at the market offering" (as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended) of the Shares (the "ATM Offering"). We are limited in the number of shares we can sell in the ATM Offering due to the offering limitations currently applicable to us under General Instruction I.B.6. of Form S-3 and our public float as of the applicable date of such sales, as well as the number of authorized and unissued shares available for issuance, in accordance with the terms of the AGP Sales Agreement.

The extent we rely on AGP as a source of funding will depend on a number of factors including, the prevailing market price of our common stock and the extent to which we are able to secure working capital from other sources. If obtaining sufficient funding from AGP were to prove unavailable or prohibitively dilutive, we will need to secure another source of funding in order to satisfy our working capital needs. Even if we sell all $22.0 million under the AGP Sales Agreement, we may still need additional capital to fully implement our business, operating and development plans. Should the financing we require to sustain our working capital needs be unavailable or prohibitively expensive when we require it, the consequences could be a material adverse effect on our business, operating results, financial condition and prospects. From April 2, 2021 through the date the consolidated financial statements were issued, we received approximately $16.0 million in gross proceeds through the AGP Sales Agreement from the sale of 5,119,656 shares of common stock, leaving us with an additional $6.0 million available for future sales pursuant to the AGP Sales Agreement.

On March 27, 2023, we entered into receivables factoring agreement with Culain Capital Funding LLC ("Culain"). Under the terms of this agreement, we may offer for sale, and Culain in its sole discretion may purchase eligible

receivables of the Company (the "Purchased Accounts"). Upon purchase, Culain becomes the absolute owner of the Purchased Accounts, which are payable directly to Culain, subject to certain repurchase obligations of the Company. The willingness of Culain to make advances to us by purchasing eligible accounts receivable is subject to customary conditions for financings of this nature. If we are unable to satisfy those conditions, Culain could refrain from providing financing to us, and we might not have sufficient cash on hand to fund our ongoing operations.

We may have to raise significant additional capital or obtain additional credit to fund our operations in the future. 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.

Substantially all of our consolidated assets are subject to a security interest in favor of Culain under our Factoring Agreement.

Our obligations under certain accounts receivable financing arrangements are secured by a lien on substantially all our consolidated tangible and intangible assets, including receivables from the operations of our business and outstanding ownership interests in each of our direct and indirect subsidiaries. Pursuant to the Factoring Agreement with Culain, we are advanced funds against future accounts receivable. We remain responsible for collecting the accounts receivable. If we are unable to meet our payment obligations under this arrangement, including as the result of failure to collect accounts receivable, Culain would have the right to liquidate our assets to pay off the amounts owed. If any of our assets were to be liquidated, our business could be materially and adversely affected. As of the date of issuance of this Annual Report on Form 10-K, we did not have any receivables outstanding under these arrangements.

We may need to raise substantial additional capital to commercialize our diagnostic technology, and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts or force us to restrict or cease operations.

As of December 31, 2022, we had cash of $3.4 million and our working capital was $1.3 million. Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we may be required to raise additional capital to complete the development and commercialization of our current product candidates and to pay off our obligations. To date, to fund our operations and develop and commercialize our products, we have relied primarily on equity and debt financings. In future periods, when we seek additional capital, we may seek to sell additional equity and/or debt securities or to obtain a credit facility, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of one or more of our product candidates, restrict or cease our operations or obtain funds by entering into agreements on unattractive terms.

We have incurred losses since our inception and expect to incur losses for the foreseeable future. We cannot be certain that we will achieve or sustain profitability.

We have incurred losses since our inception and expect to incur losses in the future. At December 31, 2022, we had working capital of $1.3 million. For the year ended December 31, 2022, we had an operating cash flow deficit of $7.7 million and a net loss of $12.2 million. For the year ended December 31, 2022, 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 substantial net losses through at least 2023 as we further develop and commercialize our diagnostic technology. We also expect that our selling, general and administrative expenses will continue to 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.

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, 2022 and 2021, no customer individually represented 10% or more of our total revenue. 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, 2022, one customer accounted for approximately 12% of our total accounts receivable and at December 31, 2021, two customers accounted for approximately 33% 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 bad debt 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, 2022.

We have been, and may continue to be, subject to costly litigation.

We have been, and may continue to be, subject to legal proceedings. 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.

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 two groups, consisting of companies that specialize in oncology and offer directly competing services to our diagnostic services, offering their services to oncologists and pathology departments within hospitals, as well as 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 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.

We face risks related to health pandemics and other widespread outbreaks of contagious disease, including the novel coronavirus, COVID-19, which could significantly disrupt our operations and impact our financial results.

The COVID-19 pandemic continues to evolve. Despite recent progress in the administration of vaccines, COVID-19 had an adverse impact on the global economy and to some extent on our business. The COVID-19 pandemic continues to have a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services may be slow to return to pre-pandemic levels, if they return to pre-pandemic levels. Our laboratory operations resumed to near-normal capacity, but we may continue to experience challenges in procuring materials and supplies in a consistently timely manner due to COVID-19-related supply chain issues. The demand for COVID-19 vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, during a public health emergency may make it more difficult to obtain materials or manufacturing. If any of our third-party manufacturers is adversely impacted by the COVID-19 pandemic or if they divert resources or manufacturing capacity to accommodate the development or manufacture of COVID-19 coronavirus vaccines, our supply chain may be disrupted, limiting our ability to produce our diagnostic tests.

We have been and will continue to be prudent in managing through this economic crisis. Digital connectivity is now fundamental to the continuity of our business operations. The extent to which the COVID-19 pandemic continues to impact our results of operations and financial condition will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity and longevity of COVID-19 and its variants, the resurgence of COVID-19 in regions that have begun to recover from the initial impact of the pandemic, the impact of COVID-19 on economic activity, and the actions to contain its impact on public health and the global economy.

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;
- 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;
- 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, ("UK"), Bribery Act of 2010 and anti-bribery requirements of member states in the European Union, ("EU"); and
- our products (including HemeScreen® reagents which are authorized under the previous EU Directive on In-Vitro Diagnostic Devices (98/79/EC)) may not be compliant with the new regulatory framework brought in by the In-Vitro Diagnostic Devices Regulation ((EU) 2017/746), and approvals of our products under the new regulatory regime may be delayed and consequently our ability to continue to commercialize them in the EU may be impacted.

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 24, 2022, we received CE-IVD approval for the sale of HemeScreen® reagents in the UK and the EU in accordance with the requirements of the EU IVDD. However, the new EU In-Vitro Diagnostic Devices Regulation ((EU) 2017/746), came into effect on May 26, 2022 and repealed the IVDD. The transitional provisions under the IVDR allow for devices with a notified body certificate issued under the IVDD and which are placed on the EU market prior to May 26, 2022 to continue to be placed on the market in the EU until May 26, 2025. Our device will need to be re-certified under the IVDR by such date in order to remain on the EU market, which will include evaluation by an EU notified body to confirm whether our device meets the general safety and performance requirements under the IVDR. There is no guarantee that our device will be determined to be compliant with such requirements. It should also be appreciated that there currently is a severe shortage of capacity of the EU notified bodies to assess all devices that will require notified body certification under the IVDR. There can be no assurance that our ability to market HemeScreen® reagents in the EU in the future will not be interrupted and this could, in turn, have a negative impact on our business and operating results.

The regulatory framework for medical devices in the UK is likely to evolve now that the UK is no longer part of the EU. 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.

Now that the UK has left the EU, the new UKCA mark will replace the EU CE mark in Great Britain, ("GB"). The EU legal framework remains applicable in Northern Ireland (indeed any products placed on the market in Northern Ireland must be compliant with EU law). EU CE marks will continue to be recognized in GB for in-vitro diagnostic devices for the time being, however, from July 2024, transitional arrangements will apply for CE and UKCA marked devices placed on the GB market. These transitional arrangements have not yet been brought into force through the UK medical devices regulations, but the UK Government intends to introduce legislation by Spring 2023 that will bring these into force. In addition, all devices must now be registered with the MHRA in order to be placed on the GB market. These new requirements under the UK medical devices legislation and any other changes that are brought into force could result in delays in our ability to obtain a UKCA mark and to continue to market our product in the UK. The UK's departure from the EU has also impacted customs regulations as well as timing and ease of shipments into the EU from UK.

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

Over the twelve months ended June 2022, the US Bureau of Labor and Statistics reported that inflation increased 9.1 percent as against prices from June 2021. This represents the largest 12-month advance since 1981.

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 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 could strain our collaborators and suppliers, possibly resulting in supply disruption, or cause delays in their payments to us.

In addition, the Company's operations and access to capital may be impacted by disruptions to the banking system and financial market volatility resulting from bank failures, particularly in light of the recent events that have occurred with respect to Silicon Valley Bank and other financial institutions.

Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

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. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC may be unable to access undrawn amounts thereunder. If any of our suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. In this regard, counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis.

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.

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 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.

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

We are a small company with 53 full-time employees and 3 part-time employees as of March 15, 2023. 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 organization 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.

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, attack, or damage. We rely on our information systems to provide security for processing, transmission and storage of confidential information about our patients, customers and personnel, such as names, addresses and other individually identifiable information protected by the Health Insurance Portability and Accountability Act, ("HIPAA"), other privacy laws. We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. 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 cyber-attacks 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 security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, 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, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud 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 have not experienced any known attacks on our information technology systems that compromised any confidential information. We maintain our information technology systems with safeguard protection against cyber-attacks including passive intrusion protection, firewalls and virus detection software. However, these safeguards do not ensure that a significant cyber-attack 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 cyber-attacks.

Security breaches, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches can create system disruptions or shutdowns or the unauthorized disclosure of confidential information. If personal information or protected health information is improperly accessed, tampered with or disclosed as a result of a security breach, we may incur significant costs to notify and mitigate potential harm to the 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 security breach of 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.

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

The rules dealing with U.S. federal, state, and local and non-U.S. taxation are constantly under review by persons involved in the legislative process, the Internal Revenue Service, the U.S. Treasury Department and other taxing authorities. Changes to tax laws or tax rulings, or changes in interpretations of existing laws (which changes may have retroactive application), could adversely affect us or holders of our common stock. These changes could subject us to additional income-based taxes and non-income taxes (such as payroll, sales, use, value-added, digital tax, net worth, property, and goods and services taxes), which in turn could materially affect our financial position and results of operations. Additionally, new, changed, modified, or newly interpreted or applied tax laws could increase our customers' and our compliance, operating and other costs, as well as the costs of our products. In recent years, many such changes have been made, and changes are likely to continue to occur in the future. As we expand the scale of our business activities, any changes in the U.S. and non-U.S. taxation of such activities may increase our effective tax rate and harm our business, 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, 2022, we had approximately $74 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, 2022, we had approximately $2.4 million of state NOLs. For state NOLs expiration dates, it varies from 2022 to unlimited. Under current law, federal NOLs generated in taxable years ending 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, 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. 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). 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.

Laboratory and R&D facilities located in New Haven, Connecticut and Omaha, Nebraska house development teams that collaborate on new products and services. The Company operates CLIA laboratories in both the New Haven, Connecticut and Omaha, Nebraska locations providing 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 while our facilities were 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 certification 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.

The Clinical Laboratory Improvement Amendments of 1988, ("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. The 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 the 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 in the CLIA law 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.

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, the FDA has stated it intends to end its policy of enforcement discretion and to actively regulate LDTs. For example, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory

Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Regulatory Oversight of Laboratory Developed Tests (LDTs)", that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The timing of when, if at all, the draft guidance documents will be finalized is unclear. In January 2017, the FDA issued a "Discussion Paper on Laboratory Developed Tests (LDTs)," which includes a possible approach to LDT oversight that is intended to advance public discussion on the topic. Additionally, legislative proposals have been introduced in Congress or have been publicly circulated. Such proposals would implement differing approaches to the regulation of LDTs, including in certain instances to require marketing authorization from the FDA. We cannot predict whether any of these legislative proposals will be enacted into law or the impact such new legal requirements would have on our business.

If the FDA asserts that our RUO products and/or LDTs are subject to marketing authorization, or that our RUO products and/or LDTs are adulterated or misbranded, our business, financial condition or results of operations could be adversely affected.

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.

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. 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. 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.

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 have one company-owned, pending patent application directed to our HemeScreen test. This provisional patent application is not eligible to become an issued patent until, among other things, we file a non-provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non-provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications.

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.

On September 1, 2022, we terminated the license agreement with Dana-Farber pursuant to which we previously licensed our ICP technology. For more information regarding this license agreement termination, please see "Management's Discussion and Analysis of Financial Condition and Results of Operations-Recent Developments". In the future, we may enter into other 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 do not and will not own the patents, patent applications or other intellectual property rights that are the subject of the Dana-Farber license or these other future licenses. 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, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Recently, under U.S. patent reform, new procedures including *inter partes* review and post grant review have been implemented. As stated above, this reform will 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 formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, 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. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. 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 the 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) is scheduled to come into force during 2023. The UPC will be a common patent court to hear patent infringement and revocation proceedings effective for member states of the European Union. 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. Although we do not currently own any European patents or applications, if we obtain 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 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.

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. In the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit 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.

On October 28, 2022, we received a letter from The Nasdaq Stock Market LLC, notifying us that the closing bid price per share of our common stock was below the $1.00 minimum bid price requirement for continued listing on Nasdaq, as required by Nasdaq Listing Rule 5550(a)(2) ("Bid Price Rule"). As a result, Nasdaq notified us that we are not in compliance with the Bid Price Rule. Nasdaq has provided us with 180 calendar days, or until April 26, 2023, to regain compliance with the Bid Price Rule. This notification has no immediate effect on our listing on Nasdaq or on the trading of the our common stock.

To regain compliance with the Bid Price Rule, the closing bid price of our common stock must meet or exceed $1.00 per share for a minimum of ten consecutive business days during the 180-calendar day grace period. If our common stock does not regain compliance with the Bid Price Rule during this grace period, we may be eligible for an additional grace period of 180 calendar days provided that we satisfy Nasdaq's continued listing requirement for market value of

publicly held shares and all other initial listing standards for listing on Nasdaq, other than the minimum bid price requirement, and provide written notice to Nasdaq of our intention to cure the delinquency during the second grace period, by effecting a reverse stock split, if necessary. If we meet these requirements, Nasdaq will grant us an additional 180 calendar days. However, if it appears to Nasdaq that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will provide notice that our securities will 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;
- 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.

We intend to monitor the closing bid price of our common stock and may, if appropriate, evaluate various courses of action to regain compliance with the Bid Price rule. However, there can be no assurance that we will be able to regain compliance with the Bid Price Rule.

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.

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 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.

The sale or issuance of our common stock to, or through, AGP may cause significant dilution and the sale of the shares of common stock acquired by AGP, or the perception that such sales may occur, could cause the price of our common stock to fall.

On April 2, 2021, we entered into a sales agreement with AGP, pursuant to which we may offer and sell our Common Stock, having aggregate sales proceeds of up to $22.0 million, to or through AGP, from time to time, in the ATM Offering. We are limited in the number of shares it can sell in the ATM Offering due to the offering limitations currently applicable to the Company under General Instruction I.B.6. of Form S-3 and the Company's public float as of the applicable date of such sales, as well as the number of authorized and unissued shares available for issuance, in accordance with the terms of the AGP Sales Agreement. Sales to, or through, AGP by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common

stock, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

From April 2, 2021 through the date the consolidated financial statements were issued, we received approximately $16.0 million in gross proceeds through the AGP Sales Agreement from the sale of 5,119,656 shares of Common Stock, leaving us with an additional $6.0 million available for future sales pursuant to the AGP Sales Agreement.

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.

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, including most recently in connection with the ongoing COVID-19 pandemic, 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 he 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 2. Properties

We currently lease approximately 7,630 square feet of laboratory and office space in New Haven, Connecticut, which we occupy under a lease expiring in December 2026 with annual rental payments of $0.2 million. We also lease approximately 5,300 square feet of laboratory space in Omaha, Nebraska, which we occupy under a lease expiring in May 2025 with annual rental payments of less than $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. Therefore, although management considers the likelihood of such an outcome to be remote, 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 adversely affected. In general, the resolution of a legal matter could 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.

The Company is involved in legal proceedings related to matters, which are incidental to its business and 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. As previously reported, on February 6, 2017, CPA Global claimed that we owed 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, 2022 and 2021.

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 28, 2023, there were 23,353,893 shares of our common stock outstanding and approximately 38 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, 2022. Therefore, tabular disclosure is not presented.

Recent Sales of Unregistered Securities. None.

Item 6. [Reserved]

Not Applicable.

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 solutions company focused on cancer diagnostics. Our business mission is to address the pervasive problem of cancer misdiagnoses by developing solutions to mitigate the root causes of this problem in the form of diagnostic products, reagents and services. Misdiagnoses originate from aged commercial diagnostic cancer testing technologies, lack of subspecialized expertise, and sub-optimal laboratory processes that are needed in today's diagnostic cancer testing in order to provide accurate, rapid, and resource-effective results to treat patients. Industry studies estimate 1 in 5 blood-cancer patients are misdiagnosed. As cancer diagnostic testing has evolved from cellular to molecular (genes and exons), laboratory testing has become extremely complex, requiring even greater diagnostic precision, attention to process and a more appropriate evaluation of the abundance of genetic data to effectively gather, consider, analyze and

present information for the physician for patient treatment. We view cancer diagnostics as requiring a holistic approach to improve diagnostic data for improved interpretations with the intent to reduce misdiagnoses. By delivering diagnostic products, reagents and services that improve the accuracy and efficiency of diagnostics, leading to fewer misdiagnoses, we believe patient outcomes can be improved through the selection of appropriate therapeutic options. Furthermore, we believe that better patient outcomes will have a positive impact on healthcare expenses as misdiagnoses are reduced. Better diagnostic results – Better Patient Outcome – Lower Healthcare Expenditures.

To deliver our strategy, we have structured our organization in order to drive development of diagnostic products. Laboratory and R&D facilities located in New Haven, Connecticut and Omaha, Nebraska house development teams that collaborate on new products and services. The Company operates CLIA laboratories in both the New Haven, Connecticut and Omaha, Nebraska locations providing 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 laboratory to support R&D beta-testing of the products we develop, in a clinical environment.

In April 2020, we formed a Joint Venture with Poplar. Poplar provides specialized laboratory testing services to a nationwide client base of gastroenterologists, dermatologists, oncologists, urologists, gynecologists and their patients. The business purpose of the Joint Venture is to facilitate and capitalize on the combined capabilities, resources and healthcare industry relationships of its members by partnering, promoting and providing oncology services to office based physicians, hospitals and medical centers. Under the terms of the Joint Venture, Precipio SPV has a 49% ownership interest in the Joint Venture, with Poplar having a 51 % ownership. We have determined that we hold a variable interest in the Joint Venture and that we are the primary beneficiary of the Joint Venture. Due to this determination, we consolidate the Joint Venture. See Note 2 - Summary of Significant Accounting Policies to our consolidated financial statements appearing elsewhere in this report for further discussion. We are working with Poplar to dissolve the Joint Venture with an effective date of December 31, 2022.

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. The Company has incurred substantial operating losses and has used cash in its operating activities for the past several years. For the year ended December 31, 2022, the Company had a net loss of $12.2 million and net cash used in operating activities of $7.7 million. As of December 31, 2022, the Company had an accumulated deficit of $92.3 million and working capital of $1.3 million. We believe the existing cash, cash equivalents and marketable securities on hand will enable us to fund our operating expenses and capital expenditure requirements through the first half of 2023. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and Capital Resources." The Company's 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 its business plan, including generating additional revenue, and raising additional financing to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

To meet our current and future obligations we have taken the following steps to capitalize the business and successfully achieve our business plan:

- On April 2, 2021, we entered into a sales agreement with A.G.P./Alliance Global Partners ("AGP"), pursuant to which we may offer and sell our common stock, par value $0.01 per share (the "Common Stock") (the "Shares"), having aggregate sales proceeds of up to $22.0 million, to or through AGP, as sales agent (the "AGP Sales Agreement"). From April 2, 2021 through the date the consolidated financial statements were issued, we have already received approximately $16.0 million in gross proceeds through the AGP Sales Agreement from the sale of 5,119,656 shares of common stock, leaving us an additional $6.0 million available for future sales pursuant to the AGP Sales Agreement.

Notwithstanding the aforementioned circumstances, 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.

Outlook - COVID-19 related

The COVID-19 outbreak, which spread worldwide in the first quarter of 2020, has caused significant business disruption. The extent of the impact of the ongoing COVID-19 pandemic on the Company's operational and financial performance will depend on future developments. While our laboratory operations resumed to near-normal capacity, we may continue to experience challenges in procuring materials and supplies in a consistently timely manner due to COVID-19-related supply chain issues. In addition, delays in the development of COVID-19 vaccines or the deployment of vaccines which are approved or otherwise authorized for emergency use, a recurrence or "subsequent waves" of COVID-19 cases, or the discovery of vaccine-resistant COVID-19 variants, the emergence of subvariants, or the discovery of vaccine-resistant COVID-19 variants could cause other widespread or more severe impacts. We have been actively monitoring the COVID-19 pandemic and its impact on the global economy and the Company. As the global pandemic evolves, we will continue to monitor the extent to which COVID-19 impacts our revenues, expenses and liquidity.

Results of Operations for the Years Ended December 31, 2022 and 2021

Net Sales. Net sales were as follows:

	Dollars in Thousands			
	Year Ended December 31,		Change	
	2022	2021	$	%
Service revenue, net, less allowance for doubtful accounts	$ 8,010	$ 7,935	$ 75	1 %
Other	1,402	914	488	53 %
Net Sales	$ 9,412	$ 8,849	$ 563	6 %

Net sales for the year ended December 31, 2022 were $9.4 million, an increase of $0.6 million, as compared to the same period in 2021. During the year ended December 31, 2022, despite the fact that we had a decrease in cases processed, patient diagnostic service revenue increased $0.1 million as compared to the same period in 2021 due to better reimbursement rates achieved for the tests billed in the current year. We billed 4,109 cases during the year ended December 31, 2022 as compared to 4,345 cases during the same period in 2021, or a 5% decrease in cases. Patient diagnostic service revenue accounted for 85% and 89% our total net sales for the years ended December 31, 2022 and 2021, respectively. The increase in patient diagnostic service revenue was partially offset by a decrease of less than $0.1 million in service revenue from contract diagnostics for the year ended December 31, 2022 as compared to the same period in 2021. Other revenues increased by $0.5 million for the year ended December 31, 2022 as compared to the same period in 2021. The increase is the result of a $0.6 million increase in revenues related to our HemeScreen Reagent Rental ("HSRR") program, partially offset by a $0.1 million decrease in other miscellaneous revenues.

Cost of Sales. Cost of sales includes material and supply costs for the patient tests performed, costs related to HSRR 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 $0.4 million for the year ended December 31, 2022 as compared to the same period in 2021. The increase is in line with the changes in related revenues discussed above.

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

	Dollars in Thousands			
	Year Ended December 31,		Margin %	
	2022	2021	2022	2021
Gross Profit	$ 2,510	$ 2,392	27 %	27 %

Gross margin was 27% of total net sales, for the years ended December 31, 2022 and 2021, respectively, and the gross profit was approximately $2.5 million and $2.4 million during the years ended December 31, 2022 and 2021, respectively. 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 would enable our laboratory to yield economies of scale and to leverage fixed expenses. We anticipate case volume to increase in the future and for our costs per case to improve as additional economies of scale are possible.

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 $3.3 million to $15.3 million for the year ended December 31, 2022 as compared to $12.0 million for the year ended December 31, 2021. The increase included the following: an increase of $1.2 million in sales and marketing expenses resulting from increased personnel costs largely due to increased headcount in our product sales force; an increase of $0.4 million in research and development expenses due to a $0.1 million increase in personnel costs and a $0.3 million increase in operating supplies; and, an increase of $1.9 million in stock based compensation expenses for the year ended December 31, 2022 as compared to the prior year. These increases were partially offset by a decrease of $0.2 million in general and administrative expenses due to a $0.3 million decrease in legal and professional fees and a decrease of $0.2 million in personnel costs partially offset by a $0.3 million increase in franchise and other tax expenses.

Other Income (Expense). We recorded net other income of $0.6 million and $1.1 million for the years ended December 31, 2022 and 2021, respectively. The current year period other income of $0.6 million is attributable to non-cash income recorded on warrant revaluations. The other income for the year ended December 31, 2021 includes $0.8 million of a gain on forgiveness of debt related to the forgiveness of our Paycheck Protection Program Loan and $0.3 of non-cash income recorded on warrant revaluations.

Liquidity and Capital Resources

Our working capital positions at December 31, 2022 and 2021 were as follows (in thousands):

	December 31, 2022	December 31, 2021	Change
Current assets (including cash of $3,445 and $11,668 respectively)	$ 5,710	$ 13,478	$ (7,768)
Current liabilities	4,361	4,213	148
Working capital	$ 1,349	$ 9,265	$ (7,916)

To date, we have incurred significant net losses and have funded our operations primarily through cash generated from operations, the issuance of convertible debt and the issuance of shares of our common stock.

During the year ended December 31, 2022 we received net proceeds of $0.1 million from sale of 85,023 shares of our common stock and less than $0.1 million from the issuance of 26,795 shares of our common stock in connection with the exercise of 26,795 warrants.

Analysis of Cash Flows - Years Ended December 31, 2022 and 2021

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

	Year Ended December 31,		
	2022	2021	Change
Net cash used in operating activities	$ (7,721)	$ (6,577)	$ (1,144)
Net cash used in investing activities	(277)	(682)	405
Net cash (used in) provided by financing	(225)	16,271	(16,496)
Net change in cash	$ (8,223)	$ 9,012	$ (17,235)

Net Change in Cash. Cash decreased by $8.2 million and increased by $9.0 million during the years ended December 31, 2022 and 2021, respectively.

Cash Flows Used in Operating Activities. The cash flows used in operating activities of $7.7 million during the year ended December 31, 2022 included a net loss of $12.2 million, an increase in accounts receivables of $0.7 million, a decrease accrued expenses of $0.3 million, an increase in inventories of $0.1 million and a decrease in operating lease liabilities of $0.2 million. These were partially offset by a decrease in other assets of $0.5 million, an increase in accounts payable of $0.1 million, an increase in deferred revenue of $0.1 million and non-cash adjustments of $5.1 million. The non-cash adjustments included $0.4 million for the change in provision for losses on doubtful accounts. We routinely provide a reserve for doubtful accounts as a result of having limited in-network payer contracts. The other non-cash adjustments to net loss of approximately $4.7 million include, among other things, depreciation and amortization, warrant revaluations and stock-based compensation. The cash flows used in operating activities in the year ended December 31, 2021 included the net loss of $8.5 million, an increase in inventories and other assets of $0.6 million and a decrease in accrued expenses and operating lease liabilities of $0.3 million. These were partially offset by a decrease in in accounts receivable of $0.3 million, an increase in accounts payable of $0.1 million and non-cash adjustments of approximately $2.4 million.

Cash Flows Used In Investing Activities. Cash flows used in investing activities were $0.3 million and $0.7 million for the years ended December 31, 2022 and 2021, respectively, resulting from purchases of property and equipment.

Cash Flows Provided by Financing Activities. Cash flows used in financing activities totaled $0.2 million for the year ended December 31, 2022, which included payments on our long-term debt and finance lease obligations of $0.3 million partially offset by $0.1 million of proceeds from the issuance of common stock. Cash flows provided by financing activities totaled $16.3 million for the year ended December 31, 2021, which included proceeds of $16.2 million from the issuance of common stock and $0.4 million from warrant exercises. These were partially offset by payments on our long-term debt and finance lease obligations of $0.2 million and payments on common stock warrant liabilities of $0.1 million.

At each of December 31, 2022 and December 31, 2021, 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, 2022, 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]	$ 426	$ 268	$ 70	$ 71	$ 17
Finance lease obligations[2]	272	101	145	26	—
Operating lease obligations[2]	891	252	444	195	—
Purchase obligations[3]	1,333	1,113	220	—	—
	$ 2,922	$ 1,734	$ 879	$ 292	$ 17

(1) Total payments include $404,000 in principal and $22,000 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 Policies and Estimates

The following discussion and analysis of financial condition and results of operations are based upon the Company's consolidated financial statements, which have been prepared in conformity with accounting principles generally accepted in the United States of America. The Company's significant accounting policies are more fully described in Note 2 of the Notes to Consolidated Financial Statements included with this Annual Report on Form 10-K. Certain accounting estimates are particularly important to the understanding of the Company's financial position and results of operations and require the application of significant judgment by the Company's management and can be materially affected by changes from period to period in economic factors or conditions that are outside the control of management. The Company's management uses its judgment to determine the appropriate assumptions to be used in the determination of certain estimates. Those estimates are based on historical operations, future business plans and projected financial results, the terms of existing contracts, the observance of trends in the industry, information provided by customers and information available from other outside sources, as appropriate. The following discusses the Company's critical accounting policies and estimates:

Revenue Recognition

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; diagnostic product sales.

Service revenues are comprised of patient diagnostic services for cancer as well as contract diagnostic services for pharmacogenomics trials. Service revenue is recognized upon completion of the testing process and when the diagnostic result is delivered to the ordering physician and/or customer. Net patient 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. Revenue under third-party payer agreements is subject to audit and retroactive adjustment. 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.

Revenue from clinical research grant is recognized over time as the service is being performed using a proportional performance method. The Company uses an "efforts based" method of assessing performance. If the

arrangement requires the performance of a specified number of similar acts (i.e. test), then revenue is recognized in equal amounts as each act is completed.

Other revenues are comprised of the Company's sales to bio-pharma customers, clinical research, and HemeScreen and other product sales.

For the year ended December 31, 2022, service revenue represented 85% of our consolidated revenues and other revenues represented 15%. For the year ended December 31, 2021, service revenue represented 90% of our consolidated revenues and other revenues represented 10%.

Allowance for Contractual Discounts

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 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.

Allowance for Doubtful Accounts

The allowance for doubtful accounts is based on estimates of losses related to receivable balances. The risk of collection varies based upon the service, the payer (commercial health insurance and government) and the patient's ability to pay the amounts not reimbursed by the payer. We estimate the allowance for doubtful accounts based upon several factors including the age of the outstanding receivables, the historical experience of collections, adjusting for current economic conditions and, in some cases, evaluating specific customer accounts for the ability to pay. Collection agencies are employed and legal action is taken when we determine that taking collection actions is reasonable relative to the probability of receiving payment on amounts owed. Management judgment is used to assess the collectability of accounts and the ability of our customers to pay. Judgment is also used to assess trends in collections and the effects of systems and business process changes on our expected collection rates. We review the estimation process quarterly and make changes to the estimates as necessary. When it is determined that a customer account is uncollectible, that balance is written off against the existing allowance.

Accounts Receivable

Accounts Receivable results from diagnostic services provided to self-pay and insured patients, project based testing services, clinical research and miscellaneous product sales. The services provided by the Company are generally due within 30 days from the invoice date. Accounts receivable are reduced by an allowance for doubtful accounts. 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 doubtful accounts. For receivables associated with self-pay patients, including patients with insurance and a deductible and copayment, the Company records an allowance for doubtful accounts 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 doubtful accounts.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date, based on the estimated fair value of the award, and is recognized as expense over the grantee's requisite vesting period. For the purpose of valuing stock options granted to

our employees, directors and officers, we use the Black-Scholes option pricing model. To determine the risk-free interest rate, we utilized the U.S. Treasury yield curve in effect at the time of the grant with a term consistent with the expected term of our awards. The expected term of the options granted is in accordance with Staff Accounting Bulletins 107 and 110, and is based on the average between vesting terms and contractual terms. The expected dividend yield reflects our current and expected future policy for dividends on our common stock. The expected stock price volatility for our stock options was calculated by examining the trading history for our common stock. We will continue to analyze the expected stock price volatility and expected term assumptions and will adjust our Black-Scholes option pricing assumptions as appropriate.

Impairment of Long-Lived Assets

We assess the recoverability of our long-lived assets, which include property and equipment and definite-lived intangible assets, whenever significant events or changes in circumstances indicate impairment may have occurred. If indicators of impairment exist, projected future undiscounted cash flows associated with the asset are compared to our carrying amount to determine whether the asset's value is recoverable. Any resulting impairment is recorded as a reduction in the carrying value of the related asset in excess of fair value and a charge to operating results.

Recently Adopted Accounting Pronouncements

In July 2021, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2021-05, Lease (Topic 842), *"Lessors - Certain Leases with Variable Lease Payments"*. This guidance amends the lease classification accounting for lessors for certain leases with variable lease payments that do not depend on a reference index or a rate and would have resulted in the recognition of a loss at lease commencement if classified as a sales-type or direct financing lease. Under the new guidance, these leases will be classified as an operating lease. The Company adopted this guidance on January 1, 2022. The adoption of this standard was not material to our consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, "*Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options"* which clarifies the accounting for a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after a modification or exchange and the related EPS effects of such transaction if recognized as an adjustment to equity. The Company adopted this guidance on January 1, 2022. The adoption of this standard was not material to our consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted

In June 2022, the FASB issued ASU 2022-03, Fair Value Measurement (Topic 820) ("ASU 2022-03"). The amendments in ASU 2022-03 clarify that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The amendments also clarify that an entity cannot, as a separate unit of account, recognize and measure a contractual sale restriction. The amendments in this Update also require additional disclosures for equity securities subject to contractual sale restrictions. The provisions in this Update are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted. The Company does not expect to early adopt this ASU. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06 "*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*." This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13 "*Measurement of Credit Losses on Financial Instruments*", which replaces current methods for evaluating impairment of financial instruments not measured at fair value, including trade

accounts receivable and certain debt securities, with a current expected credit loss model. This ASU, as amended, is effective for the Company for reporting periods beginning after December 15, 2022. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

Impact of Inflation

Inflation generally affects us with increased cost of labor and operating supplies. We do not believe that price inflation had a material adverse effect on our financial condition or results of operations during the periods presented.

Item 7A. Quantitative and Qualitative Disclosure 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 Shareholders and Board of Directors of
Precipio, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Precipio, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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 audits. 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 audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits 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 audits 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 audits 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 audits 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 audits provide 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, 2022, the Company recognized gross revenue of approximately $20.3 million along with contractual allowances of approximately $10.5 million. The net revenue figure of approximately $9.8 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 is 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/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2016.

New Haven, CT
March 30, 2023

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS
December 31, 2022 and 2021
(Dollars in thousands, except share data)

	2022	2021
ASSETS		
CURRENT ASSETS:		
Cash	$ 3,445	$ 11,668
Accounts receivable, net	1,036	697
Inventories	708	564
Other current assets	521	549
Total current assets	5,710	13,478
PROPERTY AND EQUIPMENT, NET	877	836
OTHER ASSETS:		
Finance lease right-of-use assets, net	257	371
Operating lease right-of-use assets, net	763	858
Intangibles, net	13,768	14,717
Other assets	129	179
Total assets	$ 21,504	$ 30,439
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES:		
Current maturities of long-term debt, less debt issuance costs	$ 255	$ 26
Current maturities of finance lease liabilities	162	222
Current maturities of operating lease liabilities	199	166
Accounts payable	2,042	1,863
Accrued expenses	1,584	1,918
Deferred revenue	119	18
Total current liabilities	4,361	4,213
LONG TERM LIABILITIES:		
Long-term debt, less current maturities and debt issuance costs	134	160
Finance lease liabilities, less current maturities	68	159
Operating lease liabilities, less current maturities	574	697
Common stock warrant liabilities	—	606
Total liabilities	5,137	5,835
COMMITMENTS AND CONTINGENCIES (Note 8)		
STOCKHOLDERS' EQUITY:		
Preferred stock - $0.01 par value, 15,000,000 shares authorized at December 31, 2022 and December 31, 2021, 47 shares issued and outstanding at December 31, 2022 and December 31, 2021, liquidation preference of $64 at December 31, 2022	—	—
Common stock, $0.01 par value, 150,000,000 shares authorized at December 31, 2022 and December 31, 2021, 22,820,260 and 22,708,442 shares issued and outstanding at December 31, 2022 and December 31, 2021, respectively	228	227
Additional paid-in capital	108,371	104,431
Accumulated deficit	(92,297)	(80,094)
Total Precipio, Inc. stockholders' equity	16,302	24,564
Noncontrolling interest in joint venture	65	40
Total stockholders' equity	16,367	24,604
Total liabilities and stockholders' equity	$ 21,504	$ 30,439

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS
For the Years Ended December 31, 2022 and 2021
(Dollars in thousands, except per share data)

	Year Ended December 31,	
	2022	2021
SALES:		
Service revenue, net	$ 8,418	$ 7,783
Other revenue	1,402	914
Revenue, net of contractual allowances and adjustments	9,820	8,697
Adjustment for allowance for doubtful accounts	(408)	152
Net sales	9,412	8,849
COST OF SALES:		
Cost of service revenue	5,917	5,496
Cost of other revenue	985	961
Total cost of sales	6,902	6,457
Gross profit	2,510	2,392
OPERATING EXPENSES:		
Operating expenses	15,307	12,005
OPERATING LOSS	(12,797)	(9,613)
OTHER INCOME (EXPENSE):		
Interest expense, net	(12)	(20)
Warrant revaluation	606	269
Gain on settlement of liability	25	53
Gain on forgiveness of Paycheck Protection Program loan	—	794
Total other income	619	1,096
LOSS BEFORE INCOME TAXES	(12,178)	(8,517)
INCOME TAX EXPENSE	—	—
NET LOSS	(12,178)	(8,517)
Less: Net income attributable to noncontrolling interest in joint venture	(25)	(13)
NET LOSS ATTRIBUTABLE TO PRECIPIO, INC. COMMON STOCKHOLDERS	$ (12,203)	$ (8,530)
BASIC AND DILUTED LOSS PER COMMON SHARE	$ (0.54)	$ (0.40)
BASIC AND DILUTED WEIGHTED-AVERAGE SHARES OF COMMON STOCK OUTSTANDING	22,751,460	21,098,197

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
For the Years Ended December 31, 2022 and 2021
(Dollars in thousands)

	Preferred Stock		Common Stock		Additional			Noncontrolling	
	Outstanding Shares	Par Value	Outstanding Shares	Par Value	Paid-in Capital	Accumulated Deficit	Total Precipio, Inc.	Interest in Joint Venture	Total
Balance, January 1, 2021	47	$ —	17,576,916	$ 176	$ 85,523	$ (71,564)	$ 14,135	$ 27	$ 14,162
Net loss	—	—	—	—	—	(8,530)	(8,530)	13	(8,517)
Issuance of common stock in connection with purchase agreements	—	—	500,000	5	1,255	—	1,260	—	1,260
Issuance of common stock in connection with at the market offering, net of issuance costs	—	—	4,501,000	45	14,902	—	14,947	—	14,947
Proceeds upon issuance of common stock from exercise of warrants	—	—	74,000	1	399	—	400	—	400
Proceeds upon issuance of common stock from exercise of stock options	—	—	1,379	—	3	—	3	—	3
Write-off warrant liability in conjunction with warrant exercises	—	—	—	—	320	—	320	—	320
Issuance of common stock for consulting services	—	—	55,147	—	150	—	150	—	150
Non-cash stock-based compensation	—	—	—	—	1,879	—	1,879	—	1,879
Balance, December 31, 2021	47	$ —	22,708,442	$ 227	$ 104,431	$ (80,094)	$ 24,564	$ 40	$ 24,604
Net loss	—	—	—	—	—	(12,203)	(12,203)	25	(12,178)
Issuance of common stock in connection with at the market offering, net of issuance costs	—	—	85,023	1	128	—	129	—	129
Proceeds upon issuance of common stock from exercise of warrants	—	—	26,795	—	11	—	11	—	11
Non-cash stock-based compensation	—	—	—	—	3,801	—	3,801	—	3,801
Balance, December 31, 2022	47	$ —	22,820,260	$ 228	$ 108,371	$ (92,297)	$ 16,302	$ 65	$ 16,367

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Years Ended December 31, 2022 and 2021
(Dollars in thousands)

	Year Ended December 31,	
	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,178)	$ (8,517)
Adjustments to reconcile net loss to net cash flows used in operating activities:		
Depreciation and amortization	1,219	1,131
Amortization of operating lease right-of-use asset	187	219
Amortization of finance lease right-of-use asset	114	94
Amortization of deferred financing costs, debt discounts and debt premiums	4	3
Gain on forgiveness of debt	—	(794)
Gain on settlement of liability	(25)	(53)
Stock-based compensation	3,801	1,879
Value of stock issued in payment of services	—	150
Provision for losses on doubtful accounts	406	(150)
Warrant revaluation	(606)	(269)
Derecognition of finance lease right-of-use asset	—	125
Changes in operating assets and liabilities:		
Accounts receivable	(745)	327
Inventories	(144)	(214)
Other assets	491	(349)
Accounts payable	165	112
Operating lease liabilities	(182)	(225)
Deferred revenue	101	12
Accrued expenses	(329)	(58)
Net cash used in operating activities	(7,721)	(6,577)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property and equipment	(277)	(682)
Net cash used in investing activities	(277)	(682)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Principal payments on finance lease obligations	(151)	(130)
Deposits on finance lease right-of-use assets	—	(39)
Issuance of common stock, net of issuance costs	129	16,207
Proceeds from exercise of warrants	11	400
Proceeds from exercise of stock options	—	3
Principal payments on long-term debt	(214)	(40)
Payments on common stock warrant liabilities	—	(130)
Net cash flows (used in) provided by financing activities	(225)	16,271
NET CHANGE IN CASH	(8,223)	9,012
CASH AT BEGINNING OF PERIOD	11,668	2,656
CASH AT END OF PERIOD	$ 3,445	$ 11,668

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS - continued
For the Years Ended December 31, 2022 and 2021
(Dollars in thousands)

	Year Ended December 31,	
	2022	2021
SUPPLEMENTAL CASH FLOW INFORMATION		
Cash paid during the period for interest	$ 45	$ 34
SUPPLEMENTAL DISCLOSURE OF CONSULTING SERVICES OR ANY OTHER NON-CASH COMMON STOCK RELATED ACTIVITY		
Purchases of equipment financed through accounts payable	34	58
Prepaid insurance financed with loan	413	—
Operating lease right-of-use assets obtained in exchange for operating lease obligations	92	771
Finance lease right-of-use assets obtained in exchange for finance lease obligations	12	347
Write-off warrant liability in conjunction with warrant exercises	—	320

See notes to consolidated financial statements.

PRECIPIO, INC. AND SUBSIDIARIES
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
For the Years Ended December 31, 2022 and 2021

1. BUSINESS DESCRIPTION

Business Description.

Precipio, Inc., and its subsidiaries, (collectively, "we", "us", "our", the "Company" or "Precipio") is a healthcare solutions company focused on cancer diagnostics. The Company's business mission is to address the pervasive problem of cancer misdiagnoses by developing solutions to mitigate the root causes of this problem in the form of diagnostic products, reagents and services. Misdiagnoses originate from aged commercial diagnostic cancer testing technologies, lack of subspecialized expertise, and sub-optimal laboratory processes that are needed in today's diagnostic cancer testing in order to provide accurate, rapid, and resource-effective results to treat patients. Industry studies estimate 1 in 5 blood-cancer patients are misdiagnosed. As cancer diagnostic testing has evolved from cellular to molecular (genes and exons), laboratory testing has become extremely complex, requiring even greater diagnostic precision, attention to process and a more appropriate evaluation of the abundance of genetic data to effectively gather, consider, analyze and present information for the physician for patient treatment. Precipio sees cancer diagnostics as requiring a holistic approach to improve diagnostic data for improved interpretations with the intent to reduce misdiagnoses. By delivering diagnostic products, reagents and services that improve the accuracy and efficiency of diagnostics, leading to fewer misdiagnoses, we believe patient outcomes can be improved through the selection of appropriate therapeutic options. Furthermore, we believe that better patient outcomes will have a positive impact on healthcare expenses as misdiagnoses are reduced. Better Diagnostic Results – Better Patient Outcome – Lower Healthcare Expenditures.

To deliver its strategy, the Company has structured its organization in order to drive development of diagnostic products. Laboratory and R&D facilities located in New Haven, Connecticut and Omaha, Nebraska house development teams that collaborate on new products and services. The Company operates CLIA laboratories in both the New Haven, Connecticut and Omaha, Nebraska locations providing 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 laboratory 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 the Company's robust pipeline of innovative solutions designed to address the root causes of misdiagnoses.

Joint Venture.

In April 2020, the Company formed a joint venture with Poplar Healthcare PLLC ("Poplar"), which we refer to as the "Joint Venture". The Joint Venture was formed by the Limited Liability Company Agreement of Precipio Oncometrix LLC, a Delaware limited liability company ("POC"), which was entered into as of April 11, 2020 (the "Effective Date"), by and among POC, Poplar, and Precipio SPV Inc. ("Precipio SPV"), a newly formed subsidiary of the Company, together with such other persons who from time to time become party to the Limited Liability Company Agreement by executing a counterpart signature page in accordance with the terms hereof. POC was formed as a limited liability company on April 2, 2020 in accordance with the statutes and laws of the State of Delaware relating to limited liability companies. Precipio SPV was incorporated in the State of Delaware on March 10, 2020 for the sole purpose of being a party to the Joint Venture.

Under the terms of the Joint Venture, Precipio SPV has a 49% ownership interest in the Joint Venture, with Poplar having a 51 % ownership. Pursuant to the Limited Liability Company Agreement, Poplar, at any time, has the right to require Precipio SPV to purchase all, but not less than all, of Poplar's shares in the Joint Venture (the "Poplar Put Right"). The purchase price for Poplar's shares shall be $1.00 per share, or fifty-one dollars, and Precipio SPV would, therefore, become the sole 100% owner of the Joint Venture at the time the Poplar Put Right became effective. The Company has determined that it holds a variable interest in the Joint Venture and is the primary beneficiary of the variable interest entity

("VIE"). See Note 2 - Summary of Significant Accounting Policies for further discussion regarding consolidation of variable interest entities.

The business purpose of the Joint Venture is to facilitate and capitalize on the combined capabilities, resources and healthcare industry relationships of its members by partnering, promoting and providing oncology services to office based physicians, hospitals and medical centers. Operational services of the Joint Venture are performed entirely by its members and employees of its members. Precipio SPV's responsibilities include product and account management services, selling & marketing, laboratory diagnostic services and general & administrative services. Precipio SPV is entitled to a management fee for the services it provides. This management fee is established through service agreements which were executed in conjunction with the formation of the Joint Venture. Poplar receives a similar fee for the billing services that it provides.

The Company is working with Poplar to dissolve the Joint Venture with an effective date of December 31, 2022.

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. The Company has incurred substantial operating losses and has used cash in its operating activities for the past several years. For the year ended December 31, 2022, the Company had a net loss of $12.2 million and net cash used in operating activities of $7.7 million. As of December 31, 2022, the Company had an accumulated deficit of $92.3 million and working capital of $1.3 million. The Company's ability to continue as a going concern, for 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 novel coronavirus ("COVID-19") pandemic, and raising additional financing to meet its debt obligations and paying liabilities arising from normal business operations when they come due.

To meet its current and future obligations the Company has taken the following steps to capitalize the business and successfully achieve its business plan:

- On April 2, 2021, the Company entered into a sales agreement with A.G.P./Alliance Global Partners ("AGP"), pursuant to which the Company may offer and sell its common stock having aggregate sales proceeds of up to $22.0 million, to or through AGP, as sales agent (the "AGP Sales Agreement"). From April 2, 2021 through the date the consolidated financial statements were issued, we have already received approximately $16.0 million in gross proceeds through the AGP Sales Agreement from the sale of 5,119,656 shares of common stock, leaving the Company an additional $6.0 million available for future sales pursuant to the AGP Sales Agreement.

Notwithstanding the aforementioned circumstances, 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 available to be 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 and do not include any adjustments that might result should the Company be unable to continue as a going concern as a result of the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation.

The consolidated financial statements include the accounts of Precipio, Inc. and our wholly owned subsidiaries, and the Joint Venture which is a VIE in which we are the primary beneficiary. Refer to the section titled

"Consolidation of Variable Interest Entities" for further information related to our accounting for the Joint Venture. 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 doubtful accounts, 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 risks and uncertainties may be heightened by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. 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. The 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, 2022 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, 2021 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, 2022.

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 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. We have an allowance for slow moving or obsolete inventory of zero and less than $0.1 million at December 31, 2022 and 2021, 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
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, 2022 and 2021.

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, 2022 and 2021, 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 option pricing model for determining the estimated fair value for stock-based awards. Unvested awards as of December 31, 2022 had vesting periods of up to four years from the date of grant. No awards outstanding at December 31, 2022 and 2021, respectively, are subject to performance vesting conditions or market-based vesting.

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 doubtful accounts. 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 doubtful accounts. For receivables associated with self-pay patients, including patients with insurance and a deductible and copayment, the Company records an allowance for doubtful accounts 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 doubtful accounts.

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, 2022 and 2021.

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 totaled approximately $0.1 million in 2022 and 2021, 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 $1.7 million and $1.3 million for the years ended December 31, 2022 and 2021, 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, 2022 and 2021, 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, 2022 and 2021.

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).

Certain of our issued and outstanding warrants to purchase common stock do not qualify to be treated as equity and accordingly, are 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.

We have determined that we hold a variable interest in the Joint Venture, have the power to make significant operational decisions on behalf of the VIE and also have the obligation to absorb the majority of the losses from the VIE. As such we have also determined that we are the primary beneficiary of the VIE. The following table presents information about the carrying value of the assets and liabilities of the Joint Venture which we consolidate and which are included on our consolidated balance sheets. Intercompany balances are eliminated in consolidation and not reflected in the following table.

(dollars in thousands)	December 31, 2022	December 31, 2021
Assets:		
Accounts receivable, net	$ 335	$ 180
Total assets	$ 335	$ 180
Liabilities:		
Accrued expenses	$ 50	$ 36
Total liabilities	$ 50	$ 36
Noncontrolling interest in Joint Venture	$ 65	$ 40
Total stockholders' equity	$ 127	$ 79

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 4,487,967 and 3,584,688 shares of our common stock have been excluded from the computation of diluted loss per share at December 31, 2022 and 2021, 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,	
	2022	2021
Stock options	3,681,336	2,635,287
Warrants	689,131	831,901
Preferred stock	117,500	117,500
Total	4,487,967	3,584,688

Recently Adopted Accounting Pronouncements.

In July 2021, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2021-05, Lease (Topic 842), *"Lessors - Certain Leases with Variable Lease Payments"*. This guidance amends the lease classification accounting for lessors for certain leases with variable lease payments that do not depend on a reference index or a rate and would have resulted in the recognition of a loss at lease commencement if classified as a sales-type or direct financing lease. Under the new guidance, these leases will be classified as an operating lease. The Company adopted this guidance on January 1, 2022. The adoption of this standard was not material to our consolidated financial statements.

In May 2021, the FASB issued ASU 2021-04, "*Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options"* which clarifies the accounting for a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after a modification or exchange and the related EPS effects of such transaction if recognized as an adjustment to equity. The Company adopted this guidance on January 1, 2022. The adoption of this standard was not material to our consolidated financial statements.

Recent Accounting Pronouncements Not Yet Adopted.

In June 2022, the FASB issued ASU 2022-03, Fair Value Measurement (Topic 820) ("ASU 2022-03"). The amendments in ASU 2022-03 clarify that a contractual restriction on the sale of an equity security is not considered part of the unit of account of the equity security and, therefore, is not considered in measuring fair value. The amendments also clarify that an entity cannot, as a separate unit of account, recognize and measure a contractual sale restriction. The amendments in this Update also require additional disclosures for equity securities subject to contractual sale restrictions. The provisions in this Update are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted. The Company does not expect to early adopt this ASU. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06 "*Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*." This ASU amends the guidance on convertible instruments and the derivatives scope exception for contracts in an entity's own equity and improves and amends the related EPS guidance for both Subtopics. The ASU will be effective for annual reporting periods after December 15, 2023 and interim periods within those annual periods and early adoption is permitted in annual reporting periods ending after December 15, 2020. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13 "*Measurement of Credit Losses on Financial Instruments*", which replaces current methods for evaluating impairment of financial instruments not measured at fair value, including trade accounts receivable and certain debt securities, with a current expected credit loss model. This ASU, as amended, is effective for the Company for reporting periods beginning after December 15, 2022. The Company is currently assessing the potential impact that the adoption of this ASU will have on its consolidated financial statements.

Reclassification.

Certain reclassifications were made to the statements of cash flows related to splitting accruals and deferred revenue to separate lines in order to conform to the 2022 presentation. These reclassifications had no effect on previously reported retained earnings, net income, total assets or liabilities, or cash flows used in operating activities.

3. PROPERTY AND EQUIPMENT, NET

A summary of property and equipment at December 31, 2022 and 2021 is as follows:

	2022	2021
Furniture and fixtures and leasehold improvements	$ 24	$ 12
Laboratory equipment	931	794
Computer equipment and laboratory software	990	725
Construction in process	34	138
	1,979	1,669
Less—accumulated depreciation and amortization	(1,102)	(833)
Total	$ 877	$ 836

Depreciation expense was approximately $0.3 million and $0.2 million for the years ended December 31, 2022 and 2021, respectively.

4. INTANGIBLES

Intangible assets consist of the following:

	Dollars in Thousands December 31, 2022		
	Cost	Accumulated Amortization	Net Book Value
Technology	$ 18,990	$ 5,222	$ 13,768

	Dollars in Thousands December 31, 2021		
	Cost	Accumulated Amortization	Net Book Value
Technology	$ 18,990	$ 4,273	$ 14,717

	Estimated Useful Life	
Technology	20	years

Amortization expense for intangible assets was $1.0 million during the years ended December 31, 2022 and 2021, respectively. Amortization expense for intangible assets is expected to be $1.0 million for each of the years ending December 31, 2023, 2024, 2025, 2026 and 2027, respectively.

5. LONG-TERM DEBT

Long-term debt consists of the following:

	Dollars in Thousands	
	December 31, 2022	December 31, 2021
Connecticut Department of Economic and Community Development (DECD)	$ 176	$ 205
DECD debt issuance costs	(15)	(19)
Financed insurance loan	228	—
Total long-term debt	389	186
Current portion of long-term debt	(255)	(26)
Long-term debt, net of current maturities	$ 134	$ 160

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 $31,000. Amortization of the debt issuance cost was approximately $4,000 and $3,000 for the years ended December 31, 2022 and 2021, respectively. Net debt issuance costs were approximately $15,000 and $19,000 at December 31, 2022 and 2021, respectively, and are presented as a reduction of the related debt in the accompanying consolidated balance sheets. Amortization for each of the next five years is expected to be approximately $3,000.

Financed Insurance Loan.

The Company finances certain of its insurance premiums (the "Financed Insurance Loans"). In July 2022, the Company financed $0.4 million with a 5.99% interest rate and is obligated to make payments on a monthly basis through June 2023. As of December 31, 2022 and 2021, the Financed Insurance Loan's outstanding balance of $0.2 million and zero, 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.

Paycheck Protection Program.

On April 23, 2020, the Company entered into a promissory note (the "Promissory Note") evidencing an unsecured $787,200 loan under the Paycheck Protection Program (the "PPP Loan"). The Paycheck Protection Program (or "PPP") was established under the recently congressionally-approved Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") and is administered by the U.S. Small Business Administration. The PPP Loan to the Company was made through Webster Bank, N.A.

On February 11, 2021, the Company filed an application for loan forgiveness with Webster Bank and was subsequently notified by Webster Bank that effective March 24, 2021 the PPP Loan, plus accrued interest, was considered fully forgiven. As a result, the Company recorded a gain on forgiveness of debt of $0.8 million in the consolidated statements of operations for the year ended December 31, 2021.

The aggregate future maturities required on gross long-term debt at December 31, 2022 are as follows:

	2023	2024	2025	2026	2027	2028 and thereafter	Total
DECD loan	$ 30	$ 31	$ 32	$ 33	$ 34	$ 16	$ 176
Financed insurance loan	228	—	—	—	—	—	228
	$ 258	$ 31	$ 32	$ 33	$ 34	$ 16	$ 404

6. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES.

Accrued expenses at December 31, 2022 and 2021 are as follows:

(dollars in thousands)	2022	2021
Accrued expenses	$ 983	$ 1,033
Accrued compensation	491	718
Accrued franchise, property and sales and use taxes	91	148
Accrued interest	19	19
	$ 1,584	$ 1,918

The Company recorded certain settlement reductions in accrued expenses and accounts payable as gains which are included in gain on settlement of liability, net in the consolidated statements of operations. During each of the years ended December 31, 2022 and 2021, approximately $0.1 million, respectively, was recorded as a gain.

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. On November 29, 2021, we extended the lease term for our office facility in New Haven, Connecticut by modifying the expiration date from December 31, 2021 to December 31, 2026. As a result of this lease extension agreement, on the lease extension date, we recognized an additional operating lease ROU asset and corresponding operating lease liability of $0.8 million which equals the present value of the remaining payments due under the lease extension. On May 11, 2022, we extended the lease term for our office facility in Omaha, Nebraska by modifying the expiration date from May 31, 2022 to May 31, 2025. As a result of this lease extension agreement, on the lease extension date, we recognized an additional operating lease ROU asset and corresponding operating lease liability of $0.1 million which equals the present value of the remaining payments due under the lease extension

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. Derecognized finance lease ROU assets for the years ended December 31, 2022 and 2021 were zero and $0.1 million, respectively. 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 $0.1 million and $0.2 million as of December 31, 2022 and 2021, 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, 2022	December 31, 2021
Assets:		
Operating lease right-of-use assets, net	$ 763	$ 858
Finance lease right-of-use assets, net (1)	257	371
Total lease assets	$ 1,020	$ 1,229
Liabilities:		
Current:		
Current maturities of operating lease liabilities	$ 199	$ 166
Current maturities of finance lease liabilities	162	222
Noncurrent:		
Operating lease liabilities, less current maturities	574	697
Finance lease liabilities, less current maturities	68	159
Total lease liabilities	$ 1,003	$ 1,244

(1) As of December 31, 2022 and 2021, finance lease right-of-use assets included $13 and $61, respectively, of assets related to finance leases associated with the HSRR program.

As of December 31, 2022, the estimated future minimum lease payments, excluding non-lease components, are as follows:

(dollars in thousands)	Operating Leases	Finance Leases	Total
2023	$ 252	$ 101	$ 353
2024	239	80	319
2025	205	65	270
2026	195	26	221
Total lease obligations	891	272	1,163
Less: Amount representing interest	(118)	(42)	(160)
Present value of net minimum lease obligations	773	230	1,003
Less, current portion	(199)	(162)	(361)
Long term portion	$ 574	$ 68	$ 642

Other information as of December 31, 2022 and 2021:

	December 31, 2022	December 31, 2021
Weighted-average remaining lease term (years):		
Operating leases	3.7	4.7
Finance leases	2.8	3.1
Weighted-average discount rate:		
Operating leases	8.00%	8.00%
Finance leases	10.31%	10.03%

During the years ended December 31, 2022 and 2021, operating cash flows from operating leases was $0.2 million, respectively, and operating lease ROU assets obtained in exchange for operating lease liabilities was $0.1 million and $0.8 million, respectively.

Operating Lease Costs

Operating lease costs were $0.3 million during the years ended December 31, 2022 and 2021, 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, 2022 and 2021, respectively.

Finance Lease Costs

Finance lease amortization and interest expenses are included in the consolidated statements of operations for the years ended December 31, 2022 and 2021. The balances within these accounts are approximately $0.1 million, respectively.

8. COMMITMENTS AND CONTINGENCIES

PURCHASE COMMITMENTS

The Company has entered into purchase commitments for reagents from suppliers. These agreements started in 2011 and run through 2025. 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)
2023	$ 1,113
2024	170
2025	50
	$ 1,333

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, 2022 and 2021.

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

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 doubtful accounts 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, 2022 and 2021.

At December 31, 2022 and 2021, the Company had net deferred tax assets of $18.6 million and $15.2 million, respectively, against which a full valuation allowance has been recorded. The increase in the valuation allowance for the years ended December 31, 2022 and 2021 is $3.4 million and $1.7 million, respectively, 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, 2022 and 2021 are as follows:

	Dollars in Thousands	
	2022	2021
Deferred tax assets:		
Net operating loss and credit carryforwards	$ 18,410	$ 17,604
Allowance for doubtful accounts	371	403
Stock-based compensation	1,906	915
Other	140	127
Gross deferred tax assets	20,827	19,049
Deferred tax liabilities:		
Property and equipment	(274)	(257)
Intangible assets	(1,950)	(3,589)
Other	(35)	(18)
Gross deferred tax liabilities	(2,259)	(3,864)
Net deferred tax assets	18,568	15,185
Less valuation allowance	(18,568)	(15,185)
Net deferred liability	$ —	$ —

The Company's provision for income taxes for the years ended December 31, 2022 and December 31, 2021 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	
	2022	2021
Benefit at federal rate	$ (2,563)	$ (1,788)
Increase (decrease) resulting from:		
State income taxes—net of federal benefit	(747)	(289)
Miscellaneous permanent differences	51	62
Warrant liability revaluation	(153)	(97)
Meals and entertainment	32	19
PPP Loan forgiven	—	(192)
Income taxed to owners on Non-Controlling Interest (NCI)	(3)	(3)
Change in valuation allowance	3,383	2,288
Total income tax benefit	$ —	$ —

The income tax expense consists of the following for the years ended December 31, 2022 and 2021.

	Dollars in Thousands	
	2022	2021
Federal:		
Current	$ —	$ —
Deferred	—	—
Total Federal	$ —	$ —
State:		
Current	$ —	$ —
Deferred	—	—
Total State	$ —	$ —
Foreign:		
Current	$ —	$ —
Deferred	—	—
Total Foreign	$ —	$ —
Total Tax Provision	$ —	$ —

The Company had available gross federal net operating loss ("NOL") carryforwards of approximately $74 million, and state NOL carryforwards of $2.4 million as of December 31, 2022. 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. Beginning in 2018, under the TCJ Act, federal loss carryforwards 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 2022 are $47 million of federal losses that fall under these new 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, 2022, 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
	2022
2036	$ 14,277
2037	13,641
Unlimited life	46,546
Total Federal	$ 74,464

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, 2022 and 2021, the Company issued 26,795 and 74,000 shares of its common stock, respectively, in connection with the exercise of 26,795 and 74,000 warrants, respectively. The warrant exercises resulted in net cash proceeds to the Company of less than $0.1 million and $0.4 million during the years ended December 31, 2022 and 2021, respectively.

During the year ended December 31, 2021, the Company issued 55,147 shares of its common stock in connection with consulting services of approximately $0.2 million.

During the year ended December 31 2021, the Company issued 1,379 shares of its common stock in connection with the exercise of 1,379 stock options. The stock option exercises resulted in net cash proceeds to the Company of $3,000 for the year ended December 31, 2021.

LP 2020 Purchase Agreement

On March 26, 2020, the Company entered into a purchase agreement (the "LP 2020 Purchase Agreement") with Lincoln Park pursuant to which Lincoln Park agreed to purchase from us, from time to time, up to $10,000,000 of our common stock, subject to certain limitations, during the 24 month term of the LP 2020 Purchase Agreement.

During the year ended December 31, 2021, we received approximately $1.3 million from the sale of 500,000 shares of common stock to Lincoln Park under the LP 2020 Purchase Agreement. The Company terminated the LP 2020 Purchase Agreement effective June 14, 2021.

At The Market Offering Agreement

On April 2, 2021, the Company entered into a sales agreement with A.G.P./Alliance Global Partners ("AGP"), pursuant to which the Company may offer and sell its common stock, par value $0.01 per share (the "Common Stock") (the "Shares"), having aggregate sales proceeds of up to $22.0 million. Shares can be sold either directly to or through AGP as a sales agent (the "AGP Sales Agreement"), from time to time, in an "at the market offering" (as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended) of the Shares (the "ATM Offering"). The Company is limited in the number of shares it can sell in the ATM Offering due to the offering limitations currently applicable to the Company under General Instruction I.B.6. of Form S-3 and the Company's public float as of the applicable date of such sales, as well as the number of authorized and unissued shares available for issuance, in accordance with the terms of the AGP Sales Agreement.

The sale of our shares of Common Stock to or through AGP, will be made pursuant to the registration statement (the "Registration Statement") on Form S-3 (File No. 333-237445), which was declared effective by the Securities and Exchange Commission (the "SEC") on April 13, 2020, for an aggregate offering price of up to $50.0 million.

Under the AGP Sales Agreement, Shares may be sold by any method permitted by law deemed to be an "at the market offering." AGP will also be able to sell shares of Common Stock by any other method permitted by law, including in negotiated transactions with the Company's prior written consent. Upon delivery of a placement notice and subject to the terms and conditions of the AGP Sales Agreement, AGP is required to use its commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations, and the rules of The Nasdaq Capital Market to sell the Shares from time to time based upon the Company's instructions, including any price, time or size limits specified by the Company. AGP is not under any obligation to purchase any of the Shares on a principal basis pursuant to the AGP Sales Agreement, except as otherwise agreed by AGP and the Company in writing and expressly set forth in a placement notice. AGP's obligations to sell the Shares under the AGP Sales Agreement are subject to satisfaction of certain conditions, including customary closing conditions. The Company is not obligated to make any sales of Shares under the AGP Sales Agreement and any determination by the Company to do so will be dependent, among other things, on market conditions and the Company's capital raising needs.

The Company has agreed to pay AGP a cash fee of 3.0% of the aggregate gross proceeds from the sale of the Shares on the Company's behalf pursuant to the AGP Sales Agreement. The AGP Sales Agreement contains representations, warranties and covenants that are customary for transactions of this type. In addition, the Company has provided AGP with customary indemnification and contribution rights. The Company has also agreed to reimburse AGP for certain specified expenses, including the expenses of counsel to AGP. The offering of the Shares pursuant to the AGP Sales Agreement will terminate upon the termination of the AGP Sales Agreement by AGP or the Company, as permitted therein.

During the years ended December 31, 2022 and 2021, we received net proceeds of approximately $0.1 million and $14.9 million, respectively, from the sale of 85,023 and 4,501,000 shares of common stock through AGP, respectively.

As of the date of issuance of this Annual Report on Form 10-K, we have received an aggregate of $15.5 million in net proceeds, after issuance costs of approximately $0.5 million, from the sale of 5,119,656 shares of common stock through AGP, including approximately $0.4 million in net proceeds from the sale of 533,633 shares of common stock through AGP from January 1, 2023 through the date of issuance of this Annual Report on Form 10-K.

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 (the "August 2017 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, 2022 and 2021, respectively. At December 31, 2022 and 2021, 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 $0.40 per share, the outstanding shares of Series B Preferred Stock at December 31, 2022 were convertible into 117,500 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, 2022:

	Issue Year	Expiration	Underlying Shares	Exercise Price
Warrants				
(1)	2018	April 2023	148,378	$ 5.40
(2)	2018	July 2023	29,343	$ 5.40
(3)	2018	August 2023	41,806	$ 5.40
(4)	2018	September 2023	40,719	$ 5.40
(5)	2018	November 2023	75,788	$ 5.40
(6)	2018	December 2023	51,282	$ 5.40
(7)	2019	April 2024	147,472	$ 5.40
(8)	2019	May 2024	154,343	$ 9.56
			689,131	

(1) - (7) These warrants were issued in connection with a 2018 securities purchase agreement, as amended.
(8) These warrants were issued in connection with convertible notes issued in May 2019.

During the years ended December 31, 2022 and 2021, 115,975 and 239 warrants expired. These warrants had been issued in connection with transactions which were completed between 2016 and 2018.

During the year ended December 31, 2021, 357 warrants were settled for cash of approximately $0.1 million. For further discussion, see the 2016 Warrant Liability in Note 11 – Fair Value.

During the years ended December 31, 2022 and 2021, there were 26,795 and 74,000 warrants exercised, respectively, for proceeds to the Company of approximately $11,000 and $0.4 million, respectively. During the years ended December 31, 2022 and 2021, the intrinsic value of the warrants exercised was less than $0.1 million and $0.1 million, respectively.

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.

Some warrants that expired or were exercised during the years ended December 31, 2022 and 2021 contained down round provisions but such provisions had no impact on the respective expiration or exercise dates.

There were no deemed dividends recorded during the years ended December 31, 2022 and 2021.

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 and 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.

2016 Warrant Liability

The Company has a warrant liability related to warrants issued in January 2016 (the "2016 Warrant Liability") and it represents the fair value of such warrants, of which, 357 warrants were settled for cash of approximately $0.1 million in January 2021. The balance of the 2016 Warrant Liability was zero as of December 31, 2021.

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. As of December 31, 2022, assumptions used in the valuation of the Bridge Note Warrant Liabilities include: remaining life to maturity of 0.3 to 1.41 years; annual volatility of 69% to 77%; and risk free rate of 4.42 to 4.76%. As of December 31, 2021, assumptions used in the valuation of the Bridge Note Warrant Liabilities include: remaining life to maturity of 0.3 to 2.4 years; annual volatility of 61% to 199%; and risk free rate of 0.06% to 0.73%.

During the year ended December 31, 2021, the Company wrote-off $0.3 million of the Bridge Note Warrant Liability in connection with the exercise of 74,000 warrants.

During the years ended December 31, 2022 and 2021, the change in the fair value of the warrant liabilities measured using significant unobservable inputs (Level 3) were comprised of the following:

Dollars in Thousands

	Year Ended December 31, 2022
	Bridge Note Warrant Liabilities
Beginning balance at January 1	$ 606
Total losses:	
Revaluation recognized in earnings	(606)
Balance at December 31	$ –

	Year Ended December 31, 2021		
	2016 Warrant Liability	Bridge Note Warrant Liabilities	Total Warrant Liabilities
Beginning balance at January 1	$ 130	$ 1,195	$ 1,325
Total losses:			
Revaluation recognized in earnings	–	(269)	(269)
Deductions – warrant exercises and write-offs	–	(320)	(320)
Deductions – warrant liability settlement	(130)	–	(130)
Balance at December 31	$ –	$ 606	$ 606

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 3,852,853 at December 31, 2022 of which 170,218 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, 2022, the shares authorized for issuance increased by 1,135,422 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 fair value of each stock option granted is estimated on the date of grant using the Black-Scholes option pricing model, 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, 2022, the Company granted stock options to purchase up to 1,114,000 shares of common stock at a weighted average exercise price of $1.51. These awards have vesting periods of up to four years and had a weighted average grant date fair value of $1.45. The fair value calculation of options granted during 2022 used the follow assumptions: risk free interest rates of 1.60% to 3.55%, based on the U.S. Treasury yield in effect at the time of grant; expected life of six years; and volatility of 166% to 167% based on historical volatility of the Company's common stock over a time that is consistent with the expected life of the option.

The following table summarizes stock option activity under our plans during the year ended December 31, 2022:

	Number of Options	Weighted-Average Exercise Price
Outstanding at January 1, 2022	2,635,287	$ 3.38
Granted	1,114,000	1.51
Forfeited	(67,951)	2.18
Outstanding at December 31, 2022	3,681,336	$ 2.84
Exercisable at December 31, 2022	2,167,604	$ 3.24

As of December 31, 2022, there were 3,295,639 options that were vested or expected to vest with an aggregate intrinsic value of zero and a remaining weighted average contractual life of 8.2 years.

During the year ended December 31, 2021, there were 1,907,347 options granted with a weighted average exercise price of $2.89, 1,379 options exercised with a weighted average exercise price of $2.06 and 93,673 options forfeited with a weighted average exercise price of $2.82.

During the years ended December 31, 2022 and 2021, we recorded compensation expense for all stock awards of $3.8 million and $1.9 million, respectively, within operating expense in the accompanying statements of operations. As of December 31, 2022, the unrecognized compensation expense related to unvested stock awards was $3.1 million, which is expected to be recognized over a weighted-average period of 2.6 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, COVID-19 antibody tests and other product sales and are included in other revenue in our consolidated statements of operations.

Equipment leasing

The Company accounts for sales-type leases within the scope of ASC 842, Leases, as ASC 606 specifically excludes leases from its guidance. The sales-type leases result in the derecognition of the underlying asset, the recognition of profit or loss on the sale, and the recognition of an investment in leased asset. Revenue from sales-type leases is recognized upfront on the commencement date of the lease, and is included in other revenue in our consolidated statements of operations. During the year ended December 31, 2022 and 2021, revenue from sales-type leases was zero and $0.2 million, respectively.

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, 2022 and 2021 was as follows:

(dollars in thousands)	For the Year Ended December 31,					
	Diagnostic Testing		Biomarker Testing		Total	
	2022	2021	2022	2021	2022	2021
Medicaid	$ 50	$ 43	$ —	$ —	$ 50	$ 43
Medicare	3,831	3,838	—	—	3,831	3,838
Self-pay	326	234	—	—	326	234
Third party payers	4,211	3,612	—	—	4,211	3,612
Contract diagnostics	—	—	—	56	—	56
Service revenue, net	$ 8,418	$ 7,727	$ —	$ 56	$ 8,418	$ 7,783

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, 2022 and 2021, the deferred revenue was $0.1 million and $18,000, 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, 2022 and 2021.

(dollars in thousands)	For the Year Ended December 31,					
	Gross Revenues		Contractual Allowances and adjustments		Revenues, net of Contractual Allowances and adjustments	
	2022	2021	2022	2021	2022	2021
Medicaid	$ 50	$ 43	$ —	$ —	$ 50	$ 43
Medicare	3,831	3,838	—	—	3,831	3,838
Self-pay	326	234	—	—	326	234
Third party payers	14,681	12,597	(10,470)	(8,985)	4,211	3,612
Contract diagnostics	–	56	—	—	—	56
	18,888	16,768	(10,470)	(8,985)	8,418	7,783
Other	1,402	914	—	—	1,402	914
	$ 20,290	$ 17,682	$ (10,470)	$ (8,985)	$ 9,820	$ 8,697

Allowance for Doubtful Accounts

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 Bad Debt, and the Allowance for Doubtful Accounts. The change in the allowance for doubtful accounts 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, 2022 and 2021.

	For the Year Ended December 31,					
(dollars in thousands)	Revenues, net of Contractual Allowances and adjustments		Allowances for doubtful accounts		Total	
	2022	2021	2022	2021	2022	2021
Medicaid	$ 50	$ 43	$ (25)	$ (5)	$ 25	$ 38
Medicare	3,831	3,838	(110)	(58)	3,721	3,780
Self-pay	326	234	(19)	—	307	234
Third party payers	4,211	3,612	(254)	215	3,957	3,827
Contract diagnostics	—	56	—	—	—	56
	8,418	7,783	(408)	152	8,010	7,935
Other	1,402	914	—	—	1,402	914
	$ 9,820	$ 8,697	$ (408)	$ 152	$ 9,412	$ 8,849

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, 2022 and 2021:

(dollars in thousands)	December 31, 2022	December 31, 2021
Medicaid	$ 34	$ 45
Medicare	1,124	727
Self-pay	291	139
Third party payers	1,888	2,111
Contract diagnostic services and other	53	159
	$ 3,390	$ 3,181
Less allowance for doubtful accounts	(2,354)	(2,484)
Accounts receivable, net	$ 1,036	$ 697

The following table presents the roll-forward of the allowance for doubtful accounts for the year ended December 31, 2022:

(dollars in thousands)		Allowance for Doubtful Accounts
Balance, January 1, 2022		$ (2,484)
Collection Allowance:		
Medicaid	$ (25)	
Medicare	(110)	
Self-pay	(19)	
Third party payers	(254)	
	(408)	
Bad debt expense	$ 2	
Total charges		(406)
Other		536
Balance, December 31, 2022		$ (2,354)

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	
	Years Ended December 31,			
	2022	2021	December 31, 2022	December 31, 2021
Customer A	*	*	*	21 %
Customer B	*	*	*	12 %
Customer C	*	*	12 %	*

* represents less than 10%

14. SUBSEQUENT EVENTS

The Company has evaluated events and transactions subsequent to December 31, 2022 through the date the consolidated financial statements were issued. Outside of the items noted below, there are no other events to report other than what has been disclosed in the consolidated financial statements.

Factoring and Security Agreement

Effective March 27, 2023, we entered into a Factoring and Security Agreement (the "Factoring Agreement") with Culain Capital Funding, LLC ("Culain") for the purpose of factoring certain of our accounts receivable. Under the terms of the Factoring Agreement, we may offer for sale, and Culain may purchase in its sole discretion, certain accounts receivable of ours (the "Purchased Receivables"), which are payable directly by Culain, subject to certain repurchase obligations we have. The Factoring Agreement provides for a maximum of $2,000,000 in Purchased Receivables. Upon purchase of a Purchased Receivable, Culain will pay us 85% of the amount of the Purchased Receivable and the balance (less fees) is paid to us upon collection of the Purchased Account by Culain.

Culain's fee for each Purchased Receivable is based on an initial discount rate of one and twenty-five hundredths percent (1.25%) of the Gross Amount or Net Amount (as such term is defined in the Factoring Agreement) of a Purchased

Receivable, as applicable, used to determine the initial payment with respect to such Purchased Receivable for a period of 30 days (the "Fixed Discount Period ") followed by variable fees calculated as a daily percentage rate equal to forty-two thousandths percent (0.042%), commencing on the first (1st) calendar day after the end of the Fixed Discount Period with respect to such Purchased Receivable and other miscellaneous fees. We may also be required to repurchase uncollectible Purchased Receivables or upon default for an amount equal to the then-unpaid face amount due on any such accounts.

Our obligations under the Factoring Agreement are secured by a continuing security interest in all of our assets, properties, and rights, wherever located, whether owned as of the date of the Factoring Agreement or subsequent thereto including but not limited to our present and future accounts receivable and all chattel paper, instruments, general intangibles, securities, contract rights, insurance, proceeds, property rights and interests associated therewith, as well as all equipment, inventory and deposit accounts as more fully described in the Factoring Agreement, in order to secure our payment and performance obligations to Culain under the Factoring Agreement.

The Factoring Agreement has an initial term of 12 months and automatically renews for successive 12-month renewal periods unless terminated pursuant to the terms of the Factoring Agreement. We may terminate the Factoring Agreement at the end of the initial term upon 60 days' notice and payment of an early termination fee, which is equal to the Purchased Receivable Limit of $2.0 million multiplied by one and twenty-five hundredths percent (1.25%).

The Factoring Agreement contains covenants that are customary for accounts receivable-based factoring agreements and also contains provisions relating to events of default that are customary for agreements of this type.

The foregoing summary of the Factoring Agreement is qualified in its entirety by reference to the Factoring Agreement, a copy of which is filed as Exhibit 10.15 to this Annual Report on Form 10-K for the year ended December 31, 2022.

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 Interim 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 Interim 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 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 Interim 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, 2022.

(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, 2022.

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

There were no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2022, 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

Effective March 27, 2023, we entered into a Factoring and Security Agreement (the "Factoring Agreement") with Culain Capital Funding, LLC ("Culain") for the purpose of factoring certain of our accounts receivable. Under the terms of the Factoring Agreement, we may offer for sale, and Culain may purchase in its sole discretion, certain accounts receivable of ours (the "Purchased Receivables"), which are payable directly by Culain, subject to certain repurchase obligations we have. The Factoring Agreement provides for a maximum of $2,000,000 in Purchased Receivables. Upon purchase of a Purchased Receivable, Culain will pay us 85% of the amount of the Purchased Receivable and the balance (less fees) is paid to us upon collection of the Purchased Account by Culain.

Culain's fee for each Purchased Receivable is based on an initial discount rate of one and twenty-five hundredths percent (1.25%) of the Gross Amount or Net Amount (as such term is defined in the Factoring Agreement) of a Purchased Receivable, as applicable, used to determine the initial payment with respect to such Purchased Receivable for a period of 30 days (the "Fixed Discount Period ") followed by variable fees calculated as a daily percentage rate equal to forty-two thousandths percent (0.042%), commencing on the first (1st) calendar day after the end of the Fixed Discount Period with respect to such Purchased Receivable and other miscellaneous fees. We may also be required to repurchase uncollectible Purchased Receivables or upon default for an amount equal to the then-unpaid face amount due on any such accounts.

Our obligations under the Factoring Agreement are secured by a continuing security interest in all of our assets, properties, and rights, wherever located, whether owned as of the date of the Factoring Agreement or subsequent thereto including but not limited to our present and future accounts receivable and all chattel paper, instruments, general intangibles, securities, contract rights, insurance, proceeds, property rights and interests associated therewith, as well as all equipment, inventory and deposit accounts as more fully described in the Factoring Agreement, in order to secure our payment and performance obligations to Culain under the Factoring Agreement.

The Factoring Agreement has an initial term of 12 months and automatically renews for successive 12-month renewal periods unless terminated pursuant to the terms of the Factoring Agreement. We may terminate the Factoring Agreement at the end of the initial term upon 60 days' notice and payment of an early termination fee, which is equal to the Purchased Receivable Limit of $2.0 million multiplied by one and twenty-five hundredths percent (1.25%).

The Factoring Agreement contains covenants that are customary for accounts receivable-based factoring agreements and also contains provisions relating to events of default that are customary for agreements of this type.

The foregoing summary of the Factoring Agreement is qualified in its entirety by reference to the Factoring Agreement, a copy of which is filed as Exhibit 10.15 to this Annual Report on Form 10-K for the year ended December 31, 2022.

On March 28, 2023, Ilan Danieli, Chief Executive Officer and director of the Company, terminated the stock trading plan which he entered into on September 16, 2022 in accordance with Rule 10b5-1 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act") and the Company's insider trading policy (the "Plan"). The details of the Plan were included in the Company's Form 8-K filed on September 19, 2022.

Item 9C. 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 2023 Proxy Statement, not later than 120 days after the close of the fiscal year ended December 31, 2022. The information required by this item is incorporated herein by reference to the 2023 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 is incorporated herein by reference to the 2023 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2022.

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 2023 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2022.

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

The information required by this item is incorporated herein by reference to the 2023 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2022.

Item 14. Principal Accountant Fees and Services

The information required by this item is incorporated herein by reference to the 2023 Proxy Statement to be filed with the SEC within 120 days after the year ended December 31, 2022.

Our independent public accounting firm is Marcum LLP, New Haven, CT, PCAOB Auditor ID 688.

Part IV

Item 15. Exhibits, 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, 2022 and 2021.

Consolidated Statements of Operations of the Registrant and Subsidiary for the years ended December 31, 2022 and 2021.

Consolidated Statements of Stockholders' Equity of the Registrant and Subsidiary for the years ended December 31, 2022 and 2021.

Consolidated Statements of Cash Flows of the Registrant and Subsidiary for the years ended December 31, 2022 and 2021.

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).

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	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.2 of the Company's Form 8-K filed on April 23, 2018).
10.8	Form of Warrant to Purchase Common Stock (incorporated by reference to Exhibit 10.4 of the Company's Form 8-K filed on December 3, 2018).
10.9	Form of Warrant to Purchase Common Stock relating to Amendment No. 2 Agreement (incorporated by reference to Exhibit 10.45 of the Company's Form 10-K filed on April 16, 2019).
10.10	Form of Warrant to Purchase Common Stock dated May 14, 2019 (incorporated by reference to Exhibit 10.2 of the Company's Form 10-Q filed on May 16, 2019).
10.11†	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).
10.12†	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).
10.13†	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).
10.14†	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).
10.15	Factoring Agreement, dated March 27, 2023, by and between the Company and Culain Capital Funding LLC.
21.1	Subsidiaries of the Company.
23.1	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.
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.

* 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

None.

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 2023.

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, 2023
/s/ Matthew Gage **Matthew Gage**	Interim Chief Financial Officer (Principal Financial and Accounting Officer)	March 30, 2023
/s/ Richard Sandberg **Richard Sandberg**	Chairman of the Board of Directors	March 30, 2023
/s/ Kathleen LaPorte **Kathleen LaPorte**	Director	March 30, 2023
/s/ Ronald Andrews **Ronald Andrews**	Director	March 30, 2023
/s/ Douglas Fisher, M.D. **Douglas Fisher, M.D.**	Director	March 30, 2023
/s/ Jeffrey Cossman, M.D. **Jeffrey Cossman, M.D.**	Director	March 30, 2023
/s/ David Cohen **David Cohen**	Director	March 30, 2023