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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2024

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: 001-38984

CASTLE BIOSCIENCES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**77-0701774**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
505 S. Friendswood Drive, Suite 401, Friendswood, Texas	**77546**
(Address of principal executive offices)	(Zip Code)

(866) 788-9007

(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, $0.001 par value per share	**CSTL**	**The Nasdaq Global Market**

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

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

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

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

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

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

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

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

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

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

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

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2024 (the last business day of the registrant's most recently completed second fiscal quarter) was $587 million based on the closing price of the registrant's common stock on June 30, 2024, as reported by the Nasdaq Global Market.

As of February 20, 2025, there were 28,514,109 shares of common stock, $0.001 par value per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission, or SEC, subsequent to the date hereof pursuant to Regulation 14A in connection with the registrant's 2025 Annual Meeting of Stockholders, are incorporated by reference into Part III of this Annual Report on Form 10-K. The registrant

intends to file such proxy statement with the SEC not later than 120 days after the conclusion of its fiscal year ended December 31, 2024.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks and uncertainties. The forward-looking statements are contained principally in the sections entitled “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- estimates of our total addressable market (“TAM”), future revenue and addressable patient populations, expenses, capital requirements and our needs for additional financing;
- expectations with respect to reimbursement for our products, including third-party payor reimbursement and coverage decisions;
- anticipated cost, timing and success of our product candidates, and our plans to research, develop and commercialize new tests;
- the impact of geopolitical and macroeconomic developments, such as the Israel-Hamas war, the ongoing conflict between Ukraine and Russia and related sanctions on our business, and changes in trade and tariff policies;
- our ability to obtain funding for our operations, including funding necessary to complete the expansion of our operations and development of our pipeline products;
- the implementation of our business model and strategic plans for our products, technologies and business;
- expectations with respect to acquisitions of businesses, assets, products or technologies;
- our ability to manage and grow our business by expanding our sales to existing customers, introducing our products to new customers, addressing areas of high clinical need or reducing healthcare costs;
- our ability to develop and maintain sales and marketing capabilities;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers;
- the success of competing diagnostic products that are or become available;
- our ability to attract and retain key personnel; and
- our expectations regarding our ability to obtain and maintain intellectual property protection for our products and our ability to operate our business without infringing on the intellectual property rights of others.

In some cases, you can identify these statements by terms such as “anticipate,” “believe,” “could,” “estimate,” “expects,” “intend,” “may,” “plan,” “potential,” “project,” “should,” “will,” “would” or the negative of those terms, and similar expressions that convey uncertainty of future events or outcomes. These forward-looking statements reflect our management’s beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements. We discuss many of the risks associated with the forward-looking statements in this Annual Report on Form 10-K in greater detail in the section entitled “Risk Factors.” Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

RISK FACTORS SUMMARY

We face many risks and uncertainties, as more fully described in this Annual Report on Form 10-K under the heading "Risk Factors." Some of these risks and uncertainties are summarized below. The summary below does not contain all of the information that may be important to you, and you should read this summary together with the more detailed discussion of these risks and uncertainties contained in "Risk Factors."

Risks Related to our Financial Condition

- A significant portion of our revenue comes from a small number of third-party payors.
- Due to how we recognize revenue, our quarterly and annual revenues may not reflect our underlying business.
- We have incurred significant losses in the past, and we may be unable to sustain profitability in the future.
- We are an early, commercial-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.
- Our quarterly and annual operating results and cash flows may fluctuate in the future, which could cause the market price of our stock to decline substantially.
- If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause adverse effects on our business and may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.
- We may need to raise additional capital to fund our existing operations, commercialize new products or expand our operations.

Risks Related to our Business

- Our revenue currently depends primarily on sales from our DecisionDx®-Melanoma, DecisionDx®-SCC and TissueCypher® tests, and we will need to generate sufficient revenue from these products and other products to grow our business.
- Unfavorable U.S. and global economic conditions could adversely affect our business, financial condition, results of operations or cash flows.
- Billing for our products is complex and requires substantial time and resources to collect payment.
- We rely on third parties for sample collection, preparation and delivery. Any defects in sample collection or preparation by such third parties and any delays in delivery of such samples could cause errors in our test reports and affect our ability to deliver test reports in a timely manner or at all, which could significantly harm our business.
- We rely on our database of samples for some of the development and improvement of our products. Depletion or loss of our samples could significantly harm our business.
- If one or more of our primary clinical laboratory facilities become damaged or inoperable or we are required to vacate our existing facilities, our ability to conduct our laboratory analysis and pursue our research and development efforts may be jeopardized.
- New product development involves a lengthy and complex process, and we may be unable to develop and commercialize, or receive reimbursement for, on a timely basis, or at all, new products.
- We rely on limited or sole suppliers for some of the reagents, equipment, chips and other materials used by our products, and we may not be able to find replacements or transition to alternative suppliers.
- The sizes of the TAM for our current and future products have not been established with precision and may be smaller than we estimate.
- The diagnostic testing industry is subject to rapid change, which could make our current or future products obsolete.

Risks Related to Reimbursement and Government Regulation

- We generally have limited reimbursement coverage for our products, and if third-party payors, including government and commercial payors, do not provide sufficient coverage of, or adequate reimbursement for, our products, our commercial success, including revenue, will be negatively affected.

- Our products are currently marketed as Laboratory Developed Tests ("LDTs"), and any changes in regulations or the U.S. Food and Drug Administration ("FDA") enforcement discretion for LDTs, or violations of regulations by us, could adversely affect our business, prospects, results of operations or financial condition.
- We conduct business in a heavily regulated industry, and failure to comply with federal, state and foreign laboratory licensing requirements including those established by the Centers for Medicare and Medicaid ("CMS") and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.
- The FDA may modify its enforcement discretion policy with respect to LDTs in a risk-based manner, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.
- Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.
- Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our products.

Risks Related to Intellectual Property

- If we are unable to obtain and maintain sufficient intellectual property protection for our technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize diagnostic tests similar or identical to ours, and our ability to successfully commercialize our products may be impaired.
- Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.
- We depend on information technology systems that we license from third parties. Any failure of such systems or loss of licenses to the software that comprises an essential element of such systems could significantly harm our business.

Risks Related to Employee Matters and Managing Growth and Other Risks Related to Our Business

- We are highly dependent on the services of our key personnel, including our President and Chief Executive Officer.
- Our employees, clinical investigators, consultants, speakers, vendors and any current or potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.
- We have engaged in, and may continue to engage in, strategic transactions, such as the acquisition of businesses, assets, products or technologies, which could be disruptive to our existing operations, divert the attention of our management team and adversely impact our liquidity, cash flows, financial condition and results of operations.
- Product or professional liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of our products.

Risks Related to Ownership of Our Common Stock

- We have and may continue to enter into related party transactions that create conflicts of interest, or the appearance of conflicts of interest, which may harm our business and cause our stock price to decline.
- The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

PART I

Item 1. Business.

As used in this Annual Report on Form 10-K, unless the context indicates or otherwise requires, “Castle Biosciences,” the “Company,” “we”, “us”, and “our” refer to Castle Biosciences, Inc., a Delaware Corporation.

Overview

Castle Biosciences is a molecular diagnostics company offering innovative test solutions to aid clinicians in the diagnosis and treatment of dermatologic cancers, Barrett’s esophagus, uveal melanoma, and in the treatment of mental health conditions.

Since our inception in 2008, it has been our vision to transform disease management by keeping people first: patients, clinicians, employees and investors. This foundational strategy remains the guidepost for the direction of our company and the basis of long-term value creation.

Our Testing Solutions

Our tests are designed to deliver personalized information to help better inform care decisions. For our tissue based tests, we use multi-analyte assays with algorithmic analysis (“MAAA”) to characterize an individual patient’s biology to inform specific risk of progression.

Test Portfolio and Market Overview

Our portfolio consists of test offerings to aid clinicians in the diagnosis and treatment of cancers or precancerous diagnoses in the fields of dermatology, gastroenterology and ophthalmology and a pharmacogenomic (“PGx”) test to guide optimal drug treatment for patients diagnosed with depression, anxiety and other mental health conditions.

Maintaining commercial success for our existing test portfolio requires generating ongoing evidence, such as clinical performance, clinical use documentation, to support appropriate clinician adoption, reimbursement success and guideline inclusion. The clinical validity and utility of our test portfolio is supported by peer-reviewed publications and ongoing clinical studies. Collectively, approximately 157 peer-reviewed articles have been published demonstrating the analytical validity, clinical validity and clinical utility of the tests in our portfolio.

DecisionDx-Melanoma

DecisionDx-Melanoma is our proprietary risk stratification gene expression profile (“GEP”) test that predicts (i) the likelihood of positive sentinel lymph node and (ii) the risk of metastasis, or recurrence, for patients diagnosed with invasive cutaneous melanoma (“CM”), a deadly skin cancer.

In a typical year, we estimate approximately 130,000 patients are diagnosed with invasive CM in the United States, representing an estimated U.S. TAM of approximately $540 million. This estimated annual incidence number is based upon a calculation using data from the U.S. Surveillance, Epidemiology, and End Results registries and subsequently adjusted for the documented underreporting of melanoma diagnoses which range from 30%-72%. Based on currently available data, we estimate the targetable clinician base treating melanoma is between 11,000 and 15,000. Based on the substantial clinical evidence that we have developed, we have received Medicare coverage for DecisionDx-Melanoma. We estimate that approximately 50% of patients diagnosed with CM are 65 years of age or older.

As of December 31, 2024, 53 peer-reviewed articles, one of which was published in 2024, support the clinical validity, clinical utility and impact on outcomes of our DecisionDx-Melanoma test. Based on our published data, we have shown that DecisionDx-Melanoma can be an accurate, independent predictor of the risk of metastasis or recurrence, including recurrence to the sentinel lymph node.

DecisionDx-SCC

DecisionDx-SCC is our proprietary GEP test for use in patients with cutaneous squamous cell carcinoma ("SCC"), the second most common form of skin cancer, with one or more risk factors (also referred to as "high-risk" SCC). We estimate 20% of SCC patients, or approximately 200,000 annually in the United States, are classified as high risk, representing an estimated U.S. TAM of approximately $820 million.

DecisionDx-SCC is clinically validated to (i) predict responsiveness to adjuvant radiation therapy ("ART") and (ii) predict metastatic risk in patients with high-risk SCC. The validity of DecisionDx-SCC for metastasis risk prediction has been shown in a cohort of 897 in a study which was representative of a high-risk SCC population. Multivariate analysis shows DecisionDx-SCC provides strong prognostic information in patients with high-risk SCC. More recently, in 2024 two published studies confirmed the ability of DecisionDx-SCC to predict response to ART. These two propensity matched studies were the largest and second largest studies published to date that focused on the effectiveness of ART in patients diagnosed with high risk SCC. As of December 31, 2024, DecisionDx-SCC was supported by 22 peer-reviewed publications, four of which were published in 2024.

TissueCypher

TissueCypher is our proprietary risk stratification spatial-omics test designed to predict future development of high-grade dysplasia ("HGD") and/or esophageal cancer in patients with non-dysplastic ("ND"), indefinite dysplasia ("IND") or low-grade dysplasia ("LGD") Barrett's esophagus ("BE").

There are approximately four million patients in the U.S. currently diagnosed with BE and approximately 415,000 patients annually undergo an endoscopic biopsy with a subsequent diagnosis of ND, IND or LGD BE, representing an estimated U.S. TAM of approximately $1 billion.

As of December 31, 2024, our TissueCypher test is supported by 16 peer-reviewed clinical validation and utility studies.

MyPath Melanoma

MyPath® Melanoma is our proprietary, diagnostic GEP test offering for use in patients with difficult-to-diagnose melanocytic lesions. Of the two million suspicious pigmented lesions biopsied annually in the United States, we estimate approximately 300,000 of those present a difficult-to-diagnose melanocytic lesion, representing an estimated U.S. TAM of approximately $600 million.

As of December 31, 2024, our MyPath Melanoma test is supported by 20 peer-reviewed publications, one of which was published in 2024.

DecisionDx-UM

DecisionDx®-UM is our proprietary, risk stratification GEP test that predicts the risk of metastasis for patients with uveal melanoma ("UM"), also referred to as ocular melanoma. We estimate approximately 2,000 patients in the United States are diagnosed annually with UM, representing an estimated U.S. TAM of approximately $10 million.

DecisionDx-UM has been clinically validated by an independent prospective, multi-center study, by multiple retrospective and prospective single-center studies. As of December 31, 2024, our DecisionDx-UM test is supported by 27 peer-reviewed publications.

IDgenetix

IDgenetix® is our proprietary PGx test that helps guide optimal drug treatment for patients diagnosed with major depressive disorder, schizophrenia, bipolar disorder, anxiety disorders, social phobia, obsessive-compulsive personality disorder, post-traumatic stress disorder, and attention deficit hyperactivity disorder. IDgenetix is designed to provide important genetic information to clinicians to help guide personalized treatment plans for their patients, with the potential to help patients achieve a faster therapeutic response and improve their chances of remission by identifying appropriate medications more efficiently than the standard of care trial-and-error approach. We began offering the IDgenetix test following our acquisition of AltheaDx, Inc. ("AltheaDx") in April 2022.

IDgenetix is supported by a published, peer-reviewed randomized controlled trial that demonstrated clinical utility over the standard of care when physicians used IDgenetix prior to prescribing a medication. The trial was conducted across 20 independent clinical sites within the United States specializing in psychiatry, internal medicine, obstetrics & gynecology, and family medicine. As of December 31, 2024, our IDgenetix test is supported by 19 peer-reviewed publications.

Pipeline Initiatives

We have significant expertise in developing proprietary algorithms, conducting clinical studies and using the necessary instrumentation required for efficiently developing our pipeline products. Due to the biological complexity of diseases, developing accurate products takes scientific diligence, stringent clinical protocols, machine learning expertise, proprietary algorithms and significant investments of time and capital. In addition, the underlying tissue samples and associated clinical outcomes data required to develop and validate these products are difficult to obtain.

In 2021, we announced the launch of our innovative pipeline initiative to develop a genomic test, or series of tests, aimed at predicting response to systemic therapy in patients with moderate to severe atopic dermatitis ("AD"), psoriasis and related inflammatory skin conditions. In the same year, we initiated a large, prospective, multi-center clinical study to develop and validate this pipeline test, formed a steering committee comprised of leading experts in the field and received Institutional Revenue Board ("IRB") approval. On December 23, 2024, we announced that preliminary data from our ongoing prospective development and validation study for our pipeline test has shown potential to identify a subset of patients with AD who have increased likelihood to achieve a super response to targeted therapies, indicated by a 90% or greater reduction in Eczema Area and Severity Index score at three months. AD is among the most common inflammatory skin condition, and patient quality of life is severely impacted by this chronic disease. In the United States alone, there are approximately six million patients diagnosed annually with moderate-to-severe AD and approximately 760,000 of these patients seek systemic treatment. As of December 31, 2024, there were more than 39 active clinical study sites and over 1,100 patients enrolled in our inflammatory skin development and validation study. Assuming successful validation, we expect to launch this pipeline test by the end of 2025.

U.S. TAM is based on estimated patient population assuming average reimbursement rate among all payors.

We expect to continue pursuing pipeline initiatives for tests that will complement and expand our test offerings.

Acquisitions

From time to time, we may consider engaging in transactions such as acquisitions of businesses, assets, products or technologies, as well as technology licenses or investments in complementary businesses where we believe strategic opportunities exist.

In April 2022, we acquired AltheaDx, a commercial-stage molecular diagnostics company specializing in the field of PGx testing services, for total consideration of $47.6 million, consisting of $30.5 million in cash and $17.1 million in shares of our common stock, adding the IDgenetix test to our portfolio.

In December 2021, we acquired Cernostics, Inc. ("Cernostics") and the TissueCypher platform for $30.7 million in cash consideration. In May 2021, we acquired Myriad myPath, LLC and MyPath Melanoma test from Myriad Genetics, Inc. for $32.5 million in cash consideration.

Test Report Volume and Revenue

The number of test reports we generate is a key indicator that we use to assess our business. Since our inception, we have delivered more than 315,000 clinical patient test reports across our product portfolio. The numbers of test reports delivered by us and our net revenues during the past five years are presented in the table below:

	Years Ended December 31,				
	2024	2023	2022	2021	2020
DecisionDx-Melanoma	36,008	33,330	27,803	20,328	16,232
DecisionDx-SCC[1]	16,348	11,442	5,967	3,510	485
Diagnostic GEP offering[2]	3,909	3,962	3,561	2,662	73
Dermatologic Total	56,265	48,734	37,331	26,500	16,790
DecisionDx-UM	1,699	1,674	1,711	1,618	1,395
TissueCypher[3]	20,956	9,100	2,128	27	—
IDgenetix[4]	17,151	10,921	3,249	—	—
Grand Total	96,071	70,429	44,419	28,145	18,185
Net Revenues (in thousands)	$ 332,069	$ 219,788	$ 137,039	$ 94,085	$ 62,649

(1) On August 31, 2020, we commercially launched our cutaneous SCC proprietary GEP test for use in patients with one or more risk factors.
(2) Includes MyPath Melanoma and DiffDx®-Melanoma. On November 2, 2020, we commercially launched our DiffDx-Melanoma test. We began offering MyPath Melanoma following our acquisition of the Myriad MyPath Laboratory on May 28, 2021. We offered both MyPath Melanoma and DiffDx-Melanoma under our Diagnostic GEP offering until February 2023 when we suspended the clinical offering of DiffDx-Melanoma.
(3) We began offering the TissueCypher test on December 3, 2021, following our acquisition of Cernostics, Inc. ("Cernostics"). Our TissueCypher test report volumes primarily derived from processed backlog orders. We temporarily paused accepting additional orders in July 2023 and resumed accepting new orders in a phased approach in September 2023. We completed processing of our pre-existing backlog orders in October 2023 and continue to accept new orders as of December 31, 2023.
(4) We began offering the IDgenetix test on April 26, 2022, following our acquisition of AltheaDx.

Our Commercial Channel

Sales and Marketing

Our sales and marketing efforts are primarily focused on the U.S. skin cancer and gastroenterology markets. We employ our primary direct sales and marketing strategy to educate clinicians and associated personnel on the clinical and economic benefits of our products. Our sales approach is highly technical, and our team is trained to articulate the scientific and clinical evidence behind our products and how they influence the clinical care pathway and ultimately improve patient outcomes.

We continuously assess market response in determining further commercial expansions and commercial team structure.

Medical Affairs

We also deploy an experienced medical affairs group to assist education of treating clinicians and key opinion leaders, to identify and engage sites for our sponsored clinical studies and to evaluate collaborative study opportunities. Our medical affairs strategy complements our sales, marketing and clinical research operations efforts. We will continue to assess the market needs in determining further expansion of our medical affairs team.

Reimbursement

The primary source of revenue for our products is reimbursement from third-party payors, which includes government payors, such as Medicare, and commercial payors, such as insurance companies. Achieving broad coverage and reimbursement of our current products by third-party payors and continued Medicare coverage are key components of our financial success.

We bill third-party payors and patients for the tests we perform. We have received Medicare coverage for our DecisionDx-Melanoma, DecisionDx-SCC, TissueCypher, MyPath Melanoma, DecisionDx-UM and IDgenetix tests

which meet certain criteria for Medicare and Medicare Advantage beneficiaries. A “covered life” means a subscriber, or a dependent of a subscriber, who is insured under an insurance carrier’s policy.

The Medicare rates discussed below are prior to giving effect to applicable sequestration in effect from time to time as described in further detail under "—Government Regulation and Product Approval—Healthcare Reform" included in Part 1, Item 1, “Business,” in this Annual Report on Form 10-K.

Commercial Third-Party Payors

We are actively engaged in efforts to achieve broad coverage and reimbursement for our products, followed by contracting with commercial payors. Achieving positive coverage reduces the need for appeals and reduces failures to collect from the patient’s commercial insurance payor. Even with positive coverage decisions, we still experience delays in time to payment. Achieving in-network contracts with third-party payors can shorten the time required to receive payments. Implementing our strategy includes our managed care, reimbursement and medical affairs teams educating third-party payors regarding our strong clinical utility and outcomes data, which we believe validates the value of our products and will persuade more third-party payors to provide value-based reimbursement.

We have broad positive policy coverage for our DecisionDx-UM test and have executed contracts with certain commercial payors. For our other tests, we engage third-party payors for positive coverage and have received positive policy recommendations from many third-party technical assessment review groups. During the year ended December 31, 2024, we received multiple positive medical policy recommendations from many commercial payors for tests across our product line. We also received multiple positive medical policies and technology assessments from Laboratory Benefit Management (“LBM”) and Technology Evaluation Companies (“TEC”) organizations. We anticipate receiving additional positive medical policy recommendations and technology assessments in the future as we continue to develop and expand our evidence portfolio.

Dependence on Third-Party Payors

We receive a substantial portion of our revenue from a small number of third-party payors. Our revenue from patients covered by Medicare as a percentage of total revenue, was 47% for the year ended December 31, 2024. Additionally, there was a commercial payor from which 15% of our revenue from patients was derived for the year ended December 31, 2024.

Government Payors

Medicare coverage is limited to items and services that are within the scope of a Medicare benefit category and that are reasonable and necessary for the diagnosis or treatment of an illness or injury. The controlling Medicare regulation for guiding the assessment of reasonable and necessary of diagnostic laboratory tests is 42 CFR. Section 410.32(a). Medicare Administrative Contractors (“MACs”) can provide coverage through evidentiary based reviews as well as more formal processes such as development of local coverage determinations (“LCD”).

Our laboratories are located in Phoenix, Arizona and Pittsburgh, Pennsylvania. The MAC responsible for administering claims for laboratory services located in Arizona is Noridian Healthcare Solutions, LLC (“Noridian”). Noridian has a joint operating agreement with Palmetto GBA MolDX (“Palmetto”) where Palmetto is responsible for reviewing genomic based tests. The MAC responsible for administering claims for laboratory services located in Pennsylvania is Novitas Solutions (“Novitas”).

Medicare

DecisionDx-Melanoma

Palmetto issued a final expanded test-specific LCD for DecisionDx-Melanoma, effective November 22, 2020. With this expanded LCD and the accompanying billing and coding articles, we estimate that a significant majority of the DecisionDx-Melanoma tests performed for Medicare patients will meet the coverage criteria. Noridian adopted the same coverage policy as Palmetto and also issued an expanded final LCD for DecisionDx-Melanoma, effective December 6, 2020. On May 19, 2022, Palmetto finalized an LCD that converted the DecisionDx-Melanoma test-specific LCD to a “foundational” LCD with Noridian issuing the same on June 16, 2022. The final LCDs did not result in any changes in coverage.

DecisionDx-UM

Palmetto issued a final test-specific LCD for DecisionDx-UM, which became effective in July 2017, and Noridian issued a similar LCD that became effective in September 2017. We estimate that a significant majority of the DecisionDx-UM tests performed for Medicare patients will meet the coverage criteria.

MyPath Melanoma and DiffDx-Melanoma

MyPath Melanoma was covered under a test-specific LCD policy through Noridian that became effective in June 2019. Effective August 6, 2023, Palmetto and Noridian issued LCDs that converted the test-specific MyPath Melanoma LCD to a "foundational" LCD and provided coverage for both MyPath Melanoma and DiffDx-Melanoma. We estimate that a significant majority of the MyPath Melanoma and DiffDx-Melanoma tests performed for Medicare patients will meet the coverage criteria.

DecisionDx-SCC

We issue our DecisionDx-SCC tests from our Pittsburgh and Phoenix labs, with a majority of tests being issued from our Pittsburgh lab. As previously discussed, Novitas is the MAC responsible for administering claims for test reports issued by our Pittsburgh laboratory.

We requested and received an evidentiary review of our DecisionDx-SCC by Novitas during the first quarter of 2022. Based upon this review, DecisionDx-SCC test began receiving coverage in April 2022.

On June 9, 2022, Novitas posted a draft oncology biomarker LCD that proposes to rely upon evidentiary reviews sourced from three databases for all oncology biomarker tests: ClinGen, OncoKB and National Comprehensive Cancer Network ("NCCN"). We believe the purpose of the proposals in this draft LCD are to streamline future reviews. Two of the databases do not review GEP tests and NCCN has not yet, to our knowledge, reviewed DecisionDx-SCC. If finalized as proposed, then DecisionDx-SCC would not have been included as a covered test in the associated billing and coding article. The comment period for the draft LCD ended on September 6, 2022.

On June 2, 2023, Novitas posted a finalized oncology biomarker LCD pursuant to which the DecisionDx-SCC test would no longer be covered by Medicare effective July 17, 2023. However, on July 6, 2023, Novitas suspended the final version of the LCD and announced its intent to post a new proposed LCD for comment and presentation at an open meeting. On July 27, 2023, Novitas posted a nearly identical proposed oncology biomarker LCD that continued to intend to rely upon evidentiary reviews sourced from three databases: ClinGen, OncoKB and NCCN. The proposed LCD also recommends non-coverage for our DecisionDx-SCC test. The comment period for the proposed LCD ended on September 9, 2023. On July 26, 2024, Novitas posted a note that it had been granted an extension by CMS. On January 9, 2025, Novitas finalized the oncology biomarker LCD with an initial effective date of February 23, 2025. Several days later, Novitas changed the effective date for this LCD, extending the effective date to April 24, 2025. Should the LCD become effective as is, then we would anticipate not receiving Medicare reimbursement for DecisionDx-SCC tests performed on or after April 24, 2025.

As previously discussed, the Palmetto MolDX program oversees MAAA tests that are reported from our Phoenix laboratory and Noridian is the MAC responsible for administering claims for test reports issued by our Phoenix laboratory. In the second quarter of 2020, we submitted our technical assessment dossier for DecisionDx-SCC to Palmetto and Noridian. The dossier was accepted as complete in the third quarter of 2020. On June 8, 2023, Palmetto and Noridian recommended no coverage for DecisionDx-SCC in a draft LCD. After the comment period ended on July 22, 2023, the LCD was finalized on July 4, 2024, with an effective date of August 18, 2024.

Advanced Diagnostic Laboratory Tests

Advanced Diagnostic Laboratory Test ("ADLT") status is a designation granted by CMS for clinical diagnostic laboratory tests offered and furnished by a single laboratory and covered under Medicare Part B that meet one of the following criteria:

Criterion A: The test:

- Is an analysis of multiple biomarkers of DNA, RNA or proteins;
- When combined with an empirically derived algorithm, yields a result that predicts the probability a specific individual patient will develop a certain condition or conditions, or respond to a particular therapy or therapies;
- Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and
- May include other assays.

Criterion B: The test is cleared or approved by the FDA. Laboratories requesting ADLT status under this criterion are required to submit documentation of premarket approval ("PMA") or premarket notification from the FDA.

All five of our commercially available proprietary MAAA tests have been reviewed by the CMS and have been granted ADLT status. ADLT status is not an indication of future coverage.

Medicare Reimbursement Rates

DecisionDx-Melanoma

On May 17, 2019, CMS determined that DecisionDx-Melanoma meets the criteria for "new ADLT" status. Our rate is set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2024 was set using median private payor rate data from January 1, 2022 to June 30, 2022. Our rate for 2022, 2023 and 2024 was $7,193 per test. Our 2025 rate is $7,193 per test.

DecisionDx-UM

On May 17, 2019, CMS determined that DecisionDx-UM meets the criteria for "existing advanced diagnostic laboratory test" status, also referred to as "existing ADLT" status. Our rate is set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2024 was set using median private payor rate data from January 1, 2022 to June 30, 2022. Our rate for 2022, 2023 and 2024 was $7,776 per test. Our 2025 rate is $7,776 per test.

MyPath Melanoma

On September 6, 2019, MyPath Melanoma was approved as a "new ADLT". Our rate is set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2024 was set using median private payor rate data from January 1, 2022 to June 30, 2022. Our rates for 2022, 2023, and 2024 were $1,950 per test, $1,755 per test, and $1,950 per test, respectively. Our 2025 rate is $1,950 per test.

DiffDx-Melanoma

In the second quarter of 2022, we obtained a Proprietary Laboratory Analyses ("PLA") code for DiffDx-Melanoma. In 2023, DiffDx-Melanoma went through the CMS gapfill process which concluded in September 2023 with CMS posting a final MAC-specific gapfill rate of $1,950 per test. Our rate for 2024 was $1,950 per test and will continue to be $1,950 per test in 2025.

Diagnostic GEP Offering

Our Diagnostic GEP offering included MyPath Melanoma and DiffDx-Melanoma. We began offering MyPath Melanoma following our acquisition of the Myriad MyPath Laboratory on May 28, 2021. In February 2023, we suspended the clinical offering of DiffDx-Melanoma following an internal assessment of the clinical value of DiffDx-Melanoma and MyPath Melanoma, which determined that the technical performance of both tests is comparable. We continue to offer our MyPath Melanoma test.

DecisionDx-SCC

In the second quarter of 2022, following the completion of a requested medical review and pricing of our DecisionDx-SCC test by Novitas, we obtained a PLA code and began receiving reimbursement from Novitas for DecisionDx-SCC at a rate of $3,873 per test.

On June 30, 2023, CMS determined DecisionDx-SCC meets the criteria for "new ADLT" status. ADLT status determines the process by which the rate is set and is not an indication of Medicare coverage. Effective July 1, 2023 and through March 31, 2024, CMS set the initial period rate equal to the list price of $8,500 per test. Effective April 1, 2024, we continued receiving reimbursement at a rate of $8,500 per test, set by CMS using median private payor rate data for the period July 1, 2023 and November 30, 2023, and this rate will remain effective through December 31, 2025.

TissueCypher

TissueCypher is processed in our Pittsburgh, Pennsylvania laboratory under the Medicare jurisdiction managed by Novitas. From January 1, 2022 through March 31, 2022, we received payments for claims according to the published Clinical Laboratory Fee Schedule ("CLFS") rate at $2,513 per test. On March 24, 2022, CMS determined TissueCypher meets the criteria for "new ADLT" status. ADLT status exempts TissueCypher from what is called the "14-day rule," which simplifies the billing process for Medicare patients. From April 1, 2022 through December 31, 2022, CMS set the initial period rate equal to the original list price of $2,350 per test. Effective January 1, 2023, the published CLFS rate for TissueCypher was set at $4,950 per test and remained effective through December 31, 2024. This rate is based on the median private payor rates received between April 1, 2022 and August 31, 2022. Our 2025 rate will continue to be $4,950 per test based on the median private payor rate data from January 1, 2023 to June 30, 2023.

IDgenetix

IDgenetix is currently covered under a Noridian LCD policy and accompanying billing and coding article developed by MolDX. The Medicare coverage includes depression and the following seven additional mental health conditions beyond major depressive disorder: schizophrenia, bipolar disorder, anxiety disorders, social phobia, obsessive-compulsive personality disorder, post-traumatic stress disorder and attention deficit hyperactivity disorder. IDgenetix has historically been billed to Medicare using an unspecified Current Procedural Terminology ("CPT") code along with the IDgenetix test-specific MolDX Z-code (the "IDgenetix Z-Code"). We acquired AltheaDx and the IDgenetix test in April 2022 and received Medicare reimbursement at a rate of approximately $1,500 per test. In February 2023, MolDX notified us that as part of its annual CPT code updates, IDgenetix should shift billing to a different multi-test generic gene sequencing CPT code (the "New CPT Code") and continue using the IDgenetix Z-Code beginning in March 2023. The New CPT Code was set at $917 per test while the test went through CMS's Gapfill pricing process. We believed the new CPT Code, in conjunction with the IDgenetix Z-Code, did not describe all of the components of the IDgenetix test and thus, was not appropriate for IDgenetix. We subsequently obtained a test-specific PLA CPT code which became effective October 1, 2023. In November 2023, CMS posted its final CLFS determination which crosswalks our PLA CPT code to an existing PLA code at a rate of $1,336 per test effective January 1, 2024. In 2024, we were reimbursed at a rate of $1,336 per test and we will continue to be reimbursed at this rate in 2025.

Competition

We are focused on improving health through innovative tests that guide patient care.

We believe the principal competitive factors in our target markets include:

- Proprietary, disciplined approach to genomic and proteomic analysis including the use of proprietary deep learning, machine learning, artificial intelligence ("AI") and other techniques to identify and optimize biomarker selection and algorithmic approaches to answer the clinically important questions with accurate tests. This involves the ability to design and efficiently conduct the right clinical studies at the right time;
- Research and development investments to document the quality, quantity, consistency and strength of the clinical validity data, the impact our products have on clinical use, and demonstration of net health outcome improvement that reduce health system costs;
- Maintaining a strong reputation with the treating clinician by providing consistent, transparent, and clinically relevant information that will improve the appropriate management of their patients;
- Ease of use in accessing our products, reimbursement support for our patients and laboratory reports that clearly communicate the clinically relevant data points;
- Demonstrated ability to work with, and secure coverage and reimbursement from, governmental and commercial payors; and
- Ability to efficiently commercialize both our current and our pipeline products.

We believe we compete favorably on the factors described above.

Today, our principal competition for DecisionDx-Melanoma is existing traditional clinical and pathology staging criteria. While some clinical and pathology criteria have changed over time, this approach has been the standard of

care in the United States for many years, and clinicians may be unwilling to accept the validity of the published data and adopt our test until it has become incorporated into national guidelines. In addition, we currently face, or may face, competition from a limited number of companies who are working in this disease space, such as SkylineDx/Tempus/Quest, AMLo/Avero and Neracare. In the future, we may face additional competitors.

We are unaware of late-stage work being performed to develop and validate a product that would compete with DecisionDx-SCC. We believe that the current primary competitor for DecisionDx-SCC is existing traditional clinical and pathology staging criteria. In the future, we may face additional competitors.

Today, our principal competition for the TissueCypher test is existing traditional clinical and pathology assessment. In the future this assessment may include the use of immunohistochemical evaluation of individual protein biomarkers as an aid to pathology. While some clinical and pathology criteria have changed over time, this approach has been the standard of care in the United States for many years, and physicians may be unwilling to accept the validity of the published data and adopt our test until this has become incorporated into clinical guideline recommendations from gastrointestinal clinical societies, or other national guidelines. In addition, we currently face, or may face, competition from companies such as Previse, Interpace Diagnostics, Lucid Diagnostics and other companies. Other companies actively engaged in GERD screening to diagnose BE may also look to develop prognostic tests for patients diagnosed with BE, and these could compete with TissueCypher in the future. In the future, we may face additional competitors.

DecisionDx-UM competes with a subsidiary of LabCorp and several academic laboratories, all of which have had tests available for several years. To date, our data has demonstrated that DecisionDx-UM is clinically and statistically superior to these products. In the future, we may face additional competitors.

With respect to IDgenetix, our competition arises from other parties using the same or similar methods as well as alternative methods of PGx testing. IDgenetix competes with Myriad Genetics's GeneSight test, Genomind's PGx test, and tests from numerous other commercial and academic laboratories.

Laboratory Operations

In 2024, we operated laboratory facilities in Phoenix, Arizona and Pittsburgh, Pennsylvania. All of our facilities are Clinical Laboratory Improvement Amendments of 1988 ("CLIA") certified, College of American Pathologists ("CAP") accredited labs. Additionally, all of our laboratories passed inspection by New York State Department of Health Clinical Laboratory Evaluation Program ("NYS CLEP") with each of our proprietary tests approved by the New York State Department of Health ("NYSDOH"). We manage these laboratories to produce the volume of testing required to cover our portfolio of products while maintaining efficiencies, redundant capabilities, and business continuity. Our facilities are positioned to operate in all 50 states, including those requiring additional licenses or certifications such as California, Pennsylvania, Rhode Island, Maryland and New York.

Raw Materials and Suppliers

We procure certain reagents, equipment, chips/cards and other materials used to perform our tests from sole suppliers such as ThermoFisher Scientific, Inc., Promega and Qiagen, Inc. Some of these items are unique to these suppliers and vendors. While we have developed alternate sourcing strategies for these materials and vendors and have experienced no business interruption due to an inability to source these materials, we cannot be certain whether these strategies will be effective or whether alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need to perform our test services, they do not meet our quality specifications, or we cannot obtain acceptable substitute materials, our business would likely be negatively affected.

License Agreement with The Washington University

In November 2009, we entered into a license agreement ("the "License Agreement") with The Washington University in St. Louis, Missouri ("WUSTL"), granting us exclusive, worldwide rights to certain patent rights and non-exclusive rights to technical information and research property for developing melanoma-related products ("Products") and services ("Services"). These rights are utilized exclusively in DecisionDx-UM. The agreement includes provisions for sublicensing under specific conditions, while WUSTL retains the rights to use the licensed patents for research. As the licensed patents were developed with U.S. government funding, they are subject to federal regulations such as "march-in" rights, reporting requirements, and a preference for U.S.-based manufacturers.

Under the License Agreement, we are obligated to make royalty payments, including a mid-single-digit percentage of net sales from the Products and a low-single-digit percentage from Services revenue, with minimum royalties due semi-annually after the first commercial sale. The agreement remains in effect for ten years after the last patent claim expires unless terminated earlier. Termination can occur due to material breach, misuse of licensed rights, insolvency events, or at our discretion upon notice and payment of any outstanding amounts.

Intellectual Property

Our core technology for our products is related to methods and devices for analysis of genetic expression. Using this technology, we are able to provide a more accurate prediction of a patient's metastatic risk as compared to other methods. We have secured and continue to pursue intellectual property rights globally, including through patent protection covering analysis of metastasis in CM, the treatment of SCC, BE and gastroenterology, and PGx for mental illness. We also rely on trademarks, trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our proprietary position. For more information, please see "Risk Factors—Risks Related to Intellectual Property."

Patents and Patent Applications

We have developed a global patent portfolio that as of December 31, 2024, is comprised as follows:

	Number of Applications and Patents		
Commercial Focus	**United States**	**International**	**Total**
Owned Patent Families			
Methods for predicting risk of metastasis in CM	3	18	21
Methods of diagnosing and treating patients with pigmented skin lesions	1	—	1
Methods of diagnosing and treating patients with SCC	4	22	26
Determining prognosis and treatment based on clinical-pathologic factors and continuous multigene-expression profile scores	1	—	1
Diagnosing and treating AD and/or psoriasis	—	1	1
Method and kit for isolating and sequencing nucleic acid from skin samples	1	—	1
Genes and gene signatures for diagnosis and treatment of melanoma	6	29	35
Method for automated tissue analysis	2	3	5
Systems and compositions for diagnosing BE and methods of using same	3	13	16
Methods of predicting progression of BE	2	22	24
Expression profiling using microarrays	1	—	1
Licensed Portfolio from WUSTL			
Method for predicting risk of metastasis	2	—	2
Compositions and methods for detecting cancer metastasis	2	2	4
Total	28	110	138

Included in the table above are 18 issued U.S. patents and 78 issued international patents. This global patent portfolio has filing dates ranging from 2007 to 2024, and therefore are projected to expire between 2027 and 2044, subject to any patent term extension or patent term adjustment that might be available in a particular jurisdiction. The owned and licensed families contain issued patents and pending applications that relate to devices, systems, and methods for macromolecular analysis, and reflect our active and ongoing research programs.

Individual patents extend for varying periods depending on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, patents issued for regularly filed applications in the United States are granted a term of 20 years from the earliest effective non-provisional filing date. In addition, in certain instances, a patent term can be extended to recapture a period due to delay by the United States Patent and Trademark Office (the "USPTO") in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the total patent term including the restoration period must not exceed 14 years following FDA approval. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective non-provisional filing date. However, the actual protection afforded by a patent varies on a product-by-product basis, from country to country, and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions, the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Trademarks and Trade Secrets

As of the date of this Annual Report on Form 10-K, our U.S. trademark portfolio contained 22 trademark registrations.

We rely upon trade secrets, know-how, continuing technological innovation and potential in-licensing opportunities to develop and maintain our competitive position. We seek to protect our intellectual property and proprietary technology, in part, by entering into confidentiality agreements and intellectual property assignment agreements with our employees, consultants, corporate partners and, as applicable, our advisors. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed through a relationship with an employee or a third party. These agreements may be breached, and we may not have adequate remedies for any breach. We additionally seek to preserve the integrity and confidentiality of our data and trade secrets, such as our proprietary algorithms, by maintaining the physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

Government Regulation and Product Approval

Regulations

Clinical Laboratory Improvement Amendments of 1988

As a clinical reference laboratory, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. Under CLIA, we are required to hold a certificate applicable to the type of laboratory tests we perform and to comply with standards applicable to our operations, including test processes, personnel, facilities administration, equipment maintenance, recordkeeping, quality systems and proficiency testing. We must maintain CLIA compliance and certification to be eligible to bill for diagnostic services provided to Medicare beneficiaries.

To renew our CLIA certificate, we are subject to survey and inspection every two years to assess compliance with program standards. Because our Phoenix, Arizona laboratory is a CAP-accredited laboratory, CMS may defer the survey and inspection to those conducted by CAP. We may also be subject to additional unannounced inspections. The regulatory and compliance standards applicable to the testing we perform change periodically, and any such changes are published by CAP. Our standard operating procedures ("SOPs"), documents and records are updated accordingly and as needed. Any such changes may have a material effect on our business.

Penalties for non-compliance with CLIA requirements include suspension, limitation or revocation of the laboratory's CLIA certificate, directed plan of correction, state on-site monitoring, civil money penalties, civil injunctive suit or criminal penalties.

State Laboratory Licensing

In addition to federal certification requirements of laboratories under CLIA, CLIA provides that states may adopt laboratory regulations and licensure requirements that are more stringent than those under federal law. Such laws, among other things, establish standards for the day-to-day operation of a clinical reference laboratory, which includes ensuring personnel have the adequate knowledge and training to maintain quality control. We currently provide laboratory services in all 50 states. Additionally, we maintain licenses in New York, California, Maryland,

Pennsylvania and Rhode Island which require specific licensure for out-of-state laboratories that accept specimens from those states.

Because we may receive specimens from residents of the state of New York, we sought and have received approval from NYSDOH. All of our laboratories are required to be certified by NYSDOH, have a lab director with a specific certificate of qualification and are subject to biennial New York inspections to ensure the lab is compliant with New York licensing standards. New York regulations also mandate proficiency testing for laboratories licensed under New York law, regardless of whether such laboratories are located in New York. If a laboratory is out of compliance with New York statutory or regulatory standards, NYSDOH may suspend, limit, revoke or annul the laboratory's New York license, censure the holder of the license, or assess civil money penalties. All of our laboratories are inspected and our proprietary tests are approved via NYSDOH.

Federal Oversight of Laboratory Developed Tests

The laws and regulations governing the marketing of diagnostic products are evolving, extremely complex, and in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Clinical laboratory tests are regulated under CLIA, as administered by CMS, as well as by applicable state laws. In addition, the Federal Food, Drug and Cosmetic Act (the "FD&C Act") defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, and which does not achieve its primary intended purposes via chemical action or metabolism. Our in vitro testing products are considered by the FDA to be subject to regulation as medical devices. Among other things, pursuant to the FD&C Act and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market review and marketing authorization, product, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical devices distributed domestically are reasonably safe and effective for their intended uses.

Although the FDA believes it has statutory authority to assure that laboratory developed tests are reasonably safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics ("IVDs") that are intended for clinical use and are designed, manufactured, and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high-complexity testing. These tests are referred to as LDTs.

On May 6, 2024, the FDA published a final rule on the regulation of LDTs which amends the FDA's regulations to make it explicit that LDTs are IVDs and regulated as devices under the FD&C Act. Under this final rule, the FDA issued a policy to phaseout, over the course of four years, its general enforcement discretion approach to LDTs and also issued targeted enforcement discretion policies for certain categories of LDTs, including LDTs marketed as of the date of publication of the final rule on May 6, 2024, as well as LDTs that have received approval from the New York State Department of Health. Specifically, the FDA intends to exercise enforcement discretion and not enforce certain medical device requirements (including the requirements for premarket review and marketing authorization and compliance with certain elements of the Quality System Regulation ("QSR") with respect to LDTs that were marketed as of the date of the final rule's publication, although such products must still comply with certain other FDA requirements, including registration and listing, portions of the QSR, medical device reporting, labeling, and corrections and removals reporting. However, where these tests are modified in certain ways from the version of the test marketed as of the final rule's publication date, this enforcement discretion policy will no longer apply, and the FDA intends to enforce all applicable FDA requirements (including premarket review and marketing authorization requirements) consistent with the phaseout policy. In addition, for LDTs that receive approval from NYSDOH, FDA intends to not enforce premarket review and marketing authorization requirements when these requirements are phased in more generally at either three and a half years (for high-risk LDTs) or four years (for low-moderate risk LDTs) following the date of publication of the final rule. Our proprietary tests, outlined above, are all NYSDOH approved. We believe this final ruling will have no material impact on our existing test offerings given all of our tests were marketed before May 6, 2024.

Separately, Congress has considered a number of proposals in the last several years, which, if enacted, would subject LDTs to certain regulatory requirements. For example, in recent years, Congress has worked on legislation to create a novel regulatory framework governing a new category of FDA-regulated products, referred to as in vitro clinical tests ("IVCTs"), which would govern LDTs and would be separate and distinct from existing medical device regulatory framework. For example, in March 2023, the Verifying Accurate Leading-edge IVCT Development Act of 2023 (the "VALID Act") was introduced. The bill would establish a risk-based approach to imposing requirements related to premarket review, quality systems, and labeling requirements on all IVCTs, including LDTs, but would

grandfather certain LDTs marketed before the effective date of the bill and exempt them from certain requirements. Depending on the approach adopted under any potential legislation, certain LDTs (likely those of higher risk) may be required to undergo some form of premarket review of LDTs as IVCTs, potentially with a transition period for compliance and a grandfathering provision.

Medical Device Regulatory Framework

Although we currently market our proprietary testing products as LDTs, which are currently subject to enforcement discretion, we could be subject to FDA compliance obligations in the future. Unless an exemption applies under the FDA's targeted enforcement discretion policies for certain categories of LDTs, each new or significantly modified medical device we seek to commercially distribute in the United States will require either a premarket notification to the FDA requesting authorization for commercial distribution under Section 510(k) of the FD&C Act, also referred to as a 510(k) clearance, *de novo* classification under Section 513(f)(2) of the FD&C Act, or approval of a PMA application under Section 515(c). These premarket review processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device Classification

Under the FD&C Act, medical devices are classified into one of three classes-Class I, Class II or Class III depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I devices are those with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to a set of FDA regulations, referred to as the General Controls for Medical Devices, which require compliance with the applicable portions of the QSR, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below. Most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, and Special Controls, as deemed necessary by the FDA, to provide reasonable assurance of the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries, FDA guidance documents and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk such as life-supporting or life-sustaining devices, or implantable devices, in addition to those devices of new types that were marketed after May 28, 1976 (the date of the enactment of the Medical Devices Amendments). The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the 510(k) process and *de novo* classification process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA’s satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, pre-clinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA’s satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The Investigational Device Process

In the United States, all clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA’s investigational device exemption (“IDE”) regulations. If the device presents a “significant risk” to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA’s approval of an IDE allows clinical testing to go forward for a specified number

of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

The IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with the FDA's good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed, halted, or be inadequate to support approval of a PMA application, for any number of reasons.

The 510(k) Clearance Process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a "predicate" device. A predicate device is a legally marketed device that is not subject to a PMA, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) submissions are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will "clear" the device for marketing.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process.

After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by a letter-to-file in which the manufacturer documents the change in an internal letter-to-file. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or approval of a PMA application is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite notification.

The De Novo *Classification Process*

The *de novo* classification process is an alternate pathway to classify medical devices of new types marketed after May 28, 1976, that are automatically classified into Class III but that are low to moderate risk. A manufacturer can submit a request for *de novo* classification if the manufacturer is unable to identify a predicate device and the new device or new use of the device presents a moderate or low risk.

Under the *de novo* classification pathway, FDA may reclassify the device from Class III to class II or Class I, as appropriate. If the manufacturer seeks reclassification to Class II, the reclassification request must include proposed special controls that provide reasonable assurance of safety and effectiveness of the device.

The PMA Approval Process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If

it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, however, in practice the application review process often exceeds this deadline. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA typically conducts inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from pre-clinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post-approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer-term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to our manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

Federal and State Physician Self-Referral Prohibitions

We are subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, and to comparable state laws. Together these restrictions generally prohibit us from billing a patient or any governmental or private payor for certain designated health services, including clinical laboratory services, when the physician ordering the service, or any member of such physician's immediate family, has a financial interest, such as an ownership or investment interest in or compensation arrangement with us, unless the arrangement meets an exception to the prohibition.

Sanctions for a Stark Law violation include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty for each bill or claim for a service arising out of the prohibited referral;
- the imposition of up to three times the amounts for each item or service wrongfully claimed;
- possible exclusion from federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty for each arrangement or scheme that the parties know (or should know) has the principal purpose of circumventing the Stark Law's prohibition.

These prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the federal False Claims Act (the "FCA"), which can result in additional civil and criminal penalties.

Federal and State Anti-Kickback Laws

The federal Anti-Kickback Statute (the "AKS") makes it a felony for a person or entity, including a clinical laboratory, to knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in order to induce business that is reimbursable under any federal healthcare program. A violation of the AKS may result in imprisonment for up to ten years and fines for each violation and administrative civil money penalties, including an additional amount of up to three times the amount of the remuneration paid. Convictions under the AKS result in mandatory exclusion from federal healthcare programs for a minimum of five years. In addition, The U.S. Department of Health and Human Services ("HHS") has the authority to impose civil assessments and fines and to exclude healthcare providers and others engaged in prohibited activities from Medicare, Medicaid and other federal healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the FCA, which is discussed in greater detail below. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Although the AKS applies only to items and services reimbursable under any federal healthcare program, a number of states have passed statutes substantially similar to the AKS that apply to all payors. Penalties of such state laws include imprisonment and significant monetary fines.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. Generally, courts have taken a broad interpretation of the scope of the AKS, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

In addition to statutory exceptions to the AKS, regulations provide for a number of safe harbors. If an arrangement meets the provisions of a safe harbor, it is deemed not to violate the AKS. An arrangement must fully comply with each element of an applicable safe harbor in order to qualify for protection.

Failure to meet the requirements of the safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances.

The Eliminating Kickbacks in Recovery Act

The Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") prohibits knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a laboratory; or paying or offering any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a laboratory or in exchange for an individual using the services of that laboratory. EKRA was enacted to help reduce opioid-related fraud and abuse. However, EKRA defines the term "laboratory" broadly and without reference to any connection to substance use disorder treatment. EKRA applies to all payors including commercial payors and government payors. The law includes a limited number of exceptions, some of which closely align with corresponding AKS exceptions and safe harbors, and others that materially differ. Currently, there is no regulation interpreting or implementing EKRA, nor any guidance released by a federal agency regarding the scope of EKRA.

Other Federal and State Healthcare Laws

In addition to the requirements discussed above, several other healthcare fraud and abuse laws could have an effect on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal healthcare programs substantially in excess of its usual charges for its services. The terms "usual charge" and "substantially in excess" are subject to varying interpretations.

The FCA prohibits, among other things, a person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval and from, making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim in order to secure payment or retaining an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud, through the FCA's "qui tam" or whistleblower provision. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. Finally, the Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. Several states have enacted comparable false claims laws which may be broader in scope and apply regardless of payor.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented, or caused to be presented, a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. A person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable under the civil monetary penalties statute. Moreover, in certain cases, providers who routinely waive co-payments and deductibles for Medicare and Medicaid beneficiaries, for example, in connection with patient assistance programs, can also be held liable under the AKS and the FCA. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of co-payments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The U.S. Department of Health and Human Services Office of Inspector General (the "OIG") emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud, may also be implicated for similar practices offered to patients covered by commercial payors.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") created additional federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of, or payment for, healthcare benefits, items or services. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA") also imposed annual reporting requirements on manufacturers of certain devices, drugs and biologics for certain payments and transfers of value by them and in some cases their distributors to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Any failure to comply with these reporting requirements could result in significant fines and penalties. Because we and other companies with LDTs are considered healthcare providers rather than device manufacturers, we believe that we are exempt from these reporting requirements. We cannot assure you, however, that the government will agree with our determination. Despite maintaining it has clear regulatory authority over LDTs, the FDA generally has not regulated them and has traditionally exercised enforcement discretion, choosing not to enforce applicable statutory and regulatory requirements. Therefore, most of these tests have neither undergone premarket review nor received FDA clearance, authorization or approval for marketing. We will continue to monitor the FDA's position as changes in this respect could materially affect our business, prospects, results of operations or financial condition.

State equivalents of each of the above federal laws, such as anti-kickback and false claims laws, may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by non-governmental third-party payors, including private insurers.

If our operations are found to be in violation of any of the fraud and abuse laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, integrity oversight and reporting obligations, diminished profits and future earnings, and the curtailment or restructuring of our operations.

International Regulations

Many countries in which we may offer any of our testing products in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national healthcare program. In situations involving physicians employed by state-funded institutions or national healthcare agencies, violation of the local anti-kickback law may also constitute a violation of the U.S. Foreign Corrupt Practices Act (“FCPA”).

The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity to offer or provide, directly or through a third party, including any potential distributors we may rely on in certain markets, anything of value to a foreign government official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. In addition, it is illegal for a company that reports to the Securities and Exchange Commission (the “SEC”) to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We will also be required to maintain accurate information and control over sales and distributors’ activities that may fall within the purview of the FCPA, its books and records provisions and its anti-bribery provisions.

The standard of intent and knowledge in the Anti-Bribery cases is minimal-intent and knowledge are usually inferred from the fact that bribery took place. The accounting provisions do not require intent. Violations of the FCPA’s anti-bribery provisions for corporations and other business entities are subject to a fine of up to $2 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to $100,000 and imprisonment for up to five years. Other countries, including the United Kingdom (“UK”) and other OECD Anti-Bribery Convention members, have similar anti-corruption regulations, such as the United Kingdom Anti-Bribery Act.

When marketing our testing products outside of the United States, we may be subject to foreign regulatory requirements governing human clinical testing, prohibitions on the import of tissue necessary for us to perform our testing products or restrictions on the export of tissue imposed by countries outside of the United States or the import of tissue into the United States, and marketing approval. These requirements vary by jurisdiction, differ from those in the United States and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

Privacy and Security Laws

Health Insurance Portability and Accountability Act

Under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”) HHS has issued regulations to protect the privacy and provide for the security of protected health information (“PHI”) used or disclosed by certain entities including healthcare providers, such as us. HIPAA also regulates standardization of data content, codes and formats used in certain healthcare transactions and standardization of identifiers for health plans and providers. Penalties for violations of HIPAA and HITECH laws and regulations include significant civil and criminal penalties.

Three standards have been promulgated under HIPAA’s and HITECH’s regulations: the Standards for Privacy of Individually Identifiable Health Information, which restrict the use and disclosure of certain individually identifiable health information, the Standards for Electronic Transactions, which establish standards for common healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures, and the Security Standards for the Protection of Electronic Protected Health Information, which require covered entities and business associates to implement and maintain certain security measures to safeguard certain electronic health information, including the adoption of administrative, physical and technical safeguards to protect such information.

The HIPAA privacy regulations cover the use and disclosure of PHI by covered entities and business associates, which are defined to include subcontractors that create, receive, maintain, or transmit PHI on behalf of a covered entity, as well as their covered subcontractors. They also set forth certain rights that an individual has with respect to

his or her PHI maintained by a covered entity, including the right to access or amend certain records containing PHI, or to request restrictions on the use or disclosure of PHI. The HIPAA security regulations establish requirements for safeguarding the confidentiality, integrity, and availability of PHI that is electronically transmitted or electronically stored. HITECH, among other things, established certain health information security breach notification requirements. A covered entity must notify any individual whose PHI is breached according to the specifications set forth in the breach notification rule. The HIPAA privacy and security regulations establish a uniform federal "floor" and do not preempt state laws that are more stringent or provide individuals with greater rights with respect to the privacy or security of, and access to, their records containing PHI or insofar as such state laws apply to personal information that is broader in scope than PHI.

Individuals (or their personal representatives, as applicable) have the right to access test reports directly from laboratories and to direct the copies of those reports to be transmitted to persons or entities designated by the individual.

HIPAA authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of HHS conduct periodic compliance audits of HIPAA covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

As a covered entity with downstream vendors and subcontractors and, in certain instances, as a business associate of other covered entities with whom we have entered into a business associate agreement, we have certain obligations under HIPAA regarding the use and disclosure of any PHI that may be provided to us. HIPAA and HITECH impose civil and criminal penalties against covered entities and business associates for noncompliance with privacy and security requirements. Further, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information ("PII").

Numerous other federal, state and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of personal information.

Reimbursement for Clinical Laboratory Services

We generate revenue on our products from several sources, including third-party payors, laboratory services intermediaries, and self-paying individuals. Depending on the billing arrangement and applicable law, we must bill various third-party payors, such as insurance companies, Medicare, Medicaid, and patients, all of which have different billing requirements. Compliance with applicable laws and regulations as well as internal compliance policies and procedures adds further complexity to the billing process. CMS establishes new procedures and continuously evaluates and implements changes to the reimbursement process for billing the Medicare program.

To receive reimbursement from third-party payors, we bill our tests using a variety of CPT codes, as defined by the AMA CPT Editorial Panel. For those genetic tests we conduct that do not have a dedicated CPT code, tests may be billed under a miscellaneous code for an unlisted molecular pathology procedure. Because these miscellaneous codes do not describe a specific service, the third-party payor claim may need to be examined to determine the service that was provided, whether the service was appropriate and medically necessary and whether payment should be rendered. This process can require a letter of medical necessity and other types of medical documentation from the ordering physician and it can result in a delay in processing the claim, a lower reimbursement amount, or denial of the claim.

With the evolution of genetic testing, we have seen individual third-party payors' medical coverage policies around the CPT codes we bill and their associated payment rates change over time, resulting in changes to our reimbursement. We believe all of our products provide significant clinical value and reduction in downstream healthcare spend, as evidenced in research studies and clinical publications, which we believe will continue to support and drive third-party payor reimbursement.

Under Medicare, payment for products like ours is generally made under the CLFS with payment amounts assigned to specific procedure billing codes. In April 2014, Congress passed the Protecting Access to Medicare Act ("PAMA"), which included substantial changes to the way in which clinical laboratory services will be paid under Medicare. Under PAMA, certain laboratories were required to report to CMS private payor payment rates and volumes for their

tests. CMS uses this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare CLFS reimbursement rates for the test. Laboratories that fail to report the required payment information may be subject to substantial civil penalties. We bill Medicare for our products, and therefore we are subject to reporting requirements under PAMA. See “Reimbursement—Government Payors” above for additional information.

PAMA also authorizes the adoption of new, temporary billing codes and/or unique test identifiers for FDA-cleared or approved tests as well as ADLTs. The AMA's CPT Editorial Panel now issues PLA codes in support of this section of PAMA. These PLA codes may be requested by a clinical laboratory or manufacturer to specifically identify their test. If approved, the codes are issued by the AMA on a quarterly basis. Our DecisionDx-UM test was granted a Category I MAAA CPT code and was effective January 1, 2020. Our DecisionDx-Melanoma test was granted a Category I MAAA CPT code and was effective January 1, 2021. Our MyPath Melanoma test was granted a PLA CPT code prior to our May 2021 acquisition of the Myriad MyPath Laboratory. Our TissueCypher test was granted a PLA CPT code prior to our December 2021 acquisition of Cernostics. Our DecisionDx-SCC and DiffDx-Melanoma tests were granted PLA CPT codes effective April 1, 2022. Our IDgenetix test was granted a new PLA CPT code and was effective October 1, 2023.

Healthcare Reform

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the ACA became law. This law substantially changed the way healthcare is financed by both government and commercial third-party payors, and significantly impacted our industry.

Since 2016, there have been efforts to repeal, replace, or amend all or part of the ACA. Further, there have been a number of health reform measures by the previous administration that have impacted the ACA. For example, on August 16, 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any forthcoming healthcare reform measures of the Trump administration will impact the ACA and our business.

On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute including the Infrastructure Investment and Jobs Act, will remain in effect through 2032, unless additional Congressional action is taken.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes or delays in implementation of certain measures due to changes in administrations could impose additional limitations on the prices we will be able to charge for our products, the coverage of or the amounts of reimbursement available for our products from third-party payors, including government and commercial payors.

Human Capital Resources

Overview

Our vision is to transform disease management by keeping people first: patients, clinicians, employees and investors. We understand the importance of maintaining a strong corporate culture with our employees at the center, based on the cornerstones we laid in 2008 at our inception: trust, excellence, collaboration, integrity, innovation and excitement. We strive to find members of our team who embody the values of our company. As of December 31, 2024, we had 761 full-time employees. During the year ended December 31, 2024, we added 151 employees to our team, a 25% increase from 2023. We face competition for experienced, qualified personnel in our industry, particularly for highly skilled scientists, laboratory technicians and salespeople versed in diagnostic testing services.

The tables below provide information on the distribution of our employees by functional area and by location as of December 31, 2024:

	Number of Employees
Laboratory Testing Operations	247
Research & Development	109
Sales & Marketing	218
Administrative & General	187
Total as of December 31, 2024	761

	Number of Employees
Friendswood, Texas	102
Phoenix, Arizona	202
Pittsburgh, Pennsylvania	120
Home-based	337
Total as of December 31, 2024	761

Our employees are not represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Employee Engagement

We value the unique perspective our employees bring to the organization and encourage open channels of communication. In June 2024, we conducted our fourth annual employee engagement survey to understand what was working well at Castle and what opportunities we had for improvement. We received feedback from over 95% of our employees and achieved an engagement score of 85%, meaning that 85% of our employees are engaged or enthusiastically engaged in the culture at Castle. Our engagement score was higher than the healthcare benchmark average of 70% for other healthcare companies who conducted the same employee engagement survey in 2024.

Compensation, Benefits and Professional Development

We are committed to offering competitive benefits and compensation packages to our employees. In addition to competitive base pay, we offer the following benefits, among others, to our full-time employees:

- a defined contribution 401(k) plan with employer matching contributions;
- an annual bonus opportunity;
- equity compensation, including stock options and/or restricted stock units (“RSUs”) and an employee stock purchase plan;
- medical, dental and vision plans;
- paid maternity, paternity and adoption leave policies;
- paid holidays and paid time off; and
- an employee assistance program.

We survey all new hires 90 days after the start of their employment to solicit feedback on employee engagement. We provide performance reviews at least once per year, with pay raises commensurate with market and performance indicators. Our regrettable turnover remains low at 1.7% for the year ended December 31, 2024.

We prioritize and encourage internal growth and professional development of our employees. To encourage employee development, we offer a professional development reimbursement program to eligible employees who attend job-related professional development activities.

Corporate and Other Information

We were incorporated in Delaware in September 2007. Our principal executive offices are located at 505 S. Friendswood Drive, Suite 401, Friendswood, Texas 77456 and our telephone number is (866) 788-9007. Our

corporate website address is www.CastleBiosciences.com. Information contained on, or accessible through, our website is not considered part of this Annual Report on Form 10-K or our other filings with the SEC. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to such reports filed or furnished pursuant to Section 13(a) and 15(d) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") are available free of charge on our website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

We may use our website as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the U.S. Securities and Exchange Commission. These disclosures will be included on our website under the "Company—Investors" section.

This Annual Report on Form 10-K contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend our use or display of other companies' trade names or trademarks to imply a relationship with, endorsement of or sponsorship of us by, any other companies.

Item 1A. Risk Factors.

Risk Factors

You should consider carefully the risks described below, as well as the other information in this Annual Report on Form 10-K, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the factors described as well as the other information in this Annual Report on Form 10-K, including our consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" when evaluating our business. If any of the following risks actually occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. In these circumstances, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Financial Condition

A significant portion of our revenue comes from a small number of third-party payors.

Our revenue for our test reports provided for patients covered by Medicare as a percentage of total revenue, was 47% and 49% for the years ended December 31, 2024 and 2023, respectively. Additionally, there was a commercial payor from which 15% of our revenue from patients were derived for the year ended December 31, 2024. If our largest current payors were to significantly reduce, or cease to pay, the amount they reimburse for our products, or if they do not reach favorable coverage and reimbursement decisions for our products, or attempt to recover amounts they had already paid, it could have a material adverse effect on our business, financial condition and results of operations and cause significant fluctuations in our results of operations.

Due to how we recognize revenue, our quarterly and annual revenues may not reflect our underlying business.

We have concluded that our contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured at the expected value using the ''most likely amount'' method under Accounting Standards Codification (''ASC'') Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). The amounts are estimated using historical average collection rates by test type and payor category taking into consideration the range of possible outcomes, the predictive value of our past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of our influence, such as the judgment and actions of third parties. Determining variable consideration through a consideration of these factors involves a significant level of estimation uncertainty, and our estimations may turn out to be incorrect. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in the absence of a predictable pattern and history of collectability with a payor. Variable consideration for claims for which there are no existing positive coverage decisions, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e.g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. As a result of the timing and amount of adjustments for variable consideration, our operating results and comparisons of such results on a period-to-period basis may be difficult to understand and may not be meaningful. In addition, these fluctuations in revenue may make it difficult for us, for research analysts and for investors to accurately forecast our revenue and operating results. If our revenue or operating results fall below expectations, the price of our common stock would likely decline.

We incurred significant losses in the past, and we may be unable to achieve sustained profitability in the future.

Since our inception, we have had a history of net losses. For the year ended December 31, 2024, we had net income of $18.2 million, and as of December 31, 2024, we had an accumulated deficit of $200.1 million. We cannot predict if we will continue to achieve profitability in the future. We may incur losses in the future as we plan to invest

significant additional funds toward the expansion of our commercial organization, the conduct of clinical utility and validity studies to support adoption of our products and the development or acquisition of additional products. We also expect increases in our stock-based compensation expense in future periods due to additional awards outstanding, attributable to increased headcount. Additionally, our performance could be affected by the impacts of geopolitical and macroeconomic developments, such as the invasion of Ukraine by Russia and related sanctions or the Israel-Hamas war, economic slowdowns, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, bank failures or other disruptions in the banking system or financing markets, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments. Due to the requirements associated with being a public company, we expect to continue incurring significant additional legal, accounting and other expenses. We also expect that any acquisitions of businesses, assets, products or technologies will increase our expenses. These increased expenses will make it harder for us to achieve future profitability or generate positive cash flows. Furthermore, our revenues from our DecisionDx-SCC test represented a significant portion of our 2024 revenues, but that is not expected to be the case for our 2025 operating results. See "—Risks Related to Our Business—Our revenue currently depends primarily on sales from our DecisionDx-Melanoma, DecisionDx-SCC and TissueCypher tests, and we will need to generate sufficient revenue from these products and other products to grow our business." We may also incur significant losses in the future for a number of reasons, many of which are beyond our control, including the other risks described in this Annual Report on Form 10-K, adoption of our products, coverage of and reimbursement rates for our products from third-party payors, and future research and development activities. Our failure to achieve profitability in the future could cause the market price of our common stock to decline and make it more difficult or costly for us to raise additional capital.

We are an early, commercial-stage company and have a limited operating history, which may make it difficult to evaluate our current business and predict our future performance.

We are an early commercial-stage company and have a limited operating history. Our limited operating history may make it difficult to evaluate our current business and this makes predictions about our future success or viability subject to significant uncertainty. In particular, we intend to use a portion of our working capital to increase our headcount, including through the expansion of our laboratory testing operations, sales and marketing and research and development teams, which will increase our operating costs in a manner not historically reflected in our consolidated financial statements. These anticipated changes in our operating expenses may make it difficult to evaluate our current business, assess our future performance relative to prior performance and accurately predict our future performance.

We will continue to encounter risks and difficulties frequently experienced by early commercial-stage companies, including those associated with increasing the size of our organization and the prioritization of our commercial, research and business development activities. If we do not address these risks successfully, our business could suffer.

Changes in financial accounting standards or practices may cause adverse, unexpected financial reporting fluctuations and affect our reported operating results.

Accounting principles generally accepted in the United States of America ("U.S. GAAP") is subject to interpretation by the Financial Accounting Standards Board ("FASB"), the SEC, and various bodies formed to promulgate and interpret appropriate accounting principles. A change in accounting standards or practices can have a significant effect on our reported results and may even affect our reporting of transactions completed before the change is effective. New accounting pronouncements and varying interpretations of accounting pronouncements have occurred and may occur in the future. Changes to existing rules or the questioning of current practices may adversely affect our reported financial results or the way we conduct our business.

Our quarterly and annual operating results and cash flows may fluctuate in the future, which could cause the market price of our stock to decline substantially.

Numerous factors, many of which are outside our control may cause or contribute to significant fluctuations in our quarterly and annual operating results. These fluctuations may make financial planning and forecasting uncertain. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. In addition, one or more of such factors may cause our revenue or operating expenses in one period to be disproportionately higher or lower relative to the others. As a result, comparing our operating results on a period-to-period basis may be difficult to understand and may not be meaningful. You should not rely on our past results as indicative of our future performance.

In addition, a significant portion of our operating expense is relatively fixed in nature, and planned expenditures are based in part on expectations regarding future revenue. Accordingly, unexpected revenue shortfalls could decrease our gross margins and cause significant changes in our operating results from quarter to quarter. If this occurs, the trading price of our stock could fall substantially.

This variability and unpredictability caused by factors such as those described above could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any guidance we may provide, or if the guidance we provide is below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause adverse effects on our business and may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis.

If we fail to adequately staff our accounting and finance function or fail to maintain adequate internal control over financial reporting, any new or recurring material weaknesses could prevent our management from concluding our internal control over financial reporting is effective and could result in our auditor issuing an adverse opinion on our internal control over financial reporting. If we identify any future significant deficiencies or material weaknesses, the accuracy and timeliness of our financial reporting may be adversely affected, our ability to prevent material misstatements in our consolidated financial statements could be impaired, a material misstatement in our consolidated financial statements could occur and we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, which could cause our business to suffer and our stock price to decline.

Since becoming a publicly traded company in 2019, we have increased the headcount of our accounting and finance functions to further support the demands placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act of 2002 (“Sarbanes-Oxley”). We expect to continue expending significant time and resources related to our internal control over financial reporting, including by further expanding our finance and accounting staff over time, but there can be no assurance our efforts will be effective.

We may need to raise additional capital to fund our existing operations, commercialize new products or expand our operations.

We believe our existing cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products will be sufficient to fund our operations for at least the next 12 months. If our available cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products are insufficient to satisfy our liquidity requirements including because of lower demand for our products, lower than currently expected rates of reimbursement from third-party payors or other risks described in this Annual Report on Form 10-K, we may finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. On March 26, 2024 (the “Closing Date”), we entered into a loan and security agreement (the “2024 LSA”), by and between us, our wholly owned subsidiary, Castle Narnia Real Estate Holding 1, LLC and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (the “Lender”). The 2024 LSA provides for (i) on the Closing Date, $10.0 million aggregate principal amount of term loans (“Term Loans”), and (ii) from the Closing Date until March 31, 2025, an additional line of credit of $25.0 million with the same interest rate and maturity as the term debt available at our option (the “2024 Credit Line”). We drew $10.0 million in Term Loans on the Closing Date. We expect to use the proceeds for the purpose of developing a commercial office building to be used as our future corporate headquarters, and the remainder for working capital and other general corporate purposes.

We may consider raising additional capital in the future to expand our business, to pursue strategic investments, to take advantage of financing opportunities or for other reasons, including to:

- increase our sales and marketing efforts for our existing tests and address competitive developments among these or future commercial products;

- fund ongoing evidence development for our existing products as well as our pipeline programs;
- expand our laboratory facility and related testing capacity;
- expand our technologies into other areas within the dermatology, gastroenterology and ophthalmology cancer fields;
- acquire, license or invest in technologies;
- acquire or invest in complementary businesses or assets; and
- finance capital expenditures and general and administrative expenses.

Our present and future funding requirements will depend on many factors, including:

- our ability to achieve revenue growth;
- our rate of progress in establishing payor coverage and reimbursement arrangements with third-party payors;
- our rate of progress in, and cost of the sales, marketing, coverage and reimbursement activities associated with, establishing adoption of our lead products, DecisionDx-Melanoma, DecisionDx-SCC, and TissueCypher, among our other products;
- the cost of expanding our laboratory operations and offerings, including our sales, marketing, coverage and reimbursement efforts;
- our rate of progress in, and cost of research and development activities associated with, diagnostic products in research and early development;
- the potential cost of, and delays in, the development of new products as a result of changes in regulatory oversight applicable to our products;
- acquisitions of businesses, assets, products or technologies;
- the duration and effects of elevated inflation;
- the effects on our operations of general political and economic conditions and evolving macroeconomic developments, including geopolitical and macroeconomic developments, such as the ongoing conflict between Ukraine by Russia and related sanctions or the Israel-Hamas war, public health crises, economic slowdowns, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, bank failures or other disruptions in the banking system or financing markets, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments; and
- the effect of competing technological and market developments.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends.

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

Any disruptions to, or volatility in, the credit and financial markets or any deterioration in overall economic conditions may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our commercialization, research and development efforts or grant rights to third parties to market and/or develop products that we would otherwise prefer to market and develop ourselves.

The terms of the 2024 LSA place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.

In March 2024, we entered into the 2024 LSA with the Lender, which provides for (i) on the Closing Date, $10.0 million aggregate principal amount of Term Loans, and (ii) from the Closing Date until March 31, 2025, the 2024

Credit Line. The 2024 LSA includes customary affirmative and negative covenants, as well as standard events of default, including an event of default based on the occurrence of a material adverse event. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. In addition, the Lender could declare a default upon the occurrence of any event that it interprets could have a material adverse effect, as defined in the 2024 LSA. Upon the occurrence and continuance of an event of default, the Lender may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the 2024 LSA. Any declaration by the Lender of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. We may not have enough available cash or be able to raise additional funds through equity or debt financing to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

Risks Related to Our Business

Our revenue currently depends primarily on sales from our DecisionDx-Melanoma, DecisionDx-SCC and TissueCypher tests, and we will need to generate sufficient revenue from these products and other products to grow our business.

Our revenue in 2024 was primarily derived from the sale of our DecisionDx-Melanoma, DecisionDx-SCC and TissueCypher tests. While we also derive revenue from our other tests, we expect that the majority of our revenue for the next several years will be derived from sales of our DecisionDx-Melanoma and TissueCypher tests. Revenues from our DecisionDx-SCC test represented a significant portion of our 2024 revenues but are not expected to be so in our 2025 operating results. On January 9, 2025, Novitas finalized the oncology biomarker LCD with an initial effective date of February 23, 2025. Several days later, Novitas changed the effective date for this LCD, extending the effective date to April 24, 2025. Should the LCD become effective as is, then we would anticipate not receiving Medicare reimbursement for DecisionDx-SCC tests performed on or after April 24, 2025.

We believe that our long-term commercial success, and ability to generate revenue, will depend on our ability to develop and market additional products, on our ability to increase market penetration for our existing and potential future products and on our ability to obtain favorable coverage and reimbursement policies from government payors, such as Medicare, and from private payors, such as insurance companies.

Without positive coverage policies, our products may not be reimbursed and we may not be able to recognize revenue. If we are unable to increase sales and expand coverage and reimbursement for DecisionDx-Melanoma, TissueCypher, and our other tests, develop and commercialize other products, and successfully obtain coverage and adequate reimbursement for such products, our revenue and our ability to achieve profitability would be impaired, and the market price of our stock could decline substantially.

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

Our results of operations could be adversely affected by general conditions in the U.S. and global economies, the U.S. and global financial markets and adverse macroeconomic developments. U.S. and global market and economic conditions have been, and continue to be, disrupted and volatile due to many factors, including public health crises, geopolitical and macroeconomic developments, such as the Israel-Hamas war and the ongoing conflict between Ukraine and Russia and related sanctions, economic slowdowns, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, liquidity concerns, at, and failures of, banks and other financial institutions or other disruptions in the banking system or financial markets, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments, among others. General business and economic conditions that could affect our business, financial condition or results of operations include fluctuations in economic growth, debt and equity capital markets, liquidity of the global financial markets, changes in trade and tariff policies, the availability and cost of credit, investor and consumer confidence, and the strength of the economies in which we, our collaborators, our manufacturers and our suppliers operate.

A severe or prolonged global economic downturn could result in a variety of risks to our business. For example, inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our

ability to access credit or otherwise raise capital on acceptable terms, if at all. In addition, the U.S. Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Furthermore, the closures of specific financial institutions, or the broader financial services industry, may lead to market-wide liquidity shortages that could materially harm our business and financial condition. For example, closures of Silicon Valley Bank, Signature Bank and First Republic Bank in 2023 resulted in broader financial institution liquidity risk and concerns.

Risks of a prolonged global economic downturn are particularly true in Europe, which is undergoing a continued severe economic crisis. A weak or declining economy could also strain our suppliers and manufacturers, possibly resulting in supply disruption. 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.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. In response to the invasion, the United States, UK and European Union ("EU"), along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability and/or supply chain continuity in both Europe and globally, and has introduced significant uncertainty into global markets. In particular, the Russia-Ukraine conflict has contributed to rapidly rising costs of living (driven largely by higher energy prices) in Europe and other advanced economies. Further, a weak or declining economy could strain our suppliers, manufacturers and collaborators, possibly resulting in additional supply disruption for our product candidates. As a result, our business and results of operations may be adversely affected by the ongoing conflict between Ukraine and Russia, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict. If economic conditions in Europe and other key markets for our business and the business of our suppliers, manufacturers and collaborators remain uncertain or deteriorate further, we could experience adverse effects on our business, financial condition, results of operations or cash flows.

Billing for our products is complex and requires substantial time and resources to collect payment.

Billing for clinical laboratory testing services is complex, time-consuming and expensive. Depending on the billing arrangement and applicable law, we bill various payors, including Medicare, Medicaid, private insurance companies, private healthcare institutions, and patients, all of which have different billing requirements. We generally bill third-party payors for products and pursue reimbursement on a case-by-case basis where pricing contracts are not in place. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of accounts receivable and long collection cycles, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the billing rates and reimbursement rates for our products;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare, Medicaid, Veterans Health Administration and TRICARE;
- risk of government audits related to billing;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance and our ability to collect such payments from patients;
- changes to billing codes used for our products;
- changes to requirements related to our current or future clinical studies, including our registry studies, which can affect eligibility for payment;

- ongoing monitoring provisions of LCDs for our products, which can affect the circumstances under which a claim would be considered medically necessary;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

We use CPT codes to bill for our products. If these codes were to change, there is a risk of an error being made in the claim adjudication process. Such errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in the amount of the payment we receive.

As we introduce new products, we may need to add new codes to our billing process as well as our financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Additionally, our billing activities require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. When payors deny our claims, we may challenge the reason, low payment amount or payment denials. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received.

Additionally, the ACA requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. These billing complexities, and the related uncertainty in obtaining payment for our products, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

In addition to the complexities noted above, we rely upon a third-party software application in the administration of our billing and collection process. Any significant disruption in our billing operations or the discovery of a deficiency in the design of our billing process could adversely impact our ability to generate and send invoices, calculate revenues, track payments and collect our accounts receivable. Although to date we have not experienced any disruptions or identified any deficiencies with our billing process or billing system, there can be no assurances that any disruptions or deficiencies will not occur in the future. Additionally, any failure in the design or operation of our internal controls related to our billing and collection processes could adversely impact our ability to conclude on the effectiveness of our internal control over financial reporting and could cause our auditor to issue an adverse opinion on our internal control over financial reporting.

We rely on third parties for sample collection, preparation and delivery. Any defects in sample collection or preparation by such third parties and any delays in delivery of such samples could cause errors in our test reports and affect our ability to deliver test reports in a timely manner or at all, which could significantly harm our business.

The samples that we test are biopsied (if applicable), preserved, prepared and delivered to us by third parties, including dermatopathologists and laboratory facilities. As such, we rely on these third parties to prepare, label and deliver the samples that we test in compliance with applicable laws and guidelines, and in a timely manner. Therefore, the accuracy and correctness of the test reports that we deliver are dependent on proper chain of custody and appropriate methods of sample collection, or preparation, storage and delivery utilized by these third parties, and our ability to timely deliver reports is dependent upon the ability of these third parties to provide these samples to us in a timely manner. The ability of these third parties to provide these samples to us in a timely manner could be delayed by events beyond our control, including but not limited to operational problems, natural disasters and public health crises. Any errors in any part of the sample collection, preparation and storage process could render us unable to process tests, or deliver test reports, or cause us to deliver incorrect test reports, potentially resulting in harm to patients whose clinicians implement a change in treatment decisions based upon our test report. If we are unable to timely deliver test reports, clinicians may be less likely to recommend and order our products and our revenues could be adversely affected. The occurrence of any of the foregoing could significantly harm our reputation and our results of operations, causing significant harm to our business.

We rely on our database of samples for some of the development and improvement of our products. Depletion or loss of our samples could significantly harm our business.

The development and validation of accurate products is a complex process that requires access to tissue specimens and long-term outcomes data. Our research and development efforts to improve our existing commercial products and develop new pipeline products may require the depletion of our existing database of samples. If our samples are lost or destroyed, or substantially depleted before we are able to generate meaningful data, we may be unable to improve our existing products, continue the development of pipeline products or validate product candidates. While we have historically been able to create and maintain a large sample bank to expand the clinical use of our products and develop new products, we may be unable to do so in the future. If we were unable to maintain or replenish our sample bank, we may be unable to improve our products or develop new products.

If one or more of our primary clinical laboratory facilities become damaged or inoperable or we are required to vacate our existing facilities, our ability to conduct our laboratory analysis and pursue our research and development efforts may be jeopardized.

We currently perform our testing and store our database of tumor samples at both our Phoenix, Arizona and Pittsburgh, Pennsylvania clinical laboratory facilities. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications failure, terrorism, burglary, public health crises (including restrictions that may be imposed on businesses by state and local governments under stay-at-home or similar orders and mandates such as those imposed during the COVID-19 pandemic) or other events, which may make it difficult or impossible for us to perform our testing services for some period of time or to receive and store samples. The inability to perform tests or to reduce the backlog of sample analysis that could develop if our facilities become inoperable, for even a short period of time, may result in the loss of revenue, loss of customers or harm to our reputation, and we may be unable to regain that revenue, those customers or repair our reputation in the future. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters and man-made disasters or other sudden, unforeseen and severe adverse events.

In addition, the loss of our tissue samples due to such events could limit or prevent our ability to conduct research and development analysis on existing tests as well as tests in active pipeline development. Generators at our laboratory facilities and related equipment and contingent measures to be used in the event of a loss of power may not be sustainable for extended periods of time, or be sufficient to fully mitigate loss of tissue samples and inventory.

While we have a business continuity plan in place, and intentionally built out two clinical laboratories in adjacent buildings in Phoenix, Arizona to not only support our growth but to provide certain operational redundancy, our facilities and the equipment we use to perform our testing and research and development could be unavailable or costly and time-consuming to repair or replace. It would be difficult, time-consuming and expensive to rebuild our facilities, to locate and qualify a new facility, replace certain pieces of equipment or license or transfer our proprietary technology to a third-party, particularly in light of licensure and accreditation requirements. Even in the unlikely event that we are able to find a third party with qualifications enabling us to resume our operations, we may be unable to negotiate commercially reasonable terms.

We carry insurance for damage to our property and the disruption of our business, but this insurance may not cover all of the risks associated with damage or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses and may not continue to be available to us on acceptable terms, if at all.

Our current or future products may not achieve or maintain significant commercial market acceptance.

We believe our success is dependent upon our ability to continue to successfully commercialize our products, to continue to expand our current relationships and develop new relationships with healthcare providers, to expand and maintain coverage for our products, and to develop and commercialize new products. Our ability to achieve and maintain commercial market acceptance of our existing and future products will depend on a number of factors, including:

- our ability to increase awareness of our products through successful clinical utility and validity studies;
- the rate of adoption of our products by physicians and other healthcare providers;
- our ability to achieve guideline inclusion for our products;
- the timeliness with which we can provide our clinical reports to the ordering clinician;
- the timing and scope of any regulatory approval for our products, if such approvals become required, and maintaining ongoing compliance with regulatory requirements;

- our ability to obtain and maintain positive coverage decisions for our products from government and commercial payors;
- our ability to obtain and maintain adequate reimbursement from third-party payors, such as Medicare, which accounted for 47%, 49% and 53% of our revenue from test reports for the years ended December 31, 2024, 2023 and 2022, respectively, with an additional third-party payor accounting for 15% of our revenue from test reports for the year ended December 31, 2024;
- the impact of our investments in research and development and commercial growth;
- negative publicity regarding our or our competitors' products resulting from scientific publications, or defects or errors in the products; and
- our ability to further validate our products through clinical research and accompanying publications.

We cannot assure you that we will be successful in addressing each of these factors or other factors that might affect the market acceptance of our products. If we are unsuccessful in achieving and maintaining market acceptance of our products, our business and results of operations will suffer.

New product development involves a lengthy and complex process, and we may be unable to develop and commercialize, or receive reimbursement for, on a timely basis, or at all, new products.

We continually seek to develop new product offerings, which requires us to devote considerable resources to research and development. Before we can commercialize a new pipeline product, we will need to expend significant resources in order to conduct substantial research and development, including clinical utility and validity studies, and further develop and scale our laboratory processes and infrastructure to accommodate additional products. For example, in 2021, we launched our innovative pipeline to develop a genomic test, or series of genomic tests, aimed at predicting response to systemic therapy in patients with moderate to severe psoriasis, AD and related inflammatory skin conditions. With this launch, we initiated a large prospective, multi-center clinical study to develop and validate this inflammatory skin disease pipeline program. We announced early discovery data from this study in October 2023. On December 23, 2025, we announced that preliminary data from our ongoing prospective development and validation study for our pipeline test has shown potential to identify a subset of patients with AD who have increased likelihood to achieve a super response to targeted therapies. Assuming successful validation, we are targeting to launch this pipeline test by the end of 2025.

Our product development process takes time and involves a high degree of risk, and such development efforts may fail for many reasons, including failure of the product to perform as expected, failure to successfully complete analytic and clinical validation, or failure to demonstrate the clinical utility of the product.

As we develop new products, we will have to make significant investments in research and development, marketing, selling, coverage and reimbursement activities. Typically, few research and development projects result in a commercialized product, and there can be no assurance that we will be able to successfully develop new products that can be commercialized. At any point, we may abandon development of a product or we may be required to expend considerable resources conducting research, which would adversely affect the timing for generating potential revenue from a new product and our ability to invest in other products in our pipeline. If a clinical validation study fails to demonstrate the prospectively defined endpoints of the study or if we fail to sufficiently demonstrate analytical validity or clinical utility, we might choose to abandon the development of the product, which could harm our business. In addition, competitors may develop and commercialize competing products or technologies faster than us or at a lower cost.

We may experience limits on our revenue if we are unable to increase and support adoption of our products by physicians and other healthcare providers.

Physicians and other healthcare providers may be unwilling to adopt our products due to their reliance on existing traditional clinical and pathology staging criteria and our ability to generate revenue from our products would be significantly impaired if we were unable to educate physicians, healthcare providers, patients and third-party payors about the benefits and advantages of our products. We will need to continue to educate physicians and pathologists about the benefits and cost-effectiveness of our products through published papers, presentations at scientific conferences, one-on-one marketing efforts by our sales force and one-on-one education by our medical affairs team. However, physicians and other healthcare providers may be reluctant to adopt our products in circumstances where our products are not incorporated into the current standard of care or practice guidelines. For example, while clinical utility of DecisionDx-Melanoma has been demonstrated in peer-reviewed publications, SLNB surgery is the most widely used pathology staging tool by clinicians for determining a CM patient's metastatic risk. Whether

healthcare providers adopt DecisionDx-Melanoma as a complementary or triage diagnostic method relative to the SLNB surgery will depend on our ability to increase awareness of DecisionDx-Melanoma and its clinical validation.

In addition, all of our testing services are performed by our certified laboratories located in Phoenix, Arizona and Pittsburgh, Pennsylvania, under CLIA rather than by local laboratory or pathology practices. Accordingly, it may be difficult for us to collect samples from pathologists, and pathologists may be reluctant to support our testing services.

We rely on limited or sole suppliers for some of the reagents, equipment, chips and other materials used by our products, and we may not be able to find replacements or transition to alternative suppliers.

We rely on limited or sole suppliers for certain reagents and other materials and components that we use for our products. Some of these items are unique to these suppliers and vendors. While we have developed alternate sourcing strategies for these materials and vendors, we cannot be certain whether these strategies will be effective or the alternative sources will be available when we need them. If these suppliers can no longer provide us with the materials we need, if the materials do not meet our quality specifications or are otherwise unusable, if we cannot obtain acceptable substitute materials, or if we elect to change suppliers, an interruption in laboratory operations could occur, we may not be able to deliver patient reports on a timely basis, or at all, and we may incur higher one-time switching costs. Any such interruption may significantly affect our future revenue, cause us to incur higher costs, and harm our customer relationships and reputation. In addition, in order to mitigate these risks, we maintain inventories of these supplies at higher levels than would be the case if multiple sources of supply were available. If our testing volume decreases or we switch suppliers, we may hold excess supplies with expiration dates that occur before use which would adversely affect our losses and cash flow position. As we introduce any new products, we may experience supply issues as we ramp up test volume, or encounter additional disruptions to trade, commerce, pricing stability, credit availability and global supply chain continuity as a result of the invasion of Ukraine by Russia, particularly if we contract with suppliers with operations or commercial relationships in Eastern Europe or to the extent the conflict escalates to involve additional countries, further economic sanctions or wider military conflict. If we should encounter delays or difficulties in securing, reconfiguring or revalidating the equipment, reagents or other materials we require for our products, our business, financial condition, results of operations and reputation could be adversely affected.

If our products do not meet the expectations of clinicians and patients, our operating results, reputation and business could suffer.

Our success depends on clinician and patient confidence that we can provide reliable, high-quality information that will improve treatment outcomes, lower healthcare costs and enable better patient care. We believe that patients, physicians and other healthcare providers are likely to be particularly sensitive to defects and errors in our products, including if our products fail to accurately predict risk of metastasis with high accuracy from samples, and there can be no guarantee that our products will meet their expectations. As a result, the failure of our products to perform as expected could significantly impair our operating results and our reputation, including if we become subject to legal claims arising from any defects or errors in our products or reports.

If we are unable to compete successfully, our business will suffer and we may be unable to increase or sustain our revenue or achieve profitability.

We face competition from companies and academic institutions that have either developed or may seek to develop products intended to compete with our products.

In addition, competitors may develop their own versions of our solutions in countries where we do not have patents or where our intellectual property rights are not recognized and compete with us in those countries, including encouraging the use of their solutions by clinicians in other countries.

Some potential competitors may have longer operating histories, larger customer bases, greater brand recognition and market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and more experience dealing with third-party payors. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their products than we do or sell their products at prices designed to win significant levels of market share. We may not be able to compete effectively against these organizations. Increased competition and cost-saving initiatives on the part of governmental entities and other third-party payors are likely to result in pricing pressures, which could harm our sales, profitability or ability to gain market share. In addition, competitors may be acquired by, receive investments from or enter into other commercial relationships with larger, well-established and well-financed companies. Certain potential competitors may be able to secure key inputs from vendors on more favorable terms, devote greater resources to marketing and promotional campaigns, adopt more aggressive pricing

policies and devote substantially more resources to test development than we can. In addition, companies or governments that control access to testing through umbrella contracts or regional preferences could promote our competitors or prevent us from performing certain services. If we are unable to compete successfully against current and future competitors, our business will suffer and we may be unable to increase market acceptance and sales of our products, which could prevent us from increasing our revenue or achieving profitability and could cause our stock price to decline. As we add new tests and services, we will face many of these same competitive risks for these new tests.

Impairment of our goodwill or other intangible assets could have a material adverse effect on our operating results and financial condition.

Goodwill represents the excess of amounts paid for acquiring businesses over the fair value of the net assets acquired, and intangible assets are measured at fair value upon the acquisition of a business for purposes of such calculations. As of December 31, 2024, our goodwill and other intangible assets balances were $10.7 million and $95.5 million, respectively. Goodwill is evaluated for impairment annually, or more frequently if conditions warrant, by comparing the carrying value of a reporting unit to its estimated fair value. Intangible assets with finite lives are reviewed for impairment when events or circumstances indicate that their carrying value may not be recoverable. Declines in operating results, divestitures, sustained market declines and other factors could result in an impairment of goodwill or other intangible assets and, in turn, a charge to net income or loss. Any future charges could have a material adverse effect on our results of operations or financial condition.

For example, on June 2, 2023, a MAC finalized an LCD pursuant to which the DecisionDx-SCC test would no longer be covered by Medicare effective July 17, 2023. On June 5, 2023, our stock price decreased significantly and did not recover before June 30, 2023. In response to this trigger, we tested goodwill for impairment at June 30, 2023. We elected to bypass the optional qualitative assessment and proceeded directly to the quantitative assessment. Our impairment test indicated that the fair value of our reporting unit exceeded its carrying value by 13% and therefore no impairment was indicated.

Factors that could result in a future impairment of goodwill include declines in the price of our common stock, increased competition, changes in macroeconomic developments, unfavorable government or regulatory developments and changes in coverage or reimbursement conditions.

The sizes of the TAM for our current and future products have not been established with precision and may be smaller than we estimate.

Our estimates of the TAM for DecisionDx-Melanoma, DecisionDx-SCC, TissueCypher, MyPath Melanoma, DecisionDx-UM and IDgenetix tests are based on a number of internal and third-party estimates, including, without limitation, the annual rate of patients with the applicable indications, the list price of our products relative to the reimbursement we expect to receive from third-party payors and the assumed prices at which we can sell our products in markets that have not been established. While we believe our assumptions and the data underlying our estimates are reasonable, these assumptions and estimates may not be correct and the conditions supporting our assumptions or estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the annual TAM for our current or future products may prove to be incorrect. If the actual number of patients who would benefit from our products, the price at which we can sell future products, or the annual TAM for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business and results of operations.

The diagnostic testing industry is subject to rapid change, which could make our current or future products obsolete.

Our industry is characterized by rapid changes, including technological and scientific breakthroughs, developments related to application of generative artificial intelligence (“AI”), frequent new product introductions and enhancements and evolving industry standards, all of which could make our current products and the other products we are developing obsolete. Our future success will depend on our ability to keep pace with the evolving needs of clinicians and patients on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to the diagnosis and treatment of cancer. There have also been advances in methods used to analyze very large amounts of molecular information. We must continuously enhance our existing products and develop new products to keep pace with evolving standards of care. If we do not update our products to reflect new scientific knowledge about cancer biology, information about new cancer therapies or relevant clinical studies, our products could become obsolete and sales of our current products and any new products we develop could decline or fail to grow as expected.

Our business operations may subject us to disputes, claims, government investigations and lawsuits, which may be costly and time-consuming and could materially and adversely impact our financial position and results of operations.

From time to time, we may become involved in disputes, claims, government investigations and lawsuits relating to our business operations. In particular, we may face claims related to the safety of our products, intellectual property matters, financial arrangements with health care providers, regulatory compliance, product promotional practices, and documentation, coding and billing practices, employment matters, tax matters, commercial disputes, competition, sales and marketing practices, environmental matters, personal injury, insurance coverage, and acquisition or divestiture-related matters. Any dispute, claim, government investigation or lawsuit may divert management's attention away from our business, we may incur significant expenses in addressing or defending any dispute, claim or lawsuit, and we may be required to pay damage awards or settlements or become subject to equitable remedies that could adversely affect our operations and financial results. For example, as described further in "Item 3. Legal Proceedings," on February 1, 2024 we received a subpoena from United States Department of Health and Human Services Office of Inspector General. This inquiry, and any potential resulting claim asserted against us, with or without merit, could be time-consuming, expensive to address and divert management's attention and other resources. These claims also could subject us to significant liability for damages and harm our reputation. Our insurance and indemnities may not cover all claims that may be asserted against us.

Additionally, the associated uncertainty could lead to increased volatility in our stock price and governmental enforcement action may result in substantial fines, penalties or administrative remedies, including exclusion from government reimbursement programs and entry into corporate integrity agreements with governmental agencies, which would entail significant obligations and costs and could damage our reputation.

Risks Related to Reimbursement and Government Regulation

We generally have limited reimbursement coverage for our products, and if third-party payors, including government and commercial payors, do not provide sufficient coverage of, or adequate reimbursement for, our products, our commercial success, including revenue, will be negatively affected.

Our revenue depends on achieving broad coverage and adequate reimbursement for our products from third-party payors, including both government and commercial third-party payors. If third-party payors do not provide coverage of, or do not provide adequate reimbursement for, a substantial portion of the list price of our products, we may need to seek additional payment from the patient beyond any co-payments and deductibles, which may adversely affect demand for our products. Coverage determinations by a third-party payor may depend on a number of factors, including, but not limited to, a third-party payor's determination of whether our products are appropriate, medically necessary or cost-effective. If we are unable to provide third-party payors with sufficient evidence of the clinical utility and validity of our products, they may not provide coverage, or may provide limited coverage, which will adversely affect our revenues and our ability to succeed. To the extent that more competitors enter our markets, the availability of coverage and the reimbursement rate for our products may decrease as we encounter pricing pressure from these competitors.

Since each third-party payor makes its own decision as to whether to establish a policy to cover our products, enter into a contract with us and set the amount it will reimburse for a product, these negotiations are a time-consuming and costly process, and they do not guarantee that the third-party payor will provide coverage or adequate reimbursement for our products. In addition, the determinations by a third-party payor whether to cover our products and the amount it will reimburse for them are often made on an indication-by-indication basis.

In cases where there is no coverage policy or we do not have a contracted rate for reimbursement as a participating provider, the patient is typically responsible for a greater share of the cost of the product, which may result in further delay of our revenue, increase our collection costs or decrease the likelihood of collection.

Our claims for reimbursement from third-party payors may be denied upon submission, and we may need to take additional steps to receive payment, such as appealing the denials. Such appeals and other processes are time-consuming and expensive and may not result in payment. Third-party payors may perform audits of historically paid claims and attempt to recoup funds years after the funds were initially distributed if the third-party payors believe the funds were paid in error or determine that our products were medically unnecessary. If a third-party payor audits our claims and issues a negative audit finding, and we are not able to overturn the audit findings through appeal, the recoupment may result in a material adverse effect on our revenue. Additionally, in some cases commercial third-party payors for whom we are not a participating provider may elect at any time to review claims previously paid and determine the amount they paid was too much. In these situations, the third-party payor will typically notify us of their decision and then offset whatever amount they determine they overpaid against amounts they owe us on

current claims. We cannot predict when, or how often, a third-party payor might engage in these reviews and we may not be able to dispute these retroactive adjustments.

Under ASC 606, we recognize revenue at the amount we expect to be entitled, subject to a constraint for variable consideration, in the period in which our tests are delivered to the treating clinician. We have determined that our contracts contain variable consideration under ASC 606 because the amounts paid by third-party payors may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration is recognized only to the extent it is probable that a significant reversal of revenue will not occur in future periods when the uncertainties are resolved.

Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Variable consideration for Medicare claims that are not covered by Medicare, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e.g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. For these fully constrained claims, we generally recognize revenue in the period the uncertainties are resolved, if favorable. Due to potential future changes in Medicare coverage policies and appeal cycles, insurance coverage policies, contractual rates and other trends in the reimbursement of our tests, our revenues may fluctuate significantly from period to period.

Although we are an in-network participating provider with some commercial third-party payors, including several Blue Cross Blue Shield plans, and certain large, national commercial third-party payors, including Aetna, other commercial third-party payors have issued non-coverage policies that currently categorize our tests as experimental or investigational. If we are not successful in obtaining coverage from third-party payors, in reversing existing non-coverage policies, or if other third-party payors issue similar non-coverage policies, this could have a material adverse effect on our business and operations.

The process to obtain Medicare coverage is lengthy, time-consuming, has changed over time, may change in the future and requires significant dedication of resources, and as we develop or acquire new products, we may be unsuccessful in receiving Medicare coverage for those products or in maintaining our current Medicare coverage. On a periodic basis, CMS requests bids for its MAC services, and MAC jurisdictions have changed in the past. A change in our MAC, or future changes in the MolDX program, the elimination of the program, or a change in the administrator of that program, may affect our ability to maintain Medicare coverage and reimbursement for products for which we have coverage, obtain Medicare coverage for products for which we do not yet have coverage, or obtain Medicare coverage for any products we may launch in the future, or delay payments for our tests. Additionally, MACs that currently provide coverage for our products may periodically reevaluate their coverage decisions and decide to withdraw coverage based on a number of factors that we may not be able to predict or control. Accordingly, current Medicare coverage of our tests or a history of coverage by Medicare is no guarantee of future Medicare coverage. We have received positive coverage decisions and receive Medicare reimbursement for our DecisionDx-Melanoma, MyPath Melanoma, DecisionDx-UM and IDgenetix tests and also receive Medicare reimbursement for our TissueCypher test.

Following medical review in early 2022, we also received Medicare reimbursement for our DecisionDx-SCC test. On June 2, 2023, Novitas, the MAC responsible for administering claims for test reports issued by our Pittsburgh laboratory, posted a finalized oncology biomarker LCD pursuant to which the DecisionDx-SCC test would no longer be covered by Medicare effective July 17, 2023. However, on July 6, 2023, Novitas suspended the final version of the LCD and announced its intent to post a new proposed LCD for comment and presentation at an open meeting.

On June 8, 2023, Palmetto and Noridian recommended no coverage for DecisionDx-SCC in a draft LCD. After the comment period ended on July 22, 2023, the LCD was finalized on July 4, 2024, with an effective date of August 18, 2024.

On July 27, 2023, Novitas posted a nearly identical proposed oncology biomarker LCD that continued to intend to rely upon evidentiary reviews sourced from three databases: ClinGen, OncoKB and NCCN. On July 26, 2024, Novitas posted a note that it had been granted an extension by CMS. On January 9, 2025, Novitas finalized the oncology biomarker LCD with an initial effective date of February 23, 2025. Several days later, Novitas changed the effective date for this LCD, extending the effective date to April 24, 2025. Should the LCD become effective as is, then we would anticipate not receiving Medicare reimbursement for DecisionDx-SCC tests performed on or after April 24, 2025. We expect the loss of Medicare coverage for our DecisionDx-SCC test will adversely impact our 2025 and future results. If coverage for one or more of our other products is withdrawn, our business could be more adversely impacted.

Under Medicare, payment for products like ours is generally made under the CLFS with payment amounts assigned to specific procedure billing codes. Medicare reimbursement rates for our tests are subject to change and may decrease from those currently in effect. For example, in February 2023, MolDX notified us that IDgenetix should shift billing to a different multi-test generic gene sequencing CPT code and continue using the IDgenetix Z-Code beginning in March 2023. As a result of this change, the Medicare reimbursement rate for the IDgenetix multi-gene panel decreased from approximately $1,500 to $917 per test. We subsequently obtained a test-specific PLA CPT code which became effective October 1, 2023. In November 2023, CMS posted its final CLFS determination which crosswalks our PLA CPT code to an existing PLA code at a rate of $1,336 per test effective January 1, 2024.

In April 2014, Congress passed the PAMA which included substantial changes to the way in which clinical laboratory services are paid under Medicare. Under PAMA, certain laboratories are required to report to CMS commercial third-party payor payment rates and volumes for each test they perform. CMS uses this data to calculate a weighted median payment rate for each test, which will be used to establish revised Medicare CLFS reimbursement rates for the test. Laboratories that fail to report the required payment information may be subject to substantial civil monetary penalties. We bill Medicare for our products, and therefore we are subject to reporting requirements under PAMA.

If we are unable to obtain and maintain adequate reimbursement rates from commercial third-party payors, this may adversely affect our Medicare rate. It is unclear what impact new pricing structures, such as those adopted under PAMA, may have on our business, financial condition, results of operations or cash flows.

The U.S. federal government continues to show significant interest in pursuing healthcare reform and reducing healthcare costs. Similarly, commercial third-party payors may seek to reduce costs by limiting coverage or reducing reimbursement for our products. Any government-adopted reform measures or changes to commercial third-party payor coverage and reimbursement policies could cause significant pressure on the pricing of, and reimbursement for, healthcare products and services, including our products, which could decrease demand for our products, and adversely affect our sales and revenue.

In addition, some third-party payors have implemented, or are in the process of implementing, laboratory benefit management programs, often using third-party benefit managers to manage these programs. The stated goals of these programs are to help improve the quality of outpatient laboratory services, support evidence-based guidelines for patient care and lower costs. The impact on laboratories, such as ours, of active laboratory benefit management by third parties is unclear, and we expect that it could have a negative impact on our revenue in the short term. It is possible that third-party payors will resist reimbursement for the products that we offer, in favor of less expensive products, may require pre-approval for our products or may impose additional pricing pressure on and substantial administrative burden for reimbursement for our products.

We expect to continue to focus substantial resources on increasing coverage and reimbursement for our current products and any future products we may develop. We believe it may take several years to achieve broad coverage and adequate contracted reimbursement with a majority of third-party payors for our products.

However, we cannot predict whether, under what circumstances, or at what payment levels third-party payors will cover and reimburse our products. If we fail to establish and maintain broad adoption of, and coverage and reimbursement for, our products, our ability to generate revenue could be harmed and our future prospects and our business could suffer.

Our products are currently marketed as LDTs, and any changes in regulations or the FDA's enforcement discretion for LDTs, or violations of regulations by us, could adversely affect our business, prospects, results of operations or financial condition.

The diagnostics industry is highly regulated, and we cannot assure you that the regulatory environment in which we operate will not change significantly and adversely in the future. In many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Although the FDA has statutory authority to provide reasonable assurance that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to in vitro diagnostics ("IVD") that are intended for clinical use and are designed, manufactured and used within a single laboratory that is certified under CLIA and meets the regulatory requirements under CLIA to perform high-complexity testing. These tests are referred to as LDTs. We currently market our products as LDTs.

On May 6, 2024, the FDA published a final rule on the regulation of LDTs, which amends the FDA regulations under 21 CFR Part 809 to make explicit that LTDs are IVDs and are regulated as devices under the FD&C Act. Under this final rule, the FDA issued a policy to phaseout, over the course of four years, its general enforcement discretion approach to LDTs and also issued targeted enforcement discretion policies for certain categories of LDTs, including

LDTs marketed as of the date of publication of the final rule on May 6, 2024, as well as LDTs that have received approval from the NYSDOH. Specifically, the FDA intends to exercise enforcement discretion and not enforce certain medical device requirements (including the requirements for premarket review and marketing authorization and compliance with certain elements of the Quality System Regulation ("QSR") with respect to LDTs that were marketed as of the date of the final rule's publication, although such products must still comply with certain other FDA requirements, including registration and listing, portions of the QSR, medical device reporting, labeling, and corrections and removals reporting. However, where these tests are modified in certain ways from the version of the test marketed as of the final rule's publication date, this enforcement discretion policy will no longer apply, and the FDA intends to enforce all applicable FDA requirements (including premarket review and marketing authorization requirements) consistent with the phaseout policy. In addition, for LDTs that receive approval from NYSDOH, FDA intends to not enforce premarket review and marketing authorization requirements when these requirements are phased in more generally at either three and a half years (for high-risk LDTs) or four years (for low-moderate risk LDTs) following the date of publication of the final rule.

We believe the LDT final rule will have no material impact on our existing test offerings given all of our tests were marketed before May 6, 2024. We believe that our tests will continue to be subject to FDA enforcement discretion in their current forms. Additionally, pursuant to the final rule, the FDA will gradually end its general enforcement discretion approach in five stages over a four-year period for other LDTs not approved by NYSDOH or not already on market. Each stage of the proposed phaseout period would subject LDTs to a set of regulatory requirements. For example, the first stage of the phaseout would require LDT developers to comply with medical device reporting requirements and correction and removal reporting requirements by May 6, 2025. LDTs that are considered higher risk IVDs would be subject to premarket review requirements within three and a half years, and LDTs that are considered low to moderate risk IVDs would be subject to premarket submission requirements within four years after publication of the final rule. While the enforcement policy is phased out, the FDA could still decide to pursue enforcement action at any time against LDTs that it deems to be violative of its regulations when appropriate.

All of our existing tests were marketed prior to May 6, 2024 and are conducted in labs licensed by the NYSDOH. If the FDA were to determine that our tests, or modifications thereof, are not within the scope of the FDA's enforcement discretion policy for LDTs for any reason, including based on the final LDT rule or new rules, policies or guidance, or due to changes in statute, our existing tests may become subject to extensive FDA requirements, or our business may otherwise be adversely affected and lead to potential adverse effects on our business, prospects, results of operations and financial condition. Furthermore, under the terms of this final LDT rule, any future Castle tests developed and commercialized are likely to be subject to extensive FDA requirements which may adversely impact our business, prospects, results of operations and financial conditions. Based on the final LDT rule, any such future Castle tests would be required to obtain marketing authorization by November 6, 2027 (if the tests are considered high risk) or by May 6, 2028 (if the tests are considered low to moderate risk and are otherwise not exempt from premarket review requirements). We would also be subject to other device requirements, such as establishment registration and device listing requirements, medical device reporting requirements and current good manufacturing practice requirements. We may be required to conduct clinical trials prior to continuing to sell our existing products or launching any other products we may develop. This may increase the cost of conducting, or otherwise harm, our business.

Even if the FDA does not modify its policy of enforcement discretion, the FDA may disagree that we are marketing our LDTs within the scope of its policy of enforcement discretion and may impose significant regulatory requirements. While we believe that we are currently in material compliance with applicable laws and regulations as historically enforced by the FDA, we cannot assure you that the FDA will agree with our determination. A determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

We may be required to obtain marketing authorization under Section 510(k), 513(f)(2) or 515 of the FD&C Act for any future test we wish to offer. The process for submitting a premarket notification (501(k) and receiving FDA clearance usually takes from three to 12 months, but it can take significantly longer and clearance is never guaranteed. Similarly, the process for submitting a *de novo* authorization request and receiving FDA's granting of the request usually takes from 4 to 18 months, but it can take significantly longer and such granting of the request is never guaranteed. The process for submitting and obtaining FDA approval of a PMA is much more costly, lengthy and uncertain. It generally takes from one to three years or even longer, and approval is not guaranteed. PMA approval typically requires extensive clinical data and can be significantly longer, more expensive and more uncertain than the 510(k) clearance process or *de novo* authorization process. Despite the time, effort and expense expended, there can be no assurance that a particular device ultimately will receive FDA's marketing authorization

through the 510(k) clearance process, *de novo* authorization process or the PMA process on a timely basis, or at all. Moreover, there can be no assurance that any FDA-authorized labeling claims will be consistent with our current claims or adequate to support continued adoption of and reimbursement for our products. If premarket review is required for some or all of our products, the FDA may require that we stop selling our products pending marketing authorization, which would negatively impact our business. Even if our products are allowed to remain on the market prior to marketing authorization, demand or reimbursement for our products may decline if there is uncertainty about our products, if we are required to label our products as investigational by the FDA, or if the FDA limits the labeling claims we are permitted to make for our products. As a result, we could experience significantly increased development costs and a delay in generating additional revenue from our products, or from other pipeline products. Furthermore, it could reduce our revenues or increase our operating costs and adversely affect our business, prospects, results of operations or financial condition.

We conduct business in a heavily regulated industry, and failure to comply with federal, state and foreign laboratory licensing requirements including those established by CMS and the applicable requirements of the FDA or any other regulatory authority, could cause us to lose the ability to perform our tests, experience disruptions to our business, or become subject to administrative or judicial sanctions.

The diagnostics industry is highly regulated, and the laws and regulations governing the marketing of diagnostic tests are extremely complex. Areas of the regulatory environment that may affect our ability to conduct business include, without limitation:

- federal and state laws applicable to test ordering, documentation of tests ordered, billing practices and claims payment and/or regulatory agencies enforcing those laws and regulations;
- federal and state fraud and abuse laws;
- federal and state laboratory anti-mark-up laws;
- coverage and reimbursement levels by Medicare, Medicaid, other governmental payors and private insurers;
- restrictions on coverage of and reimbursement for tests;
- federal and state laws governing laboratory testing, including CLIA, and state licensing laws and accreditation requirements;
- federal and state laws and enforcement policies governing the development, use and distribution of diagnostic medical devices, including LDTs;
- federal, state and local laws governing the handling and disposal of medical and hazardous waste;
- federal and state Occupational Safety and Health Administration rules and regulations; and
- HIPAA and similar health data privacy laws.

In particular, the FD&C Act defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component, part, or accessory, which is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, and which does not achieve its primary intended purposes via chemical action or metabolism. Our products are considered by the FDA to be subject to regulation as medical devices, and marketed under FDA's policy of enforcement discretion for LDTs. Among other things, pursuant to the FD&C Act and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, premarket review and marketing authorization, marketing and promotion, and sales and distribution of medical devices in the United States to provide reasonable assurance that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the import and export of medical devices manufactured between the United States and international markets.

We are subject to CLIA, a federal law that regulates clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA regulations establish specific standards with respect to personnel qualifications, facility administration, proficiency testing, quality control, quality assurance and inspections. Any testing subject to CLIA regulation must be performed in a CLIA-compliant lab with either a certificate of compliance or a certificate of accreditation. CLIA certification or

accreditation is also required in order for us to be eligible to bill state and federal healthcare programs, as well as commercial third-party payors, for our products.

CAP maintains a clinical laboratory accreditation program. While not required for the operation of a CLIA-certified laboratory, many private insurers require CAP accreditation as a condition to contracting with clinical laboratories to cover their tests. In addition, some countries outside the United States require CAP accreditation as a condition to permitting clinical laboratories to test samples taken from their citizens. CAP accredited laboratories are surveyed for compliance with CAP standards every two years in order to maintain accreditation. Failure to maintain CAP accreditation could have a material adverse effect on the sales of our products and the results of our operations. Therefore, to maintain our CLIA accreditation, we have elected to be subject to survey and inspection every two years by CAP. Moreover, CLIA inspectors may make random inspections of our laboratory from time to time.

All of our laboratories maintain CLIA accreditation under the CAP program. The most recent CAP inspections for the Phoenix and Pittsburgh laboratories occurred in October 2024.

In addition, certain states require our laboratories to be licensed in specific states in order to test specimens from those states. Accordingly, our laboratories are licensed by California, Maryland, Pennsylvania, Rhode Island and New York. Other states do not currently require additional licensure but they may adopt similar requirements in the future.

Although we have obtained licenses from states where we believe we are required to be licensed, we may become aware of other states that require out-of-state laboratories to obtain licensure in order to accept specimens from the state, and it is possible that other states currently have such requirements or will have such requirements in the future.

In order to test specimens from New York, LDTs must be approved by the NYSDOH on a test-by-test basis before they are offered. Our laboratory director and laboratory operations must also be separately qualified and approved through the state of New York. DecisionDx-Melanoma, DecisionDx-CMSeq, DecisionDx-SCC, TissueCypher, MyPath Melanoma, DecisionDx-UM, DecisionDx-PRAME, DecisionDx-UMSeq, IDgenetix and DiffDx-Melanoma have each been approved. New York State Laboratory Permits are held for both the Phoenix and Pittsburgh labs from NYSDOH. Our laboratory director has been qualified by the NYSDOH. We are subject to periodic inspection by the NYS CLEP and are required to demonstrate ongoing compliance with the NYSDOH regulations and standards. Our most recent inspections were in October 2022 for Phoenix and October 2023 for Pittsburgh and were deemed to be compliant with the NYSDOH regulations and standards and both labs remain in good standing as of December 31, 2024. To the extent the NYSDOH had identified any instances of non-compliance, and we were unable to remedy such non-compliance, the State of New York could withdraw approval for our products to test samples from New York state. We will need to seek the NYSDOH approval of any future LDTs we develop and want to offer for clinical testing to New York residents, and there can be no assurance that we will be able to obtain such approval.

We may also be subject to regulation in foreign jurisdictions as we seek to expand international utilization of our products or such jurisdictions adopt new licensure requirements, which may require review of our products in order to offer them or may have other limitations such as restrictions on the transport of human tissue samples necessary for us to perform our tests that may limit our ability to make our products available outside of the United States. Complying with licensure requirements in new jurisdictions may be expensive, time-consuming and subject us to significant and unanticipated delays.

Failure to comply with applicable clinical laboratory licensure requirements may result in a range of enforcement actions, including suspension, limitation or revocation of our CLIA accreditation and/or state licenses, imposition of a directed plan of action, onsite monitoring, civil monetary penalties, criminal sanctions and revocation of the laboratory's approval to receive Medicare and Medicaid payment for its services, as well as significant adverse publicity. Any sanction imposed under CLIA, its implementing regulations, or state or foreign laws or regulations governing clinical laboratory licensure or our failure to renew our CLIA accreditation, or a state or foreign license, could have a material adverse effect on our business, financial condition and results of operations. Even if we were able to bring our laboratory back into compliance, we could incur significant expenses and potentially lose revenue in doing so.

Doing business with the public sector, including the U.S. government, subjects us to risk of audits, investigations, sanctions and penalties.

We have entered into, and may enter into in the future, contracts with the U.S. government or other governmental entities, and this subjects us to statutes and regulations applicable to companies doing business with the government. For example, we have a U.S. Federal Supply Schedule contract with the Veterans Health

Administration covering tests with the exception of DecisionDx-UM. Government contracts normally contain additional requirements that may increase our costs of doing business, reduce our profits (or increase our losses) and expose us to liability for failure to comply with these terms and conditions. Such requirements may include mandatory socioeconomic compliance requirements, including labor requirements, non-discrimination and affirmative action programs and environmental compliance requirements. Being a government contractor also subjects us to reviews, audits and investigations regarding our compliance. If we fail to comply with our obligations associated with being a government contractor, our contracts may be subject to termination, and we may be subject to financial and/or other liability under our contracts, which could adversely affect our results of operations.

The FDA may modify its enforcement discretion policy with respect to LDTs in a risk-based manner, and we may become subject to extensive regulatory requirements and may be required to conduct additional clinical trials prior to continuing to sell our existing tests or launching any other tests we may develop, which may increase the cost of conducting, or otherwise harm, our business.

On May 6, 2024, the FDA published a final rule which amends 21 CFR Part 809 to make explicit that LDTs are IVDs and are regulated as devices under the FD&C Act. In conjunction with this final rule, the FDA issued a policy to phaseout, over the course of four years, its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory would generally fall under the same enforcement approach as other IVDs.

If the FDA changes or ends its policy of enforcement discretion with respect to LDTs, and our products become subject to the FDA's requirements for premarket review of medical devices, we may be required to cease commercial sales of our products and conduct clinical trials prior to making submissions to the FDA to obtain premarket authorization or approval. If we are required to conduct such clinical trials, delays in the commencement or completion of clinical trials could significantly increase our product development costs and delay commercialization of any currently marketed testing that we may be required to cease selling or the commercialization of any future tests that we may develop. Many of the factors that may cause or lead to a delay in the commencement or completion of clinical trials may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for the clinical trial.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, known as the Quality System Regulation, which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures during the manufacturing process; the medical device reporting regulation, which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; labeling regulations, including the FDA's general prohibition against promoting products for unapproved or ''off-label'' uses; and the reports of corrections and removals regulation, which requires manufacturers to report to the FDA if a device correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FD&C Act caused by the device which may present a risk to health.

Even if we were able to obtain FDA marketing authorization for one or more of our products, if required, a diagnostic test may be subject to limitations on the indications for which it may be marketed or to other regulatory conditions. In addition, such marketing authorization may contain requirements for costly post-market testing and surveillance to monitor the safety or efficacy of the test.

In addition, the FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approvals. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

Furthermore, government funding of the FDA other government agencies on which our operations may rely is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other government agencies may impact the ability of such agencies to timely review and process our regulatory and other submissions, which could have a material adverse effect on our business.

Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical studies that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as more patient data becomes available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and marketing efforts.

Further, others, including healthcare providers or payors, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding our business. If the topline or interim data that we report differ from actual results, or if others, including healthcare providers or payors, disagree with the conclusions reached, our ability to commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Changes in healthcare policy could increase our costs, decrease our revenues and impact sales of and reimbursement for our products.

In March 2010, the ACA became law. This law substantially changed the way healthcare is financed by both government and commercial third-party payors, and significantly impacted our industry.

Since 2016, there have been efforts to repeal, replace, or amend all or part of the ACA. Further, there have been a number of health reform measures by the previous administration that have impacted the ACA. For example, on August 16, 2022, the IRA was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is unclear how any forthcoming healthcare reform measures of the Trump administration will impact the ACA and our business.

On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, reduced Medicare payments to providers by 2% per fiscal year, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Infrastructure Investment and Jobs Act, will remain in effect until 2032, unless additional Congressional action is taken.

We anticipate there will continue to be proposals by legislators at both the federal and state levels, regulators and commercial third-party payors to reduce costs while expanding individual healthcare benefits. Certain of these changes could impose additional limitations on the prices we will be able to charge for our products, the coverage of or the amounts of reimbursement available for our products from third-party payors, including government and commercial payors.

We are subject to numerous federal and state healthcare statutes and regulations, and complying with laws pertaining to our business is an expensive and time-consuming process. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties and a material adverse effect to our business and operations.

Physicians, other healthcare providers and third-party payors play a primary role in the recommendation of our products. Our arrangements with healthcare providers, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that affect the business and financial

arrangements and relationships through which we market and sell our products. The laws that affect our ability to operate include, but are not limited to:

- the AKS, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term ‘‘remuneration’’ has been broadly interpreted to include anything of value, such as specimen collection materials or test kits. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, however these are drawn narrowly. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and monetary penalties of up to $100,000 for each violation, plus up to three times the remuneration involved, imprisonment of up to ten years and exclusion from government healthcare programs. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA;
- the Stark Law, which prohibits a physician from making a referral for certain designated health services covered by the Medicare or Medicaid program, including laboratory and pathology services, if the physician or an immediate family member of the physician has a financial relationship with the entity providing the designated health services and prohibits that entity from billing, presenting or causing to be presented a claim for the designated health services furnished pursuant to the prohibited referral, unless an exception applies. Sanctions for violating the Stark Law include denial of payment, civil monetary penalties and exclusion from the federal healthcare programs. Failure to refund amounts received as a result of a prohibited referral on a timely basis may constitute a false or fraudulent claim and may result in civil penalties and additional penalties under the FCA;
- federal civil and criminal false claims laws, such as the FCA, which can be enforced by private citizens through civil qui tam action, and civil monetary penalty laws prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented through distribution of template medical necessity language or other coverage and reimbursement information, false, fictitious or fraudulent claims for payment or approval by the federal government, including federal healthcare programs, such as Medicare and Medicaid, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the FCA. Private individuals can bring FCA ‘‘qui tam’’ actions, on behalf of the government and such individuals, commonly known as ‘‘whistleblowers,’’ may share in amounts paid by the entity to the government in fines or settlement. When an entity is determined to have violated the federal civil FCA, the government may impose civil fines and penalties, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- the EKRA prohibits payments for referrals to recovery homes, clinical treatment facilities, and laboratories. EKRA's reach extends beyond federal healthcare programs to include private insurance (i.e., it is an “all payor” statute). For purposes of EKRA, the term “laboratory” is defined broadly and without reference to any connection to substance use disorder treatment. The law includes a limited number of exceptions, some of which closely align with corresponding federal AKS exceptions and safe harbors, and others that materially differ;
- HIPAA, which, among other things, imposes criminal liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as

covered entities, and their respective business associates, individuals or entities that perform services for them that involve individually identifiable health information as well as their covered subcontractors. Failure to comply with the HIPAA's obligations can result in civil monetary penalties, and, in certain circumstances, criminal penalties. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions;

- state laws that prohibit other specified practices, such as billing physicians for tests that they order or providing tests at no or discounted cost to induce physician or patient adoption; insurance fraud laws; waiving coinsurance, co-payments, deductibles, and other amounts owed by patients; billing a state Medicaid program at a price that is higher than what is charged to one or more other third-party payors employing, exercising control over or splitting professional fees with licensed professionals in violation of state laws prohibiting fee splitting or the corporate practice of medicine and other professions;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the ACA, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals and information regarding physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members. Failure to submit required information may result in civil monetary penalties for all payments, transfers of value or ownership or investment interests that are not timely, accurately, and completely reported in an annual submission, and may result in liability under other federal laws or regulations. We believe that we are exempt from these reporting requirements. We cannot assure you, however, that our regulators, principally the federal government, will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business;
- the prohibition on reassignment of Medicare claims, which, subject to certain exceptions, precludes the reassignment of Medicare claims to any other part;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, which may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and
- federal, state, local and foreign laws that govern the privacy and security of health information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal data, many of which differ from each other in significant ways and may not be pre-empted by HIPAA, thus complicating compliance efforts.

As a clinical laboratory, our business practices may face additional scrutiny from government regulatory agencies such as the Department of Justice, the OIG and CMS. Certain arrangements between clinical laboratories and referring physicians have been identified in fraud alerts issued by the OIG as implicating the AKS. The OIG has stated that it is particularly concerned about these types of arrangements because the choice of laboratory, as well as the decision to order laboratory tests, typically are made or strongly influenced by the physician, with little or no input from patients. Moreover, the provision of payments or other items of value by a clinical laboratory to a referral source could be prohibited under the Stark Law unless the arrangement meets all criteria of an applicable exception. The government has been active in enforcement of these laws as they apply to clinical laboratories.

We have entered into consulting and scientific advisory board arrangements, speaking arrangements and clinical research agreements with physicians and other healthcare providers, including some who could influence the use of our products. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of our products to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities may conclude that our business practices, including our consulting arrangements with physicians, as well as our financial assistance programs, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. Responding to investigations can be time and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations is costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt our operations. If any of the physicians or other healthcare providers or entities with whom we do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to certain U.S. anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations and may become subject to their similar foreign equivalents. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations prohibit, among other things, companies and their employees, agents, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of these trade laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect that we may engage in non-U.S. activities over time. We expect to rely on third-party suppliers and/or third parties to obtain necessary permits, licenses, and patent registrations. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

We are subject to stringent and changing state, federal, local, foreign, and other privacy and security laws, regulations and rules, contractual obligations, industry standards, policies and other obligations, and our failure to comply or perceived failure to comply with those obligations could result in regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse business consequences.

In the ordinary course of our business, we collect, store, use, transmit, disclose, or otherwise process ("Process") confidential, proprietary, and sensitive data, including PHI, personal data, credit card and other financial information, intellectual property and proprietary business information owned or controlled by ourselves or our customers, payors and other parties. Our data processing activities subject us to numerous data privacy and security obligations, such as laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts and other obligations that govern the Processing of personal data by us and on our behalf.

In the United States, numerous federal, state, and local governments have enacted data privacy and security laws, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). For example, HIPAA, as amended by HITECH, imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information and other personal

data. Additionally, numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business and ability to provide our products and services. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018, as amended ("CCPA"), applies to personal data of consumers, business representatives and employees who are California residents and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Similar laws have been enacted in several other states. We expect more similar laws in the future. Although certain of these laws exempt some personal data processed in the context of provision of services to covered entities and conducting clinical trials, these developments, to the extent applicable to our business and operations, may complicate our compliance efforts and costs and increase legal risk for us and the third parties upon whom we rely.

Outside the United States, there are also an increasing number of laws, regulations, industry standards and other obligations concerning privacy and data security. For example, we are subject to the European Union's General Data Protection Regulation ("EU") 2016/679 ("EU GDPR") and the United Kingdom's GDPR ("UK GDPR") (collectively, "GDPR"). Under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

Our employees and personnel use generative AI technologies to perform their work, and the disclosure and use of personal data in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages.

In the ordinary course of business, we transfer personal data from Europe and other jurisdictions to the United States or other countries. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area ("EEA") and the UK have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt, or may have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and the UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activist groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

In addition, privacy advocates and industry groups have proposed, and may in the future propose, standards with which we are legally or contractually bound to comply. In addition to data privacy and security laws, we are (and may in the future become) contractually subject to industry standards adopted by industry groups. For example, we are subject to the Payment Card Industry Data Security Standard ("PCI DSS"). The PCI DSS requires companies to

adopt certain measures to ensure the security of cardholder information, including using and maintaining firewalls, adopting proper password protections for certain devices and software, and restricting data access. Noncompliance with PCI-DSS can result in penalties ranging from $5,000 to $100,000 per month by credit card companies, litigation, damage to our reputation, and revenue losses. We rely on vendors to process payment card data, and those vendors may be subject to PCI DSS, and our business may be negatively affected if our vendors are fined or suffer other consequences as a result of PCI DSS noncompliance.

More generally, we are also bound by contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful. For example, certain privacy laws, such as the GDPR, may require our customers to impose specific contractual restrictions on their service providers. Additionally, we publish privacy policies and other statements regarding data privacy and security. Regulators are increasingly scrutinizing these statements, and, if these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we could experience material adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing in an increasingly stringent fashion, creating uncertainty as to the effective future legal framework. These obligations are subject to varying applications and interpretations, which may be inconsistent or conflicting among jurisdictions, creating complex compliance issues for us and our clients. Preparing for and complying with these obligations requires us to devote significant resources (including, without limitation, financial and time-related resources).

These obligations have in the past and may in the future necessitate changes to our information technologies, systems, and practices and to those of any third party that processes personal data on our behalf. In addition, these obligations have in the past and may in the future require us to change our business model or to take on more onerous obligations in our contracts.

Failure or perceived failure to comply with our privacy and security obligations could result in significant consequences, including but not limited to government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar), litigation (including class-action claims) and mass arbitration demands, additional reporting requirements and/or oversight, bans on processing personal data, and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: inability to process personal data or to operate in certain jurisdictions, increase our cost of providing our services, decrease demand for our services, reduce our revenue, interrupt our business operations (including our clinical trials), limit our ability to develop our services, expenditure of time and resources to defend any claim or inquiry, adverse publicity, or substantial changes to our business model or operations.

Ethical, legal and social concerns related to the use of genetic information could reduce demand for our products.

Genetic testing has raised ethical, legal, and social issues regarding privacy and the appropriate uses of the resulting information. Governmental authorities have, through the Genetic Information Nondisclosure Act of 2008, and could further, for social or other purposes, limit or regulate the use of genetic information or genetic testing or prohibit testing for genetic predisposition to certain conditions, particularly for those that have no known cure. Ethical and social concerns may also influence governmental authorities to deny or delay the issuance of patents for technology relevant to our business. While we do not currently perform genetic tests for genetic predisposition to certain conditions, these concerns may lead patients to refuse to use, or clinicians to be reluctant to order, our genomic tests or genetic tests for somatic mutations even if permissible. These and other ethical, legal and social concerns may limit market acceptance of our products or reduce the potential markets for our products, either of which could have an adverse effect on our business, financial condition, or results of operations.

Evolving expectations around corporate responsibility practices, specifically related to environmental, social and governance ("ESG") matters, may expose us to reputational and other risks.

Investors, stockholders, customers, suppliers and other third parties are increasingly focusing on ESG and corporate social responsibility endeavors and reporting. Companies that do not adapt to or comply with the evolving investor or stakeholder expectations and standards, or that are perceived to have not responded appropriately, may suffer from reputational damage, which could result in the business, financial condition and/or stock price of a company being materially and adversely affected. Further, this increased focus on ESG issues may result in new regulations and/or third-party requirements that could adversely impact our business, or certain shareholders

reducing or eliminating their holdings of our stock. Additionally, an allegation or perception that we have not taken sufficient action in these areas could negatively harm our reputation.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our technology, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize diagnostic tests similar or identical to ours, and our ability to successfully commercialize our products may be impaired.

We rely on patent protection as well as trademark, copyright, trade secret and other intellectual property rights protection as well as nondisclosure, confidentiality and other contractual restrictions to protect our brands and proprietary tests and technologies, all of which provide limited protection and may not adequately protect our rights or permit us to gain or keep any competitive advantage. If we fail to protect our intellectual property, third parties may be able to compete more effectively against us. In addition, we may incur substantial litigation costs in our attempts to recover or restrict use of our intellectual property.

As is the case with other life science companies, our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely or jointly with others or in-license from others, particularly patents, in the United States and other countries with respect to our products and technologies. We apply for patents covering our products and technologies and uses thereof, as we deem appropriate. However, obtaining and enforcing life sciences patents is costly, time-consuming and complex, and we may fail to apply for patents on important tests, services and technologies in a timely fashion or at all, or we may fail to apply for patents in potentially relevant jurisdictions. We may not be able to file and prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

We may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the rights to patents licensed from or to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

Our patent portfolio as of December 31, 2024 includes 18 issued U.S. patents and 10 pending U.S. patent applications, with foreign counterparts. It is possible that none of our pending patent applications will result in issued patents in a timely fashion or at all, and even if patents are granted, they may not provide a basis for intellectual property protection of commercially viable tests or services, may not provide us with any competitive advantages, or may be challenged and invalidated by third parties. It is possible that others will design around our future patented technologies. We may not be successful in defending any such challenges made against our patents or patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents and increased competition to our business. Even if our patents are held valid and enforceable, they may still be found insufficient to provide protection against competing products and services sufficient to achieve our business objectives. We may have to challenge the patents or patent applications of third parties, such as to counter infringement or unauthorized use. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, or may refuse to enjoin the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. Even if we prevail against an infringer in a U.S. district court or foreign trial-level court, there is always the risk that the infringer will file an appeal and the initial court judgment will be overturned at the appeals court and/or that an adverse decision will be issued by the appeals court relating to the validity or enforceability of our patents. The outcome of patent litigation or other proceeding can be uncertain, and any attempt by us to enforce our patent rights against others or to challenge the patent rights of others may not be successful, or, if successful, may take substantial time and result in substantial cost, and may divert our efforts and attention from other aspects of our business.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States or elsewhere. Courts frequently render opinions in the life sciences field that may affect the patentability of certain inventions or discoveries, including opinions that may affect the patentability of methods for analyzing or comparing DNA sequences.

In particular, the patent positions of companies engaged in the development and commercialization of genomic diagnostic tests are particularly uncertain. Various courts, including the U.S. Supreme Court, have rendered decisions that affect the scope of patentability of certain inventions or discoveries relating to certain diagnostic tests

and related methods. These decisions state, among other things, that a patent claim that recites an abstract idea, natural phenomenon or law of nature (for example, the relationship between particular genetic variants and cancer) are not themselves patentable. Precisely what constitutes a law of nature is uncertain, and it is possible that certain aspects of genetic diagnostics tests would be considered natural laws. Accordingly, the evolving case law in the United States may adversely affect our ability to obtain patents and may facilitate third-party challenges to any owned or licensed patents. The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to life science technologies, which could make it difficult for us to stop the infringement of our patents in such countries. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

To the extent our intellectual property offers inadequate protection, or is found to be invalid or unenforceable, we would be exposed to a greater risk of direct competition, and our competitive position could be adversely affected, as could our business. Both the patent application process and the process of managing patent disputes can be time-consuming and expensive. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The following examples are illustrative:

- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology, but that are not covered by the claims of the patents that we own or control, assuming such patents have issued or do issue;
- we or our licensors or any future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by the issued patents or pending patent applications that we own or have exclusively licensed;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors 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 tests for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights over that intellectual property;
- we may not develop or in-license additional proprietary technologies that are patentable;
- we may not be able to obtain and maintain necessary licenses on commercially reasonable terms, or at all; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operations.

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

As is the case with other life sciences companies, our success is heavily dependent on intellectual property, particularly patents relating to our research programs and products. Obtaining and enforcing patents in the life sciences industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or the USPTO rules and regulations could increase these uncertainties and costs. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (“AIA”), signed into law on

September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The AIA includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent in USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. For applications filed after March 15, 2013 that do not claim the benefit of applications filed before that date, the AIA transitioned the United States from a first to invent system to a first-inventor-to-file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. The AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations.

Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Our in-licensed intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies, and compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Intellectual property rights that have been in-licensed pursuant to the License Agreement with WUSTL have been generated through the use of U.S. government funding, and are therefore subject to certain federal regulations. As a result, the United States federal government may retain certain rights to intellectual property embodied in our current or future product candidates under the Bayh-Dole Act. These federal government rights include a "nonexclusive, nontransferable, irrevocable, paid-up license" to use inventions for any governmental purpose. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants" if it determines that (1) adequate steps have not been taken to commercialize the invention, (2) government action is necessary to meet public health or safety needs or (3) government action is necessary to meet requirements for public use under federal regulations. If the patent owner refuses to do so, the government may grant the license itself.

The U.S. government also has the right to take title to these inventions if the licensor fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States, and the License Agreement requires that we comply with this requirement. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our owned or future in-licensed intellectual property is also generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

Issued patents covering our products and related technologies could be found invalid or unenforceable if challenged.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability. Some of our patents or patent applications (including licensed patents) have been, are being or may be challenged at a future point in time in an opposition, nullification, derivation, reexamination, *inter partes* review, post-grant review or interference action in court or before patent offices or similar proceedings for a given period after allowance or

grant, during which time third parties can raise objections against such grant. In the course of such proceedings, which may continue for a protracted period of time, the patent owner may be compelled to limit the scope of the allowed or granted claims thus attacked, or may lose the allowed or granted claims altogether. Any successful third-party challenge to our patents in this or any other proceeding could result in the unenforceability or invalidity of such patents, which may lead to increased competition to our business, which could harm our business. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future diagnostic tests.

We may not be aware of all third-party intellectual property rights potentially relating to our products. 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 approximately 18 months after filing or, in some cases (e.g., U.S. applications for which a request not to publish has been filed), not until such patent applications issue as patents. We might not have been the first to make the inventions covered by each of our pending patent applications and we might not have been the first to file patent applications for these inventions. To determine the priority of these inventions, we have and may have to participate in interference proceedings, derivation proceedings or other post-grant proceedings declared by the USPTO that could result in substantial cost to us. The outcome of such proceedings is uncertain. We can give no assurance that all of the potentially relevant art relating to our patents and patent applications has been found; overlooked prior art could be used by a third party to challenge the validity, enforceability and scope of our patents or prevent a patent from issuing from a pending patent application. As a result, we may not be able to obtain or maintain protection for certain inventions. No assurance can be given that other patent applications will not have priority over our patent applications. In addition, changes to the patent laws of the United States allow for various post-grant opposition proceedings that have not been extensively tested, and their outcome is therefore uncertain. Therefore, the validity, enforceability and scope of our patents in the United States and other countries cannot be predicted with certainty and, as a result, any patents that we own or license may not provide sufficient protection against our competitors. Furthermore, if third parties bring these proceedings against our patents, we could experience significant costs and management distraction.

Our commercial success depends significantly on our ability to operate without infringing upon the intellectual property rights of third parties.

The life sciences industry is subject to rapid technological change and substantial litigation regarding patent and other intellectual property rights. Our potential competitors in both the United States and abroad, may have substantially greater resources and are likely to make substantial investments in patent portfolios and competing technologies, and may apply for or obtain patents that could prevent, limit or otherwise interfere with our ability to make, use and sell our products. Numerous third-party patents exist in fields relating to our products and technologies, and it is difficult for industry participants, including us, to identify all third-party patent rights relevant to our products and technologies. Moreover, because some patent applications are maintained as confidential for a certain period of time, we cannot be certain that third parties have not filed patent applications that cover our products and technologies.

Patents could be issued to third parties that we may ultimately be found to infringe. Third parties may have or obtain valid and enforceable patents or proprietary rights that could block us from using our technology. Our failure to obtain or maintain a license to any technology that we require may materially harm our business, financial condition and results of operations. Furthermore, we would be exposed to a threat of litigation.

From time to time, we may be party to, or threatened with, litigation or other proceedings with third parties, including non-practicing entities, who allege that our products, components of our products, and/or proprietary technologies infringe, misappropriate or otherwise violate their intellectual property rights. The types of situations in which we may become a party to such litigation or proceedings include:

- we may initiate litigation or other proceedings against third parties seeking to invalidate the patents held by those third parties or to obtain a judgment that our products or technologies do not infringe those third parties' patents;
- we may participate at substantial cost in International Trade Commission proceedings to abate importation of products that would compete unfairly with our products or technologies;
- if a competitor files patent applications that claim technology also claimed by us or our licensors, we or our licensors may be required to participate in interference, derivation or opposition proceedings to determine the priority of invention, which could jeopardize our patent rights and potentially provide a third party with a dominant patent position;

- if third parties initiate litigation claiming that our products or technologies infringe their patent or other intellectual property rights, we will need to defend against such proceedings;
- if third parties initiate litigation or other proceedings seeking to invalidate patents owned by or licensed to us or to obtain a declaratory judgment that their products, services, or technologies do not infringe our patents or patents licensed to us, we will need to defend against such proceedings;
- we may be subject to ownership disputes relating to intellectual property, including disputes arising from conflicting obligations of consultants or others who are involved in developing our products and technologies; and
- if a license to necessary technology is terminated, the licensor may initiate litigation claiming that our products or technologies infringe or misappropriate their patent or other intellectual property rights and/or that we breached our obligations under the license agreement, and we would need to defend against such proceedings.

These lawsuits and proceedings, regardless of merit, are time-consuming and expensive to initiate, maintain, defend or settle, and could divert the time and attention of managerial and technical personnel, which could materially adversely affect our business. Any such claim could also force us to do one or more of the following:

- incur substantial monetary liability for infringement or other violations of intellectual property rights, which we may have to pay if a court decides that the diagnostic test or technology at issue infringes or violates the third party's rights, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the third party's attorneys' fees;
- stop manufacturing, offering for sale, selling, using, importing, exporting or licensing the diagnostic test or technology incorporating the allegedly infringing technology or stop incorporating the allegedly infringing technology into such test or technology;
- obtain from the owner of the infringed intellectual property right a license, which may require us to pay substantial upfront fees or royalties to sell or use the relevant technology and which may not be available on commercially reasonable terms, or at all;
- redesign our products and technologies so they do not infringe or violate the third party's intellectual property rights, which may not be possible or may require substantial monetary expenditures and time;
- enter into cross-licenses with applicable third party, which could weaken our overall intellectual property position;
- lose the opportunity to license our technology to others or to collect royalty payments based upon successful protection and assertion of our intellectual property against others;
- find alternative suppliers for non-infringing technologies, which could be costly and create significant delay; or
- relinquish rights associated with one or more of our patent claims if our claims are held invalid or otherwise unenforceable.

Third parties may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity, adversely impact our business, cause delays, or prohibit us from marketing or otherwise commercializing our products and technologies. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operation, financial condition or cash flows.

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 this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our common stock. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. The occurrence of any of these events may have a material adverse effect on our business, results of operation, financial condition or cash flows.

We depend on information technology systems that we license from third parties. Any failure of such systems or loss of licenses to the software that comprises an essential element of such systems could significantly harm our business.

We depend on information technology systems for significant elements of our operations, such as our Laboratory Information Management System, including test validation, specimen tracking and quality control, our bioinformatics analytical software systems, our test report generating systems and billing systems. Essential elements of these systems depend on software that we license from third parties. If we are unable to maintain the licenses to this software or our software providers discontinue or alter the programs on which we rely, it could render our test reports unreliable or hinder our ability to generate accurate test reports, among other things. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We rely on licenses from third parties, and if we lose these licenses or are not able to obtain licenses to third-party technology on reasonable grounds or at all, then we may not be able to continue to commercialize existing diagnostic tests, be subjected to future litigation and may not be able to commercialize new diagnostic tests in the future.

We are party to certain royalty-bearing license agreements that grant us rights to use certain intellectual property, including patents and patent applications, in certain specified fields of use. Although we intend to develop products and technologies through our own internal research, we may need to obtain additional licenses from others to advance our research, development and commercialization activities. Our license agreements impose, and we expect that future license agreements will impose, various development, diligence, commercialization and other obligations on us.

In the future, we may identify third-party technology we may need, including to develop or commercialize new diagnostic tests or services. In return for the use of a third party's technology, we may agree to pay the licensor royalties based on sales of our solutions. Royalties are a component of the cost of our products or services and affect our margins. We may also need to negotiate licenses to patents or patent applications before or after introducing a commercialized test. The in-licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to in-license or acquire third-party intellectual property rights for technologies that we may consider attractive or necessary.

These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in-licensing or acquisition of third-party intellectual property rights for technologies that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may not be able to obtain necessary or strategic licenses to patents or patent applications, and our business may suffer if we are unable to enter into these licenses on acceptable terms or at all, if any necessary licenses are subsequently terminated, if the licensors fail to abide by the terms of the licenses or fail to prevent infringement by third parties, or if the licensed patents or other rights are found to be invalid or unenforceable.

In spite of our efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing or limiting our ability to develop and commercialize tests and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to seek regulatory approval of, and to market, tests identical to ours and we may be required to cease our development and commercialization activities. For example, we license certain intellectual property from WUSTL that is incorporated into DecisionDx-UM. In 2024, we provided over 1,600 test reports for DecisionDx-UM. If the License Agreement were terminated, we would be unable to continue to issue test reports and thus sales of DecisionDx-UM. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

Moreover, disputes may arise with respect to any one of our licensing agreements, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our products, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;

- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

If we do not prevail in such disputes, we may lose any of such license agreements.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected diagnostic tests, which could have a material adverse effect on our business, financial conditions, results of operations and prospects.

Our failure to maintain such licenses could have a material adverse effect on our business, financial condition and results of operations. Any of these licenses could be terminated, such as if either party fails to abide by the terms of the license, or if the licensor fails to prevent infringement by third parties or if the licensed patents or other rights are found to be invalid or unenforceable. Absent the license agreements, we may infringe patents subject to those agreements, and if the license agreements are terminated, we may be subject to litigation by the licensor. Litigation could result in substantial costs and be a distraction to management. If we do not prevail, we may be required to pay damages, including treble damages, attorneys' fees, costs and expenses, royalties or, be enjoined from selling our products or services, which could adversely affect our ability to offer our products or services, our ability to continue operations and our financial condition.

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

Filing, prosecuting and defending patents on our products in all countries throughout the world would be prohibitively expensive. The requirements for patentability may differ in certain countries, particularly developing countries, and the breadth of patent claims allowed can be inconsistent. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and we may encounter difficulties in protecting and defending such rights in foreign jurisdictions. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own tests or products and may also export infringing tests or products to territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products. Our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many other countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to life science technologies, which could make it difficult for us to stop the infringement of our patents in such countries. We do not have patent rights in certain foreign countries in which a market may exist. Moreover, in foreign jurisdictions where we do have patent rights, proceedings to enforce our patent rights could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. We may not be able to stop a competitor from marketing and selling in foreign countries tests, products and services that are the same as or similar to our products and technologies, in which case our competitive position in the international market would be harmed.

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

In addition to pursuing patents on our technology, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We take steps to protect our trade secrets, in part, by entering into agreements, including confidentiality agreements, non-disclosure agreements

and intellectual property assignment agreements, with our employees, consultants, academic institutions, corporate partners and, when needed, our advisers. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. For example, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and once disclosed, we are likely to lose trade secret protection and may not be able to obtain adequate remedies for such breaches. Such agreements may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure or other breaches of the agreements, and we may not be able to prevent such unauthorized disclosure. If we are required to assert our rights against such party, it could result in significant cost and distraction.

Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets.

We also seek to preserve the integrity and confidentiality of our confidential proprietary information by maintaining physical security of our premises and physical and electronic security of our information technology systems, but it is possible that these security measures could be breached. If any of our confidential proprietary information were to be lawfully obtained or independently developed by a competitor, absent patent protection, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We do and may employ individuals who previously worked with universities or other companies, including potential competitors. We could in the future be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer or competitor. Although, we are currently not subject to any such claims.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Therefore, we could be required to obtain a license from such third-party employer to commercialize our products or technology. Such a license may not be available on commercially reasonable terms or at all.

Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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.

We have not yet registered certain of our trademarks in all of our potential markets, although we have registrations for, among others, DecisionDx, DiffDx-Melanoma, DecisionDx-UM, DecisionDx-Melanoma, DecisionDx-SCC, MyPath Melanoma, TissueCypher and IDgenetix in the United States. Our current or future registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered

trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In addition, third parties have used trademarks similar and identical to our trademarks in foreign jurisdictions and have filed or may in the future file for registration of such trademarks. If they succeed in registering or developing common law rights in such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our products in those countries. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Although these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, right to use, or right to exclude others from using, intellectual property that is important to our products. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

Obtaining and maintaining our patent protection depends on compliance with various required procedures, document submissions, fee payments 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, renewal fees, annuity fees and various other governmental fees on patents and/or applications must be paid to the USPTO and various governmental patent agencies outside of the United States at several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees due to non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance 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, such as failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we, or our licensors, fail to maintain the patents and patent applications covering our products and technologies, potential competitors may be able to enter the market without infringing our patents and this circumstance would have a material adverse effect on our business.

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

Patents have a limited lifespan, and the protection patents afford is limited. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, is limited. Even if patents covering our products are obtained, once the patent term has expired, we may be open to competition from competitive tests or products. Given the amount of time required for the development, testing and regulatory review of potential new tests or products, patents protecting such tests or products might expire before or shortly after such tests or products are commercialized. As a result, our owned and licensed patent portfolio may not

provide us with sufficient rights to exclude others from commercializing tests or other products similar or identical to ours.

Risks Related to Employee Matters and Managing Growth and Other Risks Related to Our Business

We are highly dependent on the services of our key personnel, including our President and Chief Executive Officer.

We are highly dependent on the services of our key personnel, including Derek J. Maetzold, our President and Chief Executive Officer. Although we have entered into agreements with our key personnel regarding their employment, they are not for a specific term and each may terminate their employment with us at any time, though we are not aware of any present intention of any of these individuals to leave us.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the competition for qualified personnel among life science businesses, particularly near our laboratory facilities and office spaces located in Phoenix, Arizona; Pittsburgh, Pennsylvania; and our corporate headquarters in Friendswood, Texas. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting or retaining qualified salespeople. Recruiting and retention difficulties can limit our ability to support our research and development and sales programs. We may also experience employee turnover as a result of the ongoing “great resignation.” In response to competition, rising inflation rates and labor shortages, we may need to adjust employee cash compensation, which would affect our operating costs and our margins, or equity compensation, which would affect our outstanding share count and cause dilution to existing stockholders. All of our employees are at-will, which means that either we or the employee may terminate their employment at any time.

The 2019 Equity Incentive Plan (the “2019 Plan”) provides for automatic increases in the number of shares authorized for issuance annually through January 1, 2029, however, there can be no assurances that these increases will be adequate to support our requirements for future equity awards or that we will be able to obtain approval from our stockholders in the future should we require authorization for the issuance of additional shares. For example, for the year ended December 31, 2022, we had granted awards in excess of the number of shares authorized for issuance under our 2019 Plan. As of December 31, 2024, there were 791,974 shares available for grant under the 2019 Plan. In December 2022, our board of directors adopted a separate equity plan, the 2022 Inducement Plan (the “Inducement Plan”), to be used exclusively for grants of awards as an inducement material to new employees entering into employment with us, which was subsequently amended in November 2023 to increase the shares reserved under the plan. However, the Inducement Plan cannot be used to grant ongoing equity awards to existing employees. If we are unable to provide adequate or competitive equity compensation, we may have to adjust other elements of our compensation packages and may encounter difficulties attracting and retaining personnel.

Our employees, clinical investigators, consultants, speakers, vendors and any current or potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical study investigators, consultants, speakers, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: federal laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information; manufacturing standards; federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad; sexual harassment and other workplace misconduct; or laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual

damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We have experienced significant revenue growth in a short period of time. We may not achieve similar growth rates in future periods. You should not rely on our operating results for any prior periods as an indication of our future operating performance. To effectively manage our anticipated future growth, we must continue to maintain and enhance our financial, accounting, human resources, laboratory operations, customer support and sales administration systems, processes and controls. Failure to effectively manage our anticipated growth could lead us to over-invest or under-invest in development, operational and administrative infrastructure, result in weaknesses in our infrastructure, systems, or internal controls, give rise to operational mistakes, losses, loss of customers, productivity or business opportunities, and result in loss of employees and reduced productivity of remaining employees.

We also anticipate further growth in our business operations. For example, since December 2021, we have completed the acquisitions of Cernostics and AltheaDx. These acquisitions and other future growth could create strain on our organizational, administrative and operational infrastructure, including laboratory operations, quality control, customer service and sales organization management. We expect to continue increasing our headcount and hire more specialized personnel in the future as we grow our business and expand our product offerings. We will need to continue to hire, train and manage additional qualified scientists, laboratory personnel, client and account services personnel, and sales and marketing staff and improve and maintain our technology to effectively manage our growth. If our new hires perform poorly, if we are unsuccessful in hiring, training, managing and integrating these new employees or if we are not successful in retaining our existing employees, our business may be harmed.

In addition, our anticipated growth could require significant capital expenditures and might divert financial resources from other projects such as the development of new diagnostic tests and services. As we commercialize additional tests, we may need to incorporate new equipment, implement new technology systems, automate or otherwise improve the efficiency of our operational processes or hire new personnel with different qualifications. Failure to manage this growth or transition could result in turnaround time delays, higher costs, declining quality, deteriorating customer service, and slower responses to competitive challenges. Failure in any one of these areas could make it difficult for us to meet market expectations for our products and could damage our reputation and the prospects for our business.

For example, we experienced initial operational challenges in expanding business for our TissueCypher test. In July 2023, we elected to temporarily pause accepting additional TissueCypher orders to focus on scaling efforts and to work through a significant backlog of orders. In September 2023, we resumed accepting new orders for testing in a phased approach consistent with continued scaling activity aimed at accommodating current demand and future growth. As of mid-October 2023, we completed the pre-existing backlog orders. However, there can be no assurance that our efforts will be successful, which could damage our reputation and the prospects for our business. As we expanded our TissueCypher business line, we also incurred additional rent and overhead costs through the opening of our new Pittsburgh facilities in the second quarter of 2023 and through our expansion of these facilities in 2024. Furthermore, we have made significant capital expenditures for leasehold improvements and purchase of lab equipment for these facilities to support business growth for our TissueCypher test. We cannot be certain that our existing investments will be sufficient to sustain continued growth, or that we may be successful in such business strategy and expansion efforts.

After completing our initial launch of the IDgenetix test in 2022, we commenced measured commercial investments to grow this business line through sales force and territory expansions. These efforts continued into late 2024; however, operational results did not meet prior expectations. Consequently, in late 2024, we revised our commercial strategy for the IDgenetix test, reallocating resources to inside sales and non-personal promotions. In December 2024, we observed month-to-month decreases in IDgenetix test reports, which persisted through year-end. We continue to offer the IDgenetix test and monitor its performance; nevertheless, we anticipate that test report volumes and net revenues will decrease in 2025 and long-term performance of this test remains uncertain.

We may not be able to maintain the quality or expected turnaround times of our products, or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial and management controls, as well as our reporting systems and procedures. The time and resources required to implement these new systems and procedures is uncertain, and failure to complete this in a

timely and efficient manner could adversely affect our operations. If our management is unable to effectively manage our anticipated growth, our expenses may increase more than expected, our revenue could decline or grow more slowly than expected and we may be unable to implement our business strategy. The quality of our products and services may suffer, which could negatively affect our reputation and harm our ability to retain and attract customers.

We have engaged in, and may continue to engage in, strategic transactions, such as the acquisition of businesses, assets, products or technologies, which could be disruptive to our existing operations, divert the attention of our management team and adversely impact our liquidity, cash flows, financial condition and results of operations.

From time to time, we may consider strategic opportunities and engage in transactions such as acquisitions of businesses, assets, products or technologies, as well as technology licenses or investments in complementary businesses. For example, in December 2021 and April 2022, we completed the acquisitions of Cernostics and AltheaDx, respectively. These and any other strategic acquisition transactions may entail numerous operational and financial risks, including:

- delays, difficulties and higher than expected costs associated with integration activities, such as those involving operational processes, regulatory and licensure compliance, personnel and information technology systems;
- difficulties in scaling and growing the operations of acquired businesses in a cost-efficient manner;
- disruption of our existing business operations and diversion of management's time, focus and attention;
- decreases in our liquidity and operating cash flows, increases in our overall operating costs, substantial amounts of amortization expense, increased capital expenditure requirements and non-recurring charges, including possible impairments of acquired assets and losses on the remeasurement of contingent consideration;
- incurrence of substantial debt or dilutive issuances of equity securities, the assumption of additional liabilities, exposure to unknown liabilities and being subject to disputes with former owners of acquired businesses;
- inability to retain key personnel of any acquired businesses; and
- failure to realize any of the anticipated revenues, synergies, efficiencies or other benefits of a transaction within our estimated time frame or at all.

Any acquisition, integration or expansion of our business may cause actual results may differ materially from our plans and expectations. Further, there are inherent execution and business risks associated with managing the integration and growth objectives of more than one acquisition, integration, and growth strategy at the same time and such circumstances may have the effect of heightening the operational and financial risks related to acquisitions noted above and the other risks described in this "Risk Factors" section. For example, we began offering the TissueCypher test following our acquisition of Cernostics and the IDgenetix test following our acquisition of AltheaDx, and we have experienced certain challenges related to those tests. See "—We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy."

For example, we began offering the TissueCypher test following our acquisition of Cernostics and the IDgenetix test following our acquisition of AltheaDx, and we have experienced certain challenges related to those tests. See "—We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy."

We are unable to predict the timing, size or nature of any future transactions, whether they will be completed or financed on favorable terms, if at all, or what the impact of those transactions might be on our financial results, including if such transactions are not effectively and profitably integrated into our business. Our failure to successfully complete the integration of any business that we acquire could have an adverse effect on our prospects, business activities, cash flows, financial condition, results of operations and stock price. Additionally, our ability to successfully integrate, manage and derive financial and other benefits from any acquired business, asset, product or technology cannot be assured given our limited historical experience with such transactions.

Our ability to use net operating loss carryforwards and certain other tax attributes to offset future taxable income and taxes may be subject to limitations.

As of December 31, 2024, we had federal net operating loss ("NOL") carryforwards of approximately $129.4 million, of which $52.9 million will begin to expire in 2031 if not utilized to offset taxable income, and $76.5 million may be carried forward indefinitely. Also, as of December 31, 2024, we had state NOL carryforwards of $86.5 million, which begin to expire in 2028 if not utilized to offset state taxable income.

Under the legislation known as the Tax Cuts and Jobs Act of 2017 ("TCJA"), as modified by the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), federal NOLs generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such NOL carryforwards in a taxable year is limited to 80% of taxable income in such year.

In addition, under Sections 382 and 383 of the Internal Revenue Code, and corresponding provisions of state law, if a corporation undergoes an ''ownership change'' (which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes may be limited. For example, with respect to the NOLs we obtained in our acquisitions of Cernostics and AltheaDx, $36,347,000 of NOLs are expected to expire unused as a result of Section 382 limitations. We have experienced ownership changes in the past and we may also experience additional ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside of our control. If an ownership change occurs and our ability to use our NOL carryforwards is materially limited, it could harm our future operating results by effectively increasing our future tax obligations. In addition, at the state level, there may be periods during which the use of NOL carryforwards is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, in June 2024, California enacted legislation that, with certain exceptions, suspends the use of California net operating losses to offset California income and limits the use of California business tax credits to offset California taxes, for taxable years beginning after 2023 and before 2027.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the TCJA, the CARES Act and the IRA enacted many significant changes to the U.S. tax laws. Further guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to federal tax laws. Future tax reform legislation could have a material impact on the value of our deferred tax assets and could increase our future U.S. tax expense.

Effective January 1, 2022, the TCJA eliminated the option to deduct research and development expenses for tax purposes in the year incurred and requires taxpayers to capitalize and subsequently amortize such expenses over five years for research activities conducted in the United States and over 15 years for research activities conducted outside the United States. Unless the United States Department of the Treasury issues regulations that narrow the application of this provision to a smaller subset of our research and development expenses or the provision is modified or repealed by Congress, it could harm our future operating results by effectively increasing our future tax obligations. The actual impact of this provision will depend on multiple factors, including the amount of research and development expenses we will incur, whether we achieve sufficient income to fully utilize such deductions and whether we conduct our research and development activities inside or outside the United States.

If our information technology systems, or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences.

In the ordinary course of business, we and the third parties with whom we work (such as contractors and consultants) process proprietary, confidential, and sensitive information (including but not limited to intellectual property, proprietary business information and personal data).

Cyber-attacks, malicious internet-based activity, online and offline fraud and other similar activities threaten the confidentiality, integrity and availability of our proprietary, confidential, and sensitive information and information technology systems, and those of the third parties with whom we work. Such threats are prevalent, continue to

increase, and are becoming increasingly difficult to detect. These threats come from a variety of sources, including threat actors, traditional computer “hackers,” organized criminal threat actors, personnel (such as through theft or misuse), hacktivists, sophisticated nation-states, and nation-state-supported actors. Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our goods and services. We and the third parties upon which we rely (such as our contractors and consultants) are vulnerable to a variety of evolving threats including but not limited to service interruptions, system malfunction, natural disasters, terrorism, war, public health crises, telecommunication and electrical failures, malware (including as a result of advanced persistent threat intrusions), malicious code (such as viruses and worms), ransomware, supply chain attacks, credential harvesting, denial-of-service attacks, credential stuffing, personnel misconduct or error, social engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), attacks enhanced or facilitated by AI, and other similar threats. In particular, severe ransomware attacks have become increasingly prevalent and severe and can lead to significant interruptions in our operations, loss of data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments. Future or past business transactions (such as acquisitions or integrations) expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

Remote work has increased risks to our information technology systems and data, as our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

We manage and maintain our applications and information utilizing a combination of on-site systems, managed data centers, and cloud-based data centers. We also have outsourced elements of our operations to third parties, including third-party service providers and technologies to help operate critical business systems to Process proprietary, confidential and sensitive information, and as a result we also manage a number of third parties who have access to our proprietary, confidential and sensitive information including information related to our clinical trials. Our ability to monitor these third parties’ cybersecurity information security practices is limited, and these third parties may not have adequate information security measures in place. While we may be entitled to damages if the third parties with whom we work fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. Additionally, supply-chain attacks have also increased in frequency and severity, and we cannot guarantee that third parties and infrastructure in our supply chain or the supply chains of the third parties with whom we work have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems (including our services) or the third-party information technology systems that support us and our services.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect and remediate vulnerabilities in our information systems (such as our hardware and/or software, including that of third parties upon which we rely). We have not in the past and may not in the future, however, be able to detect and remediate all such vulnerabilities including on a timely basis. Further, we have (and may in the future) experienced delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. Applicable data privacy and security obligations require us, or we may voluntarily choose, to notify relevant stakeholders of certain security incidents, including affected individuals, regulators, customers, and investors. Such disclosures are costly, and the disclosures or failure to comply could lead to adverse consequences.

It may be difficult or costly to detect, investigate, mitigate, contain, and remediate a security incident. Our efforts to do so may not be successful. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and security.

Certain of the previously identified or similar threats have in the past and could in the future cause a disruption or security incident, which could result in unauthorized, unlawful, or accidental loss of, damage to, modification of,

destruction of, alteration of, encryption of, disclosure of, access to, or acquisition of our information or our information technology systems, or those of the third parties upon whom we rely. A security incident could disrupt our ability (and that of the third parties upon whom we rely) to provide our services.

We have in the past and may in the future expend significant resources or modify our business activities (including our clinical research activities) to try to protect against security incidents. Certain data privacy and security obligations require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive information.

Security incidents or perceived security incidents may result in material adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections), additional reporting requirements and/or oversight, restrictions on processing data (including personal data), litigation (including class action claims), indemnification obligations, negative publicity, reputational harm, monetary fund diversions, diversion of management attention, interruptions in our operations, and other harms. Such consequences may disrupt our operations (including our ability to conduct our analyses, provide test results, bill payors or patients, process claims and appeals, provide customer assistance, conduct research and development activities, collect, process, and prepare company financial information, provide information about our products and other patient and physician education and outreach efforts through our website, and manage the administrative aspects of our business), negatively impact our ability to grow our business, and others. For example, we maintain a tumor specimen database comprised of over 60,000 samples. Some of these samples were used to develop and validate DecisionDx-Melanoma, and, of those, some are currently being used to improve upon the test and some will be used in the future. If we were to lose this database, our ability to further validate, improve and therefore maintain and grow sales of DecisionDx-Melanoma could be significantly impaired.

Some of our contracts do not contain limitations of liability, and there can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages. Additionally, while we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or adequately mitigate liabilities or damages with respect to claims, costs, expenses, litigation, fines, penalties, business loss, information loss, regulatory actions or material adverse impacts arising out of our privacy and security practices, processing or security incidents we may experience, or that such coverage will continue to be available on commercially reasonable terms or at all.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Additionally, sensitive information of the Company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

Product or professional liability lawsuits against us could cause us to incur substantial liabilities and could limit our commercialization of our products.

We face an inherent risk of product and professional liability exposure related to our products. The marketing, sale and use of our products could lead to the filing of product liability claims were someone to allege that our products identified or reported inaccurate or incomplete information, or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of or inappropriate reliance upon, the information we provide in the ordinary course of our business activities.

If we cannot successfully defend ourselves against claims that our products caused injury or otherwise failed to function properly, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our current tests, or any tests that we may develop, and the inability to commercialize such tests;
- injury to our reputation and significant negative media attention;
- reluctance of experts willing to conduct our clinical studies;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;

- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or labeling, or marketing or promotional restrictions; and
- loss of revenue.

We currently carry product liability insurance. However, the amount of this insurance may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

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

While we currently accept orders from customers outside of the United States, our historical business strategy has been directed toward customers within the United States. Our long-term business strategy contemplates potential international expansion. Doing business internationally involves a number of risks, including:

- multiple, conflicting and changing laws and regulations such as privacy regulations, tax laws, export and import restrictions, economic sanctions and embargoes, employment laws, regulatory requirements and other governmental approvals, permits and licenses;
- limits in our ability to penetrate international markets if we are not able to perform tests locally;
- logistics and regulations associated with shipping and handling tissue samples, including infrastructure conditions and transportation delays;
- difficulties in staffing and managing foreign operations;
- failure to obtain regulatory approvals for the commercialization of our products in various countries;
- complexities and difficulties in obtaining intellectual property protection and enforcing our intellectual property;
- complexities associated with managing multiple payor reimbursement regimes, government payors, or patient self-pay systems;
- 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 exposure to foreign currency exchange rate fluctuations;
- natural disasters, political and economic instability, including wars, terrorism, and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- regulatory and compliance risks that relate to maintaining accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions, or its anti-bribery provisions.

Additionally, financial markets around the world experienced volatility following the invasion of Ukraine by Russia in February 2022. In response to the invasion, the United States, UK and EU, along with others, imposed significant new sanctions and export controls against Russia, Russian banks and certain Russian individuals and may implement additional sanctions or take further punitive actions in the future. The full economic and social impact of the sanctions imposed on Russia (as well as possible future punitive measures that may be implemented), as well as the counter measures imposed by Russia, in addition to the ongoing military conflict between Ukraine and Russia, which could conceivably expand into the surrounding region, remains uncertain; however, both the conflict and related sanctions have resulted and could continue to result in disruptions to trade, commerce, pricing stability, credit availability, and/or supply chain continuity, in both Europe and globally, and has introduced significant uncertainty into global markets. While we do not operate in Russia or Ukraine, as the adverse effects of this conflict continue to develop and potentially spread, both in Europe and throughout the rest of the world, our business and results of operations may be adversely affected, particularly to the extent this conflict escalates to involve additional countries, further economic sanctions or wider military conflict. Any of these factors could significantly harm our future international expansion and operations and, consequently, our revenue and results of operations.

Requirements associated with being a public company, including those related to our status as an accelerated filer and no longer qualifying as a smaller reporting company, have increased our costs and diverted significant company resources and management attention.

We are subject to the reporting requirements of the Exchange Act and other rules and regulations of the SEC and any securities exchange relating to public companies. Sarbanes-Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring the establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory ‘‘say on pay’’ voting requirements. Stockholder activism, the current political environment, and the high level of government intervention and regulatory reform have led to substantial new regulations and disclosure obligations. For example, during 2022, the SEC adopted new rules covering pay versus performance disclosures, "clawback" policies, and insider trading plans. Future changes in regulations and disclosure obligations may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention from management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

We expect that the rules and regulations applicable to public companies will continue to increase our legal and financial compliance costs and make certain activities more time-consuming and costly. For example, we lost our smaller reporting company status, effective January 1, 2024. Since our Quarterly Report on Form 10-Q for the three months ended March 31, 2024, we have not qualified for the scaled disclosure provisions extended to smaller reporting companies which has further increased the complexity and cost we incur to fulfill our reporting obligations.

If we are unable to comply with these requirements on a timely basis or if the attention of our management and personnel is diverted from other business concerns, it could have a material adverse effect on our business, financial condition and results of operations. The increased costs could reduce our net income or exacerbate our net loss, potentially requiring us to reduce spending in other areas of our business or increase the prices of our products. Additionally, as we expand, it may become more difficult or costly to obtain certain types of insurance, including directors’ and officers’ liability insurance. We may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. These challenges could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees, or as executive officers.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of tissue samples, certain inventory and materials, hazardous materials and wastes. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

Although we maintain workers’ compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business could be adversely impacted by inflation.

In 2021, the rate of inflation in the United States significantly increased until the second half of 2022 when the rate began to subside. In 2023 and 2024, the inflation rate continued to subside but remained higher than rates experience between 2015 and 2020. We continue to experience inflationary pressures, primarily in increased

personnel costs and price increases for certain lab supplies. We anticipate possible inflationary impacts on other cost areas in the future. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long the elevated inflation levels persist and the extent to which the rate of inflation were to further increase, if at all, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents and marketable investment securities may be further diminished, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Further, given the complexities of the reimbursement landscape in which we operate, our payors may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts. As such, the effects of inflation may adversely impact our results of operations, financial condition and cash flows.

Our business could be adversely affected by natural disasters, public health crises and other events beyond our control.

Although we maintain crisis management plans, our business operations are subject to interruption by natural disasters and other events and catastrophes beyond our control, including, but not limited to, earthquakes, floods, fires, tornadoes, hurricanes, power or other utility outages, telecommunications failures and public health crises. Further, the ongoing conflict between Ukraine and Russia, or the fear of similar events, could provoke responses, including government-imposed travel restrictions that could impede the mobility and effectiveness of our sales force, disrupt our operations or those of our suppliers and service providers. The ultimate impact of any of these or similar events is highly uncertain and could have a material adverse impact on our operations.

Risks Related to Ownership of Our Common Stock

The price of our common stock may be volatile or may decline regardless of our operating performance, and you may lose all or part of your investment.

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- our operating performance and the performance of other similar companies;
- our success in marketing and selling our products;
- our ability to achieve guideline inclusion for our products;
- reimbursement determinations by third-party payors, including MACs, and reimbursement rates for our products;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries;
- the level of expenses related to product development and clinical studies for our products;
- our ability to achieve product development goals in the timeframes we announce;
- announcements of clinical study results, regulatory developments, acquisitions, strategic alliances or significant agreements by us or by our competitors;
- the success or failure of our efforts to acquire, license or develop additional tests;
- recruitment or departure of key personnel;
- general economic conditions and market conditions specific to our industry;
- interest rates and the rate of inflation;
- changes in trade and tariff policies;
- the extent and duration of the impacts on our operations of general political and economic conditions, including the Israel-Hamas war, the ongoing conflict between Ukraine and Russia, economic slowdowns, recessions or market corrections, the duration and effects of elevated inflation, rising interest rates and tightening of credit markets resulting from the conflict or other evolving macroeconomic developments;
- trading activity by a limited number of stockholders who together beneficially own a significant percentage of our outstanding common stock;

- the size of our market float; and
- any other factors discussed in this Annual Report on Form 10-K.

For example, on June 5, 2023 our stock price decreased 49% after Novitas published a final LCD that would have impacted Medicare coverage for our DecisionDx-SCC test. In addition, the stock market in general, and diagnostic and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our securities, regardless of our actual operating performance. In the past, stockholders of other companies have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. Shares held by directors, executive officers and other affiliates are subject to volume limitations under Rule 144 under the Securities Act of 1933, as amended (the "Securities Act").

Certain of our stockholders have rights, subject to some conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or our stockholders. We have registered shares of common stock that we have issued and may issue under our employee equity incentive plans. As a result, these shares will be able to be sold freely in the public market upon issuance.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares.

We have broad discretion in the use of working capital and may not use it effectively or in ways that increase our share price.

We cannot specify with any certainty the particular uses of working capital, but we currently expect such uses will include: funding selling and marketing activities, including expansion of our sales force to support the ongoing commercialization of current and future products; research and development related to the continued support of our current products, as well as the development of our product pipeline; and other general corporate purposes, including acquisitions and the costs associated with being a public company. The failure by our management to apply our working capital effectively could adversely affect our business and financial condition. Pending its use, we may invest working capital in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of a simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent

limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas.

We have and may continue to enter into related party transactions that create conflicts of interest, or the appearance of conflicts of interest, which may harm our business and cause our stock price to decline.

We have entered into related party transactions that create conflicts of interest between our interests and the interests of our directors and executive officers. For example, we currently employ three children and a brother-in-law of Derek J. Maetzold, our President and Chief Executive Officer, two children and a son-in-law of Kristen M. Oelschlager, our Chief Operating Officer, and the son of Tobin W. Juvenal, our Chief Commercial Officer, in each case in non-officer positions.

These types of related party arrangements are required to be disclosed in our public filings based on certain criteria. We may engage in other transactions in the future involving our executive officers, directors and their family members and/or entities which they control or are affiliated, which could cause individuals in our management to seek to advance their economic interests or the economic interests of certain related parties above ours. Although we have a written policy on related party transactions that involves independent review and oversight by the audit committee of our board of directors, there can be no assurances that conflicts of interest will not exist, or that we will be able to adequately address or mitigate any actual or perceived conflicts of interest, and stockholders, analysts, proxy advisory firms, the news media and other parties may view these transactions as representing conflicts of interest or as otherwise inappropriate, which may result in negative public perception and reputational harm, and could impair our ability to enter into new customer relationships or attract and retain employees. Potential, perceived and actual conflicts of interest could cause investors to question the independence of our management, the adequacy and effectiveness of our disclosure controls and procedures or the integrity of our corporate governance procedures and compensation practices, which could have a material adverse effect on the trading price of our common stock and our business, financial condition and results of operations.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Based upon shares outstanding as of December 31, 2024, our executive officers, directors and the known holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 34% of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;

- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meetings of stockholders and not be taken by written consent;
- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairperson of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors;
- provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees, arising out of or pursuant to any provision of the Delaware General Corporation Law, our certificate of incorporation or our bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions of our amended and restated certificate of incorporation and amended and restated bylaws will not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and
- provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law 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 our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf; (ii) any action or proceeding asserting a claim of breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (iii) any action or proceeding asserting a claim against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action or proceeding to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws; (v) any action or proceeding as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and (vi) any action asserting a claim against us or any of our directors, officers or other employees that is governed by the internal affairs doctrine, in all cases to the fullest extent permitted by law and subject to the court's having personal jurisdiction over the indispensable parties named as defendants; provided these provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation and amended and restated bylaws provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, subject to and contingent upon a final adjudication in the State of Delaware of the enforceability of such exclusive forum provision. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees and may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy

We have implemented and maintain various information security processes designed to identify, assess and manage material risks from cybersecurity threats to our critical computer networks, third party hosted services, communications systems, hardware and software, and our critical data, including intellectual property, confidential information that is proprietary, strategic or competitive in nature, and data related to our clinical trials and commercial and pipeline tests ("Information Systems and Data").

Our Director of Cyber Security & Infrastructure ("DCSI") oversees our information security function, which in conjunction with our security and engineering operations, Security Operations Center, a third-party managed

security provider, helps identify, assess and manage the Company's cybersecurity threats and risks. This group identifies and assesses risks from cybersecurity threats by monitoring and evaluating our threat environment and the Company's risk profile using various methods including, for example: manual and automated tools; subscribing to and analyzing certain reports of cybersecurity threats and threat actors; conducing scans of our environment; evaluating our and our industry's risk profile and certain threats reported to us; coordinating with law enforcement concerning certain threats; conducting internal and external audits and threat assessments; conducting vulnerability assessments; using external intelligence feeds; and working with a third-party to test our incident response processes.

Depending on the environment, we implement and maintain various technical, physical, and organizational measures, processes, standards and policies designed to manage and mitigate material risks from cybersecurity threats to our Information Systems and Data, including, for example: an incident response and business continuity plan; vulnerability management policy; risk assessments; implementing certain certifications and security standards; encrypting certain of our data; network security controls; segregating certain data; access and physical security controls; asset management, tracking, and disposal; monitoring our systems; employee training; penetration tests; maintaining cybersecurity insurance; and dedicated cybersecurity staff.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall risk management processes. For example, cybersecurity risk is addressed as a component of the Company's enterprise risk management program; our information security function works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business; our senior management evaluates material risks from cybersecurity threats against our overall business objectives and reports to the audit committee of the board of directors, which is primarily responsible for overseeing our risk management processes on behalf of our board of directors.

We use third-party service providers to assist us from time to time to identify, assess, and manage material risks from cybersecurity threats, including for example professional services firms (including legal counsel), threat intelligence service providers, cybersecurity consultants, cybersecurity software and managed service providers, penetration testing firms, and dark web monitoring services.

We use third-party service providers to perform a variety of functions throughout our business, such as application providers and hosting companies. We have vendor management processes to manage cybersecurity risks associated with our use of certain providers. These processes may include reviewing vendors' written security programs and security assessments, conducting security assessment calls with vendor personnel, and imposing contractual obligations related to information security on certain of our vendors. Depending on the nature of the services provided, the sensitivity of the Information Systems and Data at issue, and the identity of the provider, our vendor management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider and impose contractual obligations related to cybersecurity on the provider.

For a description of the risks from cybersecurity threats that may materially affect the Company and how they may do so, see our risk factors under Part 1. Item 1A. Risk Factors in this Annual Report on Form 10-K, including "If our information technology systems, or those of third parties with whom we work, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; loss of customers or sales; and other adverse consequences."

Governance

Our board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The board of directors' audit committee oversees the risk assessment, risk management and internal controls over cyber security matters, as outlined in its committee charter.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our DCSI. Our DCSI has over 20 years of experience as a security professional, has a CISSP certification, and has completed the Carnegie Melon Insider Risk Management Program.

The DCSI is responsible for hiring appropriate personnel, leading enterprise-wide cybersecurity strategy, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel.

Our cybersecurity incident response plan is designed to escalate certain cybersecurity incidents to members of management depending on the circumstances, including Security Management. Security Management works with the Company's incident response team to help the Company mitigate and remediate cybersecurity incidents of

which they are notified. In addition, the Company's incident response plan includes reporting to the audit committee of the board of directors for certain cybersecurity incidents.

The DCSI provides periodic reports to our board of directors, as well as our Chief Operating Officer, Chief Executive Officer and other members of our senior management as appropriate, concerning the Company's significant cybersecurity threats and risk and the processes the Company has implemented to address them. The audit committee also receives various reports, summaries or presentations related to cybersecurity threats, risk and mitigation, and assessment of our cybersecurity program against programs of other organizations.

Item 2. Properties.

We lease approximately 27,000 square feet of commercial office space located in Friendswood, Texas where our corporate headquarters is currently located. This lease commenced in late 2020 under a 60-month term that will expire in November 2025, and provides for a single five-year renewal option which we have not used.

We lease approximately 46,000 square feet of commercial real estate located in Phoenix, Arizona under two agreements with terms expiring in July 2033 and October 2033, respectively. Each contract provides us with two five-year renewal options, none of which have been used. Most of the square footage at these locations is dedicated laboratory space.

We lease approximately 45,000 square feet of commercial real estate located in Pittsburgh, Pennsylvania. This lease commenced in April 2023 under a 10.5-year term, expiring in October 2033, and provides us with a single five-year renewal option which we have not used. A majority of the square footage in this facility is dedicated for laboratory use.

We own 23 acres of land in Friendswood, Texas. We have contracted for the development and construction of an 80,000 square foot commercial office building on this land. Construction is currently underway and is expected to be completed in early 2026 and will be the future location for our corporate headquarters. We intend to lease out approximately 33,000 square feet of office space in our building.

Item 3. Legal Proceedings.

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. Legal proceedings, including litigation, government investigations and enforcement actions could result in material costs, occupy significant management resources and entail civil and criminal penalties, even if we ultimately prevail. On February 1, 2024, we received a subpoena from United States Department of Health and Human Services, Office of Inspector General, seeking documents and information concerning claims submitted for payment under federal healthcare programs. The subpoena requested that we produce documents relating primarily to interactions with medical providers and billing to government-funded healthcare programs for our tests. The time period covered by the subpoena is January 1, 2015 through the date of issuance of the subpoena. We are continuing to cooperate with the government's request and is in the process of responding to the subpoena. We are unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General, or any other governmental authority as a result of the matters related to this subpoena. No claims have been made against us at this time. This inquiry, and any potential resulting claim asserted against us, with or without merit, could be time-consuming, expensive to address and divert management's attention and other resources. These claims also could subject us to significant liability for damages and harm our reputation. Our insurance and indemnities may not cover all claims that may be asserted against us. We are unable to predict the outcome and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information

Our common stock, $0.001 par value per share, trades on the Nasdaq Global Market under the symbol "CSTL".

Holders of Record

As of February 20, 2025, there were approximately 90 stockholders of record of our common stock, which does not include stockholders who hold shares in street name.

Dividend Policy

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on, among other factors, our financial condition, operating results, capital requirements, contractual restrictions, general business conditions and other factors that our board of directors may deem relevant.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from the IPO of Common Stock

On July 29, 2019, we completed the initial public offering of our common stock (our "IPO"), pursuant to which we issued and sold 4,600,000 shares of our common stock, including 600,000 shares associated with the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $16.00 per share.

The offer and sale of all of the shares of our common stock in the IPO were registered under the Securities Act of 1933, as amended (the "Securities Act") pursuant to our Registration Statements on Form S-1, as amended (File Nos. 333-232369 and 333-232796), which were declared or became effective on July 24, 2019.

There has been no material change in our planned use of the net proceeds from the IPO as described in the final prospectus filed with the Securities and Exchange Commission (the "SEC") on July 26, 2019 relating to our Registration Statements on Form S-1 (File Nos. 333-232369 and 333-232796).

Since the effective date of our registration statement through December 31, 2024, we have not used any of the net proceeds from the IPO. Pending such uses, we have invested, and plan to continue to invest, the balance of the net proceeds from the IPO in cash and cash equivalent securities or highly liquid investment securities.

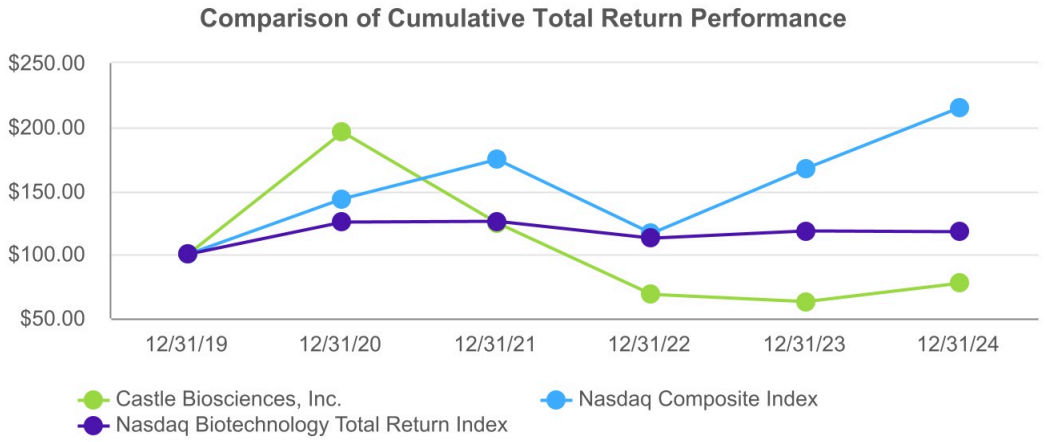
Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

Stock Performance Graph

The following information is not deemed to be "soliciting material" or to be "filed" with the SEC or subject to Regulation 14A or 14C under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or to the liabilities of Section 18 of the Exchange Act, and will not be deemed to be incorporated by reference into any filing under the Securities Act or the Exchange Act, except to the extent we specifically incorporate it by reference into such a filing.

The graph below compares the cumulative total stockholder return of our common stock to the Nasdaq Composite Index and the Nasdaq Biotechnology Total Return Index. The graph and table below assume that $100 was invested on December 31, 2019, and dividends, if any, were reinvested on the date of payment without payment of any commissions. The comparisons in the table are required by the SEC and are not intended to forecast or be indicative of future performance of our common stock.



	12/31/2019	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024
Castle Biosciences, Inc.	$ 100.00	$ 195.37	$ 124.73	$ 68.49	$ 62.79	$ 77.54
Nasdaq Composite Index	$ 100.00	$ 143.64	$ 174.36	$ 116.65	$ 167.30	$ 215.22
Nasdaq Biotechnology Total Return Index	$ 100.00	$ 125.46	$ 125.49	$ 112.78	$ 117.96	$ 117.30

Item 6. [Reserved].

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

You should read the following discussion and analysis of financial condition and results of operations together with our consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K. This discussion and other parts of this Annual Report on Form 10-K contain forward-looking statements that involve risk and uncertainties, such as statements of our plans, objectives, expectations and intentions. Our actual results, performance or achievements could differ materially from any future results, performance or achievements discussed in these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed under the heading "Special Note Regarding Forward-Looking Statements" and "Risk Factors."

The following generally compares our results of operations for the years ended December 31, 2024 and 2023. A detailed discussion comparing our results of operations for the years ended December 31, 2023 and 2022 can be found in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our Annual Report on Form 10-K for the year ended December 31, 2023 filed with the SEC on February 28, 2024.

Overview

Castle Biosciences is a molecular diagnostics company offering innovative test solutions to aid clinicians in the diagnosis and treatment of dermatologic cancers, Barrett's esophagus ("BE"), uveal melanoma ("UM"), and in the treatment of mental health conditions.

Our Test Portfolio

We currently offer five commercially available proprietary multi-analyte assays with algorithmic analysis ("MAAA") tests for use in the fields of dermatology, gastroenterology and ophthalmology. We also offer a proprietary a pharmacogenomic ("PGx") test to guide optimal drug treatment for patients diagnosed with depression, anxiety and other mental health conditions.

Currently, our revenue is primarily generated by our DecisionDx-Melanoma risk stratification test for cutaneous melanoma ("CM") and our DecisionDx-SCC risk stratification test for cutaneous squamous cell carcinoma ("SCC"), which is supplemented by revenue generated from our TissueCypher risk stratification test for BE and our DecisionDx-UM risk stratification test for UM.

All five of our MAAA tests have been granted Advanced Diagnostic Laboratory Test ("ADLT") status by the Centers for Medicare and Medicaid ("CMS") which means each test has demonstrated that (i) when combined with an empirically derived algorithm, it yields a result that predicts the probability a specific individual patient will develop a certain condition or conditions, or will respond to a particular therapy or therapies; and (ii) it provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests. We believe this designation not only demonstrates our focus on developing and validating innovative tests but also enables our Medicare reimbursement rate to be set, over the long term, by the median private payor rate, which we believe provides a fair exchange of value. Further information about Medicare coverage and ADLT status with respect to each of our tests is set forth below.

Test Overview

Our Dermatology Tests

DecisionDx-Melanoma is our proprietary risk stratification gene expression profile ("GEP") test that predicts the risk of metastasis or recurrence, including a positive sentinel lymph node, for patients diagnosed with invasive CM. In a typical year, we estimate approximately 130,000 patients are diagnosed with invasive CM in the United States, representing an estimated U.S. total addressable market ("TAM") of approximately $540 million. We estimate that approximately 50% of patients diagnosed with CM are 65 years of age or older.

DecisionDx-SCC is our proprietary GEP test for use in patients with SCC, with one or more risk factors (also referred to as "high-risk" SCC) that both predicts the risk of metastasis as well as response to adjuvant radiation therapy. We estimate 20% of SCC, or 200,000 annually in the United States, are classified as high risk, representing an estimated U.S. TAM of approximately $820 million.

MyPath Melanoma is our proprietary GEP test for use in patients with a melanocytic lesion and uncertainty related to the malignancy of the lesion. We estimate that approximately 300,000 patients each year present with a diagnostically ambiguous lesion, representing an estimated U.S. TAM of approximately $600 million. We began offering MyPath Melanoma following our acquisition of the Myriad MyPath Laboratory in May 2021 at which point we offered both our MyPath Melanoma test and our DiffDx-Melanoma test under an offering that we referred to as our Diagnostic GEP offering. However, following an internal assessment of the clinical value of offering both tests, we made the decision to suspend the clinical offering of DiffDx-Melanoma in February 2023 and now the focus of this offering is MyPath Melanoma.

Our Gastroenterology Test

TissueCypher is our proprietary risk stratification spatial-omics test designed to predict future development of progression of high-grade dysplasia ("HGD") and/or esophageal cancer in patients with non-dysplastic ("ND"), indefinite dysplasia ("IND") or low-grade dysplasia ("LGD") BE. We estimate a U.S. TAM of approximately $1 billion.

Our Ophthalmology Test

DecisionDx-UM is a proprietary, risk stratification GEP test that predicts the risk of metastasis for patients with UM. We believe DecisionDx-UM is the standard of care in the management of newly diagnosed UM in the majority of ocular oncology practices in the United States. We estimate a U.S. TAM of approximately $10 million.

Our Mental Health Test

IDgenetix is a PGx test that guides personalized mental health medication selection and management for patients with depression, anxiety and other mental health conditions.

Commercial Expansion Efforts

During the year ended December 31, 2023, we expanded our dermatologic and gastrointestinal commercial sales forces through territory and headcount expansions with focus being on our dermatology and gastroenterology teams.

During the year ended December 31, 2024, we further expanded our dermatology and gastroenterology teams. In late 2024, we changed our commercial strategy for our IDgenetix test, shifting resources to inside sales and non-personal promotion.

We will continue to assess market response in determining further commercial expansions and commercial team structure.

Reimbursement

The primary source of revenue for our products is reimbursement from third-party payors, which includes government payors, such as Medicare, and commercial payors, such as insurance companies. Achieving broad coverage and reimbursement of our current products by third-party payors and continued Medicare coverage are key components of our financial success.

We bill third-party payors and patients for the tests we perform. We have received Medicare coverage for our DecisionDx-Melanoma, DecisionDx-SCC, TissueCypher, MyPath Melanoma, DecisionDx-UM and IDgenetix tests which meet certain criteria for Medicare and Medicare Advantage beneficiaries.

The Medicare rates discussed below are prior to giving effect to applicable sequestration in effect from time to time as described in further detail under "Government Regulation and Product Approval—Healthcare Reform" included in Item 1, Business, of this Annual Report on Form 10-K.

DecisionDx-Melanoma

DecisionDx-Melanoma tests are processed from our Phoenix laboratory and since the second quarter of 2022, have been covered under “foundational” local coverage determinations (“LCD” or “LCDs”) finalized by Medicare Administrative Contractors (“MACs”) Palmetto and Noridian.

DecisionDx-Melanoma has met ADLT status, as determined by the CMS, since 2019. Since 2022, the rate for DecisionDx-Melanoma is set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2023 was set using median private payor rate data from January 1, 2021 to June 30, 2021. Our rate for 2022, 2023 and 2024 was $7,193 per test. Our rate for 2025 is $7,193 per test.

DecisionDx-SCC

We issue our DecisionDx-SCC tests from our Pittsburgh and Phoenix labs, with a majority of tests being issued from our Pittsburgh lab. Palmetto’s MolDX program oversees MAAA tests that are reported from our Phoenix laboratory and Noridian is the MAC responsible for administering claims for test reports issued by our Phoenix laboratory.

In the second quarter of 2022, following the completion of a requested medical review and pricing of our DecisionDx-SCC test by Novitas, we obtained a PLA code and began receiving reimbursement from Novitas for DecisionDx-SCC at a rate of $3,873 per test.

On July 4, 2024, Palmetto and Noridian finalized an LCD recommending no coverage for DecisionDx-SCC with an effective date of August 18, 2024. On January 9, 2025, Novitas finalized an oncology biomarker LCD that will become effective on April 24, 2025. If the LCD becomes effective as is, then we would anticipate not receiving Medicare reimbursement for DecisionDx-SCC tests performed on or after April 24, 2025.

DecisionDx-SCC was reimbursed at a rate of $3,873 per test under a Proprietary Laboratory Analyses (“PLA”) code from second quarter of 2022 through June 30, 2023 when CMS determined DecisionDx-SCC meets the criteria for “new ADLT” status. ADLT status determines the process by which the rate is set and is not an indication of Medicare coverage. Effective July 1, 2023 and through March 31, 2024, CMS set the initial period rate equal to the list price of $8,500 per test. Effective April 1, 2024 and through December 31, 2025, the published Clinical Laboratory Fee Schedule (“CLFS”) rate for DecisionDx-SCC will be based on the median private payor rates received between July 1, 2023 and November 30, 2023. We submitted the median private payor data to CMS during the data reporting period in December 2023. Effective April 1, 2024, the updated CLFS rate will continue at $8,500 through December 31, 2025. Future rates will be set annually based upon the median private payor rate for the first half of the second preceding calendar year.

TissueCypher

Most of our TissueCypher tests are processed in our Pittsburgh laboratory under the Medicare jurisdiction managed by Novitas.

On March 24, 2022, CMS determined that TissueCypher meets the criteria for "new ADLT" status. ADLT status exempts TissueCypher from what is called the "14-day rule," which simplifies the billing process for Medicare patients. Effective January 1, 2023, the published CLFS rate for TissueCypher was set at $4,950 per test, which will remain effective through December 31, 2024. This rate is based on the median private payor rates received between April 1, 2022 and August 31, 2022. Thereafter, the rate will be set annually based upon the median private payor rate for the first half of the second preceding calendar year. Our 2025 rate will continue to be $4,950 per test based on the median private payor rate data from January 1, 2023 to June 30, 2023.

MyPath Melanoma and DiffDx-Melanoma

MyPath Melanoma was covered under a test-specific LCD policy through Noridian that became effective in June 2019. Effective August 6, 2023, Palmetto and Noridian issued LCDs that converted the test-specific MyPath Melanoma LCD to a "foundational" LCD and provided coverage for both MyPath Melanoma and DiffDx-Melanoma.

MyPath Melanoma was approved as a "new ADLT" in September 2019. The rate for our MyPath Melanoma test is set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2024 was set using median private payor rate data from January 1, 2022 to June 30, 2022. Our rates for 2022, 2023, and 2024 were $1,950 per test, $1,755 per test, and $1,950 per test, respectively. Our rate for 2025 is $1,950 per test.

In the second quarter of 2022, we obtained a PLA code for DiffDx-Melanoma. In 2023, DiffDx-Melanoma went through the CMS gapfill process which concluded in September 2023 with CMS posting a final MAC-specific gapfill rate of $1,950 per test. Our rate for 2024 was $1,950 per test and will continue to be $1,950 per test in 2025.

Diagnostic GEP Offering

Our Diagnostic GEP offering included MyPath Melanoma and DiffDx-Melanoma. We began offering MyPath Melanoma following our acquisition of the Myriad MyPath Laboratory on May 28, 2021. Our internal data indicates that we have improved the technical performance of MyPath Melanoma and that it is comparable to the technical performance of DiffDx-Melanoma. As such, following an internal assessment of the clinical value of offering both tests, we made the decision to suspend the clinical offering of DiffDx-Melanoma in February 2023.

DecisionDx-UM

DecisionDx-UM tests are processed from our Phoenix laboratory and are covered under LCDs finalized by MAC administrators Palmetto and Noridian in July 2017.

DecisionDx-UM has met the criteria of "existing advanced diagnostic laboratory test" status, also referred to as "existing ADLT" status, as determined by the CMS, since May 2019. Our rate is set annually based upon the median private payor rate for the first half of the second preceding calendar year. For example, the rate for 2024 was set using median private payor rate data from January 1, 2022 to June 30, 2022. Our rate for 2022, 2023 and 2024 was $7,776 per test. Our 2025 rate is $7,776 per test.

IDgenetix

IDgenetix is currently covered under a Noridian LCD policy and accompanying billing and coding article developed by MolDX.

Our IDgenetix multi-gene panel was reimbursed by Medicare at approximately $1,500 per test from April 2022 through February 2023, when MolDX notified us that as part of its annual Current Procedural Terminology ("CPT") code updates, IDgenetix should shift billing to a different generic gene sequencing CPT code (the "New CPT Code") and continue using the IDgenetix Z-Code beginning in March 2023. The New CPT Code was set at $917 per test while the test went through CMS's Gapfill pricing process. We believed the new CPT Code, in conjunction with the IDgenetix Z-Code, did not describe all of the components of the IDgenetix test and thus, was not appropriate for IDgenetix. We subsequently obtained a test-specific PLA CPT code which became effective October 1, 2023. In November 2023, CMS posted its final CLFS determination which crosswalks our PLA CPT code to an existing PLA code at a rate of $1,336 per test effective January 1, 2024. Our reimbursement rate for 2024 was $1,336 per test, and our rate will continue to be $1,336 per test in 2025.

Government Regulation and Oversight of Laboratory Developed Tests

On May 6, 2024, the U.S. Food and Drug Administration ("FDA") published a final rule on the regulation of LDTs which amends the FDA's regulations to make explicit that LDT's are devices under the FD&C Act. The FDA issued a policy to phaseout, over the course of four years, its general enforcement discretion approach to LDTs and also issued targeted enforcement discretion policies for certain categories of LDTs. The FDA is continuing enforcement discretion for currently marketed tests offered as LDTs (that were first marketed before May 6, 2024) that are approved by NYSDOH. Our proprietary tests, outlined above, are all NYSDOH approved. We believe this final ruling will have no material impact on our existing test offerings given all of our tests were marketed before May 6, 2024.

Delivered Test Reports

The number of test reports we deliver is a key indicator that we use to assess our business. A test report is generated when we receive a sample in our laboratory, and then the relevant test information is entered into our Laboratory Information Management System, the laboratory portion of the test is performed, including proprietary algorithmic analysis of the combined biomarkers and a report is then delivered to the clinician who ordered the test.

The number of test reports delivered by us during the years ended December 31, 2024 and 2023 are presented in the table below:

	Proprietary Dermatologic GEP Tests							
	DecisionDx-Melanoma	DecisionDx-SCC	Diagnostic GEP offering [1]	Dermatologic Total	DecisionDx-UM	TissueCypher[2]	IDgenetix[3]	Grand Total
Q1 2024	8,384	3,577	998	12,959	422	3,429	4,078	20,888
Q2 2024	9,585	4,277	1,099	14,961	456	4,782	4,903	25,102
Q3 2024	9,367	4,195	933	14,495	397	6,073	5,045	26,010
Q4 2024	8,672	4,299	879	13,850	424	6,672	3,125	24,071
For the year ended December 31, 2024	36,008	16,348	3,909	56,265	1,699	20,956	17,151	96,071
Q1 2023	7,583	2,411	980	10,974	409	1,383	2,150	14,916
Q2 2023	8,597	2,681	953	12,231	461	1,447	2,681	16,820
Q3 2023	8,559	2,820	1,011	12,390	399	2,829	2,791	18,409
Q4 2023	8,591	3,530	1,018	13,139	405	3,441	3,299	20,284
For the year ended December 31, 2023	33,330	11,442	3,962	48,734	1,674	9,100	10,921	70,429

(1) Our GEP offering included our MyPath Melanoma and DiffDx-Melanoma until we suspended our DiffDx-Melanoma in February 2023. We continue to offer our MyPath Melanoma test.

(2) We temporarily paused accepting additional orders in July 2023 and resumed accepting new orders in a phased approach in September 2023. We completed processing of our pre-existing backlog orders in October 2023 and continue to accept new orders as of December 31, 2023.

(3) We began offering the IDgenetix test in April 2022, following our acquisition of AltheaDx.

For the years ended December 31, 2024 and 2023, our dermatologic test report volume increased by 15.5% and 30.5%, respectively, largely driven by continued growth from our DecisionDx-Melanoma and DecisionDx-SCC tests. Increases from our other tests (non-dermatologic), primarily IDgenetix and TissueCypher, also contributed to the overall volume increase. For a discussion of how we recognize revenue derived from our tests, refer to "Net Revenues" under "Components of Results of Operations" below.

In August 2024, we amended our Pittsburgh commercial real estate lease to add 23,821 square feet to our existing facilities, most of which will be used as dedicated lab space for processing our TissueCypher test. As of December 31, 2024, substantially all leasehold improvements for this added space were complete and the added

lab space was ready for use. We expect the additional space will allow us to continue developing our business through our TissueCypher product line.

For our DecisionDx-SCC product line, we continue to see opportunities for leverage, where many of the clinicians ordering our DecisionDx-Melanoma are the same clinicians who order our DecisionDx-SCC test. For both years ended December 31, 2024 and 2023, approximately 78% of all clinicians ordering DecisionDx-SCC had also ordered our DecisionDx-Melanoma test during that same period.

Information About Certain Metrics

The following provides additional information about certain metrics we have disclosed in this Management's Discussion and Analysis of Financial Condition and Results of Operations.

Test Reports Delivered

Test reports delivered represent the number of completed test reports delivered by us during the reporting period indicated. The period in which a test report is delivered does not necessarily correspond with the period in which the related revenue, if any, is recognized, due to the timing and amount of adjustments for variable consideration under Accounting Standards Codification ("ASC") Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). We use this metric to evaluate the growth in adoption of our tests and to measure against our internal performance objectives. We believe this metric is useful to investors in evaluating the volume of our business activity from period-to-period that may not be discernible from our reported revenues under ASC 606.

Other Events

Impact of Macroeconomic Conditions

Macroeconomic conditions, including uncertainties associated with the Israel-Hamas war, the ongoing conflict between Ukraine and Russia, economic slowdowns, public health crises, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, liquidity concerns at, and failures of, banks and other financial institutions or other disruptions in the banking system or financing markets, higher interest rates and financial and credit market fluctuations, volatility in the capital markets or other evolving macroeconomic developments, continue to have direct and indirect impacts on our business and could in the future materially impact our results of operations and financial condition. We continue to actively monitor the impact of these macroeconomic factors on our results of operations, financial condition and cash flows. The extent of the impact of these factors on our operational performance and financial condition, including our ability to execute our business strategies and initiatives in the expected timeframe, will depend on future developments, which are uncertain and cannot be predicted; however, any continued or renewed disruption resulting from these factors could negatively impact our business.

Our Financial Results

Our net income (loss) may fluctuate significantly from period to period, depending on the timing of our planned development activities, the growth of our sales and marketing activities and the timing of revenue recognition under ASC 606. We expect our expenses will increase substantially over time as we:

- execute clinical studies to generate evidence supporting our current and future product candidates;
- execute our commercialization strategy for our current and future commercial products;
- continue our ongoing and planned development of new products in our pipeline;
- seek to discover and develop additional product candidates;
- hire additional scientific and research and development staff;
- add additional operational, financial and management information systems and personnel; and
- make additional capital expenditures to support business growth and sustain existing operations.

Factors Affecting Our Performance

We believe there are several important factors that have impacted, and that we expect will continue to impact, our operating performance and results of operations, including:

- **Report volume.** We believe that the number of reports we deliver to clinicians is an important indicator of the growth of adoption among the healthcare provider community. Our revenue and costs are affected by the volume of testing and mix of customers. Our performance depends on our ability to retain and broaden

adoption with existing prescribing clinicians, as well as attract new clinicians. Our report volume could be negatively impacted by developments related to evolving macroeconomic developments, as discussed above.

- **Reimbursement.** We believe that expanding reimbursement is an important indicator of the value of our products. Payors require extensive evidence of clinical utility, clinical validity, patient outcomes and health economic benefits in order to provide reimbursement for diagnostic products. Our revenue depends on our ability to demonstrate the value of our products to these payors.
- **Gross margin.** We believe that our gross margin is an important indicator of the operating performance of our business. Higher gross margins reflect the average selling price of our tests, as well as the operating efficiency of our laboratory operations.
- **Expansion of our sales force and marketing programs.** We believe the expansion of our direct sales force and marketing organization to educate clinicians and pathologists on the value of our molecular testing products will significantly impact our performance.
- **Integrating acquisitions.** Revenue growth, operational results and advances to our business strategy depend on our ability to integrate any acquisitions into our existing business and effectively scale their operations. The integration of acquired assets may impact our revenue growth, increase the cost of operations or may require management resources that otherwise would be available for ongoing development of our existing business.
- **New product development.** A significant aspect of our business is our investment in research and development activities, including activities related to the development of new products. In addition to the development of new product candidates, we believe these studies are critical to gaining clinician adoption of new products and driving favorable coverage decisions by payors for such products.

Components of the Results of Operations

Net Revenues

We generate revenues from the sale of our products. Currently, our revenues are primarily derived from the sale of DecisionDx-Melanoma, DecisionDx-SCC, TissueCypher and DecisionDx-UM. We bill third-party payors and patients for the tests we perform.

Under ASC 606, we recognize revenue at the amount we expect to be entitled, subject to a constraint for variable consideration, in the period in which our tests are delivered to the treating clinicians. We have determined that our contracts contain variable consideration under ASC 606 because the amounts paid by third-party payors may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration is recognized only to the extent it is probable that a significant reversal of revenue will not occur in future periods when the uncertainties are resolved. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Variable consideration for Medicare claims that are not covered by Medicare, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e.g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. For these fully constrained claims, we generally recognize revenue in the period the uncertainty is favorably resolved, if at all. Due to potential future changes in Medicare coverage policies and appeal cycles, insurance coverage policies, contractual rates and other trends in the reimbursement of our tests, our revenues may fluctuate significantly from period to period. Our ability to recognize revenue for a test is dependent on the development of reimbursement experience and obtaining coverage decisions. For tests with limited reimbursement experience or no coverage, we recognize revenues on the basis of actual cash collections.

Our ability to increase our revenues will depend on our ability to further penetrate our target markets, and, in particular, generate sales through our direct sales force, maintain Medicare coverage for our currently marketed products, develop and commercialize additional tests, including through acquisitions, obtain reimbursement from additional third-party payors and increase our reimbursement rate for tests performed.

Cost of Sales (exclusive of amortization of acquired intangible assets)

The components of our cost of sales are material and service costs associated with testing samples, personnel costs (including salaries, bonuses, benefits and stock-based compensation expense), electronic medical record set up costs, order and delivery systems, shipping charges to transport samples, third-party test fees, and allocated overhead including rent, information technology costs, equipment and facilities depreciation and utilities. Costs

associated with testing samples are recorded when the test is processed regardless of whether and when revenues are recognized with respect to that test. As a result, our cost of sales as a percentage of revenues may vary significantly from period to period because we do not recognize all revenues in the period in which the associated costs are incurred. We expect cost of sales in absolute dollars to increase as the number of tests we perform increases. Additionally, we expect cost of sales to increase prior to our launching of new tests, or prior to our initiating significant commercial expansion efforts, as we ready our operations to support anticipated business growth. For example, prior to opening our new Pittsburgh facilities during the second quarter of 2023, we incurred additional rent expense as we readied the space for future use.

Gross margin and gross margin percentage are key indicators we use to assess our business. See the table in "—Results of Operations—Comparison of the years ended December 31, 2024 and 2023" for details.

Research and Development

Research and development expenses include costs incurred to develop our tests, collect clinical samples and conduct clinical studies to develop and support our products. These costs consist of personnel costs (including salaries, bonuses, benefits and stock-based compensation expense), prototype materials, laboratory supplies, consulting costs, regulatory costs, electronic medical records set up costs, costs associated with setting up and conducting clinical studies and allocated overhead, including rent, information technology, equipment depreciation and utilities. We expense all research and development costs in the periods in which they are incurred. We expect our research and development expenses to increase in absolute dollars as we continue to invest in research and development activities related to developing enhanced and new products.

We expect to use a portion of our cash and cash equivalents and marketable investment securities to further support and accelerate our ongoing and future clinical studies and pipeline initiatives.

Selling, General and Administrative

Selling, general and administrative ("SG&A") expenses include executive, selling and marketing, legal, finance and accounting, human resources and billing functions. These expenses consist of personnel costs (including salaries, bonuses, benefits and stock-based compensation expense), direct marketing expenses, audit and legal expenses, consulting costs, payor outreach programs and allocated overhead, including rent, information technology, equipment depreciation, and utilities. Other administrative and professional services expenses within SG&A are expected to increase with the scale of our business, but selling and marketing-related expenses are expected to increase significantly, consistent with our growth strategy.

Amortization of Acquired Intangible Assets

Amortization of acquired intangible assets is primarily associated with developed technology obtained through acquisitions, such as our acquisitions of Cernostics in December 2021 and AltheaDx in April 2022.

Interest Income

Interest income consists primarily of earnings on cash and cash equivalents, primarily money market funds, and our short-term U.S. government obligations are a component of our marketable investment securities.

Change in Fair Value of Trading Securities

Change in fair value of trading securities is primarily attributable to unrealized gains and losses on our equity securities which we present as marketable investment securities.

Interest Expense

Interest expense is primarily attributable to long term debt and finance leases.

Income Tax Expense

Income tax expense consists primarily of income taxes related to federal and state jurisdictions in which we conduct business. We maintain a full valuation allowance for deferred tax assets including operating loss carryforwards and research and development credits and other tax credits. Our consolidated financial statements do not reflect any federal or state income tax benefits attributable to the pre-tax losses we have incurred, due to the uncertainty of realizing a benefit from those items. As of December 31, 2024, we had federal NOL carryforwards of $129.4 million, of which $52.9 million will begin to expire in 2031 if not utilized to offset federal taxable income, and $76.5 million may be carried forward indefinitely. Also, as of December 31, 2024, we also had state NOL carryforwards of $86.5 million, which begin to expire in 2028 if not utilized to offset state taxable income.

Results of Operations

Comparison of the Years Ended December 31, 2024 and 2023

The following table summarizes our results of operations for the periods indicated (in thousands, except percentages):

	Years Ended December 31,			
	2024	2023	Change	
NET REVENUES	$ 332,069	$ 219,788	$ 112,281	51.1 %
OPERATING EXPENSES AND OTHER OPERATING INCOME				
Cost of sales (exclusive of amortization of acquired intangible assets)	60,205	44,982	15,223	33.8 %
Research and development	52,041	53,618	(1,577)	(2.9)%
Selling, general and administrative	200,047	180,152	19,895	11.0 %
Amortization of acquired intangible assets	11,106	9,013	2,093	23.2 %
Total operating expenses, net	323,399	287,765	35,634	12.4 %
Operating income (loss)	8,670	(67,977)	76,647	112.8 %
Interest income	12,916	10,623	2,293	21.6 %
Changes in fair value of trading securities	555	—	555	NA
Interest expense	(577)	(11)	(566)	NM
Income (loss) before income taxes	21,564	(57,365)	78,929	137.6 %
Income tax expense	3,319	101	3,218	NM
Net income (loss)	$ 18,245	$ (57,466)	$ 75,711	131.7 %

(1) NA = Not applicable
(2) NM = Not meaningful

The following table indicates the amount of stock-based compensation expense (non-cash) reflected in the line items above (in thousands):

	Years Ended December 31,		
	2024	2023	Change
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 5,529	$ 4,938	$ 591
Research and development	9,598	10,119	(521)
Selling, general and administrative	35,193	36,162	(969)
Total stock-based compensation expense	$ 50,320	$ 51,219	$ (899)

The following table provides a disaggregation of net revenues by type (in thousands):

	Years Ended December 31,		
	2024	2023	Change
Dermatologic[1]	$ 256,996	$ 183,375	$ 73,621
Non-Dermatologic[2]	75,073	36,413	38,660
Total net revenues	$ 332,069	$ 219,788	$ 112,281

(1) Consists of DecisionDx-Melanoma, DecisionDx-SCC and our Diagnostic Gene Expression Profile offering (MyPath Melanoma and DiffDx-Melanoma).
(2) Consists of TissueCypher, DecisionDx-UM and IDgenetix.

The following table presents the calculation of gross margin (in thousands, except percentages):

	Years Ended December 31,		
	2024	2023	Change
Net revenues	$ 332,069	$ 219,788	$ 112,281
Less: Cost of sales (exclusive of amortization of acquired intangible assets)	60,205	44,982	15,223
Less: Amortization of acquired intangible assets	11,106	9,013	2,093
Gross margin	$ 260,758	$ 165,793	$ 94,965
Gross margin percentage	78.5 %	75.4 %	3.1 %

Net Revenues

Net revenues for the year ended December 31, 2024 increased by $112.3 million, or 51.1%, to $332.1 million compared to the year ended December 31, 2023 due to a $73.6 million increase in revenue from our dermatologic tests and a $38.7 million increase in revenue from our non-dermatologic tests.

The $73.6 million increase in net revenues for our dermatologic tests was primarily attributable to our DecisionDx-SCC test, which was due to higher test report volumes and a higher realized average selling price (“ASP”), as well as our DecisionDx-Melanoma test which had higher test report volumes and a slightly higher realized ASP. For the year ended December 31, 2024 compared to the year ended December 31, 2023, test report volumes for our DecisionDx-SCC and DecisionDx-Melanoma tests increased by 42.9% and 8.0%, respectively. Increases in realized ASP for our DecisionDx-SCC test were primarily attributable to receiving Medicare reimbursement at a higher rate beginning in July 2023.

The $38.7 million increase in net revenues from our non-dermatologic tests was largely attributable to a 130.3% increase in test report volumes for our TissueCypher test, and, to a lesser extent, to our IDgenetix test which also had higher test report volumes. Increases in our TissueCypher test report volumes reflect growth through our sales force efforts. Net revenue from our non-dermatologic tests as a percentage of total net revenue increased from 16.6% for the year ended December 31, 2023 to 22.6% for the year ended December 31, 2024.

Cost of Sales (exclusive of amortization of acquired intangible assets)

Cost of sales (exclusive of amortization of acquired intangible assets) for the year ended December 31, 2024 increased by $15.2 million, or 33.8%, compared to the year ended December 31, 2023, primarily due to higher personnel costs and higher expense for supplies and depreciation. Increases in personnel costs reflect higher headcount to support business growth in response to growing test report volumes, commencement operations at our new Pittsburgh laboratory in the second quarter of 2023, as well as merit and annual inflationary wage adjustment for existing employees. Higher expense for supplies and lab services also reflects higher test report volumes.

Due to the nature of our business, a significant portion of our cost of sales expenses represents fixed costs associated with our testing operations. Accordingly, our cost of sales expense will not necessarily increase or decrease commensurately with the change in net revenues from period to period. We expect our cost of sales expenses (exclusive of amortization of acquired intangible assets) to continue to increase in future periods as we hire additional laboratory personnel and related resources to support expected operational growth and higher test volumes.

Gross Margin

Our gross margin percentage was 78.5% for the year ended December 31, 2024, compared to 75.4% the same period in 2023. The increase was primarily due to higher revenues, partially offset by higher personnel costs, higher expense for supplies and depreciation and higher expense incurred through our expanded laboratory capacity and higher test report volumes.

Research and Development

Research and development expenses decreased by $1.6 million, or 2.9%, for the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily reflecting lower clinical studies costs, lower organizational development costs, and lower expense for laboratory supplies, partially offset by higher personnel costs.

We expect to continue incurring research and development expenses through our continued investments in our ongoing pipeline initiatives and as we seek opportunities to build evidentiary support and new tests where commercial opportunities exist.

Selling, General and Administrative

The following table provides a breakdown of SG&A expenses (in thousands):

	Years Ended December 31,		
	2024	2023	Change
Sales and marketing	$ 123,467	$ 113,657	$ 9,810
General and administrative	76,580	66,495	10,085
Total selling, general and administrative expense	$ 200,047	$ 180,152	$ 19,895

Sales and marketing expenses increased by $9.8 million, or 8.6%, for the year ended December 31, 2024 compared to the year ended December 31, 2023. The increase is primarily due to higher personnel costs, higher sales related travel expense, and higher incurred organizational and business development activities. Increases in personnel costs reflect a higher headcount as well as merit and annual inflationary wage adjustment for existing employees. The higher test report volumes are a result of our continued investments in human capital for our sales organization. Stock based compensation expense included in sales and marketing expense was $17.3 million for the year ended December 31, 2024, compared to $18.3 million for the year ended December 31, 2023.

General and administrative expenses increased by $10.1 million, or 15.2%, for the year ended December 31, 2024, compared to the year ended December 31, 2023. The increase is primarily due to higher personnel costs, professional fees and information technology-related cost expenses. Increases in personnel costs reflect headcount expansions in our administrative support functions as well as merit and annual inflationary wage adjustment for existing employees. Stock-based compensation expense included in general and administrative expense was $17.8 million for the year ended December 31, 2024, compared to $17.9 million for the year ended December 31, 2023.

Amortization of Acquired Intangible Assets

Amortization expense increased by approximately $2.1 million for the year ended December 31, 2024, compared to the year ended December 31, 2023, due primarily to our revision of the estimated useful life of our IDgenetix developed technology intangible assets in December 2024, where we determined the estimated remaining useful life was 13 months, with the useful life now expected to end on December 31, 2025. We expect amortization expense will increase by approximately $24.3 million for the year ended December 31, 2025 due to this change in estimate.

Interest Income

Interest income increased by $2.3 million for the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily as a result of higher balances held in marketable investment securities.

Changes in Fair Value of Trading Securities

The change in fair value of trading securities increased by $0.6 million for the year ended December 31, 2024, compared to the year ended December 31, 2023, and was entirely associated with our investments in equity securities in October 2024 where we had no such investments during the comparative period.

Interest Expense

Interest expense increased by $0.6 million for the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily due to interest incurred on our long-term debt where we had no debt outstanding during the comparative period.

Income Tax Expense

Income tax expense increased by $3.2 million for the year ended December 31, 2024, compared to the year ended December 31, 2023, primarily as a result of state income taxes and the realization of pre-tax income during the year ended December 31, 2024 and a net operating loss in the year ended December 31, 2023.

Stock-Based Compensation Expense

Stock-based compensation expense, which is allocated among cost of sales, research and development expense and SG&A expense, totaled $50.3 million for the year ended December 31, 2024 compared to $51.2 million for the

year ended December 31, 2023. We expect material increases in stock-based compensation expense in future periods, attributable to both existing awards outstanding and anticipated additional grants to our current and future employees. We had 761 employees as of December 31, 2024, compared to 610 as of December 31, 2023. As of December 31, 2024, total unrecognized stock-based compensation cost related to outstanding awards was $71.1 million, which is expected to be recognized over a weighted-average period of 2.2 years.

Liquidity and Capital Resources

Sources of Liquidity

Our principal sources of liquidity are our cash and cash equivalents, marketable investment securities, and cash generated from the sale of our products and our line-of-credit under the 2024 LSA. All of our marketable investment securities are considered investment grade, are readily available for use in current operations and have contractual maturities of one year or less. As of December 31, 2024 and 2023, we had marketable investment securities of $173.4 million and $144.3 million, respectively, and cash and cash equivalents of $119.7 million and $98.8 million, respectively. Additionally, as of December 31, 2024, we had a $25.0 million credit line available under the 2024 LSA.

Our liquidity has been primarily derived from the revenue generated from the sale of our products, and proceeds from our IPO in July 2019 and our follow-on public offerings of common stock in June and December of 2020. We believe that our existing cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products will be sufficient to fund our operations for at least the next 12 months. However, we have based these estimates on assumptions that may prove to be wrong, and could result in us depleting our capital resources sooner than expected.

As mentioned above, we expect to use a portion of our cash and cash equivalents and marketable investment securities to further support and accelerate our research and development activities, including the clinical studies noted above in "—Components of the Results of Operations—Research and Development."

Material Cash Requirements

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, clinical research and development services, laboratory operations, equipment and related supplies, legal and other regulatory expenses, general administrative costs and, from time to time, expansion of our laboratory and office facilities in support of our growth, such as the construction of our future corporate headquarters. We anticipate that a substantial portion of our cash requirements in the foreseeable future will relate to the further commercialization of our currently marketed products, the development of our future product candidates in our pipeline and the potential commercialization of these pipeline products, should their development be successful and the construction of our future corporate headquarters.

In July 2023, we entered into a definitive agreement to purchase a plot of land located in Friendswood, Texas for a purchase price of $7.6 million, subject to certain adjustments, for the purpose of developing a commercial office building where our future corporate headquarters will be located. In February 2024, we closed on the purchase of the land for cash consideration of $7.2 million. The development project will include a four-story building, which will encompass approximately 80,000 square feet of Class A office space. Construction began in May 2024 and is expected to continue through early 2026, at which time the building is expected to be ready for occupancy and use. Over the duration of this project, we expect to make significant capital expenditures in the form of payments to the developer under a percentage of completion basis. As of December 31, 2024, the development project is expected to cost a total of approximately $42.3 million. During the year ended December 31, 2024, we made $9.3 million in capital expenditures for this development project. We intend to use the proceeds from the 2024 Term Loan (as defined below), the 2024 Credit Line (as defined below) and our existing cash and cash equivalents to pay for this project.

Since our inception, we have generally incurred significant losses and negative operating cash flows, and we have relied heavily on proceeds from our financing activities to fund capital expenditures, business expansion campaigns, and to offset operating deficits. For the year ended December 31, 2024, we recognized net income of $18.2 million and had positive operating cash flow of $64.9 million, though we may be unable to sustain profitability and positive cash flows in future periods. Collections on Medicare claims for our DecisionDx-SCC test represented a significant portion of our 2024 operating cash flows. We will lose Medicare coverage for our DecisionDx-SCC test in April 2025 and decreases in revenues and cash inflows from this test are expected to follow. Our ability to maintain profitability will heavily depend on us maintaining Medicare coverage for our currently marketed products, on the successful commercialization of the products we plan to launch in the future, and our ability to manage operating expenses. We expect to incur additional expenses in the future as we invest in the commercialization of our existing products and the development and commercialization of our current pipeline products and future product candidates. We

believe that our existing cash and cash equivalents, marketable investment securities and anticipated cash generated from the sale of our commercial products will be sufficient to fund our operations for at least the next 12 months. We believe we will meet longer-term expected cash requirements and obligations through a combination of existing cash and cash equivalents, marketable investment securities and anticipated cash generated from sales of our products and issuances of equity securities or debt offerings. However, we have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. There are numerous risks and uncertainties associated with developing genomic tests, including, among others, the uncertainty of:

- successful commencement and completion of clinical study protocols;
- successful identification and acquisition of tissue samples;
- the development and validation of genomic classifiers; and
- acceptance of new genomic tests by clinicians, patients and third-party payors including competitor actions.

Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate our exact working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of, many factors, including those listed above as well as those listed in Part I, Item 1A., “Risk Factors” in this Annual Report on Form 10-K and in our other filings with the SEC.

In the event additional funding is required, we expect that we would use a combination of equity and debt financings, which may not be available to us when needed, on terms that we deem to be favorable or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures or declaring dividends. Any disruptions to, or volatility in, the credit and financial markets or any deterioration in overall economic conditions may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we are unable to raise additional funds through debt or equity financing or other arrangements when needed, we may be required to delay, limit, reduce or terminate our product discovery and development activities or future commercialization efforts.

Long-Term Debt

We had no debt as of December 31, 2023. Our long-term debt as of December 31, 2024 is presented in the table below (in thousands):

	As of December 31, 2024
Term debt	$ 10,200
Unamortized discount	(177)
Less: Current portion of long-term debt	(278)
Total long-term debt	$ 9,745

2024 Loan and Security Agreement

On March 26, 2024 (the ‘‘Closing Date’’), we entered into the 2024 LSA, by and between the Company, its wholly owned subsidiary, Castle Narnia Real Estate Holding 1, LLC and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (the “Lender’’). The 2024 LSA provides for (i) on the Closing Date, $10.0 million aggregate principal amount of Term Loans (the “2024 Term Loan,” as more fully discussed in the ‘‘2024 Term Loan’’ section below), and (ii) from the Closing Date until March 31, 2025, an additional line of credit of $25.0 million with the same interest rate and maturity as the term debt available (the “2024 Credit Line,” as more fully discussed in ‘‘2024 Credit Line’’ below) at our option.

The obligations under the 2024 LSA are secured by substantially all of our assets, excluding intellectual property, the real property held by the Company, and are subject to certain other exceptions and limitations. We have the right to prepay the 2024 LSA in whole, subject to a prepayment fee of approximately 1.50% if paid prior to March 26, 2026. Amounts repaid under the 2024 LSA may not be reborrowed.

In addition, the 2024 LSA contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a

material adverse change, we could be liable for immediate repayment of all obligations under the 2024 LSA. Should we seek to amend the terms of the 2024 LSA, the consent of the Lender would be required. As of December 31, 2024, we were in compliance with these covenants.

The 2024 LSA bears interest at a floating rate equal to the greater of (a) the WSJ Prime Rate plus 0.25% or (b) 6.00% per annum. The Term Loans are interest only from the Closing Date through November 30, 2025, which may be extended at our option through November 30, 2026 as long as no event of default under the 2024 LSA has occurred. After the end of the interest only period, we are required to pay equal monthly installments of principal through the maturity date of November 1, 2028.

We are also obligated to make an additional final payment of 2.00% of the aggregate original principal amounts of Term Loans advanced by the Lender, due at the earlier of the maturity date or date the Term Loans are repaid in full.

2024 Term Loan

On the Closing Date, we drew $10.0 million in Term Loans under the terms and provisions of the 2024 LSA. We are obligated to make a final payment of $0.2 million under the terms of the 2024 LSA final payment provisions. A discount on debt equal to this obligation was recorded on the draw date and is being amortized as additional interest expense using the effective interest method over the term of the debt. As of December 31, 2024, the effective interest rate for all outstanding debt under the 2024 Term Loan was 8.19%.

2024 Credit Line

We have a $25.0 million line of credit under the terms and provisions of the 2024 LSA available from the Closing Date until March 31, 2025. Amounts repaid under the 2024 Credit Line may not be reborrowed. As of December 31, 2024, no draws had been made on the 2024 Credit Line.

Leases

We have entered into various operating and finance leases, which are primarily associated with our laboratory facilities and office space.

Total undiscounted future minimum payment obligations under our operating leases and finance leases as of December 31, 2024 totaled approximately $23.3 million, of which $3.1 million is payable in 2025 and $20.2 million is payable through early 2034. The leases expire on various dates through 2034 and provide certain options to renew for additional periods.

We expect our lease obligations may increase in the future as we expand our facilities, operations and headcount in support of the anticipated growth in our portfolio of commercial products and pipeline tests. Refer to Note 11 of the consolidated financial statements for additional information on our leasing arrangements.

Cash Flows

The following table summarizes our sources and uses of cash and cash equivalents for each of the periods presented (in thousands):

	Years Ended December 31,	
	2024	**2023**
Net cash provided by (used in) operating activities	$ 64,866	$ (5,626)
Net cash used in investing activities	(50,137)	(16,183)
Net cash provided by (used in) financing activities	6,139	(2,298)
Net change in cash and cash equivalents	20,868	(24,107)
Cash and cash equivalents, beginning of year	98,841	122,948
Cash and cash equivalents, end of year	$ 119,709	$ 98,841

Operating Activities

Net cash provided by operating activities was $64.9 million for the year ended December 31, 2024, and was primarily attributable to the net income of $18.2 million, non-cash stock-based compensation expense of $50.3 million, depreciation and amortization of $16.0 million, increases in accrued compensation of $3.6 million, increases in deferred income taxes of $1.4 million, partially offset by increases in accounts receivable of $12.6 million, increases in accretion of discounts on marketable investment securities of $6.7 million, increases in accounts payable of $4.4 million and increases in prepaid expenses and other current assets of $1.1 million.

Net cash used in operating activities was $5.6 million for the year ended December 31, 2023, and was primarily attributable to the net loss of $57.5 million, increases in accounts receivable of $14.9 million, increases in accretion of discounts on marketable investment securities of $5.5 million and increases in inventory of $4.0 million, partially offset by non-cash stock-based compensation expense of $51.2 million, depreciation and amortization of $12.3 million, increases in accounts payable of $5.7 million, increases in accrued compensation of $4.6 million and increases in other accrued and current liabilities of $2.1 million.

The $70.5 million increase in net cash provided by operating activities for the year ended December 31, 2024 compared to the year ended December 31, 2023 is primarily due to increases in collections from customers attributable to higher net revenues partially offset by increases in operating expenditures. In part, the cash used during the year ended December 31, 2024 reflects the payment of annual cash bonuses to our employees as well as certain health care benefit payments totaling $20.8 million. In comparison, we paid $17.7 million during the same period in 2023 towards annual cash bonuses and certain health care benefits.

Investing Activities

Net cash used in investing activities was $50.1 million for the year ended December 31, 2024 and consisted primarily of purchases of marketable investment securities of $205.7 million, and purchases of property and equipment of $28.3 million, partially offset by the maturity of marketable investment securities of $183.9 million.

Net cash used in investing activities was $16.2 million for the year ended December 31, 2023 and consisted primarily of purchases of marketable investment securities of $189.1 million and purchases of property and equipment of $13.6 million, partially offset by the maturity of marketable investment securities of $186.5 million.

The $34.0 million increase in cash used in investing activities for the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to purchasing $16.7 million more in marketable investment securities and collecting $2.6 million fewer proceeds from maturing marketable investment securities. We also increased our purchases of property and equipment by $14.7 million for the year ended December 31, 2024 compared to the year ended December 31, 2023, primarily due to our purchase of land for cash consideration of $7.2 million on February 9, 2024 and $6.8 million in cash payments relating to the development of our future corporate headquarters.

Financing Activities

Net cash provided by financing activities was $6.1 million for the year ended December 31, 2024, and consisted primarily of $10.0 million of proceeds from issuance of long-term debt and $3.0 million of proceeds from contributions to our 2019 Employee Stock Purchase Plan (the “ESPP”) and $2.0 million of proceeds from the exercise of stock options, partially offset by the $8.8 million payment of employee taxes attributable to the vesting of RSUs.

Net cash used in financing activities was $2.3 million for the year ended December 31, 2023, and consisted primarily of payment of employees’ taxes on vested RSUs of $5.1 million, partially offset by $2.7 million of proceeds from contributions to our 2019 ESPP.

Inflation

In 2021, the rate of inflation in the United States significantly increased until the second half of 2022 when the rate began to subside. In 2023 and 2024, the inflation rate continued to subside but remained higher than rates experience between 2025 and 2020. We continue to experience inflationary pressures, primarily in increased personnel costs and price increases for certain lab supplies. We anticipate possible inflationary impacts on other cost areas in the future. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long the elevated inflation levels persist and the extent to which the rate of inflation were to further increase, if at all, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents and marketable investment securities may be further diminished, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Further, given the complexities of the reimbursement landscape in which we operate, our payors may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts. As such, the effects of inflation have had, and may continue, to adversely impact our results of operations, financial condition and cash flows.

Critical Accounting Estimates

Our consolidated financial statements are prepared in accordance with U.S. GAAP. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect

the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition

We recognize revenue in accordance with ASC 606. In accordance with ASC 606, we follow a five-step process to recognize revenues: (1) identify the contract with the customer, (2) identify the performance obligations, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations and (5) recognize revenues when the performance obligations are satisfied. We have determined that we have a contract with the patient when the treating clinician orders the test. Our contracts generally contain a single performance obligation, which is the delivery of the test report, and we satisfy our performance obligation at a point-in-time upon the delivery of the test report to the treating clinician, at which point we can bill for the report. The amount of revenue recognized reflects the amount of consideration to which we expect to be entitled, or the transaction price, and considers the effects of variable consideration.

All of our revenues from contracts with customers are associated with the provision of diagnostic, prognostic and predictive testing services. Our revenues are primarily attributable to DecisionDx-Melanoma for CM and our DecisionDx-SCC test for SCC. We also provide a test for patients diagnosed with BE, the TissueCypher test, a test for patients with suspicious pigmented lesions, MyPath Melanoma and DiffDx-Melanoma, and a test for UM, DecisionDx-UM. We also began offering a PGx testing service focused on mental health, IDgenetix, following a business combination completed in April 2022.

Once we satisfy our performance obligations and bill for the service, the timing of the collection of payments may vary based on the payment practices of the third-party payor and the existence of contractually established reimbursement rates. The payments for our services are primarily made by third-party payors, including Medicare and commercial health insurance carriers. Certain contracts contain a contractual commitment of a reimbursement rate that differs from our list prices. However, absent a contractually committed reimbursement rate with a commercial carrier or governmental program, our diagnostic tests may or may not be covered by these entities' existing reimbursement policies. In addition, patients do not enter into direct agreements with us that commit them to pay any portion of the cost of the tests in the event that their insurance provider declines to reimburse us. We may pursue, on a case-by-case basis, reimbursement from such patients in the form of co-payments and co-insurance, in accordance with the contractual obligations that we have with the insurance carrier or health plan. These situations may result in a delay in the collection of payments.

The Medicare claims that are covered are generally paid at the established rate by our Medicare contractor within 30 days from receipt. Medicare claims that were either submitted to Medicare prior to a medical review and coverage, or an LCD's effective date, or are not covered, but meet the definition of being medically reasonable and necessary pursuant to the controlling Section 1862(a)(1)(A) of the Social Security Act may be paid upon initial claim submission or if denied for payment are generally appealed and may ultimately be paid at the first (termed "redetermination"), second (termed "reconsideration") or third level of appeal (*de novo* hearing with an ALJ). A successful appeal at any of these levels results in payment.

In the absence of Medicare coverage or contractually established reimbursement rates, we have concluded that our contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured at the expected value using the "most likely amount" method under ASC 606. The amounts are estimated using historical average collection rates by test type and payor category taking into consideration the range of possible outcomes, the predictive value of our past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of our influence, such as the judgment and actions of third parties. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in the absence of a

predictable pattern and history of collectability with a payor. Variable consideration for Medicare claims for which there are no existing positive coverage decisions, including those claims subject to approval by an ALJ at an appeal hearing, is deemed to be fully constrained due to factors outside our influence (i.e., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Included in revenues for the years ended December 31, 2024 and 2023 were $1.8 million of net negative revenue adjustments and $4.5 million of net negative revenue adjustments, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. These amounts include (i) adjustments for actual collections versus estimated amounts and (ii) cash collections and the related recognition of revenue in current period for tests delivered in prior periods due to the release of the constraint on variable consideration.

Stock-Based Compensation

Stock-based compensation expense for equity instruments issued to employees and non-employees, including stock options, RSUs, performance-based restricted stock units (“PSUs”) and purchase rights issued under the ESPP is measured based on the grant date fair value of the awards. For stock options and purchase rights granted under the ESPP, we estimate the grant date fair value using the Black-Scholes option-pricing valuation model. For RSUs and PSUs, we use the closing price of our common stock on the date of grant to determine the fair value. We recognize compensation costs on a straight-line basis for awards with only service conditions, which is generally the awards’ vesting period, typically four years for options and RSUs and the two-year offering period for the ESPP. PSUs vest upon the achievement of certain performance conditions and the provision of service with us through a specified period. Accruals of compensation cost for PSUs are based on the probable outcome of the performance conditions and are reassessed each reporting period. We recognize compensation cost for PSUs separately for each vesting tranche on a ratable basis over the requisite service period. The requisite service period for PSUs is based on an analysis of vesting requirements and performance conditions for the particular award. Under specific circumstances, certain employees may be eligible for accelerated vesting of a portion of their awards upon retirement, contingent upon meeting predefined criteria related to age, tenure, and notice. The determination of the requisite service period considers the employee's retirement eligibility and is reassessed at each reporting date. Forfeitures are accounted for as they occur.

Certain employees are entitled to acceleration of vesting of a portion of their awards upon retirement, subject to age, service and notice requirements. In these cases, the requisite service period takes into consideration the employee’s retirement eligibility, and is reassessed at each reporting date. For the ESPP, the requisite service period is generally the period of time from the offering date to the purchase date.

Set forth below is a description of the significant assumptions used in the option pricing model:

- *Expected term*. The expected term is the period of time that granted options are expected to be outstanding. For stock options, we have set the expected term using the simplified method based on the weighted average of both the period to vesting and the period to maturity for each option, as we have concluded that our stock option exercise history does not provide a reasonable basis upon which to estimate the expected term. For the ESPP, the expected term is the period of time from the offering date to the purchase date.
- *Expected volatility*. Previously, because of the limited period of time our stock had been traded in an active market, we calculated expected volatility by using the historical stock prices of a group of similar companies looking back over the estimated life of the option or the purchase rights under the ESPP and averaging the volatilities of these companies. In the third quarter of 2021, we adjusted this calculation to include our own stock price on a relative basis to the peer group in the calculation of expected volatility, as our common stock has now been traded in an active market for more than two years.
- *Risk-free interest rate*. We base the risk-free interest rate used in the Black-Scholes valuation model on the market yield in effect at the time of option grant and at the offering date for the ESPP provided from the Federal Reserve Board’s Statistical Releases and historical publications from the Treasury constant maturities rates for the equivalent remaining terms.
- *Dividend yield*. We have not paid, and do not have plans to pay, cash dividends. Therefore, we use an expected dividend yield of zero in the Black-Scholes option valuation model.

The fair value of our common stock is also an assumption used to determine the fair value of stock options. Prior to our IPO, the estimated fair value of our common stock had been determined by our board of directors as of the date of each award, with input from management, considering our most recently available third-party valuations of common stock and our board of directors’ assessment of additional objective and subjective factors that it believed

were relevant and which may have changed from the date of the most recent valuation through the date of the grant, which intended all options granted to be exercisable at price per share not less than the per share fair value of our common stock underlying those options on the grant date. Subsequent to our IPO, the fair value of our common stock is the closing selling price per share of our common stock as reported on the Nasdaq Global Market on the date of grant or other relevant determination date.

The following table sets forth the assumptions used to determine the fair value of stock options:

	Years Ended December 31,		
	2024	2023	2022
Average expected term (years)	5.0	5.0	5.8
Expected stock price volatility	80.20% - 80.20%	75.57% - 76.01%	68.3% - 75.0%
Risk-free interest rate	4.39% - 4.39%	3.57% - 3.57%	1.5% - 4.2%
Dividend yield	—%	—%	—%

The following table sets forth assumptions used to determine the fair value of the purchase rights issued under the ESPP:

	Years Ended December 31,		
	2024	2023	2022
Average expected term (years)	1.2	1.3	1.3
Expected stock price volatility	59.85% - 105.39%	72.80% - 130.95%	63.0% - 91.8%
Risk-free interest rate	3.82% - 5.14%	4.74% - 5.33%	0.6% - 3.5%
Dividend yield	—%	—%	—%

Intangible Assets and Goodwill

Intangible assets

Our intangible assets, which are comprised primarily of acquired developed technology, are considered to be finite-lived and are amortized on a straight-line basis over their estimated useful lives. Estimating the useful lives of our intangible assets requires considerable judgment. In determining the estimated useful lives, management considers factors such as historical experience, industry and regulatory factors, competition, patent expirations and commercial plans. If new information becomes available in future periods, we may be required to revise our estimated useful lives. If the revised useful lives are shorter than originally estimated, our future amortization expense will increase.

In late 2024, we revised our commercial strategy for the IDgenetix test, reallocating resources to inside sales and non-personal promotions. In December 2024, we observed month-to-month decreases in IDgenetix test reports, which persisted through year-end. We continue to offer the IDgenetix test and monitor its performance; nevertheless, we anticipate that test report volumes and net revenues will decrease in 2025. Long-term projections about the performance of this test remain uncertain. We believe these factors indicated a need to revise the remaining useful life of our IDgenetix developed technology intangible asset. On December 1, 2024, we adjusted the estimated remaining useful life from approximately 12 years to 13 months, with the useful life now expected to end on December 31, 2025.

Goodwill

Our goodwill is not amortized but is tested for impairment annually and whenever events or changes in circumstances indicate that it may be impaired. We perform annual impairment reviews of our goodwill balance during the fourth quarter of each year, or more frequently if management believes indicators of impairment exist. We may perform a qualitative assessment to determine if it is necessary to perform a quantitative impairment test. If we determine that a quantitative impairment test is necessary, we apply the guidance in Accounting Standards Update (“ASU”) No. 2017-04, *Intangibles—Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*, by comparing the fair value of the reporting unit to its carrying value, including the goodwill. If the carrying value exceeds the fair value, we recognize an impairment loss for the amount by which the carrying value exceeds fair value, up to the total amount of goodwill allocated to the reporting unit. We did not incur any goodwill impairment losses in any of the periods presented. We have concluded that our business is comprised of a single reporting unit. For our annual impairment test for the year ended December 31, 2024, we elected to bypass the qualitative assessment and proceeded directly to the quantitative assessment by comparing our reporting unit’s fair value to its

carrying value. Factors that could result in an impairment of goodwill in the future include declines in the price of our common stock, increased competition, changes in macroeconomic developments and unfavorable government or regulatory developments.

We conducted annual impairment testing of goodwill in the fourth quarter which indicated that the fair value of our reporting unit exceeded its carrying value by 117% and therefore no impairment was indicated. To measure the fair value of our single reporting unit, we used a market approach whereby we calculated our total market capitalization on the impairment test date, based on the closing price of our common stock as reported on the Nasdaq Global Market, and applied a reasonable control premium. The control premium was based on an analysis of control premiums paid in recent acquisitions of companies in the same or similar industry as us.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures* (“ASU 2023-07”), which require public companies disclose significant segment expenses and other segment items on an annual and interim basis and to provide in interim periods all disclosures about a reportable segment’s profit or loss and assets that are currently required annually. The guidance was effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption was permitted. The guidance was applied retrospectively to all periods presented in the financial statements, unless it was impracticable. We have adopted the guidance under this ASU 2023-07 on a retrospective basis with an effective date January 1, 2022. Please refer to Note 17 - Segment and Related Information, to our Consolidated Financial Statements for details.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures* ("ASU 2023-09"), which is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for the Company prospectively to all annual periods beginning after December 15, 2024. Early adoption is permitted. We are currently evaluating the impact this update will have on the consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income (Subtopic 220-40)—Expense Disaggregation Disclosures: Disaggregation of Income Statement Expenses* (“ASU 2024-03”), which specifies additional disclosure requirements. The amendments in ASU 2024-03 require disclosure about the composition of certain income expense line items, such as purchases of inventory, employee compensation, and other expenses, as well as disclosure about selling expenses. The ASU is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. We are currently evaluating the impact this update will have on the consolidated financial statements and disclosures.

We have evaluated all other recently issued, but not yet effective, accounting pronouncements and do not believe that these accounting pronouncements will have any material impact on our consolidated financial statements or disclosures upon adoption.

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

Interest Rate Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily relate to interest rates fluctuations. We had cash and cash equivalents of $119.7 million as of December 31, 2024, which include bank deposits and money market funds. We had marketable investment securities of $173.4 million as of December 31, 2024, which are U.S. government securities and trading securities. Due to the nature of these instruments, we believe that we have no material exposure to interest rate risk.

As of December 31, 2024, we had a term debt of $10.0 million consisting of an outstanding term loan which bears interest at a floating rate that fluctuates with the WSJ Prime Rate, subject to an interest rate floor of 6.00%. During 2024, the U.S. Federal Reserve lowered interest rates on three separate occasions: by 50 basis points in September 2024, by 25 basis points in November 2024 and by 25 basis points in December 2024. The WSJ Prime Rate decreased by the same basis points for each respective adjustment thereafter.

A hypothetical 10% change in interest rates during any of the periods presented would not have a material impact on future interest income or expense, fair values of portfolio of investments, fair value of long-term debt and related cash flows.

Inflation Risk

Our exposure to inflationary pressures is primarily in personnel and related costs. The extent of any future impacts from inflation on our business and our results of operations will be dependent upon how long the elevated inflation levels persist and if the rate of inflation were to further increase, neither of which we are able to predict. If elevated levels of inflation were to persist or if the rate of inflation were to accelerate, the purchasing power of our cash and cash equivalents may be eroded, our expenses could increase faster than anticipated and we may utilize our capital resources sooner than expected. Further, given the complexities of the reimbursement landscape in which we operate, our payors may be unwilling or unable to increase reimbursement rates to compensate for inflationary impacts.

Equity Price Risk

As of December 31, 2024, we had equity securities with a total fair value of $3.6 million. A hypothetical 10% decrease in the market price of our trading securities as of December 31, 2024 would decrease the fair value by approximately $0.4 million. These securities are subject to a wide variety and number of market-related risks that could substantially reduce or increase the fair value of our holdings.

Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary data required by this item are included after the Signature page of this Annual Report on Form 10-K beginning on page F-1.

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

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2024, our disclosure controls and procedures were effective at the reasonable assurance level.

Management’s Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as such term as defined in Exchange Act Rule 13a-15(f). Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with U.S. GAAP.

As of December 31, 2024, our management assessed the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control-Integrated Framework (2013 Framework)*. Based on this assessment, our management concluded that, as of December 31, 2024, our internal control over financial reporting was effective based on those criteria.

Our independent registered public accounting firm, KPMG LLP, has audited the effectiveness of our internal control over financial reporting as of December 31, 2024, as stated in its attestation report contained in Item 15 of this Annual Report on Form 10-K.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) or 15d-15(f) of the Exchange Act) that occurred during the fourth quarter of 2024 that have materially affected, or are reasonably likely to materially affect, the Company’s internal control over financial reporting.

Item 9B. Other Information.

Securities Trading Plans of Directors and Executive Officers

On November 11, 2024, Derek Maetzold, our Chief Executive Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of up to 301,404 shares of our common stock, less the number of shares withheld to cover tax withholding obligations in connection with the vesting and settlement of outstanding RSUs and PSUs, and less any shares that are sold under his previous arrangement. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement will be from February 24, 2025 through August 13, 2025.

On November 18, 2024, Frank Stokes, our Chief Financial Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of up to 100% of the shares of our common stock issued upon the settlement of 14,617 outstanding RSUs, less the number of shares withheld to cover tax withholding obligations in connection with the vesting and settlement of such RSUs. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement will be from February 18, 2025 through December 31, 2026 or earlier if all transactions under the trading arrangement are completed.

No other officers or directors, as defined in Rule 16a-1(f), adopted and/or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement, as defined in Regulation S-K Item 408, during the last fiscal quarter.

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

Not applicable.

PART III

Certain information required by Part III is omitted from this Annual Report on Form 10-K since we intend to file our definitive proxy statement for our 2025 Annual Meeting of Stockholders (the "Proxy Statement") pursuant to Regulation 14A of the Exchange Act, not later than 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K, and certain information to be included in the Proxy Statement is incorporated herein by reference.

Item 10. Directors, Executive Officers and Corporate Governance.

The information required by this item is to be included in the Proxy Statement as follows:

- The information relating to our executive officers is to be included in the section entitled "Executive Officers,"
- The information relating to our directors and nominees for director is to be included in the section entitled "Proposal 1: Election of Directors,"
- The information relating to our audit committee and audit committee financial expert is to be included in the section entitled "Information Regarding the Board of Directors and Corporate Governance," and
- If required, the information regarding delinquent reports under Section 16(a) of the Exchange Act is to be included in the section entitled "Delinquent Section 16(a) Reports."

Such information is to be included in the Proxy Statement and is incorporated herein by reference.

The information required by Item 408(b) of Regulation S-K will be set forth in the section captioned "Insider Trading Arrangements and Policies" in our Proxy Statement and is incorporated herein by reference.

We have adopted a written Code of Business Conduct and Ethics ("Ethics Code") that applies to all officers, directors and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. The Ethics Code is available on our website at www.CastleBiosciences.com. If we ever were to amend or waive any provision that applies to our principal executive officer, principal financial officer, principal accounting officer or any person performing similar functions, we intend to satisfy our disclosure obligations, if any, with respect to any such waiver or amendment by posting such information on our website, rather than by filing a Current Report on Form 8-K.

Item 11. Executive Compensation.

The information required by this item is to be included in the Proxy Statement under the section entitled "Executive Compensation" and is incorporated herein by reference, provided that the information required by Item 402(x) of Regulation S-K shall be set forth in the section headed "Policies and practices related to the grant of certain equity awards close in time to the release of material nonpublic information" in the Proxy Statement and is incorporated herein by reference.

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

The information required by this item with respect to equity compensation plans is to be included in the Proxy Statement under the section entitled "Equity Compensation Plan Information" and the information required by this item with respect to security ownership of certain beneficial owners and management is to be included in the Proxy Statement under the section entitled "Security Ownership of Certain Beneficial Owners and Management" and in each case is incorporated herein by reference.

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

The information required by this item is to be included in the Proxy Statement under the section entitled "Transactions with Related Persons and Indemnifications—Related Person Transactions Policy and Procedures" and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

Our independent registered public accounting firm is KPMG LLP, Houston, TX, PCAOB ID: 185.

The information required by this item is to be included in the Proxy Statement under the section entitled "Proposal 2: Ratification of Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a)(1) Financial Statements.

The consolidated financial statements and supplementary data required by this item are included after the Signature page of this Annual Report on Form 10-K beginning on page F-1.

(a)(2) Financial Statement Schedules.

All schedules have been omitted because they are not required or because the required information is given in the Consolidated Financial Statements or Notes thereto.

(a)(3) Exhibits.

The exhibits listed in the Exhibit Index below are filed or incorporated by reference as part of this Annual Report on Form 10-K.

Exhibit Index

Exhibit Number	Description of document
2.1^†	Agreement and Plan of Merger, dated October 18, 2021, by and among the Company, Space Merger Sub, Inc., Cernostics, Inc., and Shareholder Representative Services LLC, incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K, as amended, originally filed with the SEC on December 6, 2021.
2.2^†	Agreement and Plan of Merger, dated April 4, 2022, by and among the Registrant, AltheaDx, Inc., Acorn Merger Sub, Inc. and Fortis Advisors LLC, incorporated by reference to Exhibit 2.1 of the Registrant's Current Report on Form 8-K filed with the SEC on April 4, 2022.
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed with the SEC on July 29, 2019.
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed with the SEC on July 29, 2019.
4.1	Description of securities registered under Section 12 of the Exchange Act, incorporated by reference to Exhibit 4.1 of the Registrant's Annual Report on Form 10-K filed with the SEC on March 10, 2020.
4.2	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
4.3	Sixth Amended and Restated Investors' Rights Agreement, dated July 12, 2019, by and among the Registrant and certain of its stockholders, incorporated by reference to Exhibit 4.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.1+	Form of Indemnity Agreement by and between the Registrant and its directors and officers, incorporated by reference to Exhibit 10.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.2+	Castle Biosciences, Inc. 2008 Stock Plan, incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.3+	Forms of Stock Option Agreement, Exercise Notice and Investment Representation Statement under the 2008 Stock Plan, incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.4+	Castle Biosciences, Inc. 2018 Equity Incentive Plan, as amended, incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.5+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the 2018 Equity Incentive Plan, incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.6+	Castle Biosciences, Inc. 2019 Equity Incentive Plan, incorporated by reference to Exhibit 99.3 of the Registrant's Registration Statement on Form S-8 (File No. 333-232884), originally filed with the SEC on July 29, 2019.

Exhibit Number	Description of document
10.7+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the 2019 Equity Incentive Plan, incorporated by reference to Exhibit 10.7 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.8+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the 2019 Equity Incentive Plan, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 9, 2020.
10.9+	Castle Biosciences, Inc. 2019 Employee Stock Purchase Plan, incorporated by reference to Exhibit 10.8 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.10+	Form of Director Agreement by and between the Registrant and certain of its directors, incorporated by reference to Exhibit 10.9 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.11+	Castle Biosciences, Inc. 2022 Inducement Plan, incorporated by reference to Exhibit 99.1 of the Registrant's Registration Statement on Form S-8 (File No. 333-275881), filed with the SEC on December 4, 2023.
10.12+	Forms of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under the Castle Biosciences, Inc. 2022 Inducement Plan, incorporated by reference to Exhibit 10.12 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 28, 2023.
10.13+	Forms of Stock Option Grant Notice, Option Agreement and Notice of Exercise under the Castle Biosciences, Inc. 2022 Inducement Plan, incorporated by reference to Exhibit 10.13 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 28, 2023.
10.14+	Non-Employee Director Compensation Policy, as amended effective May 31, 2024, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 5, 2024.
10.15+	Amended and Restated Executive Employment Agreement, dated September 20, 2012, as amended, by and between the Registrant and Derek J. Maetzold, incorporated by reference to Exhibit 10.10 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.16+	Offer Letter Agreement, dated November 9, 2017, by and between the Registrant and Frank Stokes, incorporated by reference to Exhibit 10.13 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.17+	Executive Employment Agreement, dated September 15, 2008, as amended, by and between the Registrant and Kristen Oelschlager, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2021.
10.18+	Executive Employment Agreement, dated October 1, 2008, as amended, by and between the Registrant and Tobin Juvenal, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2021.
10.19+	Castle Biosciences, Inc. Retirement Policy, incorporated by reference to Exhibit 10.16 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 28, 2023.
10.20+†	Castle Biosciences, Inc. Severance and Change in Control Plan, incorporated by reference to Exhibit 10.20 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 28, 2024.
10.21+	Amended Participation Agreement, dated April 1, 2024, by and between the Company and Tobin Juvenal, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 2, 2024.
10.22+	Amended Participation Agreement, dated April 1, 2024, by and between the Company and Kristen Oelschlager, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 2, 2024.
10.23+	Amended Participation Agreement, dated April 2, 2024, by and between the Company and Derek Maetzold, incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 2, 2024.
10.24+	Amended Participation Agreement, dated April 2, 2024, by and between the Company and Frank Stokes, incorporated by reference to Exhibit 10.6 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 2, 2024.
10.25	Standard Office Lease, dated as of October 5, 2015, by and between the Registrant and Merced Restart Phoenix Investors II, LLC, incorporated by reference to Exhibit 10.14 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.

Exhibit Number	Description of document
10.26	First Amendment to Lease, dated December 4, 2018, by and between the Registrant and Alturas Siete I, LLC, incorporated by reference to Exhibit 10.15 of the Registrant's Annual Report on Form 10-K, filed with the SEC on March 10, 2020.
10.27	Second Amendment to Standard Office Lease, dated December 16, 2019, by and between the Registrant and Alturas Siete I, LLC, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed with the SEC on December 19, 2019.
10.28	Third Amendment to Standard Office Lease, dated November 29, 2021, by and between the Company and Alturas Siete, I, LLC, incorporated by reference to Exhibit 10.2 of the Registrant's Current Report on Form 8-K filed with the SEC on December 3, 2021.
10.29†	Fourth Amendment to Standard Office Lease, dated March 11, 2022, by and between the Registrant and Alturas Siete I, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on March 17, 2022.
10.30†	Fifth Amendment to Standard Office Lease, dated October 24, 2022, by and between the Registrant and Alturas Siete I, LLC, incorporated by reference to Exhibit 10.25 of the Registrant's Current Report on Form 10-K filed with the SEC on February 28, 2023.
10.31	Standard Office Lease, dated December 16, 2019, by and between the Registrant and Alturas Siete, II, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on December 19, 2019.
10.32	First Amendment to Standard Office Lease, dated February 16, 2021, by and between the Registrant and Alturas Siete II, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 10, 2021.
10.33	Second Amendment to Standard Office Lease, dated November 29, 2021, by and between the Company and Alturas Siete, II, LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on December 3, 2021.
10.34	Third Amendment to Standard Office Lease, dated February 9, 2023, by and between the Registrant and Alturas Siete, II, LLC, incorporated by reference to Exhibit 10.29 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 28, 2023.
10.35	Fourth Amendment to Standard Office Lease, dated April 18, 2023 by and between the Registrant and Alturas Siete II, LLC, incorporated by reference to Exhibit 10.4 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 10 2023.
10.36	Commercial Lease, dated December 17, 2019, by and between the Registrant and Tannos Land Holding III, LLC, incorporated by reference to Exhibit 10.3 of the Registrant's Current Report on Form 8-K filed with the SEC on December 19, 2019.
10.37	First Amendment to Commercial Lease, dated November 13, 2020, by and between the Registrant and Tannos Land Holdings III, LLC, incorporated by reference to Exhibit 10.23 of the Registrant's Annual Report on Form 10-K filed with the SEC on March 11, 2021.
10.38	Second Amendment to Commercial Lease, executed December 15, 2022, by and between the Registrant and Tannos Land Holdings III, LLC, incorporated by reference to Exhibit 10.32 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 28, 2023.
10.39†	Lease Agreement, dated April 1, 2022, by and between the Registrant and ACA Concourse East Unit 3 LLC, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 9, 2022.
10.40#†	First Amendment to Lease Agreement, dated March 26, 2024 by and between the Registrant and ACA Concourse East Unit 3 LLC, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 2, 2024.
10.41	Confirmation of Amendment Provisions, dated as of August 8, 2024, to the Lease Agreement, dated April 1, 2022, by and between the Registrant and ACA Concourse East Unit 3 LLC, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 4, 2024.
10.42	Purchase Sale Agreement of Land, dated Jul 10, 2023, by and between the Registrant and Hal B. Boone, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 2, 2023.
10.43	First Amendment to Purchase Sale Agreement of Land, dated October 4, 2023, by and between the Registrant and Hal B. Boone, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 2, 2023.

Exhibit Number	Description of document
10.44†	Second Amendment to Purchase Sale Agreement of Land, dated January 9, 2024, by and between the Registrant and Hal B. Boone, incorporated by reference to Exhibit 10.38 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 28, 2024.
10.45#	Exclusive License Agreement, dated as of November 14, 2009, by and between the Registrant and The Washington University, incorporated by reference to Exhibit 10.17 of the Registrant's Registration Statement on Form S-1 (File No. 333-232369), as amended, originally filed with the SEC on June 26, 2019.
10.46#	Loan and Security Agreement, dated March 26, 2024, by and among the Registrant and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K filed with the SEC on March 27, 2024.
19.1*	Insider Trading Policy
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Exchange Act, and 18 U.S.C. Section 1350.
97.1+	Castle Biosciences, Inc. Incentive Compensation Recoupment Policy, incorporated by reference to Exhibit 97.1 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 28, 2024.
101.INS*	Inline XBRL Instance Document—the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase.
104*	Cover Page Interactive Data File (embedded within the Inline XBRL and contained in Exhibit 101).

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* Filed herewith

** Furnished herewith.

\+ Indicates management contract or compensatory plan.

\# Pursuant to Item 601(b)(10) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because the Company has determined that the information is not material and is the type that the Company treats as private or confidential.

† Certain schedules or exhibits have been omitted pursuant to Item 601(a)(5) of Regulation S-K. A copy of any omitted schedule or exhibit will be furnished to the SEC upon request; provided, however, that we may request confidential treatment pursuant to Rule 24b-2 of the Exchange Act for any schedule or exhibit so furnished.

^ Pursuant to Item 601(b)(2) of Regulation S-K, certain portions of this exhibit have been omitted (indicated by "[***]") because the Company has determined that the information is not material and is the type that the Company treats as private or confidential.

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.

CASTLE BIOSCIENCES, INC.

Date: February 27, 2025

By: /s/ Derek J. Maetzold

Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

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

SIGNATURE	TITLE	DATE
/s/ Derek J. Maetzold **(Derek J. Maetzold)**	President, Chief Executive Officer and Director (*Principal Executive Officer*)	February 27, 2025
/s/ Frank Stokes **(Frank Stokes)**	Chief Financial Officer (*Principal Financial and Accounting Officer*)	February 27, 2025
/s/ Daniel M. Bradbury **(Daniel M. Bradbury)**	Chairperson of the Board of Directors	February 27, 2025
/s/ Kimberlee S. Caple **(Kimberlee S. Caple)**	Member of the Board of Directors	February 27, 2025
/s/ G. Bradley Cole **(G. Bradley Cole)**	Member of the Board of Directors	February 27, 2025
/s/ Rodney Cotton **(Rodney Cotton)**	Member of the Board of Directors	February 27, 2025
/s/ Ellen Goldberg **(Ellen Goldberg)**	Member of the Board of Directors	February 27, 2025
/s/ Miles D. Harrison **(Miles D. Harrison)**	Member of the Board of Directors	February 27, 2025
/s/ Tiffany P. Olson **(Tiffany P. Olson)**	Member of the Board of Directors	February 27, 2025

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Report of Independent Registered Public Accounting Firm

To the Stockholders and Board of Directors
Castle Biosciences, Inc.:

Opinions on the Consolidated Financial Statements and Internal Control Over Financial Reporting

We have audited the accompanying consolidated balance sheets of Castle Biosciences, Inc. and subsidiaries (the Company) as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive income (loss), stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2024, and the related notes (collectively, the consolidated financial statements). We also have audited the Company's internal control over financial reporting as of December 31, 2024, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2024, in conformity with U.S. generally accepted accounting principles. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2024 based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting 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 consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Critical Audit Matter

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

Measurement of test revenue

As discussed in Notes 2 and 3 of the consolidated financial statements, test revenue is recognized when the performance obligation is satisfied, upon delivery of the test report. The amount of revenue recognized reflects the amount of consideration to which the Company expects to be entitled and considers the effects of variable consideration. The measurement of test revenue is determined by contractually established rates as well as historical average collection rates by test type and payor category taking into consideration the range of possible outcomes, the predictive value of the Company's past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of the Company's influence, such as the judgment and actions of third parties. The Company reported net revenues of $332.1 million for the year ended December 31, 2024, a portion of which related to test revenue.

We identified the evaluation of the measurement of test revenue as a critical audit matter. Evaluating the measurement of test revenue, specifically the estimation of the amount of test revenue expected to be collectible related to commercial payors and certain others, required especially complex and subjective auditor judgment.

The following are the primary procedures we performed to address this critical audit matter. We evaluated the design and tested the operating effectiveness of certain internal controls related to the estimation of the expected collectible test revenue related to commercial payors and certain others. This included controls related to management's review of the assumptions and inputs used in the determination of test revenue expected to be collectible from commercial payors and certain others. For a selection of tests, we evaluated certain historical data inputs that are used in management's model to estimate test revenue expected to be collectible by comparing the data from the model to physician test requisition forms, proof of delivery, and cash collection activity. These data inputs included collection activity, amounts of historical claims, insurance payor categories, test dates, test types, claim aging categories, and revenue recognition dates. In addition, we inquired of the individuals who are responsible for monitoring and tracking the status of anticipated collections to understand the progress of these activities and any impact to management's estimates.

/s/ KPMG LLP

We have served as the Company's auditor since 2018.

Houston, Texas
February 27, 2025

CASTLE BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2024	2023
ASSETS		
Current Assets		
Cash and cash equivalents	$ 119,709	$ 98,841
Marketable investment securities	173,421	144,258
Accounts receivable, net	51,218	38,302
Inventory	8,135	7,942
Prepaid expenses and other current assets	7,671	6,292
Total current assets	360,154	295,635
Long-term accounts receivable, net	918	1,191
Property and equipment, net	51,122	25,433
Operating lease assets	11,584	12,306
Goodwill and other intangible assets, net	106,229	117,335
Other assets – long-term	1,228	1,440
Total assets	$ 531,235	$ 453,340
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 6,901	$ 10,268
Accrued compensation	32,555	28,945
Operating lease liabilities	1,665	1,137
Current portion of long-term debt	278	—
Other accrued and current liabilities	7,993	7,317
Total current liabilities	49,392	47,667
Long-term debt	9,745	—
Noncurrent operating lease liabilities	14,345	14,173
Noncurrent finance lease liabilities	311	25
Deferred tax liability	1,607	206
Total liabilities	75,400	62,071
Commitments and Contingencies (Note 13)		
Stockholders' Equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized as of December 31, 2024 and 2023; no shares issued and outstanding as of December 31, 2024 and 2023.	—	—
Common stock, $0.001 par value; 200,000,000 authorized as of December 31, 2024 and 2023; 28,483,195 and 27,410,532 shares issued and outstanding as of December 31, 2024 and 2023, respectively.	28	27
Additional paid-in capital	655,703	609,477
Accumulated deficit	(200,126)	(218,371)
Accumulated other comprehensive income	230	136
Total stockholders' equity	455,835	391,269
Total liabilities and stockholders' equity	$ 531,235	$ 453,340

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

CASTLE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except per share data)

	Years Ended December 31,		
	2024	**2023**	**2022**
NET REVENUES	$ 332,069	$ 219,788	$ 137,039
OPERATING EXPENSES AND OTHER OPERATING INCOME			
Cost of sales (exclusive of amortization of acquired intangible assets)	60,205	44,982	32,009
Research and development	52,041	53,618	44,903
Selling, general and administrative	200,047	180,152	143,003
Amortization of acquired intangible assets	11,106	9,013	8,266
Change in fair value of contingent consideration	—	—	(18,287)
Total operating expenses, net	323,399	287,765	209,894
Operating income (loss)	8,670	(67,977)	(72,855)
Interest income	12,916	10,623	3,968
Changes in fair value of trading securities	555	—	—
Interest expense	(577)	(11)	(17)
Income (loss) before income taxes	21,564	(57,365)	(68,904)
Income tax expense (benefit)	3,319	101	(1,766)
Net income (loss)	$ 18,245	$ (57,466)	$ (67,138)
Earnings (loss) per share:			
Basic	$ 0.66	$ (2.14)	$ (2.58)
Diluted	$ 0.62	$ (2.14)	$ (2.58)
Weighted-average shares outstanding:			
Basic	27,776	26,802	26,054
Diluted	29,255	26,802	26,054

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

CASTLE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(in thousands)

	Years Ended December 31,		
	2024	**2023**	**2022**
Net income (loss)	$ 18,245	$ (57,466)	$ (67,138)
Other comprehensive income (loss):			
Net unrealized gain (loss) on debt securities held as available-for-sale	94	517	(381)
Comprehensive income (loss)	$ 18,339	$ (56,949)	$ (67,519)

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

CASTLE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
BALANCE, JANUARY 1, 2022	25,378,520	$ 25	$ 505,482	$ (93,767)	$ —	$ 411,740
Stock-based compensation expense	—	—	36,321	—	—	36,321
Exercise of common stock options	148,735	1	832	—	—	833
Issuance of common stock from vested restricted stock units and payment of employees' taxes	183,887	—	(1,688)	—	—	(1,688)
Issuance of common stock under the employee stock purchase plan	78,652	—	2,352	—	—	2,352
Issuance of common stock in acquisition of business	763,887	1	17,110	—	—	17,111
Net unrealized loss on marketable investment securities	—	—	—	—	(381)	(381)
Net loss	—	—	—	(67,138)	—	(67,138)
BALANCE, DECEMBER 31, 2022	26,553,681	$ 27	$ 560,409	$ (160,905)	$ (381)	$ 399,150
Stock-based compensation expense	—	—	51,219	—	—	51,219
Exercise of common stock options	71,525	—	269	—	—	269
Issuance of common stock from vested restricted stock units and payment of employees' taxes	645,454	—	(5,134)	—	—	(5,134)
Issuance of common stock under the employee stock purchase plan	139,872	—	2,714	—	—	2,714
Net unrealized gain on marketable investment securities	—	—	—	—	517	517
Net loss	—	—	—	(57,466)	—	(57,466)
BALANCE, DECEMBER 31, 2023	27,410,532	$ 27	$ 609,477	$ (218,371)	$ 136	$ 391,269
Stock-based compensation expense	—	—	50,320	—	—	50,320
Exercise of common stock options	135,875	—	2,017	—	—	2,017
Issuance of common stock from vested restricted stock units, performance stock units and payment of employees' taxes	769,100	—	(8,762)	—	—	(8,762)
Issuance of common stock under the employee stock purchase plan	167,688	1	2,651	—	—	2,652
Net unrealized gain on marketable investment securities	—	—	—	—	94	94
Net income	—	—	—	18,245	—	18,245
BALANCE, DECEMBER 31, 2024	28,483,195	$ 28	$ 655,703	$ (200,126)	$ 230	$ 455,835

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

CASTLE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	Years Ended December 31,		
	2024	2023	2022
OPERATING ACTIVITIES			
Net income (loss)	$ 18,245	$ (57,466)	$ (67,138)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:			
Depreciation and amortization	15,997	12,330	10,543
Stock-based compensation expense	50,320	51,219	36,321
Change in fair value of contingent consideration	—	—	(18,287)
Change in fair value of trading securities	(555)	—	—
Deferred income taxes	1,401	(223)	(1,877)
Accretion of discounts on marketable investment securities	(6,685)	(5,491)	(1,368)
Other	268	635	158
Change in operating assets and liabilities:			
Accounts receivable	(12,643)	(14,930)	(6,218)
Prepaid expenses and other current assets	(1,142)	(435)	(1,224)
Inventory	(193)	(3,962)	(1,680)
Operating lease assets	1,322	(258)	991
Other assets	262	(330)	618
Accounts payable	(4,372)	5,707	582
Operating lease liabilities	(1,289)	852	(608)
Accrued compensation	3,610	4,587	8,495
Other accrued and current liabilities	320	2,139	(963)
Net cash provided by (used in) operating activities	64,866	(5,626)	(41,655)
INVESTING ACTIVITIES			
Purchases of marketable investment securities	(205,729)	(189,075)	(134,689)
Proceeds from maturities of marketable investment securities	183,900	186,500	—
Purchases of property and equipment	(28,326)	(13,621)	(5,632)
Proceeds from sale of property and equipment	18	13	195
Acquisition of business, net of cash and cash equivalents acquired	—	—	(26,966)
Asset acquisitions, net of cash and cash equivalents acquired	—	—	547
Net cash used in investing activities	(50,137)	(16,183)	(166,545)
FINANCING ACTIVITIES			
Proceeds from exercise of common stock options	2,017	269	833
Payment of employees' taxes on vested restricted stock units	(8,762)	(5,134)	(1,688)
Proceeds from contributions to the employee stock purchase plan	2,981	2,709	2,492
Repayment of principal portion of finance lease liabilities	(97)	(142)	(122)
Proceeds from issuance of term debt	10,000	—	—
Net cash provided by (used in) financing activities	6,139	(2,298)	1,515

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

CASTLE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS (Continued)
(in thousands)

	Years Ended December 31,		
	2024	2023	2022
NET CHANGE IN CASH AND CASH EQUIVALENTS	20,868	(24,107)	(206,685)
Beginning of year	98,841	122,948	329,633
End of year	$ 119,709	$ 98,841	$ 122,948
SUPPLEMENTAL DISCLOSURE OF CASH PAID FOR:			
Interest	$ 434	$ 11	$ 16
Income taxes	$ 2,503	$ 198	$ 120
DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Accrued purchases of property and equipment	$ 2,231	$ 1,226	$ 1,396
Property and equipment acquired with tenant improvement allowance	$ 1,389	$ 1,281	$ 51
Operating lease assets obtained in exchange for lease obligations	$ 607	$ 1,547	$ 6,075
Decrease in operating lease assets with corresponding change in lease liabilities	$ (7)	$ —	$ —
Finance lease assets obtained in exchange for lease obligations	$ 218	$ —	$ —
Common stock issued in acquisition of business	$ —	$ —	$ 17,111

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

1. Organization and Description of Business

Castle Biosciences, Inc. (the ‘‘Company,” “we,” “us” or “our”) was incorporated in the state of Delaware on September 12, 2007. We are a commercial-stage diagnostics company focused on providing clinicians and their patients with personalized, clinically actionable information to inform treatment decisions and improve health outcomes. We are based in Friendswood, Texas (a suburb of Houston, Texas) and our laboratory operations are conducted at our facilities located in Phoenix, Arizona and Pittsburgh, Pennsylvania.

2. Summary of Significant Accounting Policies

Basis of Presentation

The consolidated financial statements include the accounts of Castle Biosciences, Inc. and our wholly owned subsidiaries and have been prepared in conformity with accounting principles generally accepted in the United States of America (‘‘U.S. GAAP’’). All intercompany accounts and transactions have been eliminated in consolidation.

In connection with preparing consolidated financial statements for each annual and interim reporting period, the Company is required to evaluate whether there are conditions or events, considered in aggregate, that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. Substantial doubt exists when conditions and events, considered in aggregate, indicate that it is probable that a company will be unable to meet its obligations as they become due within one year after the date that the consolidated financial statements are issued. This evaluation initially does not take into consideration the potential mitigating effect of management’s plans and actions that have not been fully implemented as of the date that the financial statements are issued. When substantial doubt exists, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company’s ability to continue as a going concern. The mitigating effect of management’s plans, however, is only considered if both: (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued; and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the Company’s ability to continue as a going concern within one year after the date that the financial statements are issued. Generally, to be considered probable of being effectively implemented, the plans must have been approved before the date that the financial statements are issued.

We have a history of recurring net losses and negative cash flows and as of December 31, 2024, we had an accumulated deficit of $200.1 million. We believe our $119.7 million of cash and cash equivalents, and $173.4 million of marketable investment securities as of December 31, 2024, and anticipated revenue from our test reports will be sufficient to meet our cash requirements through at least the 12-month period following the date that these consolidated financial statements were issued.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities as of the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Significant items subject to such estimates include revenue recognition, the valuation of stock-based compensation, assessing future tax exposure and the realizability of deferred tax assets, the useful lives and recoverability of long-lived assets, the goodwill impairment test, the valuation of acquired intangible assets and the valuation of contingent consideration and other contingent liabilities. We base these estimates on historical and anticipated results, trends, and various other assumptions that we believe are reasonable under the circumstances, including assumptions as to future events. These estimates form the basis for making judgments about the carrying values of assets and liabilities and recorded revenues and expenses that are not readily apparent from other sources. Actual results could differ from those estimates and assumptions.

Segment Reporting

Operating segments are components of an enterprise engaging in business activities from which it may recognize revenues and incur expenses, where discrete financial information is available, and where its operating results are regularly reviewed by the public entity's chief operating decision maker (“CODM”) to make decisions about resources to be allocated to the segment and to assess its performance. A CODM may be an individual or a

decision-making group. A reportable segment consists of one or more operating segments. For additional information on our segment reporting, see Note 17.

Cash and Cash Equivalents including Concentrations of Credit Risk

Cash equivalents consist of short-term, highly liquid investments with original maturities of three months or less. Our cash equivalents consist of money market funds, which are not insured by the Federal Deposit Insurance Corporation ("FDIC"), that are primarily invested in short-term U.S. government obligations. Cash deposits at financial institutions may exceed the amount of insurance provided by the FDIC. Management believes that we are not exposed to significant credit risk on our cash deposits due to the financial position of the financial institutions in which deposits are held.

Marketable Investment Securities

Our marketable investment securities are comprised of debt and equity securities. All debt securities are recognized in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Topic 320, *Investments-Debt Securities* ("ASC 320"). Management determines the appropriate classification of debt securities at the time of purchase and re-evaluates such determination at each balance sheet date. All debt securities are classified as available-for-sale ("AFS") and are recorded at fair value in accordance with ASC 320. We recognize the unrealized gains and losses related to changes in fair value as a separate component of accumulated other comprehensive income (loss) within total stockholders' equity, net of any related deferred income tax effects, on the consolidated balance sheets. Premiums or discounts from par value are amortized over the life of the underlying investment and are included in interest income in the consolidated statements of operations. Realized gains and losses on available-for-sale securities, if any, are calculated at the individual security level and are included in interest income in the consolidated statements of operations. Impairments of available-for-sale debt securities, if any, are recorded in the consolidated statements of operations.

Our equity securities consist of investments in shares of common stock which are listed and traded on the Nasdaq Global Market. All trading securities are recognized in accordance with ASC Topic 321, *Investments-Equity Securities* and reported at their readily determinable fair values as quoted by market exchanges where changes in fair value are included in changes in fair value of trading securities in the consolidated statements of operations. All changes in a marketable security's fair value are reported in earnings as they occur, as such, the sale of our trading securities does not necessarily give rise to a significant gain or loss. Investments in equity securities are classified as either current or long-term depending upon management's intentions. See Notes 5 and 12 for further details.

Revenue Recognition

In accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"), we follow a five-step process to recognize revenues: (1) identify the contract with the customer, (2) identify the performance obligations, (3) determine the transaction price, (4) allocate the transaction price to the performance obligations and (5) recognize revenues when the performance obligations are satisfied. We have determined that we have a contract with the patient when the treating clinician orders the test. Our contracts generally contain a single performance obligation, which is the delivery of the test report, and we satisfy our performance obligation at a point in time upon the delivery of the test report to the treating clinician, at which point we can bill for the report. The amount of revenue recognized reflects the amount of consideration to which we expect to be entitled, or the transaction price, and considers the effects of variable consideration. See Note 3 for further details.

Accounts Receivable and Allowance for Credit Losses

We classify accounts receivable balances that are expected to be paid more than one year from the consolidated balance sheet date as noncurrent assets. The estimated timing of payment utilized as a basis for classification as noncurrent is determined by analyses of historical payor-specific payment experience, adjusted for known factors that are expected to change the timing of future payments.

We accrue an allowance for credit losses against our accounts receivable based on management's current estimate of amounts that will not be collected. Management's estimates are typically based on historical loss information adjusted for current conditions. We generally do not perform evaluations of customers' financial condition and generally do not require collateral. Historically, our credit losses have not been significant. The allowance for credit losses was zero as of December 31, 2024 and 2023. Adjustments for implicit price concessions attributable to variable consideration, as discussed below, are incorporated into the measurement of the accounts receivable balances and are not part of the allowance for credit losses.

Inventory

We carry inventories of test supplies in our laboratory facilities. The inventories are carried at the lower of weighted average cost and net realizable value and expensed through cost of sales as the supplies are used.

Property and Equipment

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is computed using the straight-line method over the estimated useful lives of the assets, generally between five and ten years. Leasehold improvements are amortized using the straight-line method over the shorter of the estimated useful life of the asset or the term of the lease. Our leasehold improvements primarily relate to our office and laboratory facilities in Friendswood, Texas, Phoenix, Arizona and Pittsburgh, Pennsylvania, and are generally being depreciated through the end of the lease terms in 2025 and 2033, respectively. Maintenance and repairs are charged to expense as incurred, and material improvements are capitalized. Interest costs incurred during the construction of major capital projects are capitalized until the underlying asset is ready for its intended use, at which point the capitalized interest costs are amortized using the straight-line method over the estimated useful life of the underlying asset. When assets are retired or otherwise disposed of, the cost and accumulated depreciation are removed from the consolidated balance sheet and any resulting gain or loss is reflected in the consolidated statements of operations in the period realized.

Intangible Assets

Our intangible assets, which are comprised primarily of acquired developed technology, are considered to be finite-lived and are amortized on a straight-line basis over their estimated useful lives.

Goodwill

Goodwill represents the excess of the purchase price over the fair value of the net tangible and intangible assets acquired in a business combination. Goodwill is not amortized, but is tested for impairment. We test goodwill for impairment in the fourth quarter of each fiscal year and when events, or changes in circumstances, indicate that it may be impaired. Events and changes in circumstances indicating that goodwill may be impaired include sustained declines in the price of our common stock, increased competition, changes in macroeconomic developments, unfavorable government or regulatory developments and changes in coverage or reimbursement conditions.

Goodwill is tested for impairment at the reporting until level where goodwill is held. Testing begins with completion of an optional qualitative assessment. If the qualitative assessment suggests that impairment is more likely than not, quantitative testing is conducted. If the qualitative assessment is bypassed, we proceed directly to quantitative testing. Quantitative testing consists of comparing the carrying value of goodwill to its estimated fair value. Impairment of goodwill is the condition that exists when the carrying value exceeds its fair value. Amounts by which carrying value exceed fair value, up to the total amount of goodwill allocated to the reporting unit, are recognized as an impairment loss in the consolidated statements of operations.

Long-Lived Assets

We review long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be recoverable. An impairment loss is recognized when the total of estimated future undiscounted cash flows, expected to result from the use of the asset and its eventual disposition, are less than the carrying amount. Impairment, if any, would be calculated based on the excess of the carrying amount of the long-lived asset over the long-lived asset's fair value. There were no impairment charges recognized during the years ended December 31, 2024, 2023 and 2022.

Acquisitions

We assess acquisitions under ASC Topic 805, *Business Combinations* ("ASC 805"), to determine whether a transaction represents the acquisition of assets or a business combination. Under this guidance, we apply a two-step model. The first step involves a screening test where we evaluate whether substantially all of the fair value of the gross assets acquired is concentrated in a single asset or a group of similar assets. If the screening test is met, we account for the set as an asset acquisition. If the screening test is not met, we apply the second step of the model to determine if the set meets the definition of a business based on the guidance in ASC 805. If so, the transaction is treated as a business combination. Otherwise, it is treated as an asset acquisition. Asset acquisitions are accounted for by allocating the cost of the acquisition, including transaction costs, to the individual assets acquired and liabilities assumed on a relative fair value basis without recognition of goodwill. Business combinations

are accounted for using the acquisition method. Under the acquisition method, goodwill is measured as a residual amount equal to the fair value of the consideration transferred less the net recognized fair value of the identifiable assets acquired and the liabilities assumed, as of the acquisition date, and transaction costs are expensed as incurred.

Contingent Consideration

Under the terms of business combinations or asset acquisitions, we may be required to pay additional contingent consideration if specified future events occur or if certain conditions are met.

In a business combination, in accordance with ASC 805, contingent consideration is recorded at fair value as of the acquisition date and classified as liabilities or equity based on applicable U.S. GAAP. For contingent consideration classified as liabilities, we remeasure the contingent consideration at fair value each period with changes in fair value recorded in the statements of operations each period.

For contingent consideration in transactions that are not business combinations, we apply U.S. GAAP. With respect to additional contingent consideration that must or may be settled by issuance of a variable number of shares, we account for the contingent consideration as a liability in accordance with ASC Topic 480, *Distinguishing Liabilities from Equity* (“ASC 480”). In accordance with ASC 480, we record the contingent consideration initially and subsequently at fair value with changes in fair value recorded in the statements of operations each period.

Contingent consideration is classified as current or noncurrent in the consolidated balance sheets based on the contractual timing of future settlement. For additional information on the contingent consideration, see Notes 6 and 12.

Leases

We account for leases in accordance with ASC Topic 842, *Leases (“*ASC 842”). We categorize leases at their commencement as either operating or finance leases based on the criteria in ASC 842. Under ASC 842, we record right-of-use (“ROU”) assets and lease liabilities for each lease arrangement identified, except that we have elected the short-term lease exemption for all leases with a term of 12 months or less. Lease liabilities are recorded at the present value of future lease payments discounted using our incremental borrowing rate for the lease established at the commencement date and ROU assets are measured at the amount of the lease liability plus any initial direct costs, less any lease incentives received before commencement. For our operating leases, we recognize a single lease cost over the lease term on a straight-line basis. We have elected the practical expedient of not separating nonlease components from lease components in all leases. See Note 11 for details on our leases.

Cost of Sales (exclusive of amortization of acquired intangible assets)

Cost of sales is expensed as incurred and includes material and service costs associated with testing samples, personnel costs (including salaries, bonuses, benefits and stock-based compensation expense), electronic medical records, order and delivery systems, shipping charges to transport samples, third-party test fees, and allocated overhead including rent, information technology costs, equipment and facilities depreciation and utilities.

Research and Development

Research and development (“R&D”) costs are charged to operations as incurred. Advance payments for goods and services that will be used in future R&D activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made. Upfront and milestone payments due to third parties that perform R&D services on behalf of us will be expensed as services are rendered or when the milestone is achieved.

R&D costs include, but are not limited to, payroll and personnel-related expenses, stock-based compensation expense, materials, laboratory supplies, and consulting costs.

Selling, General and Administrative Expenses

Selling, general and administrative (“SG&A”) expenses are attributable to sales, marketing, executive, finance and accounting, legal and human resources functions. These expenses consist of personnel costs (including salaries, employee benefit costs, bonuses and stock-based compensation expenses), customer services expenses, direct marketing expenses, educational and promotional expenses, market research, audit and legal expenses, and consulting. We expense all SG&A costs as incurred.

Accrued Compensation

We accrue for liabilities under discretionary employee and executive bonus plans. Our estimated compensation liabilities are based on progress against corporate objectives approved by our board of directors, compensation levels of eligible individuals and target bonus percentage levels. Our board of directors reviews and evaluates the performance against these objectives and ultimately determines the actual achievement levels attained. We also accrue for liabilities under employee sales incentive bonus plans with accruals based on performance achieved to date compared to established targets. As of December 31, 2024 and 2023, we accrued approximately $23.3 million and $21.7 million, respectively, for liabilities associated with these bonus plans. These amounts are classified as current or noncurrent accrued liabilities in the balance sheets based on the expected timing of payment.

Retirement Plan

We have an Internal Revenue Code ("IRC") Section 401(k) profit sharing plan (the "Plan") for eligible employees. The Plan is funded by employee contributions and provides for discretionary contributions in the form of matching and/or profit-sharing contributions. For the years ended December 31, 2024, 2023, and 2022 we provided a discretionary matching contribution of $5.5 million, $4.6 million, and $3.5 million respectively. The higher amount for the year ended December 31, 2024 primarily reflects an increase in the number of employees compared to the years ended December 31, 2023 and 2022.

Income Taxes

We use the asset and liability method of accounting for income taxes. Current income taxes are recognized for the estimated taxes payable or refundable on tax returns for the current year. Deferred income taxes arise from the recognition of temporary differences between financial statement carrying amounts and the tax basis of assets and liabilities. We consider all evidence, both positive and negative, with respect to our net operating loss ("NOL") carryforwards, expected levels of pre-tax financial statement income (loss), taxable income (benefit), liquidity, and prudent and reasonable tax planning strategies when evaluating whether the temporary differences will be realized. In projecting future taxable income (loss), we begin with budgeted pre-tax income (loss) adjusted for estimated taxable and non-taxable items. The assumptions about future taxable income (loss) require significant judgment and are consistent with the plans and estimates we use to manage our businesses. A valuation allowance is established when it is more likely than not that some portion of the deferred tax asset will not be realized. The evaluation of a valuation allowance considers the character of the taxable income, ordinary income versus capital income. Tax benefits are recognized only for tax positions that are more likely than not to be sustained upon examination by tax authorities. The amount recognized is measured as the largest amount of benefit that is greater than 50% likely to be realized upon settlement. A liability for unrecognized tax benefits is recorded for any tax benefits claimed in our tax returns that do not meet these recognition and measurement standards. The effect of a change in tax rates is recognized in the period of enactment. If we were to be levied interest and penalties by the Internal Revenue Service, these amounts would be recognized as a component of income tax expense in the consolidated statement of operations.

Our policy for recording interest and penalties associated with uncertain tax positions is to record such items as a component of tax expense.

Stock-Based Compensation

Stock-based compensation expense for equity instruments is measured based on the grant-date fair value of the awards. For stock option awards, and purchase rights made under the 2019 Employee Stock Purchase Plan (the "ESPP"), the fair value is estimated on the date of grant using the Black-Scholes option-pricing valuation model. For restricted stock units ("RSUs") and performance-based restricted stock units ("PSUs"), the fair value is equal to the closing price of our common stock on the date of grant. For awards with graded vesting and only service conditions, we recognize compensation costs on a straight-line basis over the requisite service period of the awards. For stock options and RSUs, the requisite service period is generally the award's vesting period (typically four years). PSUs vest upon the achievement of certain performance conditions and the provision of service with us through a specified period. Accruals of compensation cost for PSUs are based on the probable outcome of the performance conditions and are reassessed each reporting period. We recognize compensation cost for PSUs separately for each vesting tranche on a ratable basis over the requisite service period. The requisite service period for PSUs is based on an analysis of vesting requirements and performance conditions for the particular award. Certain employees are entitled to acceleration of vesting of a portion of their awards upon retirement, subject to age, service and notice requirements. Share-based awards falling into the scope of the 2023 Retirement Policy are accounted

for as a modification of existing awards under ASC Topic 718, Compensation – Stock Compensation. The modifications do not result in recognition of incremental compensation cost however, do result in a new estimate of the requisite service period, which we reassess at each balance sheet date. For the ESPP, the requisite service period is generally the period of time from the offering date to the purchase date. Forfeitures are accounted for as they occur.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive income (loss) is made up of net loss plus net unrealized gain (loss) on marketable investment securities, which is our only other item of other comprehensive income (loss).

CARES Act Payroll Tax Deferral

The CARES Act permitted employers to defer the payment of the employer share of social security taxes due for the period beginning March 27, 2020 and ending December 31, 2020. Of the amounts deferred, 50% were required to be paid by December 31, 2021 and the remaining 50% were required to be paid by December 31, 2022. We began deferring payment of the employer share of social security taxes in May 2020. Of the $0.6 million originally deferred, 50% was repaid during the year ended December 31, 2021 and the remaining $0.3 million of such taxes were repaid during the year ended December 31, 2022.

Recently Adopted Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, *Segment Reporting (Topic 280)—Improvements to Reportable Segment Disclosures* (“ASU 2023-07”), which require public companies disclose significant segment expenses and other segment items on an annual and interim basis and to provide in interim periods all disclosures about a reportable segment’s profit or loss and assets that are currently required annually. The guidance was effective for public entities for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption was permitted. The guidance was applied retrospectively to all periods presented in the financial statements, unless it was impracticable. We have adopted the guidance under this ASU 2023-07 on a retrospective basis with an effective date January 1, 2022. For additional information on our segment reporting, see Note 17.

Accounting Pronouncements Yet to be Adopted

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740)—Improvements to Income Tax Disclosures* ("ASU 2023-09"), which is intended to enhance the transparency and decision usefulness of income tax disclosures. The amendments in ASU 2023-09 provide for enhanced income tax information primarily through changes to the rate reconciliation and income taxes paid information. ASU 2023-09 is effective for the Company prospectively to all annual periods beginning after December 15, 2024. Early adoption is permitted. We are currently evaluating the impact this update will have on the consolidated financial statements and disclosures.

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income (Subtopic 220-40)—Expense Disaggregation Disclosures: Disaggregation of Income Statement Expenses* (“ASU 2024-03”), which specifies additional disclosure requirements. The amendments in ASU 2024-03 require disclosure about the composition of certain income expense line items, such as purchases of inventory, employee compensation, and other expenses, as well as disclosure about selling expenses. The ASU is effective for fiscal years beginning after December 15, 2026, and interim periods beginning after December 15, 2027. Early adoption is permitted. We are currently evaluating the impact this update will have on the consolidated financial statements and disclosures.

We have evaluated all other recently issued, but not yet effective, accounting pronouncements and do not believe that these accounting pronouncements will have any material impact on the consolidated financial statements or disclosures upon adoption.

3. Revenue

All of our revenues from contracts with customers are associated with the provision of testing services. Our revenues are primarily attributable to our DecisionDx®-Melanoma test for cutaneous melanoma and our DecisionDx®-SCC test for cutaneous squamous cell carcinoma (“SCC”). We also provide a test for patients diagnosed with Barrett’s esophagus (“BE”), the TissueCypher® test, a test for patients with suspicious pigmented

lesions, MyPath® Melanoma and DiffDx®-Melanoma, and a test for uveal melanoma ("UM"), DecisionDx®-UM. We also began offering a pharmacogenomics ("PGx") testing service focused on mental health, IDgenetix®, following a business combination completed in April 2022. Information on the disaggregation of revenues is included below.

Once we satisfy our performance obligations and bill for the service, the timing of the collection of payments may vary based on the payment practices of the third-party payor and the existence of contractually established reimbursement rates. The payments for our services are primarily made by third-party payors, including Medicare and commercial health insurance carriers. Certain contracts contain a contractual commitment of a reimbursement rate that differs from our list prices. However, absent a positive coverage policy, with or without a contractually committed reimbursement rate, with a commercial carrier or governmental program, our diagnostic tests may or may not be paid by these entities. In addition, patients do not enter into direct agreements with us that commit them to pay any portion of the cost of the tests in the event that their insurance provider declines to reimburse us. We may pursue, on a case-by-case basis, reimbursement from such patients in the form of co-payments and co-insurance, in accordance with the contractual obligations that we have with the insurance carrier or health plan. These situations may result in a delay in the collection of payments.

The Medicare claims that are covered by Medicare are generally paid at a rate established on Medicare's Clinical Laboratory Fee Schedule or by the respective Medicare contractor within 30 days from receipt. Medicare claims that were either submitted to Medicare prior to the LCD or other coverage commencement date or are not covered but meet the definition of being medically reasonable and necessary pursuant to the controlling Section 1862(a)(1)(A) of the Social Security Act are generally appealed and may ultimately be paid at the first (termed ''redetermination''), second (termed ''reconsideration'') or third level of appeal (*de novo* hearing with an Administrative Law Judge). A successful appeal at any of these levels may result in prompt payment.

In the absence of Medicare coverage, contractually established reimbursements rates or other coverage, we have concluded that our contracts include variable consideration because the amounts paid by Medicare or commercial health insurance carriers may be paid at less than our standard rates or not paid at all, with such differences considered implicit price concessions. Variable consideration attributable to these price concessions is measured at the expected value using the ''most likely amount'' method under ASC 606. The amounts are estimated using historical average collection rates by test type and payor category taking into consideration the range of possible outcomes, the predictive value of our past experiences, the time period of when uncertainties expect to be resolved and the amount of consideration that is susceptible to factors outside of our influence, such as the judgment and actions of third parties. Such variable consideration is included in the transaction price only to the extent it is probable that a significant reversal in the amount of cumulative revenue recognized will not occur when the uncertainties with respect to the amount are resolved. Variable consideration may be constrained and excluded from the transaction price in situations where there is no contractually agreed upon reimbursement coverage or in the absence of a predictable pattern and history of collectability with a payor. Accordingly, in such situations revenues are recognized on the basis of actual cash collections. Variable consideration for Medicare claims that are not covered by Medicare, including those claims undergoing appeal, is deemed to be fully constrained due to factors outside our influence (e.g., judgment or actions of third parties) and the uncertainty of the amount to be received is not expected to be resolved for a long period of time. Variable consideration is evaluated each reporting period and adjustments are recorded as increases or decreases in revenues. Included in revenues for the years ended December 31, 2024, 2023, and 2022 were $1.8 million of net negative revenue adjustments, $4.5 million of net negative revenue adjustments, and $2.0 million of net negative revenue adjustments, respectively, associated with changes in estimated variable consideration related to performance obligations satisfied in previous periods. These amounts include (i) adjustments for actual collections versus estimated amounts and (ii) cash collections and the related recognition of revenue in current period for tests delivered in prior periods due to the release of the constraint on variable consideration.

Because our contracts with customers have an expected duration of one year or less, we have elected the practical expedient in ASC 606 to not disclose information about our remaining performance obligations. Any incremental costs to obtain contracts are recorded as SG&A expenses as incurred due to the short duration of our contracts. Contract balances consisted solely of accounts receivable (both current and noncurrent) as of December 31, 2024 and 2023.

Disaggregation of Revenues

The table below provides the disaggregation of revenue by type (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Dermatologic[1]	$ 256,996	$ 183,375	$ 124,809
Non-Dermatologic[2]	75,073	36,413	12,230
Total net revenues	$ 332,069	$ 219,788	$ 137,039

(1) Consists of DecisionDx-Melanoma, DecisionDx-SCC and our Diagnostic Gene Expression Profile offering (MyPath Melanoma and DiffDx-Melanoma)

(2) Consists of TissueCypher, DecisionDx-UM and IDgenetix.

We have presented disaggregated net revenues included in our single reportable segment in the table above. The characteristics for each test in our single segment are similar, with each test having a single performance obligation. Our CODM is the single individual responsible for managing our segment and reviews consolidated results and budgets in assessing performance and in allocated resources. See Note 17 for additional information about our reportable segment.

Payor Concentration

We rely upon reimbursements from third-party government payors (primarily Medicare) and private-payor insurance companies to collect accounts receivable related to sales of our tests.

Our significant third-party payors and their related revenues as a percentage of total revenues and accounts receivable balances were as follows:

	Percentage of Revenues			Percentage of Accounts Receivable (current)		Percentage of Accounts Receivable (noncurrent)	
	Year Ended December 31,			As of December 31,		As of December 31,	
	2024	2023	2022	2024	2023	2024	2023
Medicare	47 %	49 %	53 %	18 %	20 %	*	*
Payor A	15 %	14 %	12 %	19 %	19 %	15 %	15 %
Payor B	*	*	*	20 %	10 %	12 %	11 %

* Less than 10%

There were no other third-party payors that individually accounted for more than 10% of our total revenue or accounts receivable for the periods shown in the table above.

4. Earnings (loss) Per Share

Basic earnings (loss) per share is computed by dividing net loss for the period by the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share reflects the additional dilution from potential issuances of common stock, such as stock issuable pursuant to the exercise of stock options, vesting of RSUs and PSUs or purchases under the ESPP. The treasury stock method is used to calculate the potential dilutive effect of these common stock equivalents. Contingently issuable PSU awards are included in the computation of diluted loss per share when the applicable performance criteria would be met and the common shares would be issuable if the end of the reporting period were the end of the contingency period. However, potentially dilutive shares are excluded from the computation of diluted loss per share when their effect is antidilutive.

The following table shows the computation of basic and diluted earnings (loss) per share for the following year ended December 31, 2024, 2023, and 2022 (in thousands, except per share data):

	Years Ended December 31,		
Numerator:	**2024**	**2023**	**2022**
Net income (loss)	$ 18,245	$ (57,466)	$ (67,138)
Denominator:			
Weighted-average common shares outstanding, basic	27,776	26,802	26,054
Assumed exercise of stock options	457	—	—
Assumed vesting of RSUs	858	—	—
Assumed vesting of PSUs	144	—	—
Assumed issuance of shares under the ESPP	20	—	—
Weighted-average common shares outstanding, diluted	29,255	26,802	26,054
Earnings (loss) per share:			
Basic	$ 0.66	$ (2.14)	$ (2.58)
Diluted	$ 0.62	$ (2.14)	$ (2.58)

Due to the Company reporting a net loss attributable to common stockholders for years ended December 31, 2023, and 2022, all potentially dilutive securities are antidilutive and are excluded from the computations of diluted loss per share.

The table below provides the weighted-average number of potential common shares associated with outstanding securities not included in our calculation of diluted earnings (loss) per share for the years ended December 31, 2024, 2023, and 2022 because to do so would be antidilutive. With regard to the PSUs, we assume that the associated performance targets will be met at the target level of performance for purposes of calculating diluted net income per common share until such time that it is probable that actual performance will be above or below target (in thousands):

	Years Ended December 31,		
	2024	**2023**	**2022**
Stock options	2,445	3,319	3,521
RSUs and PSUs	531	3,350	1,650
ESPP	160	330	146
Total	3,136	6,999	5,317

In addition, in connection with our acquisition of AltheaDx, Inc. (“AltheaDx”) in April 2022, no such shares were determined to have been issued and were excluded from the calculation of diluted income (loss) per share because none of the applicable conditions have been met during the earnout periods and based on the final valuation of the contingent consideration as required in the definitive agreement to acquire AltheaDx. See Notes 6 and 12 for additional information.

5. Marketable Investment Securities

Marketable investment securities consisted of the following (in thousands):

	As of December 31,	
	2024	2023
Trading securities[1]	$ 3,555	$ —
Debt securities	169,866	144,258
Marketable investment securities	$ 173,421	$ 144,258

(1) We had no trading securities as of December 31, 2023.

Trading securities

We recognized $0.6 million in gains, all of which were unrealized, on our trading securities for the year ended December 31, 2024. We recognized no gains or losses for the years ended December 31, 2023 and 2022.

Debt securities

The following tables present our debt securities (in thousands):

	December 31, 2024			
		Unrealized		
	Amortized Cost	Gains	Losses	Estimated Fair Value
U.S. government securities	$ 169,636	$ 244	$ (14)	$ 169,866
Total	$ 169,636	$ 244	$ (14)	$ 169,866

	December 31, 2023			
		Unrealized		
	Amortized Cost	Gains	Losses	Estimated Fair Value
U.S. government securities	$ 144,122	$ 143	$ (7)	$ 144,258
Total	$ 144,122	$ 143	$ (7)	$ 144,258

Although our U.S. government securities are available to be sold to meet operating needs or otherwise, these securities are generally held through maturity. We classify all investments as current assets, as these are readily available for use in current operations. The cost of securities sold is determined based on the specific identification method for purposes of recording gains and losses.

There were no realized gains or losses on sales of debt securities for the years ended December 31, 2024, 2023, and 2022.

We evaluated our U.S. government securities under the available-for-sale debt securities impairment model guidance and determined our investment portfolio is comprised of low-risk, investment grade securities.

We believe that an allowance for credit losses is unnecessary because the unrealized losses on certain of our marketable investment securities are due to market factors. Unrealized losses were immaterial for the years ended December 31, 2024, 2023, and 2022. In addition, there were no attributable credit risks, and no credit-related or noncredit-related impairment losses recognized, for the years ended December 31, 2024, 2023 and 2022. The allowance for credit losses was zero as of December 31, 2024 and 2023.

As of December 31, 2024 and 2023, all of our available-for-sale debt securities had contractual maturities of one year or less. Accrued interest receivable is included in prepaid expenses and other current assets in the consolidated balance sheets. As of December 31, 2024 and 2023 the accrued interest receivable balance was immaterial.

Additional information relating to the fair value of marketable investment securities can be found in Note 12.

6. Acquisition

AltheaDx, Inc.

On April 26, 2022, we completed the acquisition of 100% of the equity interests in AltheaDx which offers the IDgenetix test that focuses on mental health. We acquired AltheaDx for $30.5 million in cash and $17.1 million in common stock issued, for total consideration of $47.6 million. The fair value of assets acquired and liabilities assumed primarily consisted of finite-lived intangible assets of $35.0 million, goodwill of $10.7 million, cash and cash equivalents of $3.5 million and deferred tax liabilities of $1.7 million. We concluded that the transaction represents a business combination under ASC 805. The financial results of AltheaDx have been included in the consolidated financial statements since the date of the acquisition. The amount of revenue attributable to AltheaDx included in the consolidated statements of operations from the acquisition date through December 31, 2022 was $0.9 million. The loss attributable to AltheaDx included in the consolidated statements of operations from the acquisition date through December 31, 2022 was approximately $12.4 million. This amount did not reflect transaction costs from the acquisition or the effects of the valuation allowance reduction discussed in Note 16. Transaction costs associated with the acquisition were $1.7 million for the year ended December 31, 2022 and were recognized as expenses, included in SG&A expenses in the consolidated statements of operations.

In connection with the acquisition of AltheaDx, we also agreed to pay up to an additional $75.0 million in cash and common stock in connection with the achievement of certain milestones based on 2022, 2023, and 2024 commercial milestones for the IDgenetix test (the “AltheaDx Earnout Payments”). Achievement of milestones required to receive additional payment of cash and issuance of stock were not met during the years ended December 31, 2024, 2023 and 2022 and as such, no payments were made during the same periods. As of December 31, 2024, no future obligations exist relating to AltheaDx Earnout Payments and the contingent consideration period had ended. Contingent consideration liability associated with the AltheaDx Earnout Payments was zero as of the April 26, 2022 date of acquisition and remained unchanged through the ending of the milestone performance period on December 31, 2024.

Our calculations of the consideration transferred and the purchase price allocation for the acquisition of AltheaDx were finalized as of December 31, 2022. During the measurement period, we recorded adjustments to accrued liabilities, income taxes, intangible assets, contingent consideration and the resulting goodwill after finalizing our valuation of these items.

The following table presents the acquisition-date fair value of the consideration transferred, summarizes the final allocation of the fair values of assets acquired and liabilities assumed in the acquisition of AltheaDx, and includes measurement period adjustments recorded during 2022 (in thousands, except for shares):

	April 26, 2022 (as initially reported)	Measurement Period Adjustments	April 26, 2022 (as adjusted)
Consideration Transferred			
Cash	$ 30,510	$ (8)	$ 30,502
Common stock (763,887 shares)	17,111	—	17,111
Contingent consideration	1,528	(1,528)	—
Total consideration transferred	$ 49,149	$ (1,536)	$ 47,613
Fair Value Allocation			
Cash and cash equivalents	$ 3,536	$ —	$ 3,536
Accounts receivable	302	—	302
Inventory	279	—	279
Prepaid expenses and other current assets	262	—	262
Property and equipment	314	—	314
Intangible asset	37,000	(2,000)	35,000
Other assets – long-term	12	—	12
Accounts payable	(231)	—	(231)
Accrued compensation	(380)	—	(380)
Other accrued and current liabilities	(532)	119	(413)
Deferred tax liabilities	(1,819)	147	(1,672)
Other liabilities	(88)	—	(88)
Net identifiable assets acquired	38,655	(1,734)	36,921
Goodwill	10,494	198	10,692
Total fair value of net assets assumed	$ 49,149	$ (1,536)	$ 47,613

The fair value of the common stock issued was measured using the April 26, 2022 closing price of $22.40 per share, as reported by the Nasdaq Global Market. A portion of the upfront cash and stock consideration was held in escrow following closing to secure indemnification claims, if any, and were released during the year ended December 31, 2023.

During the fourth quarter of 2022, we reversed losses originally recorded during the second and third quarters of 2022 that were associated with the remeasurement of contingent consideration before finalizing the valuation. Also during the fourth quarter of 2022, we recorded an immaterial adjustment to reduce the amortization expense associated with the intangible asset.

The goodwill, which is not deductible for income tax purposes, was primarily attributable to potential future growth opportunities and the organized workforce. The intangible asset is comprised of developed technology with an estimated useful life of 15 years and is being amortized on a straight-line basis. See Note 8 for additional information on the useful life of IDgenetix developed technology.

Unaudited Pro Forma Financial Information

The following unaudited pro forma financial information for the year ended December 31, 2022 combines our historical financial results and the results of AltheaDx, assuming that the companies were combined as of January 1, 2022, and includes adjustments for amortization expense from the acquired intangible assets and additional stock-based compensation expense. Non-recurring pro forma adjustments consist of acquisition-related transaction

costs of $1.7 million and an income tax benefit of $1.6 million, both assumed to have been recognized during the year ended December 31, 2022 and therefore removed from the year ended December 31, 2022.

The following unaudited pro forma financial information (in thousands) is for informational purposes only and is not necessarily indicative of (i) the results of operations that would have been achieved if the acquisition had taken place as of January 1, 2022 or (ii) the results of operations that are expected in future periods:

	Pro Forma Data
	Year Ended December 31, 2022
Net revenues	$ 137,591
Net loss	$ (72,819)

Related Parties

Derek J. Maetzold, our President and Chief Executive Officer ("CEO"), and a member of our board of directors, and Daniel M. Bradbury, the Chairperson of our board of directors, each served on the board of directors of AltheaDx until the acquisition of AltheaDx was completed, were direct or indirect beneficial owners of AltheaDx securities and received consideration in connection with our acquisition of AltheaDx. Further, Frank Stokes, our Chief Financial Officer; Tobin W. Juvenal, our Chief Commercial Officer; Kristen Oelschlager, our Chief Operating Officer and certain immediate family members of Mr. Maetzold and Ms. Oelschlager were direct or indirect beneficial owners of AltheaDx securities and received consideration in the transaction. Our entry into the definitive agreement to acquire AltheaDx was approved by our board of directors based upon the unanimous recommendation of a special transaction committee comprised entirely of independent members of our board of directors without any financial interest in AltheaDx or any conflict of interest with respect to the acquisition of AltheaDx.

As of December 31, 2024, the milestone period ended, no future obligations existing relating to AltheaDx Earnout Payments, and contingent consideration liability was zero. The named related parties did not receive additional contingent consideration over the duration of the milestone and contingent consideration period. See Note 12 for additional information on fair value measurement of contingent consideration liability.

7. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	As of December 31,	
	2024	2023
Land[(1)]	$ 7,245	$ —
Lab equipment	23,633	16,472
Leasehold improvements	14,616	9,990
Computer equipment	5,306	4,060
Furniture and fixtures	3,541	2,385
Construction-in-progress	9,614	637
Total	63,955	33,544
Less accumulated depreciation	(12,833)	(8,111)
Property and equipment, net	$ 51,122	$ 25,433

(1) On February 9, 2024, we purchased approximately 23 acres of land in Friendswood, Texas for purpose of developing a commercial office building to be used as our future corporate headquarters.

Depreciation expense was recorded in the consolidated statements of operations as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 2,950	$ 1,758	$ 874
Research and development	354	330	337
Selling, general and administrative	1,587	1,229	1,067
Total	$ 4,891	$ 3,317	$ 2,278

8. Goodwill and Other Intangible Assets, Net

Goodwill

We had a single reporting unit where all goodwill was allocated for the years ended December 31, 2024, 2023 and 2022. No impairment charges were recorded against goodwill for the years ended December 31, 2024, 2023 and 2022. The balance of our goodwill, net zero accumulated impairments, was $10.7 million as of December 31, 2024 and 2023.

We had a single reportable segment consisting of a single operating segment where the operating segment and the single reporting unit where the same for the years ended December 31, 2024, 2023, and 2022. See Note 17 for additional information on our reportable segment.

We conducted annual impairment testing of goodwill in the fourth quarter which indicated the fair value of our reporting unit exceeded its carrying value by 117% and therefore no impairment was indicated. To measure the fair value of our single reporting unit, we used a market approach whereby we calculated our total market capitalization on the impairment test date, based on the closing price of our common stock as reported on the Nasdaq Global Market, and applied a reasonable control premium. The control premium was based on an analysis of control premiums paid in recent acquisitions of companies in the same or similar industry as us.

Other Intangible Assets, Net

Our other intangible assets, net consist of the following (in thousands):

	As of December 31, 2024			
	Gross carrying value	Accumulated amortization	Net	Weighted-Average Remaining Life (in years)
Developed technology	$ 125,317	$ (29,996)	$ 95,321	8.0
Assembled workforce	563	(347)	216	1.9
Total other intangible assets, net	$ 125,880	$ (30,343)	$ 95,537	

	As of December 31, 2023			
	Gross carrying value	Accumulated amortization	Net	Weighted-Average Remaining Life (in years)
Developed technology	$ 125,317	$ (19,003)	$ 106,314	12.2
Assembled workforce	563	(234)	329	2.9
Total other intangible assets, net	$ 125,880	$ (19,237)	$ 106,643	

The estimated future aggregate amortization expense as of December 31, 2024 was as follows (in thousands):

Years Ending December 31,	
2025	$ 33,358
2026	6,672
2027	6,569
2028	6,587
2029	6,569
Thereafter	35,782
Total	$ 95,537

On December 1, 2024, we revised the estimated remaining useful life of our IDgenetix developed technology intangible asset from approximately 12 years to 13 months, where the useful life is expected to end on December 31, 2025. The change in estimate resulted in our recognition of an additional $2.1 million in expense from amortization of acquired intangible assets, reducing net income by the same amount, for the fourth quarter and year ended December 31, 2024. The change in estimate is expected to increase expense from amortization of acquired intangible assets by approximately $24.3 million for the year ended December 31, 2025.

Amortization expense of intangible assets was $11.1 million, $9.0 million, and $8.3 million for the years ended December 31, 2024, 2023, and 2022, respectively.

9. Other Accrued and Current Liabilities

Other accrued and current liabilities consisted of the following (in thousands):

	As of December 31,	
	2024	2023
Clinical studies	$ 2,580	$ 3,475
Accrued service fees	2,338	1,939
ESPP contributions	1,225	896
Accrued taxes	1,076	401
Other	774	606
Total	$ 7,993	$ 7,317

10. Long-Term Debt

We had no debt as of December 31, 2023. Our long-term debt as of December 31, 2024 is presented in the table below (in thousands):

	As of December 31, 2024
Term debt	$ 10,200
Unamortized discount	(177)
Total debt, net	10,023
Less: Current portion of long-term debt	(278)
Total long-term debt	$ 9,745

Future maturities of principal amounts on long-term debt as of December 31, 2024 were as follows (in thousands):

Years Ending December 31,		
2025	$	278
2026		3,333
2027		3,333
2028		3,056
Total	$	10,000

2024 Loan and Security Agreement

On March 26, 2024 (the ‘‘Closing Date’’), we entered into a Loan and Security Agreement (the ‘‘2024 LSA”), by and between us, our wholly owned subsidiary, Castle Narnia Real Estate Holding 1, LLC and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (the “Lender’’). The 2024 LSA provides for (i) on the Closing Date, $10.0 million aggregate principal amount of Term Loans (the “2024 Term Loan,” as more fully discussed in the ‘‘2024 Term Loan’’ section below), and (ii) from the Closing Date until March 31, 2025, an additional line of credit of $25.0 million with the same interest rate and maturity as the term debt available (the “2024 Credit Line,” as more fully discussed in the ‘‘2024 Credit Line’’ section below) at our option.

The obligations under the 2024 LSA are secured by substantially all of our assets, excluding intellectual property, the real property held by us, and are subject to certain other exceptions and limitations. We have the right to prepay the 2024 LSA in whole, subject to a prepayment fee of approximately 1.50% if prepaid prior to March 26, 2026. Amounts repaid under the 2024 LSA may not be reborrowed.

In addition, the 2024 LSA contains customary conditions of borrowing, events of default and covenants, including covenants that restrict our ability to dispose of assets, merge with or acquire other entities, incur indebtedness and make distributions to holders of our capital stock. Should an event of default occur, including the occurrence of a material adverse change, we could be liable for immediate repayment of all obligations under the 2024 LSA. Should we seek to amend the terms of the 2024 LSA, the consent of the Lender would be required. As of December 31, 2024, we were in compliance with all of the covenants.

The 2024 LSA bears interest at a floating rate equal to the greater of (a) the WSJ Prime Rate plus 0.25% or (b) 6.00% per annum. The Term Loans are interest only from the Closing Date through November 30, 2025, which may be extended at our option through November 30, 2026 as long as no event of default under the 2024 LSA has occurred. After the end of the interest only period, we are required to pay equal monthly installments of principal through the maturity date of November 1, 2028.

We are also obligated to make an additional final payment of 2.00% of the aggregate original principal amounts of Term Loans advanced by the Lender, due at the earlier of the maturity date or date the Term Loans are repaid in full.

2024 Term Loan

On the Closing Date, we drew $10.0 million in Term Loans under the terms and provisions of the 2024 LSA. We are obligated to make a final payment of $0.2 million under the terms of the 2024 LSA final payment provisions. A discount on debt equal to this obligation was recorded on the draw date and is being amortized as additional interest expense using the effective interest method over the term of the debt. As of December 31, 2024, no payment on principal has been made. As of December 31, 2024, the weighted average effective interest rate for all outstanding debt under the 2024 Term Loan was 8.19%.

2024 Credit Line

We have a $25.0 million line of credit under the terms and provisions of the 2024 LSA available from the Closing Date until March 31, 2025. Amounts repaid under the 2024 Credit Line may not be reborrowed. As of December 31, 2024, no draws had been made on the 2024 Credit Line.

Interest Expense on Long-Term Debt

We recognized $0.5 million of interest expense for year ended December 31, 2024, the components of which included $0.7 million interest expense on long term debt less $0.2 million capitalized interest. There was no interest expense on long term debt or capitalized interest for the years ended December 31, 2023 and 2022.

11. Leases

Operating Leases

We lease office space in Friendswood, Texas (the "Friendswood Lease") for use as our corporate headquarters. The Friendswood Lease commenced in late 2020 under a 60-month term and a renewal option for one additional five-year term.

We lease two facilities in Phoenix, Arizona for laboratory and office space. For both leases, the current terms end in 2033 with options to renew for two additional five-year terms.

We lease general office and laboratory facilities in Pittsburgh Pennsylvania (the "Pittsburgh Lease"). The Pittsburgh Lease commenced in late 2022 under a term of 10.5 years, and with a five-year renewal option and an early termination clause. On August 1, 2024, we amended our Pittsburgh Lease to take early possession of additional square footage under an expansion provision in the original contract at an earlier date than provided for under the original agreement. The expansion option provided us with 23,821 additional square feet, most of which will be dedicated laboratory space, in exchange for an incremental increase in our fixed monthly payments. The amendment did not change the end date under the original lease term, or provide any additional options not already provided for under the original agreement. We evaluated the amendment under ASC Topic 842, Leases, and determined that it constituted a modification to an existing contract and assessed the classification remained an operating lease. Following the modification, our obligations for the remaining lease term increased and we used $1.3 million of lease incentives for leasehold improvements. As of December 31, 2024, we had no remaining credits for leasehold improvements under this contract. In our remeasurement, we recognized an additional $0.6 million in operating lease assets in exchange for an equal amount of additional lease liabilities.

We have not included the optional renewal periods in the measurement of the lease obligations because it is not reasonably certain that we will exercise these renewal options.

Our other operating leases primarily consist of office equipment.

Finance Lease

We lease office printers and other office equipment (the "Finance Leases") for use across our facilities. The Finance Leases commenced in June 2024 under a 64-month term, with an automatic one year extension that becomes effective unless we provide advanced notice of our intent not to extend the term, and a cash lease incentive of $0.2 million. We currently do not expect to extend the term after the original term ends.

Discount Rates

We discount our lease obligations using our incremental borrowing rate at the commencement date of the lease or as of the effective date of a lease modification. The incremental borrowing rate is the rate of interest we would have to pay to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. As of March 26, 2024, we had outstanding borrowings under the 2024 LSA and referred to the interest rate of such debt for use as our incremental borrowing rate. Prior to having outstanding borrowing under the 2024 LSA, we primarily considered industry data, our credit rating and the lease term to determine our incremental borrowing rate.

Lease Balances and Costs

Lease balances reflected in the consolidated balance sheet were as follows (in thousands):

		As of December 31,	
Lease Balance	**Classification**	**2024**	**2023**
Lease Assets			
Operating	Operating lease assets	$ 11,584	$ 12,306
Finance	Property and equipment, net	$ 222	$ 91
Lease Liabilities			
Current			
Operating	Operating lease liabilities	$ 1,665	$ 1,137
Finance	Other accrued and current liabilities	$ 101	$ 71
Noncurrent			
Operating	Noncurrent operating lease liabilities	$ 14,345	$ 14,173
Finance	Noncurrent finance lease liabilities	$ 311	$ 25

Lease costs included in the consolidated statement of operations were as follows (in thousands):

	Years Ended December 31,		
Lease Cost	**2024**	**2023**	**2022**
Operating lease cost[(1)]	$ 2,933	$ 2,625	$ 1,997
Finance lease cost			
Amortization of lease assets	87	141	129
Interest on finance lease liabilities	23	11	16
Short-term lease cost	6	108	477
Total lease cost	$ 3,049	$ 2,885	$ 2,619

(1) Includes variable lease cost of $0.4 million, $0.3 million, and $0.4 million for the years ended December 31, 2024, 2023, and 2022 respectively.

Other Information

Supplemental cash flow information for lease activities included in the consolidated statements of cash flows were as follows (in thousands):

	Years Ended December 31,		
	2024	**2023**	**2022**
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows from operating leases	$ 2,657	$ 1,723	$ 1,283
Operating cash flows from interest paid on finance leases	$ 20	$ 11	$ 16
Financing cash flows from finance leases	$ 97	$ 142	$ 122

Information regarding the weighted-average lease term and weighted-average discount rate is presented below:

	As of December 31,	
	2024	2023
Weighted-average remaining lease term (years)		
Operating leases	8.5	9.1
Finance leases	4.5	1.3
Weighted-average discount rate		
Operating leases	8.4 %	8.0 %
Finance leases	8.4 %	7.4 %

Future maturities for operating lease and finance lease liabilities as of December 31, 2024 were as follows (in thousands):

	Operating Leases	Finance Leases
Years Ending December 31,		
2025	$ 2,948	$ 128
2026	2,399	98
2027	2,443	98
2028	2,494	98
2029	2,544	73
Thereafter	9,929	—
Total lease payments	22,757	495
Less: Interest component	(6,747)	(83)
Present value of lease payments	$ 16,010	$ 412

Undiscounted future lease payments for leases that had not yet commenced as of December 31, 2024 was zero.

12. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market in an orderly transaction between market participants at the measurement date. The fair value hierarchy prioritizes the inputs to valuation techniques used in measuring fair value. There are three levels to the fair value hierarchy based on the reliability of inputs, as follows:

Level 1 – Observable inputs that reflect quoted prices (unadjusted) for identical assets or liabilities in active markets.

Level 2 – Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3 – Unobservable inputs in which little or no market data exists, therefore requiring us to develop our own assumptions.

Financial instruments measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. Our assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The use of different assumptions and/or estimation methodologies may have a material effect on estimated fair values. Accordingly, the fair value estimates disclosed, or amounts recorded may not be indicative of the amount that we or holders of the instruments could realize in a current market exchange.

The table below provides information by level within the fair value hierarchy, of our financial assets and liabilities that are accounted for at fair value on a recurring basis as of December 31, 2024 and 2023 (in thousands):

	As of December 31, 2024			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds[1]	$ 114,091	$ —	$ —	$ 114,091
U.S. government securities[2]	$ 169,866	$ —	$ —	$ 169,866
Trading securities[2]	$ 3,555	$ —	$ —	$ 3,555
Liabilities				
Term Debt [3]	$ —	$ 10,023	$ —	$ 10,023

	As of December 31, 2023			
	Quoted Prices in Active Markets for Identical Items (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets				
Money market funds[1]	$ 89,308	$ —	$ —	$ 89,308
U.S. government securities[2]	$ 144,258	$ —	$ —	$ 144,258

(1) Classified as “Cash and cash equivalents” in the consolidated balance sheets.

(2) Classified as “Marketable investment securities” in the consolidated balance sheets.

(3) Classified as “Current portion of long-term debt” and “Long term debt” in the consolidated balance sheets.

Contingent Consideration

In connection with our acquisition of Cernostics in December 2021, we recorded a liability for contingent consideration that was payable based on the achievement of certain commercial milestones relating to the year ending December 31, 2022 (“Cernostics Earnout Payments”). There were no Cernostics Earnout Payments that became payable because the commercial milestones were not achieved during the earnout period and the final valuation of the contingent consideration was assessed to be zero as of December 31, 2022, resulting in a loss of $18.3 million associated with the change in fair value of the contingent consideration.

In connection with our acquisition of AltheaDx, we agreed to pay contingent consideration of up to $75.0 million relating to the AltheaDx Earnout Payments, as discussed further in Note 6. The portions of the AltheaDx Earnout Payments associated with the commercial milestones for the years ended December 31, 2024, 2023 and 2022 were $20.0 million, $37.5 million (contained a 2022 catch-up provision for additional payment up to $17.5 million) and $35.0 million, respectively, and were not paid at each of these milestone events due to the applicable commercial milestones not being met.

The contingent consideration was classified as a Level 3 fair value measurement due to the use of significant unobservable inputs and a Monte Carlo simulation to determine its fair value. The Monte Carlo simulation uses projections of the commercial milestones for the applicable period as well as the corresponding targets and approximate timing of payment based on the terms of the arrangement. The final valuation for the contingent consideration as of the date of acquisition was assessed to be zero and resulted in a measurement period adjustment. See Note 6 for additional information on the measurement period adjustment. There were no AltheaDx Earnout Payments that became payable because the commercial milestones were not achieved during the earnout periods and the final valuation of the contingent consideration was assessed to be zero as of December 31, 2024.

No gains or losses were recorded associated with changes in fair value during the years ended December 31, 2024, 2023, and 2022.

The contingent consideration liability was remeasured at fair value at each reporting period taking into account any updated assumptions or changes in circumstances. Any changes in the fair value were recorded as gains or losses in the consolidated statement of operations. A measurement period adjustment was recognized in the fourth quarter of 2022 to reverse the preliminary valuation of the contingent consideration and losses recorded during the interim period.

13. Commitments and Contingencies

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. We believe there is no threatened litigation or litigation pending that could have, individually or in the aggregate, a material adverse effect on our financial position, results of operations or cash flows. On February 1, 2024, we received a Subpoena from the Department of Health and Human Services, Office of Inspector General, seeking documents and information concerning claims submitted for payment under federal healthcare programs. The Subpoena requested that we produce documents relating primarily to interactions with medical providers and billing to government-funded healthcare programs for our tests. The time period covered by the Subpoena is January 1, 2015 through February 1, 2024. We are continuing to cooperate with the government's request and are in the process of responding to the Subpoena. We are unable to predict what action, if any, might be taken in the future by the Department of Health and Human Services, Office of Inspector General, or any other governmental authority as a result of the matters related to this Subpoena. No claims have been made against us at this time. Any potential claims could subject us to significant liability for damages and harm our reputation. Our insurance and indemnities may not cover all claims that may be asserted against us. We are unable to predict the outcome and are unable to make a meaningful estimate of the amount or range of loss, if any, that could result from any unfavorable outcome.

14. Stockholders' Equity

Capital Stock

The Company's Amended and Restated Certificate of Incorporation, dated July 29, 2019, authorizes the Company to issue up to 200,000,000 shares of common stock with a par value of $0.001 per share. The Company is also authorized to issue up to 10,000,000 shares of preferred stock with a par value of $0.001 per share. No dividends were declared or paid during the years ended December 31, 2024 or 2023.

15. Stock Incentive Plans and Stock-Based Compensation

Equity Incentive Plans

On July 24, 2019, we adopted the 2019 Equity Incentive Plan (the "2019 Plan"). As of December 31, 2024, there were 791,974 shares remained available for grant under the 2019 Plan. The 2019 Plan provides for automatic annual increases to the number of shares authorized for issuance, equal to 5% of our common shares outstanding as of the immediately preceding year end, through January 1, 2029. Under this provision, effective January 1, 2025, an additional 1,424,159 shares became available under the 2019 Plan.

Prior to adopting the 2019 Plan, we had adopted the 2008 Stock Plan (the "2008 Plan") on September 6, 2008 and the 2018 Stock Plan (the "2018 Plan") on August 15, 2018. No additional shares have been issued from each respective plan following the chronological adoption of each succeeding plan.

Our stock incentive plans provide for the granting of awards to employees, directors, and consultants. Available awards under our incentive plans include options to purchase common stock as well as RSU, PSUs, and other equity-based awards providing recipients the right to receive common shares.

Inducement Plan

On December 22, 2022, our board of directors approved the 2022 Inducement Plan (the "Inducement Plan"). The Inducement Plan provides for the granting of awards as inducement material to the grantee's entering into employment with us to the extent such grantee was not previously an employee of ours or is entering into employment following a bona fide period of non-employment with us. Our Inducement Plan provides for the grant of RSU awards and other stock awards made as an inducement material to the grantee's entering into employment with us to the extent such grantee was not previously an employee of ours or is entering into employment following

a bona fide period of non-employment with us. As of December 31, 2024, there were 191,156 shares available for grant under the Inducement Plan.

Options Granted Under our Plans

Our 2019 Plan and Inducement Plan provide for the granting of options in form of incentive stock options ("ISO") and non-statutory stock options ("NSOs"). ISOs may only be granted to our employees and employee-directors. NSOs may be granted to our employees, employee-directors, nonemployee directors, and consultants. Options may be granted for terms up to ten years from the date of grant, as determined by the board of directors; provided, however, that with respect to an ISO granted to a person who owns stock representing more than 10% of the voting power of all classes of stock of ours, the terms shall be for no more than five years from the date of grant. The exercise price of options granted must be no less than 100% of the fair market value of the shares on the date of grant, provided, however, that with respect to an ISO granted to an employee who at the time of grant of such options owns stock representing more than 10% of the voting power of all classes of stock of ours, the exercise price shall not be less than 110% of the fair market value of the shares on the date of grant. Options generally vest over four years (generally 25% after one year and monthly thereafter), subject to the option holder's continued service with us. We issue new shares to satisfy option exercises.

Stock Options

Stock option activity under our stock plans for the years ended December 31, 2024, 2023, and 2022 is set forth below:

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of January 1, 2022	3,586,688	$ 34.75		
Granted	263,645	$ 22.35		
Exercised	(148,735)	$ 5.59		
Forfeited/Cancelled	(281,758)	$ 34.08		
Balance as of December 31, 2022	3,419,840	$ 35.11		
Granted	170	$ 25.06		
Exercised	(71,525)	$ 3.77		
Forfeited/Cancelled	(139,506)	$ 44.87		
Balance as of December 31, 2023	3,208,979	$ 35.38		
Granted	3,379	$ 71.22		
Exercised	(135,875)	$ 14.85		
Forfeited/Cancelled	(86,720)	$ 39.74		
Balance as of December 31, 2024	2,989,763	$ 36.23	5.5	$ 11,709
Exercisable at December 31, 2024	2,819,446	$ 35.88	5.5	$ 11,684

Restricted Stock Units

RSUs represent the right to receive shares of our common stock at a specified future date, subject to vesting. Our RSUs generally vest annually from the grant date in four equal installments subject to the holder's continued service with us. We issue new shares of common stock upon the vesting of RSUs.

The following table summarizes our RSU activity for the years ended December 31, 2024, 2023, and 2022:

	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of January 1, 2022	1,050,174	$ 44.31
Granted	2,988,107	$ 23.15
Vested[1]	(257,708)	$ 45.14
Forfeited/Cancelled	(302,651)	$ 27.12
Balance as of December 31, 2022	3,477,922	$ 27.56
Granted	549,296	$ 17.92
Vested[1]	(901,547)	$ 28.85
Forfeited/Cancelled	(320,596)	$ 25.62
Balance as of December 31, 2023	2,805,075	$ 25.48
Granted	1,708,028	$ 22.37
Vested [1]	(982,403)	$ 27.68
Forfeited/Cancelled	(334,476)	$ 21.79
Balance as of December 31, 2024	3,196,224	$ 23.52

(1) The aggregate number of shares withheld upon vesting for employee tax obligations was 281,275, 254,197, and 73,821 for the years ended December 31, 2024, 2023 and 2022, respectively.

Performance-Based Restricted Stock Units

PSUs represent the right to receive shares of our common stock contingent upon the achievement of certain financial performance measures. We issue new shares of common stock upon the vesting of PSUs.

On August 9, 2024 (the “Initial Vesting Date”), the Board certified that the revenue goal for the PSUs granted on December 23, 2022 (“2022 PSUs”) was achieved. Therefore, 50% of the 2022 PSUs were vested and we immediately recognized approximately $0.1 million of stock-based compensation related to this performance metric. The remaining 50% of the 2022 PSUs are all subject to time-based vesting and will vest in full on the one-year anniversary of the Initial Vesting Date.

The following table summarizes our PSU activity for the year ended December 31, 2024:

	Performance-Based Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of January 1, 2022	—	$ —
Granted	196,033	$ 23.23
Vested	—	$ —
Forfeited/Cancelled	—	$ —
Balance as of December 31, 2022	196,033	$ 23.23
Granted	—	$ —
Vested	—	$ —
Forfeited/Cancelled	—	$ —
Balance as of December 31, 2023	196,033	$ 23.23
Granted	177,513	$ 21.23
Vested[(1)]	(98,018)	$ 23.23
Forfeited/Cancelled	—	$ —
Balance as of December 31, 2024	275,528	$ 21.94

(1) The aggregate number of shares withheld upon vesting for employee tax obligations was 30,046 for the year ended December 31, 2024.

Retirement Policy

In January 2023, our board of directors approved a retirement policy (the "Retirement Policy") that provides for acceleration of a portion of unvested awards granted to and held by certain eligible employees upon meeting age, service and notice requirements. No shares vested under this policy during the years ended December 31, 2024 and 2023.

Employee Stock Purchase Plan

The ESPP became effective July 24, 2019. Offerings under the ESPP are generally 24 months in length with four six-month purchase periods unless terminated earlier, as described below. Eligible employees who enroll in an offering are able to purchase shares of our common stock at a discount through payroll deductions, subject to certain limitations. The purchase price of the shares of common stock is the lesser of (i) 85% of the fair market value of such shares on the offering date and (ii) 85% of the fair market value of such shares on the purchase date. A new offering begins approximately every six months. Offerings are concurrent, but in the event the fair market value of a share of common stock on the first day of any purchase period during an offering (the "New Offering") is less than or equal to the fair market value of a share of common stock on the offering date for an ongoing offering (the "Ongoing Offering"), then the Ongoing Offering terminates immediately following the purchase of shares on the purchase date immediately preceding the New Offering and the participants in the terminated Ongoing Offering are automatically enrolled in the New Offering. In such case, we account for this event as a modification of the Ongoing Offering. Notwithstanding the above, our board of directors (or an authorized committee thereof) may modify the terms of or suspend any future offerings prior to their commencement.

As of December 31, 2024, 1,046,680 shares remained available for issuance under the ESPP. The ESPP provides for certain automatic increases in the number of shares of common stock reserved for issuance, which resulted in an additional 284,831 shares becoming available under the ESPP effective January 1, 2025. We issue new shares to satisfy the ESPP purchases.

Determining Fair Value - Summary of Assumptions

We use the closing price of our common stock on the date of grant to determine the fair value of RSUs and PSUs.

We use the Black-Scholes option pricing model to estimate the fair value of stock options and purchase rights granted under the ESPP at the date of grant, start of the offering or other relevant measurement date. Set forth below is a description of the significant assumptions used in the option pricing model:

- *Expected term*. The expected term is the period of time that granted options are expected to be outstanding. For stock options, we have set the expected term using the simplified method based on the weighted average of both the period to vesting and the period to maturity for each option, as we have concluded that its stock option exercise history does not provide a reasonable basis upon which to estimate the expected term. For the ESPP, the expected term is the period of time from the offering date to the purchase date.
- *Expected volatility*. Previously, because of the limited period of time our stock had been traded in an active market, we calculated expected volatility by using the historical stock prices of a group of similar companies looking back over the estimated life of the option or the ESPP purchase right and averaging the volatilities of these companies. In the third quarter of 2021, we adjusted this calculation to include our own stock price on a relative basis to the peer group in the calculation of expected volatility, as our common stock had been traded in an active market for more than two years.
- *Risk-free interest rate*. We base the risk-free interest rate used in the Black-Scholes valuation model on the market yield in effect at the time of option grant and at the offering date for the ESPP, provided from the Federal Reserve Board's Statistical Releases and historical publications from the Treasury constant maturities rates for the equivalent remaining terms.
- *Dividend yield*. We have not paid, and do not have plans to pay, cash dividends. Therefore, we use an expected dividend yield of zero in the Black-Scholes option valuation model.

The fair value of our common stock is also an assumption used to determine the fair value of stock options. The fair value of our common stock is the closing selling price per share of its common stock as reported on the Nasdaq Global Market on the date of grant or other relevant determination date.

We use the Black-Scholes option pricing model to estimate the fair value of each option grant on the date of grant or any other measurement date. The following table sets forth the assumptions used to determine the fair value of stock options:

	Years Ended December 31,		
	2024	**2023**	**2022**
Average expected term (years)	5.0	5.0	5.8
Expected stock price volatility	80.20% - 80.20%	75.57% - 76.01%	68.34% - 75.02%
Risk-free interest rate	4.39% - 4.39%	3.57% - 3.57%	1.54% - 4.21%
Dividend yield	—%	—%	—%

The following table sets forth assumptions used to determine the fair value of the purchase rights issued under the ESPP:

	Years Ended December 31,		
	2024	**2023**	**2022**
Average expected term (years)	1.2	1.3	1.3
Expected stock price volatility	59.85% - 105.39%	72.80% - 130.95%	62.98% - 91.78%
Risk-free interest rate	3.82% - 5.14%	4.74% - 5.33%	0.60% - 3.45%
Dividend yield	—%	—%	—%

Fair Value and Intrinsic Value

For the years ended December 31, 2024, 2023, and 2022 the weighted-average grant date fair value of stock options was $9.23, $15.99, and $14.34 per option, respectively, and the weighted-average grant date fair value of the purchase rights granted under the ESPP was $12.66, $11.43, and $16.79 per share, respectively.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2024, 2023, and 2022 was $1.7 million, $1.3 million, and $3.7 million, respectively. The aggregate intrinsic value of shares issued under the ESPP was $1.0 million, $0.5 million, and $0.5 million during the years ended December 31, 2024, 2023, and 2022, respectively.

The aggregate fair value of RSUs that vested during the years ended December 31, 2024, 2023, and 2022 was $27.7 million, $18.1 million, and $5.9 million, respectively.

Stock-Based Compensation Expense

Stock-based compensation expense is included in the consolidated statements of operations as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 5,529	$ 4,938	$ 3,755
Research and development	9,598	10,119	7,635
Selling, general and administrative	35,193	36,162	24,931
Total stock-based compensation expense	$ 50,320	$ 51,219	$ 36,321

As of December 31, 2024, the total unrecognized stock-based compensation cost related to outstanding awards was $71.1 million, which is expected to be recognized over a weighted-average period of 2.2 years. The total unrecognized compensation cost will be adjusted for forfeitures in future periods as they occur.

Included in total stock-based compensation expense for the years ended December 31, 2024 and 2023 is $0.7 million and $1.6 million, respectively, from the accelerated recognition of expense for modifications of awards falling in scope of the Retirement Policy. The Retirement Policy was adopted in January 2023, so there was no accelerated recognition of stock-based compensation expense for the year ended December 31, 2022.

No tax benefits related to stock-based compensation expense were recorded in the consolidated statements of operations during the years ended December 31, 2024, 2023, and 2022 due to the valuation allowance on net deferred tax assets.

16. Income Taxes

The components of income tax expense (benefit) are as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Current tax expense			
U.S. federal	$ 663	$ —	$ —
State and local	1,255	324	111
Total current	1,918	324	111
Deferred tax benefit			
U.S. federal	1,622	33	(1,626)
State and local	(221)	(256)	(251)
Total deferred	1,401	(223)	(1,877)
Total income tax expense (benefit)	$ 3,319	$ 101	$ (1,766)

The differences between income taxes expected at the U.S. federal statutory rate (21%) and the reported income tax expense (benefit) are summarized as follows (in thousands):

	Years Ended December 31,		
	2024	2023	2022
Pre-tax income (loss)	$ 21,564	$ (57,365)	$ (68,904)
U.S. federal taxes at statutory rate	4,528	(12,046)	(14,470)
State income taxes	683	925	(3,751)
R&D tax credit	(3,381)	(2,186)	(1,814)
Change in valuation allowance	(4,469)	5,207	17,075
Stock-based compensation	1,528	4,323	3,323
Non-deductible officers' compensation	2,651	2,377	1,326
Change in fair value of contingent consideration	—	—	(3,840)
Transaction costs	—	—	359
Permanent differences	1,712	1,474	—
Other	67	27	26
Income tax expense (benefit)	$ 3,319	$ 101	$ (1,766)

Significant components of deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2024	2023
Deferred tax assets:		
NOL carryforwards	$ 31,782	$ 47,162
Accrued liabilities	7,301	6,466
Capitalized R&D costs	15,485	9,915
Lease liabilities	3,774	3,511
Stock-based compensation	5,128	4,416
R&D tax credit	9,747	8,025
Other	—	4
Total deferred tax assets	73,217	79,499
Less valuation allowance	(50,536)	(55,028)
Deferred tax assets, net	$ 22,681	$ 24,471
Deferred tax liabilities:		
Prepaid expenses	$ (185)	$ (182)
Property and equipment	(6,374)	(4,662)
Intangible assets	(14,986)	(17,003)
ROU assets	(2,558)	(2,799)
Other	(185)	(31)
Total deferred tax liabilities	(24,288)	(24,677)
Net deferred tax liability	$ (1,607)	$ (206)

As of December 31, 2024, we had federal NOL carryforwards of approximately $129.4 million of which $52.9 million will begin to expire in 2031 if not utilized to offset taxable income, and $76.5 million may be carried forward indefinitely. Future changes in ownership, as defined by Section 382 of the IRC, could limit the amount of NOL carryforwards used in any one year. As of December 31, 2024, we had state NOL carryforwards of approximately $86.5 million, which begin to expire in 2028 if not utilized to offset state taxable income. As of December 31, 2024,

we had R&D tax credit carryforwards of $9.7 million, which includes $0.9 million of state credits, which will begin to expire in 2034 if not utilized to offset federal income tax.

In general, under Section 382 and 383 of the IRC, a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs and certain tax credits, to offset future taxable income and tax. In general, an ownership change occurs if the aggregate stock ownership of certain stockholders changes by more than 50 percentage points over such stockholders’ lowest percentage of ownership during the testing period (generally three years). We performed a Section 382 analysis from inception through the year ended December 31, 2024 and concluded we had experienced an ownership change in 2011, 2014 and 2020. These changes in ownership did not result in the expiration of any NOLs or R&D credits. However, future changes in ownership may further limit our ability to utilize our NOL carryforwards and R&D tax credit carryforwards. We have also performed Section 382 analyses with respect to the NOLs we obtained in our acquisitions of Cernostics and AltheaDx. Based on changes in ownership that have occurred, $36.3 million of NOLs are expected to expire unused as a result of Section 382 limitations.

As of December 31, 2024 and 2023, we placed a valuation allowance of $50.5 million and $55.0 million, respectively, against our net deferred tax asset balance, as we have determined that it is more likely than not that they will not be realized. The valuation allowance as of December 31, 2024 and 2023 was primarily related to NOL and R&D tax credit carryforwards that more likely than not, will expire unused.

The net change in total valuation allowance for each of the years ended December 31, 2024, 2023 and 2022 was a decrease of $4.5 million, an increase of $5.1 million, and an increase of $32.2 million, respectively. During the year ended December 31, 2022, in connection with the acquisition of AltheaDx, we recorded additional net deferred tax liability of $1.7 million, primarily due to book-tax differences related to the acquired intangible assets. As a result of these additional deferred tax liabilities, we determined that $1.6 million of our valuation allowance should be reduced, which was reflected in our income tax benefit for the year ended December 31, 2022.

We assessed whether we had any significant uncertain tax positions related to open tax years and concluded there were none. Accordingly, no reserve for uncertain tax positions has been recorded as of December 31, 2024 and 2023. We are generally no longer subject to tax examinations for U.S. federal income tax purposes for fiscal years prior to 2021 and fiscal years prior to 2020 for multiple state jurisdictions. However, since we have been in an NOL position since 2008 until recently, our 2008 to 2020 federal tax returns and our 2008 to 2019 state tax returns are potentially subject to examination adjustments to the extent of those NOL carryforwards.

No material amounts of tax-related interest or penalties were recorded during the years ended December 31, 2024, 2023, and 2022.

17. Segment and Related Information

The Company derives revenues through the delivery of test reports for our molecular diagnostic tests. Clinicians use the results from these tests to aid in the diagnosis and treatment of dermatologic cancers, Barrett’s esophagus, uveal melanoma, and in the treatment of mental health conditions. All of our operations are located within the United States and our business is focused on the U.S. market. Budgets and financial information for net revenues are maintained and are regularly reviewed for each of our tests but expense information is not maintained and readily available below the consolidated results of operations level of aggregation.

We have a single reportable segment consisting of a single operating segment where our CEO is our CODM, which aligns with how our business is organized and is managed.

The accounting policies and measurements of income before income taxes and discontinued operations for the consolidated financial statements and the reportable segment are the same.

The CODM assesses segment performance using actual-to-actual and actual-to-budget variance analysis for segment net revenues, significant segment expenses, and net income to assess segment performance and in deciding how to allocate resources.

For the years ended December 31, 2024, 2023 and 2022, the measures of segment profit and loss for of our single reportable segment were as follows (in thousands):

	Years ended December 31,		
	2024	2023	2022
Net revenues from external customers[1]	$ 332,069	$ 219,788	$ 137,039
Significant segment expenses:			
Personnel costs	189,883	172,248	134,557
Organizational and business development costs	44,178	39,481	31,894
Inventory usage	19,930	15,475	9,859
Clinical studies and publication costs	9,951	11,924	8,997
Professional services	10,476	7,496	10,070
Other segment items	39,406	30,630	8,800
Segment profit (loss)	$ 18,245	$ (57,466)	$ (67,138)

(1) For information on disaggregation of segment revenue by type and information about payor concentration, see Note 3.

Significant segment expenses

Personnel costs

Personnel costs consist of salaries and wages, bonuses, employee benefits, stock-based compensation expense, and payroll taxes. Personnel costs are a significant portion of operating expenses and are a component of cost of sales, research and development expense, and selling and general administrative expense. Our CODM considers this information injunction with test report deliveries in assessing budgeted and actual operational performance and in allocating resources.

Organizational and business development costs

Organizational and business development costs include expense incurred for travel, transportation, meals and lodging, training, and conference and venue fees and are a component of cost of sales, research and development expense, and selling and general administrative expense. Our CODM considers this information in their assessment of operating expense results and in planning and budgeting for future corporate development activities.

Inventory usage

Inventory usage is the expense incurred through direct materials used in processing our tests, and are significant component of our cost of sales. Our CODM considers this information injunction with test report deliveries in assessing budgeted and actual operational performance and in allocating resources.

Clinical studies and publication costs

Clinical studies and publication costs include expenses incurred through our pipeline initiatives as well as in gathering evidence to support the clinical validity and utility of our existing test portfolio. Our CODM considers this information in their assessment of research and development results and in planning and budgeting activities.

Professional services

Professional services include expenses incurred for legal and advisory services across our business as well as expenses incurred for services provided by our independent auditors. Professional service expenses are a component of cost of sales, research and development expense, and selling and general administrative expense. Our CODM considers this information in their assessment of operating expense results and in planning and budgeting activities.

Other segment items

Other segment items include all other operating expenses types to included IT service and software licensing costs, fixed and variable expenses incurred for leasing of facilities and equipment, depreciation and amortization, changes in fair value of contingent consideration, gain or losses on disposal of fixed assets in the routine course of business, fair value adjustment for trading securities, realized gains or losses on investment securities, administrative costs, expense for use of prepaids to include insurance premiums and warranties for lab equipment, public company costs (less audit fees), interest and other non-operating income, and income tax expense or benefits. Our CODM does not individually review budgets or results for these activities.

Other amounts included in the measure of segment profit or loss for the years ended December 31, 2024, 2023 and 2022 were as follows (in thousands):

	Years ended December 31,		
	2024	2023	2022
Interest income	$ 12,916	$ 10,623	$ 3,968
Interest expense	577	11	17
Depreciation and amortization	15,997	12,330	10,543
Income tax expense (benefit)	3,319	101	(1,766)
Stock-based compensation expense	50,320	51,219	36,321
Changes in fair value of trading securities	555	—	—
Change in fair value of contingent consideration	—	—	(18,287)

Total assets for our reportable segment were located in the United States and were $531.2 million and $453.3 million as of December 31, 2024 and 2023, respectively. Expenditures for additions to long-lived assets were $29.3 million, $13.5 million, and $7.0 million for the years ended December 31, 2024, 2023, and 2022, respectively.

CASTLE BIOSCIENCES, INC.
INSIDER TRADING POLICY

INTRODUCTION

During the course of your relationship with Castle Biosciences, Inc. (the "***Company***"), you may receive material information that is not yet publicly available ("***material nonpublic information***") about the Company or other publicly traded companies that the Company has business relationships with. Material nonpublic information may give you, or someone you pass that information on to, a leg up over others when deciding whether to buy, sell or otherwise transact in the Company's securities or the securities of another publicly traded company. This policy sets forth guidelines with respect to transactions in Company securities by our employees, Directors and consultants who may become aware of material non-public information and the other persons subject to this policy as described below.

STATEMENT OF POLICY

It is the policy of the Company that an employee, Director or consultant of the Company (or any other person subject to this policy) who is aware of material nonpublic information relating to the Company **may not**, directly or indirectly:

1. engage in any transactions in the Company's securities, except as otherwise specified under the heading "Exceptions to this Policy" below;

2. recommend the purchase or sale of any of the Company's securities;

3. disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons, such as family, friends, business associates and investors, unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company; or

4. assist anyone engaged in the above activities.

The prohibition against insider trading is absolute. It applies ***even if*** the decision to trade is not based on such material nonpublic information. It also applies to transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) and also to very small transactions. All that matters is whether you are aware of **any** material nonpublic information relating to the Company at the time of the transaction.

The U.S. federal securities laws do not recognize any mitigating circumstances to insider trading. In addition, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct. In some circumstances, you may need to forgo a planned transaction even if you planned it before becoming aware of the material nonpublic information. So, even if you believe you may suffer an economic loss or sacrifice an anticipated profit by waiting to trade, you must wait.

It is also important to note that the laws prohibiting insider trading are not limited to trading by the insider alone; advising others to trade on the basis of material nonpublic information is illegal and squarely prohibited by this policy. Liability in such cases can extend both to the "tippee"—the person to whom the insider disclosed material nonpublic information—and to the "tipper," the insider himself or herself. In such cases, you can be held liable for your own transactions, as well as the transactions by a tippee and even the transactions of a tippee's tippee. For these and other reasons, it is the policy of the Company that no employee, Director or consultant of the Company(or any other person subject to this policy) may either (a) recommend to another person that they buy, hold or sell the Company's securities **at any time** or (b) disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons (unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company).

In addition, it is the policy of the Company that no employee, Director or consultant of the Company (or any other person subject to this policy) who, in the course of working for the Company, learns of or is otherwise aware of material nonpublic information about another publicly traded company with which the Company does business, including a customer or supplier of the Company, may trade in that company's securities until the information becomes public or is no longer material.

There are no exceptions to this policy, except as specifically noted above or below.

TRANSACTIONS SUBJECT TO THIS POLICY

This policy applies to all transactions in securities issued by the Company, as well as derivative securities that are not issued by the Company, such as exchange-traded put or call options or swaps relating to the Company's securities. Accordingly, for purposes of this policy, the terms "***trade***," "***trading***" and "***transactions***" include not only purchases and sales of the Company's common stock in the public market but also any other purchases, sales, transfers or other acquisitions and dispositions of common or preferred equity, options, warrants and other securities (including debt securities) and other arrangements or transactions that affect economic exposure to changes in the prices of these securities.

PERSONS SUBJECT TO THIS POLICY

This policy applies to you and all other employees, Directors and consultants of the Company and its subsidiaries. This policy also applies to members of your immediate family, persons with whom you share a household, persons who are your economic dependents and any other individuals or entities whose transactions in securities you influence, direct or control (including, e.g., a venture or other investment fund, if you influence, direct or control transactions by the fund). The foregoing persons who are deemed subject to this policy are referred to in this policy as "***Related Persons***." You are responsible for making sure that your Related Persons comply with this policy.

MATERIAL NONPUBLIC INFORMATION

Material information

It is not always easy to figure out whether you are aware of material nonpublic information. But there is one important factor to determine whether nonpublic information you know about a public company is material: whether the information could be expected to affect the market price of that company's securities or to be considered important by investors who are considering trading that company's securities. If the information makes you want to trade, it would probably have the same effect on others. Keep in mind that both positive and negative information can be material.

There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by relevant enforcement authorities with the benefit of hindsight. Depending on the specific details, the following items may be considered material nonpublic information until publicly disclosed within the meaning of this policy. There may be other types of information that would qualify as material information as well; use this list merely as a non-exhaustive guide:

- financial results or forecasts;
- status of product or product candidate development or regulatory approvals;
- clinical data relating to products or product candidates;
- timelines for pre-clinical studies or clinical trials;
- acquisitions or dispositions of assets, divisions or companies;
- public or private sales of debt or equity securities;
- stock splits, dividends or changes in dividend policy;
- the establishment of a repurchase program for the Company's securities;
- gain or loss of a significant licensor, licensee or supplier; and
- changes or new corporate partner relationships or collaborations.
- notice of issuance or denial of patents;
- regulatory developments;
- management or control changes;
- employee layoffs;
- a disruption in the Company's operations or breach or unauthorized access of its property or assets, including its facilities and information technology infrastructure;
- tender offers or proxy fights;
- accounting restatements;
- litigation or settlements; and
- impending bankruptcy.

When information is considered public

The prohibition on trading when you have material nonpublic information lifts once that information becomes publicly disseminated. But for information to be considered publicly disseminated, it must be widely disseminated through a press release, a filing with the Securities and Exchange Commission (the "***SEC***"), or other widely disseminated announcement. Once information is publicly disseminated, it is still necessary to afford the investing public with

sufficient time to absorb the information. Generally speaking, information will be considered publicly disseminated for purposes of this policy only after two full trading days have elapsed since the information was publicly disclosed. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. Depending on the particular circumstances, the Company may determine that a longer or shorter waiting period should apply to the release of specific material nonpublic information.

QUARTERLY TRADING BLACKOUTS

Members of our Board of Directors, officers, employees in our finance and accounting department, employees at the director level and above and other employees of and consultants to the Company who have been notified or who the Company may notify from time to time of their designation as insiders, who we collectively refer to as "***Covered Insiders***", are likely to possess material nonpublic information about the Company at certain points during the year. To minimize even the appearance of insider trading among Covered Insiders we have established "quarterly trading blackout periods" during which Covered Insiders and their respective Related Persons, regardless of whether they are aware of material nonpublic information or not, may not conduct any trades in Company securities. That means that, except as described in this policy, all Covered Insiders will be able to trade in Company securities only during limited open trading window periods that generally will begin after two full trading days have elapsed since the public dissemination of the Company's annual or quarterly financial results and end at the beginning of the next quarterly trading blackout period. Of course, even during an open trading window period, you may not (unless an exception applies) conduct any trades in Company securities if you are otherwise in possession of material nonpublic information.

For purposes of this policy, each "***quarterly trading blackout period***" will generally begin at the end of the day that is 14 days before the end of each fiscal quarter (or if such day is not a business day, then the immediately preceding business day) and end after two full trading days have elapsed since the public dissemination of the Company's financial results for that quarter. Please note that the quarterly trading blackout period may commence early or may be extended if, in the judgment of the President and Chief Executive Officer or Chief Financial Officer, there exists undisclosed information that would make trades by Covered Insiders inappropriate. It is important to note that the fact that the quarterly trading blackout period has commenced early or has been extended should be considered material nonpublic information that should not be communicated to any other person.

A Covered Insider who believes that special circumstances require him or her to trade during a quarterly trading blackout period should consult the Chief Financial Officer. Permission to trade during a quarterly trading blackout period will be granted only where the circumstances are extenuating, the Chief Financial Officer concludes that the person is not in fact aware of any material nonpublic information relating to the Company or its securities, and there appears to be no significant risk that the trade may subsequently be questioned.

EVENT-SPECIFIC TRADING BLACKOUTS

From time to time, an event may occur that is material to the Company and is known by only a few Directors, officers and/or employees. So long as the event remains material and nonpublic, the persons designated by the President and Chief Executive Officer or Chief Financial Officer may not trade in the Company's securities. In that situation, the Company will notify the designated individuals that neither they nor their Related Persons may trade in the Company's securities. The existence of an event-specific trading blackout should also be considered material nonpublic information and should not be communicated to any other person. Even if you have not been designated as a person who should not trade due to an event-specific trading blackout, you should not trade while aware of material nonpublic information. Exceptions will not be granted during an event-specific trading blackout.

The quarterly and event-driven trading blackouts do not apply to those transactions to which this policy does not apply, as described under the heading "Exceptions to this Policy" below.

EXCEPTIONS TO THIS POLICY

This policy does not apply in the case of the following transactions, except as specifically noted:

1. ***Option Exercises.*** This policy does not apply to the exercise of options granted under the Company's equity compensation plans for cash. This policy does, however, apply to any sale of stock as part of a broker-assisted cashless exercise or any other market sale, whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

2. ***Tax Withholding Transactions***. This policy does not apply to the surrender of shares directly to the Company to satisfy tax withholding obligations as a result of the issuance of shares upon vesting or exercise of restricted stock units, options or other equity awards granted under the Company's equity compensation plans. Of course, any market sale of the stock received upon exercise or vesting of any such equity awards remains subject to all provisions of this policy whether or not for the purpose of generating the cash needed to pay the exercise price or pay taxes.

3. ***ESPP***. This policy does not apply to the purchase of stock by employees under the Company's Employee Stock Purchase Plan ("***ESPP***") on periodic designated dates in accordance with the ESPP. This policy does, however, apply to any sale of stock acquired pursuant to the ESPP.

4. ***10b5-1 Automatic Trading Programs***. Under Rule 10b5-1 of the Securities Exchange Act of 1934, as amended ("***Exchange Act***"), employees, Directors and consultants may establish a trading plan under which a broker is instructed to buy and sell Company securities based on pre- determined criteria (a "***Trading Plan***"). So long as a Trading Plan is properly established, purchases and sales of Company securities pursuant to that Trading Plan are not subject to this policy. To be properly established, an employee's, Director's or consultant's Trading Plan must be established in compliance with the requirements of Rule 10b5-1 of the Exchange Act and any applicable 10b5-1 trading plan guidelines of the Company at a time when such individual was unaware of any material nonpublic information relating to the Company and when the Company

was not otherwise in a trading blackout period. Moreover, all Trading Plans must be reviewed and approved by the Company before being established to confirm that the Trading Plan complies with all pertinent company policies and applicable securities laws; *provided, that* any Trading Plan adopted by the Company's Chief Executive Officer shall be approved by the Company's Chief Financial Officer, and any Trading Plan adopted by the Company's Chief Financial Officer shall be approved by the Company's Chief Executive Officer. It is the policy of the Company that it will not verify the existence or non-existence of a trading blackout to any person adopting a Trading Plan unless the Company has been permitted to review such Trading Plan in its entirety, and in no case will the Company approve any such Trading Plan unless the Company is permitted to review such Trading Plan in its entirety prior to such Trading Plan being established.

5. ***Gifts.*** This policy does not apply to *bona fide* gifts of Company securities that have been pre-cleared by the Company's Chief Financial Officer or his or her designee. Whether a gift is truly *bona fide* will depend on the facts and circumstances surrounding each gift. Pre-clearance must be obtained at least two business days in advance of the proposed gift, and pre-cleared gifts not completed within five business days will require new pre-clearance. The Company may choose to shorten this period.

6. ***401(k) Plan***. This policy does not apply to purchases of the Company's securities in the Company's 401(k) plan resulting from your periodic contribution of money to the plan pursuant to your payroll deduction election. This policy does apply, however, to certain elections you may make under the 401(k) plan, to the extent permitted or provided for under the 401(k) plan, including: (a) an election to increase or decrease the percentage of your periodic contributions that will be allocated to the Company stock fund; (b) an election to make an intra-plan transfer of an existing account balance into or out of the Company stock fund; (c) an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of your the Company stock fund balance; and (d) an election to pre-pay a plan loan if the pre-payment will result in allocation of loan proceeds to the Company stock fund.

SPECIAL AND PROHIBITED TRANSACTIONS

1. ***Inherently Speculative Transactions.*** No Company employee, Director or consultant may engage in short sales, transactions in put options, call options or other derivative securities on an exchange or in any other organized market, or in any other inherently speculative transactions with respect to the Company's stock.

2. ***Hedging Transactions.*** Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit a Company employee, Director or consultant to continue to own the Company's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Company employee, Director or consultant may no longer have the same objectives as the Company's other shareholders. Therefore, the Company employee, Director and consultants are prohibited from engaging in any such transactions.

3. ***Margin Accounts and Pledged Securities***. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails

to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in the Company's securities, the Company employee, Director and consultants are prohibited from holding Company Securities in a margin account or otherwise pledging the Company's securities as collateral for a loan.

4. ***Standing and Limit Orders***. Standing and limit orders (except standing and limit orders under approved Trading Plans, as discussed above) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when a Company employee, Director or consultant is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on the Company's securities. If a person subject to this policy determines that they must use a standing order or limit order (other than under an approved Trading Plan as discussed above), the order should be limited to short duration and the person using such standing order or limit order is required to cancel such instructions immediately in the event restrictions are imposed on their ability to trade pursuant to the "Quarterly Trading Blackouts" and "Event-Specific Trading Blackouts" provisions above.

PRE-CLEARANCE AND ADVANCE NOTICE OF TRANSACTIONS

In addition to the requirements above, officers, Directors and other applicable members of management who have been notified that they are subject to pre-clearance requirements face a further restriction: even during an open trading window, they may not engage in any transaction in the Company's securities without first obtaining pre-clearance of the transaction from the Company's Chief Financial Officer or his or her designee at least two business days in advance of the proposed transaction. The Chief Financial Officer or his or her designee will then determine whether the transaction may proceed and, if so, will direct the Compliance Coordinator (as identified in the Company's Section 16 Compliance Program) to help comply with any required reporting requirements under Section 16(a) of the Exchange Act. Pre-cleared transactions not completed within five business days will require new pre-clearance. The Company may choose to shorten this period.

Persons subject to pre-clearance must also give advance notice of their plans to exercise an outstanding stock option to the Compliance Coordinator or Chief Financial Officer. Once any transaction takes place, the officer, Director or applicable member of management must immediately notify the Compliance Coordinator and any other individuals identified under the heading "Notification of Execution of Transaction" in the Company's Section 16 Compliance Program so that the Company may assist in any Section 16 reporting obligations.

SHORT-SWING TRADING, CONTROL STOCK AND SECTION 16 REPORTS

Officers and Directors subject to the reporting obligations under Section 16 of the Exchange Act should take care to avoid short-swing transactions (within the meaning of Section 16(b) of the Exchange Act) and the restrictions on sales by control persons (Rule 144 under the Securities Act of 1933, as amended), and should file all appropriate Section 16(a) reports (Forms 3, 4 and 5),

which are described in the Company's Section 16 Compliance Program, and any notices of sale required by Rule 144.

PROHIBITION OF TRADING DURING PENSION PLAN BLACKOUTS

No Director or executive officer of the Company may, directly or indirectly, purchase, sell or otherwise transfer any equity security of the Company (other than an exempt security) during any "blackout period'' (as defined in Regulation BTR under the Exchange Act) if a Director or executive officer acquires or previously acquired such equity security in connection with his or her service or employment as a Director or executive officer. This prohibition does not apply to any transactions that are specifically exempted, including but not limited to, purchases or sales of the Company's securities made pursuant to, and in compliance with, a Trading Plan; compensatory grants or awards of equity securities pursuant to a plan that, by its terms, permits executive officers and Directors to receive automatic grants or awards and specifies the terms of the grants and awards; or acquisitions or dispositions of equity securities involving a bona fide gift or by will or the laws of descent or pursuant to a domestic relations order. The Company will notify each Director and executive officer of any blackout periods in accordance with the provisions of Regulation BTR. Because Regulation BTR is very complex, no Director or executive officer of the Company should engage in any transactions in the Company's securities, even if believed to be exempt from Regulation BTR, without first consulting with the General Counsel.

POLICY'S DURATION

This policy continues to apply to your transactions in the Company's securities or the securities of other public companies engaged in business transactions with the Company even after your relationship with the Company has ended. If you are aware of material nonpublic information when your relationship with the Company ends, you may not trade the Company's securities or the securities of other applicable companies until the material nonpublic information has been publicly disseminated or is no longer material. Further, if you leave the Company during a trading blackout period, then you may not trade the Company's securities or the securities of other applicable companies until the trading blackout period has ended.

INDIVIDUAL RESPONSIBILITY

Persons subject to this policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in the Company's securities while aware of material nonpublic information. Each individual is responsible for making sure that he or she complies with this policy, and that any family member, household member or other person or entity whose transactions are subject to this policy, as discussed under the heading "Persons Subject to this Policy" above, also comply with this policy. In all cases, the responsibility for determining whether an individual is aware of material nonpublic information rests with that individual, and any action on the part of the Company or any employee or Director of the Company pursuant to this policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal

penalties and disciplinary action by the Company for any conduct prohibited by this policy or applicable securities laws. See "Penalties" below.

PENALTIES

Anyone who engages in insider trading or otherwise violates this policy may be subject to both civil liability and criminal penalties. Violators also risk disciplinary action by the Company, including termination of employment. Anyone who has questions about this policy should contact their own attorney or the Company's Chief Financial Officer, at fstokes@castlebiosciences.com. Please also see Frequently Asked Questions, which are attached as **Exhibit A**.

AMENDMENTS

The Company is committed to continuously reviewing and updating its policies and procedures. The Company therefore reserves the right to amend, alter or terminate this policy at any time and for any reason. A current copy of the Company's policies regarding insider trading may be obtained by contacting the Compliance Coordinator.

EXHIBIT A
INSIDER TRADING POLICY
FREQUENTLY ASKED QUESTIONS

1. ***What is insider trading?***

A: Generally speaking, insider trading is the buying or selling of stocks, bonds, futures or other securities by someone who possesses or is otherwise aware of material nonpublic information about the securities or the issuer of the securities. Insider trading also includes trading in derivatives (such as put or call options) where the price is linked to the underlying price of a company's stock. It does not matter whether the decision to buy or sell was influenced by the material nonpublic information, how many shares you buy or sell, or whether it has an effect on the stock price. Bottom line: If you are aware of material nonpublic information about the Company or another publicly traded company that the Company has business relationships with and you trade in the Company's or such other company's securities, you have broken the law.

2. ***Why is insider trading illegal?***

A: If company insiders are able to use their confidential knowledge to their financial advantage, other investors would not have confidence in the fairness and integrity of the market. This ensures that there is an even playing field by requiring those who are aware of material nonpublic information to refrain from trading.

3. ***What is material nonpublic information?***

A: Information is material if it would influence a reasonable investor to buy or sell a stock, bond future or other security. This could mean many things: financial results, clinical or regulatory results, potential acquisitions or major contracts to name just a few. Information is nonpublic if it has not yet been publicly disseminated within the meaning of our insider trading policy.

4. ***Who can be guilty of insider trading?***

A: Anyone who buys or sells a security while aware of material nonpublic information, or provides material nonpublic information that someone else uses to buy or sell a security, may be guilty of insider trading. This applies to all individuals, including officers, Directors and others who don't even work at the Company. Regardless of who you are, if you know something material about the value of a security that not everyone knows and you trade (or convince someone else to trade) in that security, you may be found guilty of insider trading.

5. ***Does the Company have an insider trading policy?***

A: Yes, the insider trading policy is available to read on our website at www.castlebiosciences.com.

6. ***What if I work in a foreign office?***

A: The same rules apply to U.S. and foreign employees and consultants. The Securities and Exchange Commission (the U.S. government agency in charge of investor protection) and the

Financial Industry Regulatory Authority (a private regulator that oversees U.S. securities exchanges) routinely investigate trading in a company's securities conducted by individuals and firms based abroad. In addition, as a Company Director, employee or consultant, our policies apply to you no matter where you work.

7. ***What if I don't buy or sell anything, but I tell someone else material nonpublic information and they buy or sell?***

A: That is called "tipping." You are the "tipper" and the other person is called the "tippee." If the tippee buys or sells based on that material nonpublic information, both you and the "tippee" could be found guilty of insider trading. In fact, if you tell family members who tell others and those people then trade on the information, those family members and the "tippee" might be found guilty of insider trading too. To prevent this, you may not discuss material nonpublic information about the company with anyone outside the Company, including spouses, family members, friends or business associates (unless the disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company). This includes anonymous discussions on the internet about the Company or companies with which the Company does business.

8. ***What if I don't tell them the information itself; I just tell them whether they should buy or sell?***

A: That is still tipping, and you can still be responsible for insider trading. You may never recommend to another person that they buy, hold or sell the Company's common stock or any derivative security related to the Company's common stock, since that could be a form of tipping.

9. ***What are the sanctions if I trade on material nonpublic information or tip off someone else?***

A: In addition to disciplinary action by the Company—which may include termination of employment—you may be liable for civil sanctions for trading on material nonpublic information. The sanctions may include return of any profit made or loss avoided as well as penalties of up to three times any profit made or any loss avoided. Persons found liable for tipping material nonpublic information, even if they did not trade themselves, may be liable for the amount of any profit gained or loss avoided by everyone in the chain of tippees as well as a penalty of up to three times that amount. In addition, anyone convicted of criminal insider trading could face prison and additional fines.

10. ***What is "loss avoided"?***

A: If you sell common stock or a related derivative security before negative news is publicly announced, and as a result of the announcement the stock price declines, you have avoided the loss caused by the negative news.

11. ***Am I restricted from trading securities of any companies other than the Company, for example a customer or competitor of the Company?***

A: Possibly. U.S. insider trading laws generally restrict everyone aware of material nonpublic information about a company from trading in that company's securities, regardless of whether the person is directly connected with that company, except in limited circumstances. Therefore, if you have material nonpublic information about another company, you should not trade in that company's securities. You should be particularly conscious of this restriction if, through your position at the Company, you sometimes obtain sensitive, material information about other companies and their business dealings with the Company.

12. ***So if I do not trade Company securities when I have material nonpublic information, and I don't "tip" other people, I am in the clear, right?***

A: Not necessarily. Even if you do not violate U.S. law, you may still violate our policies. For example, employees and consultants may violate our policies by breaching their confidentiality obligations or by recommending Company stock as an investment, even if these actions do not violate securities laws. Our policies are stricter than the law requires so that we and our employees and consultants can avoid even the appearance of wrongdoing. Therefore, please review the entire policy carefully.

13. ***So when can I buy or sell my Company securities?***

A: If you are aware of material nonpublic information, you may not buy or sell our common stock until two full trading days have elapsed since the information was publicly disclosed. At that point, the information is considered publicly disseminated for purposes of our insider trading policy. For example, if we announce material nonpublic information before trading begins on Wednesday, then you may execute a transaction in our securities on Friday; if we announce material nonpublic information after trading ends on Wednesday, then you may execute a transaction in our securities on Monday. **If you are a Covered Insider, then even if you are not aware of any material nonpublic information, you may not trade our common stock during any trading "blackout" period, with certain exceptions described in our insider trading policy**. Our insider trading policy describes the quarterly trading blackout period, and additional event-driven trading blackout periods may be announced by email.

14. ***If I am a Covered Insider and have an open order to buy or sell Company securities on the date a blackout period commences, can I leave it to my broker to cancel the open order and avoid executing the trade?***

A: No, unless it is in connection with a 10b5-1 trading plan (see Question 27 below). If you have any open orders when a blackout period commences other than in connection with a 10b5-1 trading plan, it is your responsibility to cancel these orders with your broker. If you have an open order and it executes after a blackout period commences not in connection with a 10b5-1 trading plan, you will have violated our insider trading policy and may also have violated insider trading laws.

15. ***Am I allowed to trade derivative securities of the Company's common stock?***

A: No. Under our policies, you may not trade in derivative securities related to our common stock, which include publicly traded call and put options. In addition, under our policies, you may not engage in short selling of our common stock at any time.

"Derivative securities" are securities other than common stock that are speculative in nature because they permit a person to leverage their investment using a relatively small amount of money. Examples of derivative securities include "put options" and "call options." These are different from employee options and other equity awards granted under our equity compensation plans, which are not derivative securities for purposes of our policy.

"Short selling" is profiting when you expect the price of the stock to decline, and includes transactions in which you borrow stock from a broker, sell it, and eventually buy it back on the market to return the borrowed shares to the broker. Profit is realized if the stock price decreases during the period of borrowing.

16. ***Why does the Company prohibit trading in derivative securities and short selling?***

A: Many companies with volatile stock prices have adopted similar policies because of the temptation it represents to try to benefit from a relatively low-cost method of trading on short- term swings in stock prices, without actually holding the underlying common stock, and encourages speculative trading. We are dedicated to building stockholder value, short selling our common stock conflicts with our values and would not be well-received by our stockholders.

17. ***Can I purchase Company securities on margin or hold them in a margin account?***

A: Under our policies, you may not purchase our common stock on margin or hold it in a margin account at any time.

"Purchasing on margin" is the use of borrowed money from a brokerage firm to purchase our securities. Holding our securities in a margin account includes holding the securities in an account in which the shares can be sold to pay a loan to the brokerage firm.

18. ***Why does the Company prohibit me from purchasing Company securities on margin or holding them in a margin account?***

A: Margin loans are subject to a margin call whether or not you possess material nonpublic information at the time of the call. If a margin call were to be made at a time when you were aware of material nonpublic information and you could not or did not supply other collateral, you may be liable under insider trading laws because of the sale of the securities (through the margin call). The sale would be attributed to you even though the lender made the ultimate determination to

sell. The U.S. Securities and Exchange Commission takes the view that you made the determination to not supply the additional collateral and you are therefore responsible for the sale.

19. ***Can I pledge my Company shares as collateral for a personal loan?***

A: No. Pledging your shares as collateral for a personal loan could cause the pledgee to transfer your shares during a trading blackout period or when you are otherwise aware of material nonpublic information. As a result, you may not pledge your shares as collateral for a loan.

20. ***Can I hedge my ownership position in the Company?***

A: Hedging or monetization transactions, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds are prohibited by our insider trading policy. Since such hedging transactions allow you to continue to own the Company's securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership, you may no longer have the same objectives as the Company's other shareholders. Therefore, our insider trading policy prohibits you from engaging in any such transactions.

21. ***Can I exercise options granted to me under the Company's equity compensation plans during a trading blackout period or when I possess material nonpublic information?***

A: Yes. You may exercise the options for cash (or via net exercise transaction with the Company) and receive shares, but you may not sell the shares (even to pay the exercise price or any taxes due) during a trading blackout period or any time that you are aware of material nonpublic information. To be clear, you may not effect a broker-assisted cashless exercise (these cashless exercise transactions include a market sale) during a trading blackout period or any time that you are aware of material nonpublic information

22. ***Am I subject to trading blackout periods if I am no longer an employee or consultant of the Company?***

A: It depends. If you are a Covered Insider and your employment with the Company ends during a trading blackout period, you will be subject to the remainder of that trading blackout period. If your employment with the Company ends on a day that the trading window is open, you will not be subject to the next trading blackout period. However, even if you are not subject to our trading blackout period after you leave the Company, you should not trade in Company securities if you are aware of material nonpublic information. That restriction stays with you as long as the information you possess is material and not publicly disseminated within the meaning of our insider trading policy.

23. ***Can I gift stock while I possess material nonpublic information or during a trading blackout period?***

A: It depends. Because of the potential for the appearance of impropriety, if you are a Covered Insider you may only make *bona fide* gifts of our common stock when you are aware of material nonpublic information or during a trading blackout period if (and only if) the gift has been

pre-cleared by the Company's Chief Financial Officer or his or her designee. Whether a gift is truly *bona fide* will depend on the facts and circumstances surrounding each gift.

24. ***What if I purchased publicly traded options or other derivative securities before I became a Company employee or consultant?***

A: The same rules apply as for employee stock options. You may exercise the publicly traded options at any time, but if you are a Covered Insider you may not sell the securities during a trading blackout period or at any time that you are aware of material nonpublic information.

25. ***May I own shares of a mutual fund that invests in the Company?***

A: Yes.

26. ***Are mutual fund shares holding Company common stock subject to the trading blackout periods?***

A: No. You may trade in mutual funds holding Company common stock at any time.

27. ***May I use a "routine trading program" or "10b5-1 plan"?***

A: Subject to the requirements discussed in our insider trading policy and any 10b5-1 trading plan guidelines, certain persons may use a routine trading program. A routine trading program, also known as a 10b5-1 plan, allows you to set up a highly structured program with your stock broker where you specify ahead of time the date, price, and amount of securities to be traded. If you wish to create a 10b5-1 plan, please contact our Chief Financial Officer at fstokes@castlebiosciences.com.

28. ***What happens if I violate our insider trading policy?***

A: Violating our policies may result in disciplinary action, which may include termination of your employment or other relationship with the Company. In addition, you may be subject to criminal and civil sanctions.

29. ***Who should I contact if I have questions about our insider trading policy or specific trades?***

A: You should contact our Chief Financial Officer at fstokes@castlebiosciences.com.

Adopted: June 8, 2019
Amended: August 5, 2020
Amended: September 24, 2020

Exhibit 21.1

CASTLE BIOSCIENCES, INC.
SUBSIDIARIES OF THE REGISTRANT

Name of Subsidiary	State of Incorporation
AltheaDx, Inc.	Delaware
Cernostics, Inc.	Delaware
Myriad myPath, LLC	Delaware
Castle Narnia Way Real Estate Holding 1, LLC	Texas

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the registration statements (Nos. 333-232884, 333-237062, 333-254179, 333-263094, 333-270141, 333-270146, 333-275881, and 333-277472) on Form S-8 and in the registration statement (No. 333-277470) on Form S-3 of our report dated February 27, 2025, with respect to the consolidated financial statements of Castle Biosciences, Inc. and the effectiveness of internal control over financial reporting.

/s/ KPMG LLP

Houston, Texas
February 27, 2025

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Derek J. Maetzold, certify that:

1. I have reviewed this annual report on Form 10-K of Castle Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 27, 2025

/s/ Derek J. Maetzold

Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO EXCHANGE ACT RULE 13a-14(a)/15d-14(a),
AS ADOPTED PURSUANT TO SECTION 302
OF THE SARBANES-OXLEY ACT OF 2002

I, Frank Stokes, certify that:

1. I have reviewed this annual report on Form 10-K of Castle Biosciences, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 27, 2025

/s/ Frank Stokes

Frank Stokes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER
UNDER SECTION 906 OF THE
SARBANES-OXLEY ACT OF 2002, 18 U.S.C. § 1350

In connection with the Annual Report on Form 10-K for the fiscal year ended December 31, 2024 of Castle Biosciences, Inc. (the "Company"), as filed with the Securities and Exchange Commission on the date hereof (the "Report"), Derek J. Maetzold, President and Chief Executive Officer of the Company, and Frank Stokes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to their knowledge:

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

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

Date: February 27, 2025

/s/ Derek J. Maetzold

Derek J. Maetzold
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Frank Stokes

Frank Stokes
Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Castle Biosciences, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.