CASTLE BIOSCIENCES

2025

ANNUAL REPORT

Letter from our Chief Executive Officer

Dear Fellow Stockholders,

2025 was a year of meaningful progress for Castle, marked by strong performance and continued advancement toward our mission of improving health through innovative tests that guide patient care. I am incredibly proud of what our team accomplished and grateful for the dedication, passion and people-first mindset that continue to define our culture and drive our impact.

We delivered strong operating and financial results in 2025, exceeding our full-year revenue guidance and generating approximately $344 million in revenue. Growth was fueled by sustained demand for our core revenue drivers, with total test report volume for DecisionDx®-Melanoma and TissueCypher® increasing 37% over the prior year. These results reflect strong execution by our Castle team and the expanding role our tests play across clinical practice.

A key driver of our progress in 2025 was continued growth in clinical evidence and impact, particularly within our dermatology portfolio. For our flagship test, DecisionDx®-Melanoma, we advanced a robust body of evidence, including a prospective, multicenter study addressing a critical decision point in melanoma care. The study demonstrated that patients identified as low risk by the test—below the clinically relevant 5% threshold for sentinel lymph node positivity—could safely forgo sentinel lymph node biopsy without compromising survival outcomes. Broad clinical adoption also helped us reach an important milestone in 2025. As of December 31, 2025, the DecisionDx-Melanoma test was ordered more than 230,000 times since launch, with more than 40,000 orders in 2025, reflecting the confidence clinicians place in the test to make more informed and personalized treatment decisions.

In gastroenterology, TissueCypher gained momentum as a valuable tool to help stratify risk in patients with Barrett's esophagus (BE), identifying those at meaningful risk of progression to esophageal cancer. This momentum was supported by a growing body of published studies validating the test's ability to inform risk-aligned surveillance and intervention, including a new systematic review and meta-analysis that further strengthened this foundation and provided comprehensive validation of TissueCypher's performance across six previously published studies. During the year, both DecisionDx-Melanoma and TissueCypher surpassed 10,000 test reports delivered in a single quarter for the first time, offering additional confirmation of the clinical value our tests provide in clinical practice.

We also took purposeful steps to evolve our portfolio aligned with our long-term strategy and capabilities. In dermatology, we launched AdvanceAD™-Tx, marking our entry into inflammatory skin disease, an area where patients and clinicians have had limited guidance to inform treatment selection, and initiated a collaboration with SciBase to explore complementary technologies that

may enhance care for patients with atopic dermatitis and other dermatological diseases over time. In gastroenterology, the acquisition of Previse further strengthened our pipeline and expanded our opportunity to support patients and clinicians across the Barrett's esophagus continuum. Throughout these efforts, we remained disciplined in focusing resources on areas where we believe we can make the greatest impact.

Throughout the year, we operated with discipline and a long-term perspective, supported by a strong balance sheet and close collaboration with our Board of Directors. This approach reflects our commitment to building a strong company grounded in scientific rigor, clinical relevance and trust.

Our progress in 2025 brings us closer to our vision of transforming disease management by keeping people first—patients, clinicians, employees and investors. As we look ahead to 2026, we remain focused on expanding the clinical impact of our tests, advancing our pipeline and continuing to execute with discipline, while building on the trust clinicians and patients place in Castle every day.

Thank you for your continued support of Castle Biosciences.

Sincerely,

Derek J. Maetzold
Founder, President & CEO

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2025

OR

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

For the transition period from _____ to _____

Commission File Number: 001-38984

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.)
1500 W. Parkwood Ave, Suite 400, 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**

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

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

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, 2025 (the last business day of the registrant’s most recently completed second fiscal quarter) was $576 million based on the closing price of the registrant’s common stock on June 30, 2025, as reported by the Nasdaq Global Market.

As of February 19, 2026, there were 29,731,198 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 (the “SEC”) subsequent to the date hereof pursuant to Regulation 14A in connection with the registrant’s 2026 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, 2025.

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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 ongoing conflicts in the Middle East, 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 (“U.S.”) 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.
- 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, TissueCypher® and DecisionDx®-SCC 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 ("R&D") 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 becomes 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 ("BE"), atopic dermatitis ("AD"), uveal melanoma ("UM").

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 clinical care decisions. For our core tissue-based tests, we use multi-analyte assays with algorithmic analysis ("MAAA") to characterize an individual patient's biology and generate clinically actionable information. Depending on the specific test, this information may be used to provide information to help guide treatment and patient management decisions including potential responsiveness to therapy and to assist in the diagnosis of a disease.

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 most recently includes a test to guide systemic treatment decisions in patients with moderate-to-severe AD.

Maintaining commercial success for our existing test portfolio requires generating ongoing evidence, such as clinical performance and 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 158 peer-reviewed articles have been published demonstrating the analytical validity, clinical validity and clinical utility of the tests in our portfolio.

The following table summarizes our commercially available tests:

Dermatology	Gastroenterology	Ophthalmology
DecisionDx-Melanoma	TissueCypher	DecisionDx-UM
AdvanceAD-Tx(1)		
DecisionDx-SCC		
MyPath Melanoma		

(1) We commenced a limited launch of our AdvanceAD-Tx™ test in November 2025.

DecisionDx-Melanoma

DecisionDx-Melanoma is our proprietary risk stratification gene expression profile ("GEP") test designed to predict the likelihood of a positive sentinel lymph node and 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 U.S., 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 ranges from 30%-72%. 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, 2025, 58 peer-reviewed articles, five of which were published in 2025, support the clinical validity, clinical utility and impact on outcomes of our DecisionDx-Melanoma test.

TissueCypher

TissueCypher is our proprietary risk stratification spatialomics 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") BE. There are approximately 4 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.

In 2025, we expanded our capabilities in BE through the acquisition of Capsulomics, Inc., d/b/a Previse ("Previse"), which provides complementary methylation-based intellectual property and a non-endoscopic cell-collection technology. We expect these assets to enhance the future development of TissueCypher by enabling the potential incorporation of additional molecular modalities, such as methylation markers and other genomic markers, to further strengthen the test's performance. In addition, sponge-based, swallowable cell-collection device may offer a non-endoscopic method for obtaining esophageal samples in certain patient populations, which could broaden access to molecular risk assessment and extend the reach of our BE and GI testing portfolio over time.

As of December 31, 2025, our TissueCypher test is supported by 17 peer-reviewed clinical validation and utility studies, three of which were published in 2025.

AdvanceAD-Tx

AdvanceAD-Tx is a non-invasive GEP test designed to guide systemic treatment selection for patients aged 12 years and older with moderate-to-severe AD. The test evaluates the expression of 487 genes across 12 known immune, inflammatory and skin-related pathways to identify the underlying biology driving an individual patient's disease. Results classify AD into one of two molecular profiles: Janus Kinase ("JAK") Inhibitor Responder Profile or T helper 2 ("Th2") Molecular Profile. Using multiple data sources focused on one-year prevalence, we estimate there are approximately 10 million individuals ages 12 and older in the U.S. with moderate-to-severe AD, representing an estimated U.S. TAM of approximately $33 billion. We commenced a limited access launch of the AdvanceAD-Tx test in November 2025 and plan phased expansion of availability throughout 2026.

DecisionDx-SCC

DecisionDx-SCC is our proprietary GEP test designed 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 U.S., are classified as high risk, representing an estimated U.S. TAM of approximately $820 million.

DecisionDx-SCC is clinically validated to predict responsiveness to adjuvant radiation therapy ("ART") and to 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 patients 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. 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.

MyPath Melanoma

MyPath® Melanoma is our proprietary, diagnostic GEP test for use in patients with difficult-to-diagnose melanocytic lesions. Of the two million suspicious pigmented lesions biopsied annually in the U.S., 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, 2025, our MyPath Melanoma test is supported by 20 peer-reviewed publications.

DecisionDx-UM

DecisionDx®-UM is our proprietary, risk stratification GEP test that predicts the risk of metastasis for patients with UM, also referred to as ocular melanoma. We estimate approximately 2,000 patients in the U.S. 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, and by multiple retrospective and prospective single-center studies. As of December 31, 2025, our DecisionDx-UM test is supported by 39 peer-reviewed publications.

IDgenetix

Following our acquisition of AltheaDx, Inc. ("AltheaDx") in April 2022, we began offering the IDgenetix® test, a proprietary pharmacogenomic ("PGx") test that helped guide optimal drug treatment for patients diagnosed with certain mental health conditions. IDgenetix was 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. The IDgenetix test was discontinued in May 2025.

Pipeline Initiatives

We have significant expertise in developing proprietary tests, conducting clinical studies and using the necessary instrumentation required for efficiently developing and validating our pipeline products. Discovering, developing and validating clinically actionable 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 May 2025, we expanded our capabilities in BE through the acquisition of Previse, which provides complementary methylation-based intellectual property and a non-endoscopic cell-collection technology and includes the Esopredict methylation-based risk-stratification test. We expect these assets to enhance the future development of TissueCypher by enabling the potential incorporation of additional molecular modalities, such as methylation and other genomic markers, to further strengthen the test's performance. Beginning in the first quarter of 2026, we also plan to offer the Esopredict test as a supplemental option for cases in which TissueCypher does not produce an actionable result, providing clinicians with an additional molecular tool for risk stratification when primary testing is inconclusive. In addition, Previse's sponge-based, swallowable cell-collection device is currently under development and is expected to be introduced in the future, subject to applicable regulatory clearances, and may offer a non-endoscopic method for obtaining esophageal samples in certain patient populations, which could broaden our GI testing portfolio.

In June 2025, we entered into a collaboration and license agreement with SciBase Holding AB ("SciBase") to develop and commercialize diagnostic tests for dermatologic diseases, beginning with atopic dermatitis. The collaboration combines our expertise in developing machine learning based algorithms in dermatology with SciBase's Electrical Impedance Spectroscopy technology. Under the agreement, we obtained exclusive rights to develop and commercialize tests incorporating SciBase's technology in North America, while SciBase retains rights in Europe, Switzerland, Japan, and South Korea. The initial focus of the collaboration is to develop a non-invasive diagnostic test designed to help predict disease flares in patients with atopic dermatitis. This initiative aligns with our strategic goal of expanding our pipeline beyond dermatologic cancers into inflammatory skin conditions.

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.

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 419,000 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,				
	2025	2024	2023	2022	2021
DecisionDx-Melanoma	39,083	36,008	33,330	27,803	20,328
DecisionDx-SCC	17,294	16,348	11,442	5,967	3,510
Diagnostic GEP offering[1]	4,288	3,909	3,962	3,561	2,662
Dermatologic Total[2]	60,665	56,265	48,734	37,331	26,500
TissueCypher[3]	39,014	20,956	9,100	2,128	27
DecisionDx-UM	1,769	1,699	1,674	1,711	1,618
IDgenetix[4]	3,605	17,151	10,921	3,249	—
Grand Total	105,053	96,071	70,429	44,419	28,145
Net Revenues (in thousands)	$ 344,229	$ 332,069	$ 219,788	$ 137,039	$ 94,085

(1) 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.

(2) We began offering AdvanceAD-Tx following our limited access launch in November 2025. Test reports delivered for the year ended December 31, 2025, was de minimis. We expect to expand availability throughout 2026.

(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.

(4) We began offering the IDgenetix test on April 26, 2022, following our acquisition of AltheaDx, and discontinued the test in May 2025.

Our Commercial Channel

Sales and Marketing

Our sales and marketing efforts are primarily focused on the U.S. dermatology 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 may influence clinical care pathway decisions and ultimately improve patient outcomes.

We continuously assess market response in determining commercial team structure.

Medical Affairs

We also deploy an experienced medical affairs group to assist in the education of treating clinicians and key opinion leaders, to assist in identifying and engaging sites for our sponsored clinical studies and to evaluate collaborative study opportunities. We will continue to assess the market needs in determining medical affairs 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, TissueCypher, MyPath Melanoma, DecisionDx-UM and IDgenetix tests which meet certain criteria for Medicare and Medicare Advantage beneficiaries. DecisionDx-SCC previously received Medicare coverage, which was subsequently impacted by LCD changes finalized in 2025.

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 increase implementation of value-based reimbursement with more third-party payors.

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, 2025, we continued to receive positive coverage and payment decisions on claims across our product lines from many commercial payors. We anticipate this trend to continue in the future as we 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 44% for the year ended December 31, 2025. Additionally, there was a commercial payor from which 16% of our revenue from patients was derived for the year ended December 31, 2025.

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"), which has a joint operating agreement with Palmetto GBA MolDX ("Palmetto") whereby Palmetto oversees the review of 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-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 proposed 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 an oncology biomarker LCD, Genetic Testing for Oncology: Specific Tests, which also lists DecisionDx-SCC as non-covered; that LCD became effective on 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.

In July 2025, we submitted reconsideration requests for both Novitas and MolDX LCDs. Both Novitas and MolDX subsequently confirmed that our requests were valid. These confirmations represent an important procedural step in the reconsideration process, but it does not indicate coverage or a favorable review outcome.

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-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.

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 of our commercially available proprietary MAAA tests, other than our recently launched AdvanceAD-Tx test, 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 2025 was set using median private payor rate data from January 1, 2023 to June 30, 2023. Our rate for 2023 through 2025 was $7,193 per test and remains $7,193 per test for 2026.

TissueCypher

On March 24, 2022, CMS determined TissueCypher met the criteria for "new ADLT" status. Since TissueCypher is a protein based spatialomics test, ADLT status exempts TissueCypher from what is called the "14-day rule," which impacts the billing process for protein based test. 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. Beginning with 2025, the rate for TissueCypher has been set annually based on the median private payor rate for the first half of the second preceding calendar year. Our 2025 rate was $4,950 per test based on the median private payor rate data from January 1, 2023 to June 30, 2023 and remains $4,950 per test for 2026.

DecisionDx-SCC

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 remained effective through December 31, 2025 and remains $8,500 per test for 2026.

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 2025 was set using median private payor rate data from January 1, 2023 to June 30, 2023. Our rates for 2023, 2024 and 2025 were $1,755, $1,950 and $1,950 per test, respectively. Our 2026 rate remains $1,950 per test.

DecisionDx-UM

On May 17, 2019, CMS determined that DecisionDx-UM meets the criteria for "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 2025 was set using median private payor rate data from January 1, 2023 to June 30, 2023. Our rate for 2023 through 2025 was $7,776 per test and remains $7,776 per test for 2026.

IDgenetix

IDgenetix is currently covered under a Noridian LCD policy and accompanying billing and coding article developed by MolDX. During 2023, we obtained a test-specific Proprietary Laboratory Analyses ("PLA") and Current Procedural Terminology ("CPT") code for IDgenetix which became effective October 1, 2023. The CLFS rate of $1,336 per test was effective January 1, 2024. Our reimbursement rate for 2024 was $1,336 per test and remained at $1,336 per test in the first quarter of 2025. Our IDgenetix test was discontinued in May 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;
- R&D 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 U.S. 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. 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 evolved over time, this approach has been the standard of care in the U.S. 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 may face competition from companies such as Interpace Diagnostics and other companies. Other companies actively engaged in GERD screening to diagnose BE, such as Lucid Diagnostics and other companies, may also look to develop prognostic tests for patients diagnosed with BE, and these could compete with TissueCypher in the future. In 2025, we acquired Previse, whose technology complements our TissueCypher test, expanding our offerings within the gastrointestinal vertical and market position. We may face additional competitors in the future.

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.

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.

Laboratory Operations

In 2025, 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, one lab in the Phoenix and the Pittsburgh laboratories are approved labs by New York State Department of Health Clinical Laboratory Evaluation Program (“NYS CLEP”) with each of our proprietary tests, except AdvanceAD-Tx, 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 and proteinomic 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 in our core U.S. market and select global countries, including through patent protection covering all of our proprietary tests. 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, 2025, 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	5	18	23
Methods of diagnosing and treating patients with pigmented skin lesions	1	—	1
Methods of diagnosing and treating patients with SCC	6	21	27
Diagnosing and treating AD and/or psoriasis	3	1	4
Method and kit for isolating and sequencing nucleic acid from skin samples	—	1	1
Diagnosing and treating UM	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	4	13	17
Methods of predicting progression of BE	4	31	35
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	37	119	156

Included in the table above are 22 issued U.S. patents and 87 issued international patents. This global patent portfolio has filing dates ranging from 2007 to 2025, and therefore are projected to expire between 2027 and 2045, 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 U.S. 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 U.S. 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 24 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 all of our laboratories are CAP-accredited, 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. In addition to the NYSDOH lab approval both the Phoenix and Pittsburgh laboratories are both required to 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. We also maintain processes and controls to ensure that specimens originating from New York are tested only in these NYSDOH-certified laboratories and not in our other laboratory locations. 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. Our Phoenix and Pittsburgh laboratories that are both licensed by NYSDOH, and our commercialized proprietary tests, excluding our recently launched AdvanceAD-Tx test, have been approved by 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. Some of our in vitro testing products are intended for clinical or diagnostic uses, such as the DecisionDx-Melanoma test, which is considered by the FDA to be subject to regulation as a medical device and has been granted Breakthrough Device designation by the FDA. 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 U.S. 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 Laboratory Developed Tests ("LDTs") which amended the FDA's regulations to make explicit that LDT's are devices under the FD&C Act. However, on March 31, 2025, the United States District Court for the Eastern District of Texas vacated the FDA's LDT final rule. The U.S. government did not appeal the decision, and the FDA rescinded the rule on September 19, 2025. Accordingly, the FDA's phased enforcement approach and related requirements are no longer in effect. Our proprietary tests, which were first marketed prior to May 6, 2024, remain approved by and under the oversight of the NYSDOH, and we continue to believe that changes in FDA's regulatory approach to LDTs will have no material impact on our existing test offerings.

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.

In July 2025, the FDA granted Breakthrough Device designation to our DecisionDx-Melanoma test. We believe this designation highlights the test's potential to improve melanoma care through individualized prognostic insights. The Breakthrough Device designation is intended to expedite the development and review of certain medical devices that may offer more effective diagnosis or treatment of life-threatening conditions.

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 U.S. 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 U.S., 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, the 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. The full scope and interpretation of EKRA remain unclear.

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.

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 U.S., 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 U.S. or the import of tissue into the U.S., and marketing approval. These requirements vary by jurisdiction, differ from those in the U.S. and may in some cases require us to perform additional pre-clinical or clinical testing. In many countries outside of the U.S., 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.

Federal, State and Foreign Privacy and Security Laws

Federal, state, local and foreign governments have enacted numerous data privacy and security laws, including data breach notification laws, data protection laws (e.g. European Union's General Data Protection Regulation 2016/679), personal data privacy laws, health information privacy laws (e.g., Washington's My Health My Data Act), consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). Numerous privacy laws 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 may 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 laws also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. Certain of these laws allow for statutory fines for noncompliance. These laws further complicate compliance efforts and increase legal risk and compliance costs for us and the third parties with whom we work.

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 and Medicaid, 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 and PLA codes, as defined by the American Medical Association ("AMA"). For those genetic tests we conduct that do not have a dedicated CPT or PLA code, tests may be billed under a non-specific miscellaneous CPT code. Because these miscellaneous codes do not describe a specific service, the claim may need to be examined by a third-party payor to determine what service was provided, whether the service was appropriate and medically necessary and whether payment should be rendered. This process may require additional medical record documentation from the ordering physician and could 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 and PLA 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 diagnostic laboratory tests ("CDLTs") are paid under Medicare. Under PAMA, certain laboratories are 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 is 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.

PAMA also established a category for ADLTs and specific payment methodologies for qualifying tests. Similar to CDLTs, laboratories offering ADLTs are required to report to CMS private payor payment rates and volumes for their tests and CMS uses this data to calculate a weighted median payment rate for each test. The difference is that laboratories are required to report ADLT private payer data annually to CMS and the CLFS reimbursement rates are updated annually for the test.

On February 3, 2026, the Consolidated Appropriations Act of 2026 was enacted which, among other things, delayed the impositions of Medicare CLFS cuts until 2027 and updated PAMA reporting timelines and data requirements for CDLTs that aren't ADLTs. We bill Medicare for our products, and therefore we are subject to reporting requirements under PAMA. See "Reimbursement—Government Payors" above for additional information.

Five of our tests have been granted ADLT status by CMS: DecisionDx-Melanoma, TissueCypher, DecisionDx-SCC, MyPath Melanoma and DecisionDx-UM. The CLFS rate for these tests is determined by the ADLT rules under PAMA. The CLFS rates for our tests AdvanceAD-Tx and Esopredict are determined by the CDLT rules under PAMA.

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 July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA"), was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies. It is unclear how these and other 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.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. Recent actions, for example, include directing agencies to reduce agency workforce and cut programs. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to lower government subsidies to private insurance companies and increase healthcare price transparency, among other things. Additionally, in June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. We expect that additional state, federal, and foreign healthcare reform measures will be adopted in the future.

We further 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, 2025, we had 883 full-time employees. During the year ended December 31, 2025, we added 122 employees to our team, a 16% increase from 2024. We face competition for experienced, qualified personnel in our industry, particularly for highly skilled scientists, laboratory technicians and salespeople versed in diagnostic testing services.

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 2025, we conducted our annual employee engagement survey to understand what was working well at Castle Biosciences and what opportunities we had for improvement. We received feedback from over 94% of our employees and achieved an engagement score of 83%, meaning that 83% of our employees are engaged or enthusiastically engaged in the culture at Castle Biosciences. Our engagement score was 11% higher than the healthcare benchmark average for other healthcare companies who conducted the same employee engagement survey in 2025.

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 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 2.9% for the year ended December 31, 2025.

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 currently located at 1500 W. Parkwood Ave, Suite 400, Friendswood, Texas 77546 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 SEC. 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 44% and 47% for the years ended December 31, 2025 and 2024, respectively. Additionally, there was a commercial payor from which 16% of our revenue from patients were derived for the year ended December 31, 2025. 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 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. 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, 2025, we had net loss of $24.2 million, and as of December 31, 2025, we had an accumulated deficit of $224.3 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, the ongoing conflicts in the Middle East, economic slowdowns, the recent shutdown of the federal government including regulatory agencies, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, international tariffs, liquidity concerns, bank failures 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, among other things. 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 lesser portion of our 2025 revenues compared to 2024 revenues following the discontinuance of Medicare reimbursement as of April 24, 2025. See "—Risks Related to Our Business—Our revenue currently depends primarily on sales from our DecisionDx-Melanoma, TissueCypher and DecisionDx-SCC 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 R&D 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.

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 planned 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, as amended in April 2025 (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 a term loan in the principal amount of $10.0 million, which was drawn on the Closing Date (the "2024 Term Loan") and provided for a $25.0 million line of credit that was available at our option from the Closing Date through September 30, 2025, with the same interest rate and maturity as the 2024 Term Loan (the "2024 Credit Line"). On September 30, 2025, the 2024 Credit Line expired and no draws had been made on it. We used the proceeds from the 2024 Term Loan for the purpose of developing our future corporate headquarters.

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, TissueCypher and DecisionDx-SCC, 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 R&D 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 ongoing conflicts in the Middle East, 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, R&D 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 a $10.0 million 2024 Term Loan and provided for a $25.0 million 2024 Line of Credit that was available at our option from the Closing Date through September 30, 2025. On September 30, 2025, the 2024 Credit Line expired and no draws had been made on it. 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, TissueCypher and DecisionDx-SCC tests, and we will need to generate sufficient revenue from these products and other products to grow our business.

Our revenue in 2025 was primarily derived from the sale of our DecisionDx-Melanoma, TissueCypher and DecisionDx-SCC 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 2025 revenues but are not expected to be so in our 2026 operating results. On January 9, 2025, Novitas finalized an oncology biomarker LCD that became effective on April 24, 2025, at which time, the Novitas LCD, Genetic Testing for Oncology: Specific Tests, that includes DecisionDx-SCC as noncovered, became effective.

In July 2025, we submitted reconsideration requests for both Novitas and MolDX LCDs. Both Novitas and MolDX subsequently confirmed that our requests were valid. These confirmations represent an important procedural step in the reconsideration process, but it does not indicate coverage or a favorable review outcome.

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 invasion of Ukraine by Russia and related sanctions, the ongoing conflicts in the Middle East, economic slowdowns, the recent shutdown of the federal government including regulatory agencies, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, international tariffs, liquidity concerns, bank failures 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, among other things. 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 U.S., have increased recently to levels not seen in years, and increased inflation has resulted in increased personnel costs and increased prices for certain lab supplies and may result in additional 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. Additionally, rapid changes in U.S. trade policy, such as the imposition of additional tariffs and trade barriers, as well as potential retaliatory measures taken by other governments, could increase the price of and/or affect the availability of imported raw materials used in the production of our products.

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 U.S., 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. More recently, the escalation of hostilities between Iran and Israel has introduced additional geopolitical instability and uncertainty, particularly in the Middle East. This conflict has the potential to disrupt global energy supplies, impact shipping routes, and lead to broader regional or international involvement, further straining global supply chains and financial markets. 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 and escalating tensions between Iran and Israel, particularly to the extent it escalates to involve additional countries, further economic sanctions or wider military conflict. If economic conditions in Europe, the Middle East, or 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 R&D 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 R&D 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 R&D 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 R&D 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 44%, 47% and 49% of our revenue from test reports for the years ended December 31, 2025, 2024 and 2023, respectively, with an additional third-party payor accounting for 16% of our revenue from test reports for the year ended December 31, 2025;
- the impact of our investments in R&D 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 R&D. Before we can commercialize a new pipeline product, we will need to expend significant resources in order to conduct substantial R&D, 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 a broad multi-center U.S. based study to discover, develop and validate a genomic test, or series of genomic tests, aimed at predicting response to systemic therapy in patients with moderate to severe inflammatory skin disease. We announced early discovery data from this study in October 2023. 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. We commenced a limited access launch of the AdvanceAD-Tx test in November 2025 and are planning phased, expanded availability throughout 2026.

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 R&D, marketing, selling, coverage and reimbursement activities. Typically, few R&D 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 R&D 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, 2025, our goodwill and other intangible assets balances were $10.7 million and $88.9 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, TissueCypher, AdvanceAD-Tx, DecisionDx-SCC, MyPath Melanoma, and DecisionDx-UM 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 U.S. 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 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 the oncology biomarker LCD, Genetic Testing for Oncology: Specific Tests, which also lists DecisionDx-SCC as non-covered; that LCD became effective on April 24, 2025.

In July 2025, we submitted reconsideration requests for both Novitas and MolDX LCDs. Both Novitas and MolDX subsequently confirmed that our requests were valid. These confirmations represent an important procedural step in the reconsideration process, but it does not indicate coverage or a favorable review outcome. The loss of Medicare coverage for our DecisionDx-SCC test, effective April 24, 2025, had an adverse impact on our 2025 results. Should DecisionDx-SCC remain non-covered by Medicare we expect it could continue to have an adverse impact on our 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. Our IDgenetix test was discontinued in May 2025.

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. On February 3, 2026, the Consolidated Appropriations Act of 2026 was enacted which, among other things, delayed the impositions of Medicare CLFS cuts until 2027 and updated PAMA reporting timelines and data requirements. 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 addition to laws and regulations implemented by the FDA, we may be subject to other applicable laws including health care fraud and abuse, data privacy, and transparency reporting laws, among others. 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 ("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. We currently market our products as LDTs which are subject to various coverage and reimbursement regulations and policies from governmental and commercial, third-party payors and are subject to change from time to time.

On May 6, 2024, the FDA published a final rule on the regulation of LDTs, which amended the FDA regulations under 21 CFR Part 809 to make explicit that LDTs are IVDs and are regulated as devices under the FD&C Act. However, on March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the FDA's LDT final rule. The U.S. government did not appeal the ruling, and the FDA rescinded the rule on September 19, 2025.

However, it is uncertain whether or when the FDA may be able to otherwise exercise its medical device authority with respect to LDTs or their components. This uncertainty could adversely affect the FDA's ability to apply and enforce its medical device requirements with respect to diagnostic tests more broadly, including any LDTs for which we have obtained or plan to obtain marketing authorization. Such uncertainty and the FDA's actions in response could have a material adverse effect on our business and operation.

In light of this uncertainty, we do not know if or when our offerings could become or will remain subject to FDA medical device requirements, including the need to seek and obtain marketing authorization. If we were unable to comply with any medical device requirements applicable to LDTs if and when any such requirements become applicable, we could be required to cease marketing any tests that we market as LDTs. In addition, further efforts by the FDA or Congress to impose more regulation on LDTs could create a negative public perception about the validity, safety, effectiveness, or performance of LDTs, including our tests, which could adversely affect patient, provider, and customer perception about, and confidence in our tests.

Moreover, the FDA may assert that we are improperly marketing our tests as LDTs or otherwise assert that we do not comply with applicable requirements, and in such cases may take enforcement action against us and/or require premarket review and marketing authorization, which may require us to cease marketing any commercially marketed tests that are marketed as LDTs until such marketing authorization is obtained or the applications are submitted. There can be no assurance that we will be able to obtain such marketing authorization or that any labeling claims would be consistent with the claims we have made or intend to make for such tests when launched as LDTs, or that such claims will be adequate to support continued adoption of and reimbursement for our tests.

We may also 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.

In addition, Congress has, for over the past decade, considered a number of proposals, which, if enacted, would subject LDTs to additional regulatory requirements. Any such legislation could substantially alter our marketing of LDTs and negatively impact our business, financial condition, and results of operations.

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, 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. Some of our in vitro testing products are intended for clinical or diagnostic uses, such as the DecisionDx-Melanoma test, which is considered by the FDA to be subject to regulation as a medical device and has been granted Breakthrough Device designation by the FDA. 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 U.S. 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 U.S. 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.

Laboratory accreditation can be acquired through CAP. 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. We have chosen to use CAP accreditation to maintain our CLIA certification. Additionally, some countries outside the U.S. 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 certification, 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 undergo CAP accreditation to maintain CLIA certification. 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, TissueCypher, DecisionDx-SCC, 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 2025 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, 2025. 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 U.S. 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 certification 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 certification, 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 amended 21 CFR Part 809 to make explicit that LDTs are IVDs and are regulated as devices under the FD&C Act. However, on March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the FDA's LDT final rule. The U.S. government did not appeal the ruling, and the FDA rescinded the rule on September 19, 2025.

Despite the FDA's rescission of the LDT final rule, if the FDA implements new policy that affects LDTs or their components, 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 marketing authorization. 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. Moreover, the FDA may request that we provide additional analyses and information beyond that which we intend to produce based on the designs of our current and planned validation studies or clinical trials, or that we modify or narrow our intended use or product claims. It is possible that the FDA, among other things, could disagree with our interpretation of data we have relied on to support certain intended uses. If we are required to provide additional analyses or additional data or perform additional clinical trials beyond those we currently contemplate to support the intended uses of our tests, our planned commercialization may be delayed and we may be required to cease commercialization of any tests we currently market as LDTs.

The FDA requires medical device manufacturers to comply with, among other things, current good manufacturing practices for medical devices, known as the Quality Management System Regulation ("QMSR"), 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 and 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.

Failure to timely obtain necessary marketing authorizations for our products that are intended for clinical or diagnostic uses may have a material adverse effect on our business, financial condition, results of operations, and prospects.

We intend to obtain FDA's marketing authorization for certain products that are intended for clinical or diagnostic uses, such as the DecisionDx-Melanoma test, which has been granted Breakthrough Device designation by FDA. Medical devices and their manufacturers and product developers are subject to extensive regulation in the U.S., including by the FDA. The FDA regulates, among other things, with respect to medical devices: design, development, and manufacturing; testing, labeling, content, and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales, and distribution; premarket review and marketing authorization; recordkeeping procedures; advertising and promotion; corrections and removals (recalls); post-market surveillance and adverse event reporting, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export. In the U,S, before we can market a new medical device, or a new use of, new claim for or a significant modification to an existing product medical device that is not exempt from premarket review requirements or is not subject to an established FDA enforcement discretion policy, we must first receive marketing authorization for the product from FDA either through clearance under Section 510(k) of the FDC Act, approval of a premarket approval ("PMA") application from the FDA, or grant of a *de novo* classification request from the FDA, unless an exemption applies.

In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a "predicate" device (i.e., a legally marketed device), which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), or a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified. 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 are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices.

In the *de novo* classification process, a manufacturer whose device of a new type under the FDC Act is automatically classified as Class III and would otherwise require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* classification request, the requester will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The 510(k) clearance, *de novo* classification, and PMA approval processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. 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 of obtaining a PMA is much more costly and uncertain than the 510(k) clearance or *de novo* authorization process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Clinical data may also be required in connection with a submission for 510(k) clearance or a *de novo* classification request. Despite the time, effort and cost, a device may not obtain marketing authorization by the FDA. We must obtain marketing authorization for any future devices we develop, unless they are exempt. Marketing authorizations for any of our future products, if granted, may include significant limitations on the indicated uses for the device, which may limit the potential commercial market for the device.

In the U.S., any modification to a medical device for which we have obtained 510(k) clearance may require us to submit a new 510(k) premarket notification and obtain clearance, to submit a PMA and obtain FDA approval, or to submit a *de novo* request and obtain FDA's grant of the request prior to implementing the change. For example, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, generally requires a new 510(k) clearance or other marketing authorization. The FDA requires every manufacturer to make such determinations in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with a manufacturer's decisions regarding whether new marketing authorizations are necessary.

The FDA can delay, limit or deny marketing authorization of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA that our products are substantially equivalent to a predicate device or are safe and effective for their intended uses;
- the disagreement of the FDA with the design or implementation of clinical trials or the interpretation of data from preclinical studies or clinical trials;
- serious and unexpected adverse device effects experienced by participants in clinical trials;
- the data from preclinical studies and clinical trials may be insufficient to support clearance, *de novo* classification, or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for marketing authorization regulations of the FDA to change significantly in a manner rendering our clinical data or regulatory filings insufficient for marketing authorization.

New legislation or regulation in the U.S. may make it more difficult and costly for us to manufacture, market, or distribute our products, or to obtain marketing authorizations for any future products.

From time to time, Congress may enact new legislation or the FDA may issue new regulation that could significantly change the regulation of medical devices. For example, on January 31, 2024, the FDA issued a final rule to amend the Quality System Regulation (QSR), which establishes current good manufacturing practice (cGMP) requirements for medical device manufacturers, to align more closely with the ISO standards. Specifically, this final rule, which took effect on February 2, 2026, replaces the QSR with the QMSR, and among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create market pressure that may negatively affect our business. It is unclear the extent to which any other U.S. legislative or regulatory proposal, if adopted or issued, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may make it more difficult and costly to manufacture, market, or distribute our products, or may impose additional costs, lengthen marketing authorization review times, or make it more difficult to obtain marketing authorizations for any future products we develop or for any current products for which we are required to obtain marketing authorization. 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 be subject to enforcement action and we may not achieve or sustain profitability.

Disruptions at the FDA and other government agencies caused by layoffs, funding shortages or global health concerns could negatively impact our business.

The ability of the FDA to review proposed clinical trials or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. In addition, government funding of other government agencies that fund R&D activities is subject to the political process, including executive and congressional priorities, the impacts of which are inherently fluid and unpredictable. Disruptions at the FDA and other agencies may slow the time necessary for new product candidates to be reviewed and/or approved, which would adversely affect our business. For example, over the last several years, for 43 days beginning on October 1, 2025 and for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities to the extent they are not funded by existing available user fees. In addition, the current administration has proposed, and in some cases implemented, substantial reductions in force at various government agencies including the FDA, which could significantly reduce the FDA's capacity to perform its functions in a manner consistent with its past practices and could delay reviews and negatively impact our business.

We cannot predict the likelihood, nature or extent of government regulation or other measures that may arise from future legislation or administrative or executive action, either in the U.S. or abroad.

The policies of the FDA and other regulatory authorities may change, including as a result of changes in the U.S. presidential administration, and additional government regulations or executive orders may be enacted that could change our continuing compliance obligations or otherwise adversely affect our business. 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 approval that we may have obtained, and we may not achieve or sustain profitability. In addition, significant tariffs or other restrictions imposed and related countermeasures taken by impacted foreign countries could adversely affect our operation and financial results. We cannot predict the likelihood, nature or extent of government regulation or other measures that may arise from future legislation or administrative or executive action either in the U.S. or abroad.

Interim, topline and preliminary data from our clinical studies that we announce or publish from time to time may change as more data becomes 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.

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 July 4, 2025, the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

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.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. Recent actions, for example, include directing agencies to reduce agency workforce and cut programs. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to lower government subsidies to private insurance companies and increase healthcare price transparency, among other things. Additionally, in June 2024, in Loper Bright Enterprises v. Raimondo, the U.S. Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. We expect that additional state, federal, and foreign healthcare reform measures will be adopted in the future.

We further 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 and the third parties with whom we work 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, receive, store, process, generate, use, transmit, disclose, make accessible, protect, secure, dispose of, share 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 U.S., 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 data protection laws also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. In addition, certain data protection 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 subject to the CCPA 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 U.S., 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 EU's General Data Protection Regulation 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 and regulations 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 U.S. and 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 U.S. 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 U.S. 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 U.S. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the U.S., 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 U.S., 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.

Additionally, the U.S. Department of Justice issued a rule entitled the Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons, which places additional restriction on certain data transactions involving countries of concern (e.g., China, Russia, Iran) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in transactions or agreements with certain third parties in the future.

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' 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, orders to destroy or not use personal data, and imprisonment of company officials. 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 U.S. 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 R&D 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, 2025 includes 22 issued U.S. patents and 15 pending U.S. patent applications, and their 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 one of our patents is invalid or unenforceable, or may refuse to enjoin another party from using the technology at issue on the grounds that none of our patents 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 by 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 U.S. 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) may not be 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 U.S. 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 U.S., 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 resolving 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 R&D 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 U.S. 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 U.S. or the USPTO rules and regulations could increase these uncertainties and costs. Patent reform legislation in the U.S. 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 U.S. 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 U.S. 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 U.S., 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 U.S. 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 2025, we provided over 1,700 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 U.S., 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 U.S., or from selling or importing products made using our inventions in and into the U.S. 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 U.S. 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 U.S. 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, DecisionDx-Melanoma, TissueCypher, AdvanceAD-Tx, DecisionDx-SCC, MyPath Melanoma, DecisionDx-UM, Esopredict, DiffDx-Melanoma and IDgenetix in the U.S. 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 U.S. 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 U.S., 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 R&D 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 R&D and sales programs. 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, 2025, there were 1,279,290 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 U.S. 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, AltheaDx and Previse. 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 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. In May 2025, after careful further assessment, we discontinued the test.

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, April 2022 and May 2025 we completed the acquisitions of Cernostics, AltheaDx and Previse, 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 to 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."

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, 2025, we had federal net operating loss ("NOL") carryforwards of approximately $134.8 million, of which $52.9 million will begin to expire in 2032 if not utilized to offset taxable income, and $81.9 million may be carried forward indefinitely. Also, as of December 31, 2025, we had state NOL carryforwards of $113.0 million, which begin to expire in 2030 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, $36.3 million of NOLs are expected to expire unused as a result of Section 382 limitations. With respect to Previse, we acquired $2.3 million of NOLs that can be carried forward indefinitely to offset future taxable income. 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. Legislation referred to as the OBBBA enacted in 2025, the Inflation Reduction Act enacted in 2022, CARES Act, and the TCJA made many significant changes to the U.S. tax laws. For example, for tax years beginning after December 31, 2024, the OBBBA restores the tax deductibility of domestic R&D expenses in the year incurred, which expenses had been required under the TCJA to be capitalized and subsequently amortized over five years. The OBBBA did not change the tax treatment of expenses incurred in R&D activities conducted outside the U.S., which expenses continue to be required to be capitalized and amortized over 15 years. We have evaluated the impacts this and other changes under the OBBBA may have on our business. 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 or sunset in future years. 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, could result in significant one-time charges, and could increase our future U.S. tax expense.

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 poses 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, or to take other actions, such as providing credit monitoring and identity theft protection services. Such disclosures and related actions 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. For example, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

Certain of the previously identified or similar threats have in the past and could in the future cause disruptions or security incidents that have in the past and may in the future 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 or other compromise 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 R&D 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 even where they do, 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, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay claims.

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 U.S.

While we currently accept orders from customers outside of the U.S., our historical business strategy has been directed toward customers within the U.S. 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 U.S., 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 R&D. 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 U.S. significantly increased until the second half of 2022 when the rate began to subside. In 2023 through 2025, the inflation rate continued to subside but remained higher than rates experience in 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 U.S. 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 ongoing conflicts in the Middle East, 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; R&D 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, son-in-law 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. Further, the 2024 LSA limits our ability to pay cash dividends.

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, 2025, our executive officers, directors and the known holders of more than 5% of our outstanding common stock, in the aggregate, beneficially owned approximately 39% 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; and

- 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 General Corporation Law of the State of Delaware (the "DGCL"), our amended and restated certificate of incorporation or our 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 DGCL 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 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 U.S. 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 in our amended and restated certificate of incorporation.

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 DGCL. 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 DGCL, 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 DGCL 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 provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the U.S. 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 in an effort 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 designed 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 own 23 acres of land in Friendswood, Texas. In January 2026, we completed construction of the portions of an approximately 80,000 square foot commercial office building that serves as our new corporate headquarters. Construction of the remaining portions of the building is ongoing. We intend to lease out approximately 33,000 square feet of office space within the building.

We lease approximately 27,000 square feet of commercial office space located in Friendswood, Texas where our corporate headquarters was previously located. This lease commenced in late 2020 under a 60-month term and, under a subsequent amendment, now expires in March 2026.

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 February 2034, respectively. Each contract provides two five-year renewal options, none of which have been exercised. 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 term of 10.5 years, 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 lease approximately 55,000 square feet of office and laboratory space in Scottsdale, Arizona under a lease that we entered into in May 2025. The lease covers a term of 143 months that will expire in April 2037. We also have a right of refusal to lease any additional adjacent space that may become available. The lease grants us two optional five year term extensions and a one-time option early termination right at the end of the 96 month, subject to certain conditions and payment of an early termination fee.

We believe that our existing facilities are adequate to meet our current needs, and that suitable additional alternative spaces will be available in the future on commercially reasonable terms.

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 U.S. 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 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. 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 19, 2026, there were approximately 73 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. In addition, the 2024 LSA limits our ability to pay cash dividends.

Recent Sales of Unregistered Equity Securities

During the year ended December 31, 2025, we did not issue or sell any unregistered securities not previously disclosed in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Securities Authorized for Issuance under Equity Compensation Plans

See Item 12 of Part III of this Annual Report on Form 10-K for information about our equity compensation plans which is incorporated by reference herein.

Use of Proceeds from the IPO of Common Stock

We completed the initial public offering ("IPO") of our common stock in July 2019 pursuant to our Registration Statements on Form S-1, as amended (File Nos. 333-232369 and 333-232796) (the "IPO Registration Statements") with the Securities and Exchange Commission (the "SEC"), 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 offering as described in the final prospectus filed with the SEC on July 26, 2019 related to our IPO Registration Statements. Since the effective date of our IPO Registration Statements through December 31, 2025, we have not used any of the net proceeds from the IPO. Pending their use, we plan to invest the balance of the net proceeds from the IPO in cash, cash equivalent, and highly liquid investment securities.

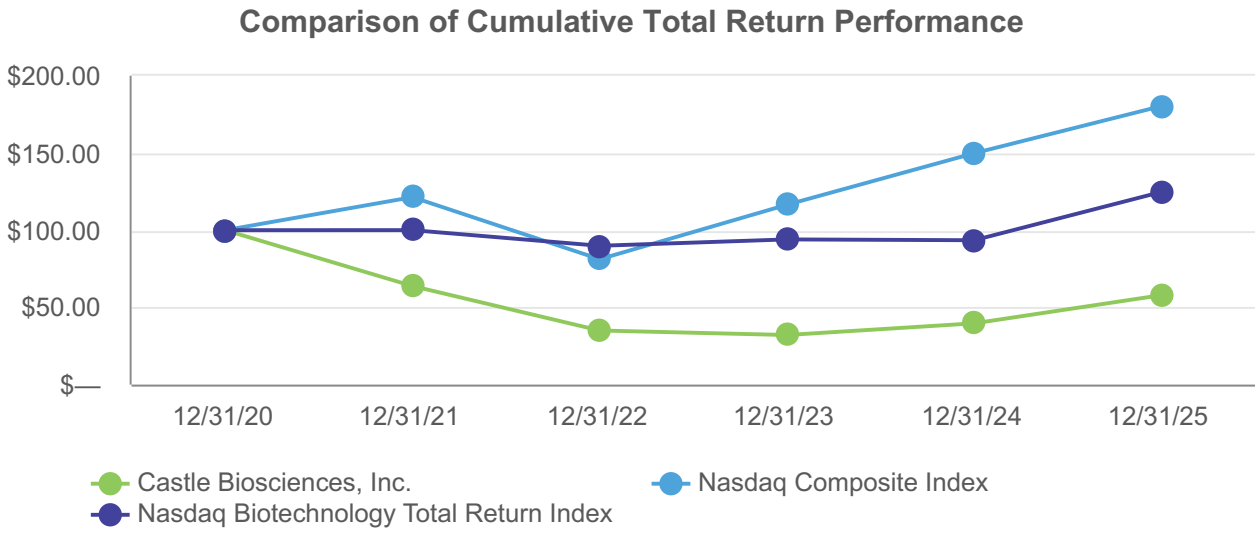
Purchases of Equity Securities by the Issuer and Affiliated Purchasers

We did not repurchase any of our equity securities during the three months ended December 31, 2025.

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, 2020, 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.



	12/31/2020	12/31/2021	12/31/2022	12/31/2023	12/31/2024	12/31/2025
Castle Biosciences, Inc.	$ 100.00	$ 63.84	$ 35.06	$ 32.14	$ 39.69	$ 57.93
Nasdaq Composite Index	$ 100.00	$ 121.39	$ 81.21	$ 116.47	$ 149.83	$ 180.33
Nasdaq Biotechnology Total Return Index	$ 100.00	$ 100.02	$ 89.90	$ 94.03	$ 93.49	$ 124.75

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 the 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, 2025 and 2024. A detailed discussion comparing our results of operations for the years ended December 31, 2024 and 2023 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, 2024 filed with the SEC on February 27, 2025.

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"), atopic dermatitis ("AD"), and uveal melanoma ("UM").

Our Test Portfolio

We currently offer six commercially available proprietary multi-analyte assays with algorithmic analysis ("MAAA") tests for use in the fields of dermatology, gastroenterology and ophthalmology, and most recently includes a test to guide systemic treatment decisions in moderate-to-severe atopic dermatitis.

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

All of our MAAA tests, excluding our recently launched AdvanceAD-Tx test, 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 designed to predict the likelihood of a positive sentinel lymph node and the risk of metastasis or recurrence, for patients diagnosed with invasive CM. In a typical year, we estimate approximately 130,000 patients are diagnosed with invasive CM in the U.S., 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.

AdvanceAD-Tx is a non-invasive GEP test designed to guide systemic treatment selection for patients aged 12 years and older with moderate-to-severe atopic dermatitis ("AD"). The test evaluates the expression of 487 genes across 12 known immune, inflammatory and skin-related pathways to identify the underlying biology driving an individual patient's disease. Results classify patients into one of two molecular profiles: Janus Kinase ("JAK") Inhibitor Responder Profile or T helper 2 ("Th2") Molecular Profile. Using multiple data sources focused on one-year prevalence, we estimate there are approximately 10.0 million individuals ages 12 and older in the U.S. with moderate-to-severe AD, representing an estimated U.S. TAM of approximately $33 billion. We commenced a limited access launch of the AdvanceAD-Tx test in November 2025.

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 patients, or approximately 200,000 annually in the U.S., are classified as high risk, representing an estimated U.S. TAM of approximately $820 million.

MyPath Melanoma is our proprietary, diagnostic GEP test for use in patients with difficult-to-diagnose melanocytic lesions. Of the 2 million suspicious pigmented lesions biopsied annually in the U.S., we estimate approximately 300,000 of those present difficult-to-diagnose melanocytic lesion, representing an estimated U.S. TAM of approximately $600 million.

Our Gastroenterology Test

TissueCypher is our proprietary risk stratification spatialomics 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") BE. We estimate a U.S. TAM of approximately $1 billion.

Our Ophthalmology Test

DecisionDx-UM is our 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 was a pharmacogenomic ("PGx") test that guided personalized mental health medication selection and management for patients with depression, anxiety and other mental health conditions. We discontinued IDgenetix in May 2025 following further evaluation.

Commercial Expansion Efforts

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.

During the year ended December 31, 2025, we made several strategic acquisitions and partnerships to expand our clinical capabilities and product portfolio. In May 2025, we acquired Previse. This acquisition was intended to expand our GI diagnostic offerings beyond our existing TissueCypher test, representing a growth strategy through acquisition as well as organic product expansion. In June 2025, we entered into a collaboration and license agreement with SciBase to develop a diagnostic test aimed at predicting disease flares in patients with atopic dermatitis. In November 2025, we launched AdvanceAD-Tx, a new gene expression profile test designed to guide systemic treatment decisions for patients with moderate-to-severe AD. This launch represents a material expansion of our product portfolio into a significant new clinical area and a substantial potential market.

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, TissueCypher, MyPath Melanoma, DecisionDx-UM and IDgenetix tests which meet certain criteria for Medicare and Medicare Advantage beneficiaries. DecisionDx-SCC previously received Medicare coverage, which was subsequently impacted by LCD changes finalized in 2025.

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 2025 was set using median private payor rate data from January 1, 2023 to June 30, 2023. Our rate for 2023 through 2025 was $7,193 per test and remains $7,193 per test for 2026.

TissueCypher

Our TissueCypher tests are processed in our Phoenix and Pittsburgh laboratories. Palmetto's MolDX program oversees MAAA tests that are reported from our Phoenix laboratory and Noridian is the MAC responsible for administering Medicare claims for test reports issued by our Phoenix laboratory. Novitas is the MAC responsible for administering Medicare claims for test reports issued by our Pittsburgh laboratory.

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. 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. Beginning with 2025, the rate for TissueCypher has been set annually based on the median private payor rate for the first half of the second preceding calendar year. Our 2025 rate was $4,950 per test based on the median private payor rate data from January 1, 2023 to June 30, 2023 and remains $4,950 per test for 2026.

DecisionDx-SCC

We issue our DecisionDx-SCC tests from our Pittsburgh and Phoenix laboratories. Palmetto's MolDX ("MolDX") program oversees MAAA tests that are reported from our Phoenix laboratory and Noridian is the MAC responsible for administering Medicare claims for test reports issued by our Phoenix laboratory. Novitas is the MAC responsible for administering Medicare claims for test reports issued by our Pittsburgh laboratory.

DecisionDx-SCC has met "new ADLT" status since 2023. 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 continue at $8,500 based on the median private payor rates received between July 1, 2023 and November 30, 2023.

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, Genetic Testing for Oncology: Specific Tests, which also lists DecisionDx-SCC as non-covered; that LCD became effective on April 24, 2025.

In July 2025, we submitted reconsideration requests for both Novitas and MolDX LCDs. Both Novitas and MolDX subsequently confirmed that our requests were valid. These confirmations represent an important procedural step in the reconsideration process, but it does not indicate coverage or a favorable review outcome.

MyPath 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 MyPath Melanoma. We estimate that a significant majority of the MyPath Melanoma tests performed for Medicare patients will meet the coverage criteria.

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 2025 was set using median private payor rate data from January 1, 2023 to June 30, 2023. Our rates for 2023, 2024 and 2025 were $1,755, $1,950 and $1,950 per test, respectively. Our 2026 rate remains $1,950 per test.

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. We estimate that a significant majority of the DecisionDx-UM tests performed for Medicare patients will meet the coverage criteria.

On May 17, 2019, CMS determined that DecisionDx-UM meets the criteria for "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 2025 was set using median private payor rate data from January 1, 2023 to June 30, 2023. Our rate for 2023 through 2025 was $7,776 per test and remains $7,776 per test for 2026.

IDgenetix

IDgenetix is currently covered under a Noridian LCD policy and accompanying billing and coding article developed by MolDX. During 2023, we obtained a test-specific PLA CPT code for IDgenetix which became effective October 1, 2023. The CLFS rate of $1,336 per test was effective January 1, 2024. Our reimbursement rate for 2024 was $1,336 per test and remained at $1,336 per test in the first quarter of 2025. Our IDgenetix test was discontinued in May 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 amended the FDA's regulations to make explicit that LDT's are devices under the FD&C Act. However, on March 31, 2025, the U.S. District Court for the Eastern District of Texas vacated the FDA's LDT final rule. The U.S. government did not appeal the ruling, and the FDA rescinded the rule on September 19, 2025. Accordingly, the FDA's phased enforcement approach and related requirements are no longer in effect. Our proprietary tests, which were first marketed prior to May 6, 2024, remain approved by and under the oversight of the New York State Department of Health ("NYSDOH"), and we continue to believe that changes in FDA's regulatory approach to LDTs will have no material impact on our existing test offerings.

In July 2025, the FDA granted Breakthrough Device designation to our DecisionDx-Melanoma test. We believe this designation highlights the test's potential to improve melanoma care through individualized prognostic insights. The Breakthrough Device designation is intended to expedite the development and review of certain medical devices that may offer more effective diagnosis or treatment of life-threatening conditions.

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 are presented in the table below:

	For the Year Ended December 31, 2025				
	Q1	Q2	Q3	Q4	FY 2025
DecisionDx-Melanoma	8,621	9,981	10,459	10,022	39,083
DecisionDx-SCC	4,375	4,762	4,186	3,971	17,294
MyPath Melanoma	926	1,166	1,151	1,045	4,288
Dermatologic Total	13,922	15,909	15,796	15,038	60,665
TissueCypher	7,432	9,170	10,609	11,803	39,014
DecisionDx-UM	470	468	436	395	1,769
IDgenetix[(1)]	2,578	1,027	—	—	3,605
Grand Total	24,402	26,574	26,841	27,236	105,053

	For the Year Ended December 31, 2024				
	Q1	Q2	Q3	Q4	FY 2024
DecisionDx-Melanoma	8,384	9,585	9,367	8,672	36,008
DecisionDx-SCC	3,577	4,277	4,195	4,299	16,348
MyPath Melanoma	998	1,099	933	879	3,909
Dermatologic Total	12,959	14,961	14,495	13,850	56,265
TissueCypher	3,429	4,782	6,073	6,672	20,956
DecisionDx-UM	422	456	397	424	1,699
IDgenetix	4,078	4,903	5,045	3,125	17,151
Grand Total	20,888	25,102	26,010	24,071	96,071

(1) The IDgenetix test was discontinued effective May 2025.

For the years ended December 31, 2025 and 2024, our dermatologic test report volume increased by 7.8% and 15.5%, respectively, largely driven by continued growth from our DecisionDx-Melanoma and DecisionDx-SCC tests. TissueCypher increased by 86.2% for the year ended December 31, 2025, further contributing to the overall volume increase. For a discussion of how we recognize revenue derived from our tests, refer to "—Components of Results of Operations—Net Revenues" below.

For our AdvanceAD-Tx product line, test reports delivered during the year ended December 31, 2025 were de minimis due to the timing of the launch. Of the approximately 150 clinician offices that were granted access, more than 50% ordered AdvanceAD-Tx during the first five weeks of clinical availability. We plan to expand availability in a phased manner throughout 2026.

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, 2025 and 2024, approximately 77% 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 ASC Topic 606, *Revenue from Contracts with Customers*. 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 ongoing conflicts in the Middle East, the ongoing conflict between Ukraine and Russia, economic slowdowns, the recent shutdown of the federal government including regulatory agencies, public health crises, labor shortages, recessions or market corrections, supply chain disruptions, inflation and monetary policy shifts, international tariffs, 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 and 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 (loss) income 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 R&D 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 ("ASP") 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 R&D 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, TissueCypher, DecisionDx-SCC 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 to receive, 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 and reassessed each reporting period and adjustments are recorded as increases or decreases in revenue. 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 because 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 based on 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 rates 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 processing testing samples, personnel costs (including salaries, bonuses, benefits and stock-based compensation expense), electronic medical record setup costs, order and delivery systems, shipping charges for sample transport, 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 revenue 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 the launch of new tests or the initiation of significant commercial expansion efforts, as we ready our operations to support anticipated business growth. This includes continued investment in and expansion of our laboratory facilities.

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, 2025 and 2024" for details.

Research and Development

R&D 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 setup costs, costs associated with setting up and conducting clinical studies and allocated overhead, including rent, information technology, equipment depreciation and utilities. We expense all R&D costs in the periods in which they are incurred. We expect our R&D expenses to increase in absolute dollars as we continue to invest in R&D activities related to developing enhanced and new products.

We expect R&D expenses to increase as we continue to invest in 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 as the scale of our business grows, but selling and marketing-related expenses are expected to increase at a higher rate, 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 the Myriad MyPath Laboratory in May 2021, Cernostics in December 2021, AltheaDx in April 2022 and Previse in May 2025.

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.

Net Gains on Equity Securities

Net gains on equity securities are primarily attributable to realized and 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.

Other Income

Other income is primarily attributable to unrealized foreign currency gains and losses on our foreign currency-denominated investments and loan receivable, which are presented as marketable investment securities and other assets, respectively.

Income Tax (Benefit) Expense

On July 4, 2025, the OBBBA was enacted into law. The OBBBA includes a broad range of tax reform provisions affecting businesses, including reinstatement of permanent expensing of domestic research and development costs, higher EBITDA cap on the deduction for interest expense and 100% bonus depreciation. We will benefit from the reinstatement of permanent expensing of domestic research and development costs and 100% bonus depreciation.

Income tax (benefit) 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, 2025, we had federal NOL carryforwards of $134.8 million, of which $52.9 million will begin to expire in 2032 if not utilized to offset federal taxable income, and $81.9 million may be carried forward indefinitely. Also, as of December 31, 2025, we also had state NOL carryforwards of $113.0 million, which begin to expire in 2030 if not utilized to offset state taxable income.

Results of Operations

Comparison of the Years Ended December 31, 2025 and 2024

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

	Years Ended December 31,			
	2025	2024	Change	
NET REVENUES	$ 344,229	$ 332,069	$ 12,160	3.7 %
OPERATING EXPENSES				
Cost of sales (exclusive of amortization of acquired intangible assets)	71,028	60,205	10,823	18.0 %
Research and development	51,850	52,041	(191)	(0.4)%
Selling, general and administrative	229,323	200,047	29,276	14.6 %
Amortization of acquired intangible assets	34,838	11,106	23,732	213.7 %
Total operating expenses, net	387,039	323,399	63,640	19.7 %
Operating (loss) income	(42,810)	8,670	(51,480)	(593.8)%
Interest income	11,772	12,916	(1,144)	(8.9)%
Net gains on equity securities	1,466	555	911	164.1 %
Interest expense	(86)	(577)	491	85.1 %
Other income	144	—	144	NA
(Loss) income before income taxes	(29,514)	21,564	(51,078)	(236.9)%
Income tax (benefit) expense	(5,356)	3,319	(8,675)	(261.4)%
Net (loss) income	$ (24,158)	$ 18,245	$ (42,403)	(232.4)%

NA = Not applicable

Net Revenues

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

	Years Ended December 31,		
	2025	2024	Change
Dermatologic[1]	$ 216,369	$ 256,996	$ (40,627)
Non-Dermatologic[2]	127,860	75,073	52,787
Total net revenues	$ 344,229	$ 332,069	$ 12,160

(1) Consists of DecisionDx-Melanoma, DecisionDx-SCC and MyPath Melanoma.
(2) Consists of TissueCypher, DecisionDx-UM and IDgenetix.

Net revenues for the year ended December 31, 2025 increased by $12.2 million, or 3.7%, to $344.2 million compared to the year ended December 31, 2024 due to a $52.8 million increase in revenue from our non-dermatologic tests offset by a $40.6 million decrease in revenue from our dermatologic tests.

The $52.8 million increase in revenues from our non-dermatologic tests was largely attributable to an 86.2% increase in test report volumes for our TissueCypher test, and, to a much lesser extent, a higher realized ASP. 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 22.6% for the year ended December 31, 2024 to 37.1% for the year ended December 31, 2025.

The $40.6 million decrease in net revenues from our dermatologic tests was primarily due to a lower ASP for our DecisionDx-SCC test, following the loss of Medicare LCD coverage effective April 24, 2025, partially offset by increases in test report volumes for our DecisionDx-SCC and DecisionDx-Melanoma tests of 5.8% and 8.5%, respectively.

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, 2025 increased by $10.8 million, or 18.0%, compared to the year ended December 31, 2024, primarily attributable to higher personnel costs, and higher expenses related to services, supplies and depreciation. The increases in personnel costs reflected higher headcount to support business growth in response to increased test report volumes, as well as merit and annual inflationary wage adjustments for existing employees. Higher expenses related to services and supplies were driven by increased test report volumes, while the increase in depreciation expense reflected continued investment in and expansion of our laboratory facilities.

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 may not necessarily increase or decrease commensurately with 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 invest in related resources to support our expected operational growth and higher test volumes.

Gross Margin

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

	Years Ended December 31,		
	2025	2024	Change
Net revenues	$ 344,229	$ 332,069	$ 12,160
Less: Cost of sales (exclusive of amortization of acquired intangible assets)	71,028	60,205	10,823
Less: Amortization of acquired intangible assets	34,838	11,106	23,732
Gross margin	$ 238,363	$ 260,758	$ (22,395)
Gross margin percentage	69.2 %	78.5 %	(9.3)%

Our gross margin percentage was 69.2% for the year ended December 31, 2025, compared to 78.5% for the same period in 2024. The decrease was primarily due to lower ASP for our DecisionDx-SCC test and higher amortization expense related to the acceleration of our IDgenetix test. In addition, gross margin was impacted by higher cost of sales, as discussed above, driven by increased personnel costs, higher expenses related to services, supplies and depreciation expense resulting from continued investment in and expansion of our laboratory facilities.

Research and Development

R&D expenses for the year ended December 31, 2025 remained comparable to the year ended December 31, 2024, primarily due to higher personnel costs offset by lower clinical studies cost. The increase in higher personnel cost is driven by increased headcount to support ongoing research activities and continued business growth.

We expect to continue incurring R&D 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,		
	2025	2024	Change
Sales and marketing	$ 138,115	$ 123,467	$ 14,648
General and administrative	91,208	76,580	14,628
Total selling, general and administrative expense	$ 229,323	$ 200,047	$ 29,276

Sales and marketing expenses increased by $14.6 million, or 11.9%, for the year ended December 31, 2025 compared to the year ended December 31, 2024. The increase is primarily due to higher personnel costs, higher expenses associated training events and speaker conferences and higher sales related travel expenses. Increases in personnel costs reflect a higher headcount as well as merit and annual inflationary wage adjustment for existing employees. 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 $15.3 million for the year ended December 31, 2025, compared to $17.3 million for the year ended December 31, 2024.

General and administrative expenses increased by $14.6 million, or 19.1%, for the year ended December 31, 2025, compared to the year ended December 31, 2024. The increase is primarily due to higher personnel costs and higher information technology-related costs. 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 $17.4 million for the year ended December 31, 2025, compared to $17.8 million for the year ended December 31, 2024.

Amortization of Acquired Intangible Assets

Amortization expense increased by approximately $23.7 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to our decision to discontinue the IDgenetix test offering beginning in May 2025. As a result of this decision, we revised the estimated useful life of the related developed technology intangible asset and fully amortized the remaining carrying value as of March 31, 2025. To a lesser extent, the increase is also attributable to amortization of the developed technology intangible asset recognized in association with the Esopredict test following our acquisition of Previse in May 2025.

Interest Income

Interest income decreased by $1.1 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily as a result of lower interest rates on our cash, cash equivalents and marketable investment securities.

Net Gains on Equity Securities

The net gains on equity securities increased by $0.9 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to changes in the fair value of our equity securities, including both unrealized and realized gains recognized during the period.

Interest Expense

Interest expense decreased by $0.5 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to the capitalization of interest expense related to the construction of our Friendswood headquarters. Construction of the headquarters commenced in late 2024, resulting in a higher level of capitalized interest in 2025 compared to the prior year.

Income Tax (Benefit) Expense

Income tax benefit increased by $8.7 million for the year ended December 31, 2025, compared to the year ended December 31, 2024, primarily due to the partial release of the valuation allowance on our federal deferred tax assets resulting from new deferred tax liabilities recognized upon consolidating Previse in the current period. The increase also reflected revised estimates of pre-tax income due to uncertainty regarding Medicare coverage for our DecisionDx-SCC test and updated financial information, along with changes in stock-based compensation, permanent differences, valuation allowance adjustments, research and development tax credits, and state income taxes. The prior-year period reflected net income compared to a net loss in the current period.

Stock-Based Compensation Expense

The following table indicates the amount of stock-based compensation expense (non-cash) included in the consolidated statements of operations (in thousands):

	Years Ended December 31,		
	2025	2024	Change
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 5,666	$ 5,529	$ 137
Research and development	7,555	9,598	(2,043)
Selling, general and administrative	32,672	35,193	(2,521)
Total stock-based compensation expense	$ 45,893	$ 50,320	$ (4,427)

Stock-based compensation expense, which is allocated among cost of sales, R&D expense and SG&A expense, totaled $45.9 million for the year ended December 31, 2025 compared to $50.3 million for the year ended December 31, 2024. The decrease was primarily attributable to lower expense associated with stock option awards, reflecting our transition to granting only restricted stock units (“RSUs”) beginning 2023 and the continued amortization of higher-fair-value stock option grants issued in prior years.

We expect stock-based compensation expense will continue to be material in future periods, attributable to both existing awards outstanding and anticipated additional grants to our current and future employees. As of December 31, 2025, we had 883 employees compared to 761 as of December 31, 2024. As of December 31, 2025, total unrecognized stock-based compensation cost related to outstanding awards was $64.7 million, which is expected to be recognized over a weighted-average period of 2.4 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. Our marketable investment securities consist primarily of investment-grade debt securities and equity securities, all of which are readily available for use in current operations. As of December 31, 2025 and 2024, we had marketable investment securities of $182.8 million and $173.4 million, respectively, and cash and cash equivalents of $116.7 million and $119.7 million, respectively.

On April 4, 2025, we amended the 2024 Loan and Security Agreement (the “2024 LSA”) to modify certain terms, including the extension of the draw period for our line of credit from March 31, 2025 to September 30, 2025. In August 2025, we exercised the interest-only milestone provision under the 2024 LSA to extend the interest-only period on the term loan from November 30, 2025 to December 1, 2026. We had not made any draws on the line of credit. The line of credit under the 2024 LSA expired on September 30, 2025 and was no longer available as a source of liquidity thereafter.

Our liquidity has been primarily derived from the revenue generated from the sale of our products. As discussed under the caption “Material Cash Requirements,” below, 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 planned 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 R&D 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 R&D 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. 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.

In February 2024, we purchased a plot of land in Friendswood, Texas for cash consideration of $7.2 million, for the purpose of developing a commercial office building to serve as our corporate headquarters. The development project included a four-story building, comprising approximately 80,000 square feet of Class A office space. Construction began in May 2024 and we completed the portions of the building that serves as our headquarters in January 2026, at which time we began occupying the building. Over the duration of this project, we incurred significant capital expenditures through payments to the developer under a percentage-of-completion basis. As of December 31, 2025, the development project is expected to cost a total of approximately $42.8 million. During the years ended December 31, 2025 and 2024, we incurred capital expenditures of $31.0 million and $9.3 million, respectively, related to this development project. We expect to incur the remaining cost for the building in the first quarter of 2026. We intend to use our existing cash and cash equivalents to pay for remainder of 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, 2025, we recognized net loss of $24.2 million and had positive operating cash flow of $64.3 million; however, we may be unable to sustain positive cash flows in future periods. Collections on Medicare claims for our DecisionDx-SCC test represented a significant portion of our operating cash flows during 2024. Medicare coverage for the DecisionDx-SCC test was discontinued in April 2025, which has resulted in reduced revenues and cash inflows from this test during 2025, and these reductions are expected to continue unless our reconsideration requests related to both the MolDX and Novitas LCDs are approved. 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

Our long-term debt is presented in the table below (in thousands):

	As of December 31,	
	2025	2024
Term debt	$ 10,200	$ 10,200
Unamortized discount	(143)	(177)
Total debt, net	10,057	10,023
Less: Current portion of long-term debt	(417)	(278)
Total long-term debt	$ 9,640	$ 9,745

2024 Loan and Security Agreement

On March 26, 2024 (the "Closing Date"), we entered into the 2024 LSA, as amended in April 2025, 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 a term loan in the principal amount of $10.0 million, which was drawn on the Closing Date (the "2024 Term Loan") and provided for a $25.0 million line of credit that was available at our option from the Closing Date through September 30, 2025, with the same interest rate and maturity as the 2024 Term Loan (the "2024 Credit Line"), which expired on September 30, 2025, as discussed below.

The Consent and First Amendment executed on April 4, 2025, modified certain terms of the 2024 LSA, including the extension of the draw period for the line of credit from March 31, 2025 to September 30, 2025.

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 paid prior to March 26, 2026. Amounts repaid may not be reborrowed.

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 further amend the terms of the 2024 LSA, the consent of the Lender would be required. As of December 31, 2025, 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 2024 Term Loan is interest-only from the Closing Date through November 30, 2025, subject to extension under the Interest-Only Extension Milestone provision (as defined in the 2024 LSA). On August 26, 2025, we elected to extend the interest-only period to December 1, 2026. Beginning in December 2026, the principal payments will be made in equal monthly installments through the maturity date of November 1, 2028.

In addition, we are required to make a final payment equal to 2.00% of the aggregate original principal amounts of the 2024 Term Loan, due at maturity or upon full repayment.

2024 Term Loan

On the Closing Date, we drew $10.0 million under the 2024 Term Loan. 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, 2025, no principal payments have been made and the weighted-average effective interest rate for all outstanding debt under the 2024 Term Loan was 7.69%.

2024 Credit Line

We had a $25.0 million line of credit under the terms and provisions of the 2024 LSA from the Closing Date through September 30, 2025. On September 30, 2025, the 2024 Credit Line expired and no draws had been made on it.

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, 2025 totaled approximately $39.9 million, of which $2.6 million is payable in 2026 and $37.3 million is payable through early 2037. The leases expire on various dates through 2037 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 10 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,	
	2025	2024
Net cash provided by operating activities	$ 64,347	$ 64,866
Net cash used in investing activities	(60,367)	(50,137)
Net cash (used in) provided by financing activities	(6,960)	6,139
Net change in cash and cash equivalents	(2,980)	20,868
Cash and cash equivalents, beginning of year	119,709	98,841
Cash and cash equivalents, end of year	$ 116,729	$ 119,709

Operating Activities

Net cash provided by operating activities was $64.3 million for the year ended December 31, 2025, and was primarily attributable to non-cash stock-based compensation expense of $45.9 million, depreciation and amortization of $40.8 million, decreases in accounts receivable of $6.9 million, increases in accrued compensation of $5.7 million and increases in accounts payable of $3.1 million partially offset by the net loss of $24.2 million, decreases in deferred income taxes of $6.2 million, increases in accretion of discounts on marketable investment securities of $4.2 million, net gains on equity securities of $1.5 million, and increases in inventory of $2.1 million.

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.

The $0.5 million decrease in net cash provided by operating activities for the year ended December 31, 2025 compared to the year ended December 31, 2024 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, 2025 reflects the payment of annual cash bonuses to our employees as well as certain health care benefit payments totaling $22.5 million compared to $20.8 million during the same period in 2024.

Investing Activities

Net cash used in investing activities was $60.4 million for the year ended December 31, 2025 and consisted primarily of purchases of marketable investment securities of $188.7 million, purchases of property and equipment of $36.0 million, our asset acquisition of Previse for $18.7 million, purchases of debt securities classified as held-to-market of $5.6 million and $2.1 million from the issuance of a loan receivable, partially offset by the maturity of marketable investment securities of $189.2 million and $1.5 million in proceeds from the sale of equity securities.

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.

The $10.2 million increase in cash used in investing activities for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to our acquisition of Previse for $18.7 million, which includes both the cash consideration and direct transaction costs, $7.7 million in increased purchases of property and equipment, $5.6 million in purchases of debt securities classified as held-to-market and $2.1 million from the issuance of a loan receivable, partially offset by an increase of $5.3 million in proceeds from maturing marketable investment securities and $17.0 million fewer purchases of such securities.

Financing Activities

Net cash used in financing activities was $7.0 million for the year ended December 31, 2025, and consisted primarily of the $11.7 million payment of employee taxes attributable to the vesting of RSUs, partially offset by $2.4 million of proceeds from contributions to our 2019 Employee Stock Purchase Plan (the “ESPP”) and $2.2 million of proceeds from the exercise of stock options.

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 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.

Inflation

In 2021, the rate of inflation in the U.S. significantly increased until the second half of 2022 when the rate began to subside. In 2023 through 2025, the inflation rate continued to subside but remained higher than rates experienced in 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 our DecisionDx-Melanoma test for CM, our TissueCypher test for patients diagnosed with BE and our DecisionDx-SCC test for SCC. We also provide our MyPath Melanoma test for patients with melanocytic lesions, our DecisionDx-UM test for UM and IDgenetix, a PGx testing service focused on mental health. We discontinued offering our IDgenetix test in May 2025.

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 ALJ). A successful appeal at any of these levels may result in prompt payment.

In the absence of Medicare coverage, contractually established reimbursement 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, 2025 and 2024 were $7.6 million and $1.8 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 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. Forfeitures are accounted for as they occur.

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 revised this approach to include our own stock price on a relative basis to the peer group, as our common stock had been actively traded for more than two years. By the third quarter of 2025, our stock price has been fully incorporated as the sole input in the calculation.

- *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 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,		
	2025[1]	2024	2023
Average expected term (years)	N/A	5.0	5.0
Expected stock price volatility	N/A	80.20% - 80.20%	75.57% - 76.01%
Risk-free interest rate	N/A	4.39% - 4.39%	3.57% - 3.57%
Dividend yield	N/A	—%	—%

(1) For the year ended December 31, 2025, no stock options were granted.

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

	Years Ended December 31,		
	2025	2024	2023
Average expected term (years)	1.2	1.2	1.3
Expected stock price volatility	56.55% - 85.21%	59.85% - 105.39%	72.80% - 130.95%
Risk-free interest rate	3.52% - 4.22%	3.82% - 5.14%	4.74% - 5.33%
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 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. During the first quarter of 2025, we made the decision to discontinue our IDgenetix test offering, effective May 2025. As a result of this decision, we further revised the estimated useful life of the asset and determined that the intangible asset should be fully amortized as of March 31, 2025. This change resulted in an acceleration of amortization expense of approximately $20.1 million.

Recent Accounting Pronouncements

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. The guidance was effective for public entities for fiscal years beginning after December 15, 2024. We adopted ASU 2023-09 prospectively in fiscal year 2025 for the annual reporting period ending December 31, 2025. Please refer to Note 15 - Income Taxes, to our Consolidated Financial Statements for details.

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.

In July 2025, the FASB issued ASU No. 2025-05, Financial Instruments—*Credit Losses (Topic 326): Practical Expedient for Certain Current Receivables* ("ASU 2025-05"), which provides a practical expedient for estimating expected credit losses on current accounts receivable and contract assets arising from transactions under ASC 606. The practical expedient allows entities to assume that current conditions remain unchanged over the remaining life of the receivables. ASU 2025-05 is effective for annual periods beginning after December 15, 2025, including interim periods within those annual periods. 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 $116.7 million as of December 31, 2025, which include bank deposits and money market funds. We had marketable investment securities of $182.8 million as of December 31, 2025, which includes U.S. government securities. Due to the nature of these instruments, we believe that we have no material exposure to interest rate risk.

As of December 31, 2025, we had a term debt of $10.1 million consisting of our outstanding 2024 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 2025, the U.S. Federal Reserve lowered interest rates on three separate occasions: by 25 basis points in September 2025, by 25 basis points in October 2025 and by 25 basis points in December 2025. The WSJ Prime Rate decreased by the same basis points for each respective adjustment thereafter. In addition, we hold a loan receivable denominated in Swedish Krona, with a principal amount of SEK 20 million, which bears interest at a rate of 2.00% plus the three-month Stockholm Interbank Offered Rate ("STIBOR").

A hypothetical 10% change in interest rates during any of the periods presented would not have had a material impact on our financial statements.

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, 2025, we had equity securities with a total fair value of $5.6 million. A hypothetical 10% decrease in the market price of our equity securities as of December 31, 2025 would decrease the fair value by approximately $0.6 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. We are also exposed to market risk related to changes in foreign currency exchange rates. We do not currently hedge our foreign currency exchange rate risk.

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, 2025. Based upon the evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2025, 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 by, or under the supervision of, our principal executive officer and principal financial officer, and effected by our board of directors, management and other personnel, 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, 2025, 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, 2025, 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, 2025, 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) under the Exchange Act) that occurred during the fourth quarter of 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Securities Trading Plans of Directors and Executive Officers

On November 13, 2025, Frank Stokes, our Chief Financial Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of 13,001 shares of our common stock. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is estimated to be from February 27, 2026 until the earlier of all transaction under the trading arrangement being completed or March 31, 2026.

On December 3, 2025, 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 252,800 shares of our common stock and up to 100% of the shares of our common stock issued upon the settlement of 121,316 shares of RSUs and PSUs, less the number of shares withheld to cover tax withholding obligations in connection with the vesting and settlement of such RSUs and PSUs. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is estimated to be from March 11, 2026 until the earlier of all transaction under the trading arrangement being completed or August 31, 2026.

On December 10, 2025, Tobin Juvenal, our Chief Commercial Officer, adopted a Rule 10b5-1 trading arrangement providing for the sale from time to time of an aggregate of up to 45,000 shares of our common stock and up to 100% of the shares of our common stock issued upon the settlement of 34,978 shares of RSUs and PSUs, less the number of shares withheld to cover tax withholding obligations in connection with the vesting and settlement of such RSUs and PSUs. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c). The duration of the trading arrangement is estimated to be from March 12, 2026 until the earlier of all transaction under the trading arrangement being completed or September 4, 2026.

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 2026 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 Policy; Prohibition on Hedging, Short Sales and Pledging" 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 controller, or any person performing similar functions, we intend to satisfy our required 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. Information found on, or accessible through, our website is not part of, and is not incorporated into, this Annual Report on Form 10-K.

Item 11. Executive Compensation.

The information required by this item is to be included in the Proxy Statement under the sections entitled "Compensation Discussion and Analysis," "Executive Compensation Tables," "Director Compensation," "Compensation Committee Interlocks and Insider Participation," and "Compensation Committee Report" 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 entitled "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. Information disclosed therein pursuant to Item 402(v) of Regulation S-K relating to pay versus performance will not be 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 sections entitled "Transactions with Related Persons and Indemnifications—Related Person Transactions Policy and Procedures" and "Information Regarding the Board of Directors and Corporate Governance" 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
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on May 23, 2025.
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed with the SEC on August 8, 2025.
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.
Equity Compensation Plans	
10.1+	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.
10.2+	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.
10.3+	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.
10.4+	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.
10.5+	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.
10.6+	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.
10.7+	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.
10.8+	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.
10.9+	Castle Biosciences, Inc. 2022 Inducement Plan, as amended and restated, incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 3, 2025.

Exhibit Number	Description of document
10.10+	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.
10.11+	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.
Agreements with Executive Officers and Directors	
10.12+	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.
10.13+	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.
10.14+	Non-Employee Director Compensation Policy, as amended, incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on November 3, 2025.
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 Toby 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 June 20, 2025 by and between the Registrant and Toby Juvenal, incorporated by reference to Exhibit 10.6 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 4, 2025.
10.22+	Amended Participation Agreement, dated June 20, 2025 by and between the Registrant and Kristen Oelschlager, incorporated by reference to Exhibit 10.7 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 4, 2025.
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 June 20, 2025 by and between the Registrant and Frank Stokes, incorporated by reference to Exhibit 10.5 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 4, 2025.
Lease Agreements	
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.
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.

Exhibit Number	Description of document
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	Third Amendment to Commercial Lease, executed April 14, 2025, by and between the Registrant and Tannos Land Holdings III, LLC incorporated by reference to Exhibit 10.2 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 5, 2025.
10.40†	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.
10.41#†	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.
10.42	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.
10.43	Office Lease Agreement dated May 14, 2025, by and between the Registrant and Perimeter Gateway Portfolio LLC, incorporated by reference to Exhibit 10.3 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on August 4, 2025.
Purchase Sale Agreements	
10.44	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.
10.45	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
10.46†	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.
Loan and Security Agreements	
10.47#	Loan and Security Agreement, dated March 26, 2024, by and among the Registrant and Silicon Valley Bank, incorporated by reference to Exhibit 10.1 of the Registrant's Current Report on Form 8-K filed with the SEC on March 27, 2024.
10.48#†	Consent and First Amendment to the Loan and Security Agreement, dated April 4, 2025, by and among the Registrant, Castle Narnia Way Real Estate Holding 1, LLC and Silicon Valley Bank incorporated by reference to Exhibit 10.1 of the Registrant's Quarterly Report on Form 10-Q filed with the SEC on May 5, 2025
Other Agreements	
10.49#	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.
Other Exhibits	
19.1	Insider Trading Policy, incorporated by reference to Exhibit 19.1 of the Registrant's Annual Report on Form 10-K filed with the SEC on February 27, 2025.
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of KPMG LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney. Reference is made to the signature page hereto.
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).

* 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 26, 2026

By: /s/ Derek J. Maetzold

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

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Derek J. Maetzold and Frank Stokes and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their or his substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

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 26, 2026
/s/ Frank Stokes **(Frank Stokes)**	Chief Financial Officer (*Principal Financial and Accounting Officer*)	February 26, 2026
/s/ Daniel M. Bradbury **(Daniel M. Bradbury)**	Chairperson of the Board of Directors	February 26, 2026
/s/ Kimberlee S. Caple **(Kimberlee S. Caple)**	Member of the Board of Directors	February 26, 2026
/s/ G. Bradley Cole **(G. Bradley Cole)**	Member of the Board of Directors	February 26, 2026
/s/ Rodney Cotton **(Rodney Cotton)**	Member of the Board of Directors	February 26, 2026
/s/ Ellen Goldberg **(Ellen Goldberg)**	Member of the Board of Directors	February 26, 2026
/s/ Miles D. Harrison **(Miles D. Harrison)**	Member of the Board of Directors	February 26, 2026
/s/ Tiffany P. Olson **(Tiffany P. Olson)**	Member of the Board of Directors	February 26, 2026

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2025 and 2024, the related consolidated statements of operations, comprehensive (loss) income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2025, 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, 2025, 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, 2025 and 2024, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2025, 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, 2025 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 $344.2 million for the year ended December 31, 2025, 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 26, 2026

CASTLE BIOSCIENCES, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and per share data)

	December 31, 2025	December 31, 2024
ASSETS		
Current Assets		
Cash and cash equivalents	$ 116,729	$ 119,709
Marketable investment securities	182,776	173,421
Accounts receivable, net	43,382	51,218
Inventory	10,254	8,135
Prepaid expenses and other current assets	7,956	7,671
Total current assets	361,097	360,154
Long-term accounts receivable, net	1,878	918
Property and equipment, net	97,443	51,122
Operating lease assets	14,795	11,584
Goodwill and other intangible assets, net	99,574	106,229
Other assets – long-term	3,769	1,228
Total assets	$ 578,556	$ 531,235
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 18,711	$ 6,901
Accrued compensation	38,287	32,555
Contingent consideration	1,000	—
Operating lease liabilities	1,325	1,665
Current portion of long-term debt	417	278
Other accrued and current liabilities	8,937	7,993
Total current liabilities	68,677	49,392
Long-term debt	9,640	9,745
Noncurrent portion of contingent consideration	1,500	—
Noncurrent operating lease liabilities	25,217	14,345
Noncurrent finance lease liabilities	314	311
Deferred tax liability	2,335	1,607
Total liabilities	107,683	75,400
Commitments and Contingencies (Note 12)		
Stockholders' Equity		
Preferred stock, $0.001 par value per share; 10,000,000 shares authorized as of December 31, 2025 and 2024; no shares issued and outstanding as of December 31, 2025 and 2024	—	—
Common stock, $0.001 par value per share; 200,000,000 authorized as of December 31, 2025 and 2024; 29,686,314 and 28,483,195 shares issued and outstanding as of December 31, 2025 and 2024, respectively	30	28
Additional paid-in capital	694,860	655,703
Accumulated deficit	(224,284)	(200,126)
Accumulated other comprehensive income	267	230
Total stockholders' equity	470,873	455,835
Total liabilities and stockholders' equity	$ 578,556	$ 531,235

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,		
	2025	**2024**	**2023**
NET REVENUES	$ 344,229	$ 332,069	$ 219,788
OPERATING EXPENSES			
Cost of sales (exclusive of amortization of acquired intangible assets)	71,028	60,205	44,982
Research and development	51,850	52,041	53,618
Selling, general and administrative	229,323	200,047	180,152
Amortization of acquired intangible assets	34,838	11,106	9,013
Total operating expenses, net	387,039	323,399	287,765
Operating (loss) income	(42,810)	8,670	(67,977)
Interest income	11,772	12,916	10,623
Net gains on equity securities	1,466	555	—
Interest expense	(86)	(577)	(11)
Other income	144	—	—
(Loss) income before income taxes	(29,514)	21,564	(57,365)
Income tax (benefit) expense	(5,356)	3,319	101
Net (loss) income	$ (24,158)	$ 18,245	$ (57,466)
(Loss) earnings per share:			
Basic	$ (0.83)	$ 0.66	$ (2.14)
Diluted	$ (0.83)	$ 0.62	$ (2.14)
Weighted-average shares outstanding:			
Basic	28,986	27,776	26,802
Diluted	28,986	29,255	26,802

The accompanying notes are an integral part of these consolidated financial statements.

CASTLE BIOSCIENCES, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE (LOSS) INCOME
(in thousands)

	Years Ended December 31,		
	2025	**2024**	**2023**
Net (loss) income	$ (24,158)	$ 18,245	$ (57,466)
Other comprehensive income:			
Net unrealized gain on marketable investment securities	37	94	517
Comprehensive (loss) income	$ (24,121)	$ 18,339	$ (56,949)

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 (Loss) Income	Total Stockholders' Equity
	Shares	Amount				
BALANCE, JANUARY 1, 2023	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, net of shares withheld for 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, net of shares withheld for 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
Stock-based compensation expense	—	—	45,893	—	—	45,893
Exercise of common stock options	108,458	—	2,206	—	—	2,206
Issuance of common stock from vested restricted stock units, net of shares withheld for taxes	933,763	1	(11,658)	—	—	(11,657)
Issuance of common stock under the employee stock purchase plan	160,898	1	2,716	—	—	2,717
Net unrealized gain on marketable investment securities	—	—	—	—	37	37
Net loss	—	—	—	(24,158)	—	(24,158)
BALANCE, DECEMBER 31, 2025	29,686,314	$ 30	$ 694,860	$ (224,284)	$ 267	$ 470,873

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,		
	2025	2024	2023
OPERATING ACTIVITIES			
Net (loss) income	$ (24,158)	$ 18,245	$ (57,466)
Adjustments to reconcile net (loss) income to net cash provided by (used in) operating activities:			
Depreciation and amortization	40,771	15,997	12,330
Stock-based compensation expense	45,893	50,320	51,219
Net gains on equity securities	(1,466)	(555)	—
Deferred income taxes	(6,228)	1,401	(223)
Accretion of discounts on marketable investment securities	(4,219)	(6,685)	(5,491)
Other	153	268	635
Change in operating assets and liabilities:			
Accounts receivable	6,876	(12,643)	(14,930)
Prepaid expenses and other current assets	(544)	(1,142)	(435)
Inventory	(2,142)	(193)	(3,962)
Operating lease assets	1,372	1,322	(258)
Other assets	(366)	262	(330)
Accounts payable	3,078	(4,372)	5,707
Operating lease liabilities	(1,275)	(1,289)	852
Accrued compensation	5,732	3,610	4,587
Other accrued and current liabilities	870	320	2,139
Net cash provided by (used in) operating activities	64,347	64,866	(5,626)
INVESTING ACTIVITIES			
Purchases of marketable investment securities	(188,714)	(205,729)	(189,075)
Proceeds from maturities of marketable investment securities	189,200	183,900	186,500
Proceeds from sale of equity securities	1,533	—	—
Purchases of debt securities classified as held-to-maturity	(5,569)	—	—
Asset acquisition, net of cash and cash equivalents acquired	(18,727)	—	—
Issuance of loan receivable	(2,114)	—	—
Purchases of property and equipment	(36,021)	(28,326)	(13,621)
Proceeds from sale of property and equipment	45	18	13
Net cash used in investing activities	(60,367)	(50,137)	(16,183)
FINANCING ACTIVITIES			
Proceeds from exercise of common stock options	2,206	2,017	269
Payment of employees' taxes on vested restricted stock units	(11,657)	(8,762)	(5,134)
Proceeds from contributions to the employee stock purchase plan	2,416	2,981	2,709
Repayment of principal portion of finance lease liabilities	(115)	(97)	(142)
Proceeds from lease incentives received	190	—	—
Proceeds from issuance of term debt	—	10,000	—
Net cash (used in) provided by financing activities	(6,960)	6,139	(2,298)
NET CHANGE IN CASH AND CASH EQUIVALENTS	(2,980)	20,868	(24,107)
Beginning of year	119,709	98,841	122,948
End of year	$ 116,729	$ 119,709	$ 98,841

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,		
	2025	2024	2023
SUPPLEMENTAL DISCLOSURE OF CASH PAID FOR:			
Interest paid, net of amounts capitalized	$ 59	$ 434	$ 11
Income taxes, net	$ 1,601	$ 2,503	$ 198
DISCLOSURE OF NON-CASH INVESTING AND FINANCING ACTIVITIES:			
Asset acquisition, liability for contingent consideration	$ 2,500	$ —	$ —
Accrued purchases of property and equipment	$ 11,337	$ 2,231	$ 1,226
Property and equipment acquired with tenant improvement allowance	$ 7,224	$ 1,389	$ 1,281
Operating lease assets obtained in exchange for lease obligations	$ 4,687	$ 607	$ 1,547
Decrease in operating lease assets with corresponding change in lease liabilities	$ (104)	$ (7)	$ —
Finance lease assets obtained in exchange for lease obligations	$ 119	$ 218	$ —

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, 2025, we had an accumulated deficit of $224.3 million. We believe our $116.7 million of cash and cash equivalents and $182.8 million of marketable investment securities as of December 31, 2025, 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, allowance for credit losses for assets measured at amortized cost, 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 16.

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. Debt securities that are classified as available-for-sale ("AFS") 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 (loss) income within total stockholders' equity, net of any related deferred income tax effects, on the consolidated balance sheets. Debt securities that are classified as held-to-maturity ("HTM") are reported at amortized cost in accordance with ASC 320. Premiums or discounts from par value are amortized to interest income over the life of the underlying investment and are included in interest income in the consolidated statements of operations. Realized gains and losses on AFS and HTM debt securities, if any, are calculated at the individual security level and are included in interest income in the consolidated statements of operations. Impairments of AFS or HTM 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 and certain foreign exchanges. All equity securities are recognized in accordance with ASC Topic 321, *Investments-Equity Securities* ("ASC 321") and reported at their readily determinable fair values based on quoted market prices where changes in fair value are included in net gains on equity securities in the consolidated statements of operations. For investments denominated in a foreign currency, the fair value is remeasured into U.S. dollars using exchange rates in effect at each balance sheet date in accordance with ASC Topic 830, *Foreign Currency Matters* ("ASC 830"). As a result, changes in fair value include the effects of both market price movements and foreign currency exchange rate fluctuations. All changes in a marketable security's fair value are reported in earnings as they occur, and the sale of our equity 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. We updated our terminology to refer to these investments as equity securities rather than trading securities to align with the terminology in ASC 321. See Notes 5 and 11 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.

Collaborative Arrangements

We assess whether our licensing and other agreements are collaborative arrangements based on whether they involve joint operating activities and whether both parties have active participation in the arrangement and are exposed to significant risks and rewards. For arrangements that we determine are collaborations, we identify each unit of account and then determine whether a customer relationship exists for that unit of account. If we determine that a performance obligation within the collaborative arrangement is with a customer, we apply ASC 606.

If a portion of a distinct bundle of goods or services within the collaborative arrangement is not with a customer, we apply recognition and measurement based on an analogy to authoritative accounting literature or, if there is no appropriate analogy, a reasonable, rational, and consistently applied accounting policy election. To the extent the arrangement is within the scope of ASC Topic 808, *Collaborative Arrangements* ("ASC 808"), we assess whether aspects of the arrangement are within the scope of other accounting literature.

In June 2025, we entered into a Collaboration and License Agreement with SciBase Holding AB ("SciBase"). Following approval under the Swedish Screening of Foreign Direct Investments Act in the third quarter of 2025, subsequent to approval, we completed our investment in SciBase. The agreement aims to jointly develop diagnostic tests for dermatologic diseases, initially focused on atopic dermatitis, by combining SciBase's Electrical Impedance Spectroscopy technology with our diagnostic and development expertise. Under the arrangement, we hold development and commercialization rights in North America, while SciBase retains rights in certain other territories. SciBase is entitled to royalties on our product sales, a mark-up on product sales to us, and a milestone payment upon achieving specified sales thresholds. Development costs are shared; however, SciBase deferred its initial clinical development costs for the initial indication and we will recover those costs through future royalty payments reductions.

We determined the agreement is a collaborative arrangement under ASC 808. Certain elements of the arrangement, including license rights and sales-based royalty provisions, represent transactions with a customer and are therefore accounted for under ASC 606. Other elements, such as shared development activities and cost reimbursements, are accounted for in accordance with ASC 808 and presented as reductions to research and development ("R&D") expenses.

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, 2025 and 2024. 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.

Convertible Loan Receivable

On November 7, 2025, we entered into a Convertible Loan Agreement with SciBase (the "Convertible Loan Receivable"), pursuant to which we loaned SEK 20.0 million, approximately $2.1 million based on the exchange rate in effect on November 7, 2025. The Convertible Loan Receivable bears interest at a rate of 2.00% plus the three-month Stockholm Interbank Offered Rate ("STIBOR"), payable quarterly. SciBase may prepay all or a portion of the Convertible Loan Receivable at any time. The Convertible Loan Receivable matures on November 7, 2030, at which time we have the option, at our sole discretion, to convert the outstanding principal plus accrued interest into shares of SciBase that are listed on the Nasdaq First North Growth Market in Sweden, receive full repayment in cash, or receive a combination of cash and shares.

We accounted for the convertible loan as a receivable within the scope of ASC Topic 310, *Receivables.* The carrying amount of the convertible loan is presented at amortized cost, within long-term other assets in the consolidated balance sheets. The Convertible Loan Agreement is remeasured into U.S. dollars using exchange rates in effect at each balance sheet date in accordance with ASC 830 with changes in exchange rates recognized in earnings. In addition, the embedded conversion feature to shares of SciBase did not meet the definition of a derivative and was not bifurcated from the host contract under ASC Topic 815, *Derivatives and Hedging*. We have determined that expected credit losses associated with the loan are insignificant and, accordingly, have not recorded a credit loss allowance under ASC Topic 326-20, *Financial Instruments - Credit Losses.*

Interest income on the Convertible Loan Receivable is recognized quarterly and included in interest income in the consolidated statements of operations. Accrued interest receivable is recorded within prepaid expenses and other current assets in the consolidated balance sheets.

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 located in Friendswood, Texas, Phoenix, Arizona and Pittsburgh, Pennsylvania, and are generally depreciated over the remaining lease terms, which end in 2026, 2034 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 unit 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, 2025, 2024 and 2023.

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. If the total consideration transferred is less than the aggregate fair value of the net assets acquired (i.e., a bargain purchase), the difference is not recognized as a gain. Instead, the difference is allocated to the cost of the acquired assets on a relative fair value basis. 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 consideration if specified future events occur or if certain conditions are met. In May 2025, we acquired Capsulomics, Inc., d/b/a Previse ("Previse"), which was recorded as an asset acquisition, and agreed to pay additional consideration of up to $2.5 million in cash based on the achievement of certain commercial milestones (the "Earnout Payments"). We account for the contingent consideration as a liability in accordance with ASC Topic 450-20, *Loss Contingencies* ("ASC 450-20") when it is both probable and reasonably estimable. In accordance with ASC 450-20, we recorded the contingent consideration at the amount required to settle the respective obligation, and subsequent changes are recognized as adjustments to the cost basis of the acquired assets. These changes are allocated to the acquired assets based on their relative fair values as of the date of acquisition. In December of 2025, one of the commercial milestones was achieved. As a result, an Earnout Payment of $0.5 million became payable and will be paid within 60 days of milestone achievement.

Contingent consideration is classified as current or noncurrent in the consolidated balance sheets based on the contractual timing of future settlement.

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 10 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

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, 2025 and 2024, we accrued approximately $28.1 million and $23.3 million, respectively, for liabilities associated with these bonus plans. These amounts are classified as current or noncurrent accrued liabilities 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, 2025, 2024 and 2023 we provided a discretionary matching contribution of $6.1 million, $5.5 million and $4.6 million respectively. The higher amount for the year ended December 31, 2025 primarily reflects an increase in the number of employees compared to the years ended December 31, 2024 and 2023.

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 statements 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 ("Retirement Policy"). Stock-based awards falling into the scope of the Retirement Policy are accounted for as a modification of existing awards under ASC Topic 718, *Compensation – Stock Compensation*. The modifications do not result in the recognition of incremental compensation cost, however, they 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 (Loss) Income

Comprehensive (loss) income is defined as a change in equity during a period from transactions and other events and circumstances from non-owner sources. Comprehensive (loss) income is made up of net (loss) income plus net unrealized gain (loss) on marketable investment securities, which is our only other item of other comprehensive (loss) income.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update ("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. The guidance was effective for public entities for fiscal years beginning after December 15, 2024. We adopted ASU 2023-09 prospectively in fiscal year 2025 for the annual reporting period ending December 31, 2025. For additional information on our tax disclosure, see Note 15.

Accounting Pronouncements Yet to be Adopted

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.

In July 2025, the FASB issued ASU No. 2025-05, Financial Instruments—*Credit Losses (Topic 326): Practical Expedient for Certain Current Receivables* ("ASU 2025-05"), which provides a practical expedient for estimating expected credit losses on current accounts receivable and contract assets arising from transactions under ASC 606. The practical expedient allows entities to assume that current conditions remain unchanged over the remaining life of the receivables. ASU 2025-05 is effective for annual periods beginning after December 15, 2025, including interim periods within those annual periods. 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, our TissueCypher® test for patients diagnosed with Barrett's esophagus and our DecisionDx®-SCC test for cutaneous squamous cell carcinoma. We also provide our MyPath® Melanoma test for patients with melanocytic lesions, our DecisionDx®-UM test for uveal melanoma, and a pharmacogenomic testing service focused on mental health, IDgenetix®.

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 local coverage determination 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 reimbursement 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, 2025, 2024 and 2023 were $7.6 million, $1.8 million 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.

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, 2025 and 2024.

Disaggregation of Revenues

The table below provides the disaggregation of revenue by type (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Dermatologic[1]	$ 216,369	$ 256,996	$ 183,375
Non-Dermatologic[2]	127,860	75,073	36,413
Total net revenues	$ 344,229	$ 332,069	$ 219,788

(1) Consists of DecisionDx-Melanoma, DecisionDx-SCC and MyPath 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 allocating resources. See Note 16 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, each of which accounted for more than 10% of total revenues or accounts receivable balances were as follows:

	Percentage of Revenues			Percentage of Accounts Receivable (current)		Percentage of Accounts Receivable (noncurrent)	
	Years Ended December 31,			As of December 31,		As of December 31,	
	2025	2024	2023	2025	2024	2025	2024
Medicare	44 %	47 %	49 %	18 %	18 %	*	*
Payor A	16 %	15 %	14 %	15 %	19 %	16 %	15 %
Payor B	*	*	*	22 %	20 %	10 %	12 %

* Less than 10%

4. (Loss) Earnings Per Share

Basic (loss) earnings per share is computed by dividing net (loss) income for the period by the weighted-average number of common shares outstanding during the period. Diluted (loss) earnings 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) earnings 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) earnings per share when their effect is antidilutive.

The following table shows the computation of basic and diluted (loss) earnings per share (in thousands, except per share data):

	Years Ended December 31,		
	2025	2024	2023
Numerator:			
Net (loss) income	$ (24,158)	$ 18,245	$ (57,466)
Denominator:			
Weighted-average common shares outstanding, basic	28,986	27,776	26,802
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	28,986	29,255	26,802
(Loss) earnings per share:			
Basic	$ (0.83)	$ 0.66	$ (2.14)
Diluted	$ (0.83)	$ 0.62	$ (2.14)

Due to the Company reporting a net loss attributable to common stockholders for years ended December 31, 2025 and 2023, 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 (loss) earnings per share for the years ended December 31, 2025, 2024 and 2023 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 earnings 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,		
	2025	2024	2023
Stock options	2,913	2,445	3,319
RSUs and PSUs	4,084	531	3,350
ESPP	174	160	330
Total	7,171	3,136	6,999

In connection with our acquisition of AltheaDx, Inc. ("AltheaDx") in April 2022, we agreed to pay up to an additional $75.0 million in cash and common stock upon the achievement of certain commercial milestones for the IDgenetix test during 2022, 2023 and 2024. The milestones required to trigger these additional payments were not met in any of those years. As a result, no cash payments were made, and no shares of common stock were issued or excluded from the calculation of diluted (loss) earnings per share during those years.

5. Marketable Investment Securities

Marketable investment securities consisted of the following (in thousands):

	As of December 31,	
	2025	2024
Current marketable investment securities:		
Equity securities	$ 5,555	$ 3,555
Debt securities - AFS	171,631	169,866
Debt securities - HTM[(1)]	5,590	—
Total current marketable investment securities	$ 182,776	$ 173,421

(1) We held no HTM debt securities as of December 31, 2024.

Equity Securities

The portion of unrealized gains related to equity securities still held during the period is as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Net gains on equity securities	$ 1,466	$ 555	$ —
Less: Net gain recognized on equity securities sold	484	—	—
Net unrealized gains recognized on equity securities still held	$ 982	$ 555	$ —

Debt Securities

The following tables present our debt securities (in thousands):

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. government securities - AFS	$ 171,364	$ 269	$ (2)	$ 171,631
U.S. government securities - HTM	5,590	11	—	5,601
Total debt securities	$ 176,954	$ 280	$ (2)	$ 177,232

	December 31, 2024			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
U.S. government securities - AFS	$ 169,636	$ 244	$ (14)	$ 169,866
U.S. government securities - HTM[(1)]	—	—	—	—
Total debt securities	$ 169,636	$ 244	$ (14)	$ 169,866

(1) We held no HTM debt securities as of December 31, 2024.

Our U.S. government securities includes both AFS and HTM securities. The AFS securities are available to be sold to meet operating needs or otherwise, but are generally held through maturity. We classify all AFS investments as current assets, as these are readily available for use in current operations. As of December 31, 2025 and 2024, all of our AFS securities had contractual maturities of one year or less.

We classify our HTM investments as current assets, as we have the positive intent and ability to hold these investments to maturity, and all such maturities are less than one year from the balance sheet date.

We evaluated our U.S. government securities under the AFS and HTM impairment model guidance, respectively, and determined our investment portfolio is comprised of low-risk, investment grade securities.

For the years ended December 31, 2025, 2024 and 2023, the unrealized losses on our AFS and HTM U.S. government securities are not attributed to credit risk. 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. The allowance for credit losses was zero as of December 31, 2025 and 2024.

There were no realized gains or losses on sales of debt securities for the years ended December 31, 2025, 2024 and 2023. In addition, there were no credit-related or noncredit-related impairment losses recognized for the years ended December 31, 2025, 2024 and 2023.

Accrued interest receivable for our AFS and HTM U.S. government securities is included in prepaid expenses and other current assets in the consolidated balance sheets. As of December 31, 2025 and 2024, the accrued interest receivable related to AFS securities was $1.1 million and $0.6 million, respectively. As of December 31, 2025, the accrued interest receivable related to HTM securities was immaterial. There were no amounts accrued as of December 31, 2024, as no securities were classified as HTM at that time.

Additional information relating to the fair value of marketable investment securities can be found in Note 11.

6. Property and Equipment, Net

Property and equipment, net consisted of the following (in thousands):

	As of December 31,	
	2025	2024
Land	$ 7,245	$ 7,245
Lab equipment	33,034	23,633
Leasehold improvements	14,834	14,616
Computer equipment	5,920	5,306
Furniture and fixtures	3,648	3,541
Construction-in-progress	51,059	9,614
Total	115,740	63,955
Less: Accumulated depreciation	(18,297)	(12,833)
Property and equipment, net	$ 97,443	$ 51,122

Depreciation expense was recorded in the consolidated statements of operations as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 3,916	$ 2,950	$ 1,758
Research and development	355	354	330
Selling, general and administrative	1,662	1,587	1,229
Total depreciation expense	$ 5,933	$ 4,891	$ 3,317

7. Goodwill and Other Intangible Assets, Net

Goodwill

We had a single reportable segment consisting of a single operating segment where the operating segment and the single reporting unit were the same for the years ended December 31, 2025, 2024 and 2023, where all goodwill was allocated. As of December 31, 2025 and 2024, our goodwill balance was $10.7 million. See Note 16 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 approximately 80%. Therefore, no impairment was indicated for the year ended December 31, 2025. 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. No impairment charges were recorded against goodwill for the years ended December 31, 2025, 2024 and 2023.

Other Intangible Assets, Net

Our other intangible assets, net consisted of the following (in thousands):

	As of December 31, 2025			
	Gross carrying value	Accumulated amortization	Net	Weighted-Average Remaining Life (in years)
Developed technology	$ 153,500	$ (64,721)	$ 88,779	10.3
Assembled workforce	563	(460)	103	0.9
Total other intangible assets, net	$ 154,063	$ (65,181)	$ 88,882	

	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	

The estimated future aggregate amortization expense as of December 31, 2025 was as follows (in thousands):

Years Ending December 31,	
2026	$ 9,019
2027	8,916
2028	8,941
2029	8,916
2030	8,916
Thereafter	44,174
Total	$ 88,882

On December 1, 2024, we revised the estimated remaining useful life of our IDgenetix developed technology intangible asset, which 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 year ended December 31, 2024.

During the first quarter of 2025, we decided to discontinue our IDgenetix test offering, effective May 2025. As a result, we revised the estimated useful life of the related intangible asset and fully amortized the asset as of March 31, 2025, resulting in an acceleration of amortization expense of approximately $20.1 million.

In May 2025, in connection with the acquisition of Previse, and in accordance with ASC 805, we determined that substantially all of the fair value of the gross assets acquired was concentrated in a single identifiable asset; accordingly, the transaction was accounted for as an asset acquisition. The acquired intangible asset consists of developed technology with a fair value of $28.2 million, an estimated useful life of 12 years, and is amortized on a straight-line basis.

Amortization expense of intangible assets was $34.8 million, $11.1 million and $9.0 million for the years ended December 31, 2025, 2024 and 2023, respectively.

8. Other Accrued and Current Liabilities

Other accrued and current liabilities consisted of the following (in thousands):

	As of December 31,	
	2025	2024
Accrued service fees	$ 3,213	$ 2,338
Clinical studies	2,674	2,580
ESPP Contributions	924	1,225
Other	2,126	1,850
Total	$ 8,937	$ 7,993

9. Long-Term Debt

Our long-term debt consisted of the following (in thousands):

	As of December 31,	
	2025	2024
Term debt	$ 10,200	$ 10,200
Unamortized discount	(143)	(177)
Total debt, net	10,057	10,023
Less: Current portion of long-term debt	(417)	(278)
Total long-term debt	$ 9,640	$ 9,745

Future maturities of principal amounts on long-term debt as of December 31, 2025 were as follows (in thousands):

Years Ending December 31,	
2026	$ 417
2027	5,000
2028	4,583
Total	$ 10,000

2024 Loan and Security Agreement

On March 26, 2024 (the “Closing Date”), we entered into a Loan and Security Agreement, as amended in April 2025 (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 a term loan in the principal amount of $10.0 million, which was drawn on the Closing Date (the “2024 Term Loan”) and provided for a $25.0 million line of credit that was available at our option from the Closing Date through September 30, 2025, with the same interest rate and maturity as the 2024 Term Loan (the “2024 Credit Line”).

The Consent and First Amendment executed on April 4, 2025, modified certain terms of the 2024 LSA, including the extension of the draw period for the 2024 Credit Line from March 31, 2025 to September 30, 2025, which expired on September 30, 2025, the 2024 Credit Line expired as discussed below.

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 may not be reborrowed.

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 further amend the terms of the 2024 LSA, the consent of the Lender would be required. As of December 31, 2025, 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 2024 Term Loan was interest-only from the Closing Date through November 30, 2025, subject to extension under the Interest-Only Extension Milestone provision (as defined in the 2024 LSA). On August 26, 2025, we elected to extend the interest-only period to December 1, 2026. Beginning in December 2026, the principal payments will be made in equal monthly installments through the maturity date of November 1, 2028.

In addition, we are required to make a final payment equal to 2.00% of the aggregate original principal amounts of the 2024 Term Loan, due at maturity or upon full repayment.

2024 Term Loan

On the Closing Date, we drew $10.0 million under the 2024 Term Loan. 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, 2025, no principal payments have been made and the weighted-average effective interest rate for all outstanding debt under the 2024 Term Loan was 7.69%.

2024 Credit Line

We had a $25.0 million line of credit under the 2024 Line of Credit, from the Closing Date through September 30, 2025. The 2024 Credit Line expired on September 30, 2025 and no amounts were drawn during the term.

Interest Expense on Long-Term Debt

Interest expense on long-term debt consisted of the following (in thousands):

	Years Ended December 31,	
	2025	2024
Interest expense on long-term debt	$ 807	$ 685
Less: Capitalized interest	(758)	(180)
Total	$ 49	$ 505

There was no interest expense on long-term debt or capitalized interest for the year ended December 31, 2023.

10. Leases

Operating Leases

We lease office space in Friendswood, Texas (the “Friendswood Lease”) which previously served as our corporate headquarters before moving in January 2026. The Friendswood Lease commenced in late 2020 under a 60-month term and, under a subsequent amendment, now expires in March 2026.

We lease two facilities in Phoenix, Arizona for laboratory and office space under two agreements with terms expiring in July 2033 and February 2034, respectively. Each contract provides two five-year renewal options.

We lease general office and laboratory facilities in Pittsburgh Pennsylvania (the “Pittsburgh Lease”). The Pittsburgh Lease commenced in April 2023 under a term of 10.5 years, and with a five-year renewal option and an early termination clause. The lease was originally executed in April 2022.

We lease general office and laboratory facilities in Scottsdale, Arizona (the "Scottsdale Lease"). On May 14, 2025, we entered into a lease agreement (the "Scottsdale Commencement Date") with Perimeter Gateway Portfolio, LLC (the "Lessor") for approximately 55,573 square feet. The Scottsdale Lease has a term of 143 months that will expire in April 2037, and provides a right of refusal to lease any additional adjacent space that may become available. The Scottsdale Lease includes two optional five-year term extensions, and a one-time option to terminate the lease on the last day of the 96th month following the Scottsdale Commencement Date, subject to certain conditions, in exchange for early termination fee. The fee would equal the unamortized balance of commissions paid to the Lessor's broker and our broker, plus the amortized balance of hard and soft costs incurred by the Lessor in connection with the tenant improvement allowance. The Scottsdale Lease also provides for $7.2 million in lease incentives in form of Lessor-paid improvements. Rent for the first twelve months is abated, totaling $1.8 million, with any unamortized amounts becoming payable in the event of a default under the lease.

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, which expire in 2029. Certain of our Finance Leases contain automatic one year extensions that become effective unless we provide advanced notice of our intent not to extend the term. In 2025, we received a cash lease incentive of $0.2 million for certain Finance Leases. There were no cash lease incentives received in 2024 or 2023.

Discount Rates

We discount our lease obligations using our incremental borrowing rate as of the lease commencement date or, for lease modifications, as of the effective date of the modification. The incremental borrowing rate represents the rate of interest we would expect to pay to borrow on a collateralized basis over a similar term in an amount equal to the lease payments in a similar economic environment. Beginning March 26, 2024, we had outstanding borrowings under the 2024 LSA and used the interest rate on those borrowings to determine our incremental borrowing rate for lease measurement. We then adjust our incremental borrowing rate for the economic environment, collateral and other information available at the lease commencement date to develop a discount rate appropriate for each lease. Prior to having outstanding borrowings 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 sheets were as follows (in thousands):

		As of December 31,	
Lease Balance	**Classification**	**2025**	**2024**
Lease Assets			
Operating	Operating lease assets	$ 14,795	$ 11,584
Finance	Property and equipment, net	$ 251	$ 222
Lease Liabilities			
Current			
Operating	Operating lease liabilities	$ 1,325	$ 1,665
Finance	Other accrued and current liabilities	$ 102	$ 101
Noncurrent			
Operating	Noncurrent operating lease liabilities	$ 25,217	$ 14,345
Finance	Noncurrent finance lease liabilities	$ 314	$ 311

Lease costs included in the consolidated statements of operations were as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Operating lease cost[1]	$ 3,980	$ 2,933	$ 2,625
Finance lease cost			
Amortization of lease assets	91	87	141
Interest on finance lease liabilities	37	23	11
Short-term lease cost	26	6	108
Total lease cost	$ 4,134	$ 3,049	$ 2,885

(1) Includes variable lease cost of $0.7 million, $0.4 million and $0.3 million for the years ended December 31, 2025, 2024 and 2023, 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,		
	2025	2024	2023
Cash paid for amounts included in the measurement of lease liabilities			
Operating cash flows from operating leases	$ 3,150	$ 2,657	$ 1,723
Operating cash flows from interest paid on finance leases	$ 37	$ 20	$ 11
Financing cash flows from finance leases	$ 115	$ 97	$ 142

The weighted-average remaining lease term and weighted-average discount rates used were as follows:

	As of December 31,	
	2025	2024
Weighted-average remaining lease term (years)		
Operating leases	9.4	8.5
Finance leases	3.8	4.5
Weighted-average discount rate		
Operating leases	8.2 %	8.4 %
Finance leases	8.2 %	8.4 %

Future maturities for operating lease and finance lease liabilities as of December 31, 2025 were as follows (in thousands):

	Operating Leases	Finance Leases
Years Ending December 31,		
2026	$ 2,503	$ 129
2027	3,629	129
2028	4,303	129
2029	4,396	97
2030	4,489	—
Thereafter	20,104	—
Total lease payments	39,424	484
Less: Interest component	(12,882)	(68)
Present value of lease payments	$ 26,542	$ 416

Undiscounted future lease payments for leases that had not yet commenced as of December 31, 2025 was zero.

11. 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. For equity securities traded on foreign exchanges, fair values are determined based on quoted market prices in the applicable foreign markets and are remeasured into U.S. dollars using exchange rates in effect at each balance sheet date in accordance with ASC 830. The use of different assumptions, exchange rates 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 tables below provide 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 (in thousands):

	As of December 31, 2025			
	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]	$ 108,914	$ —	$ —	$ 108,914
U.S. government securities - AFS[2]	$ 171,631	$ —	$ —	$ 171,631
Equity securities[2]	$ 5,555	$ —	$ —	$ 5,555
Liabilities				
Term Debt[3][4]	$ —	$ 10,057	$ —	$ 10,057

	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 - AFS[2]	$ 169,866	$ —	$ —	$ 169,866
Equity securities[2]	$ 3,555	$ —	$ —	$ 3,555
Liabilities				
Term Debt[3][4]	$ —	$ 10,023	$ —	$ 10,023

(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.
(4) Borrowings approximate their fair value as the interest rate is variable and reflects market rates.

We have U.S. government securities that are HTM investments and are carried at amortized costs. The fair value of our HTM investments is classified as Level 1 of the fair value hierarchy. For additional information on the carrying amount and fair value of our HTM investments, see Note 5.

The Convertible Loan Receivable with SciBase is carried at amortized cost which approximates fair value due to the variable interest rate and market-based terms of the instrument. Fair value is estimated using a discounted cash flow model. The inputs used to fair value the Convertible Loan Receivable are classified as Level 2 in the fair value hierarchy and include three-month STIBOR and a market credit spread. For additional information on the carrying amount and estimated fair value of our Convertible Loan Receivable, see Note 2.

12. Commitments and Contingencies

From time to time, we may be involved in legal proceedings arising in the ordinary course of business. 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.

In November 2025, we entered into a subscription agreement in connection with SciBase's proposed rights offering. Under the agreement, we are committed to subscribe for its pro rata share of shares issuable under the rights offering and, if requested by SciBase, to subscribe for up to an additional 115.0 million shares. The subscription commitment is subject to an ownership limitation such that our ownership interest in SciBase may not reach or exceed 20% of the outstanding shares following the offering. The rights offering was completed in January 2026, see Note 17.

13. Stockholders' Equity

Capital Stock

Our Amended and Restated Certificate of Incorporation, dated July 29, 2019, authorizes us to issue up to 200,000,000 shares of common stock with a par value of $0.001 per share. We are 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, 2025 or 2024.

14. 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, 2025, there were 1,279,290 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, 2026, an additional 1,484,315 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. On August 5, 2025, our compensation committee amended the Inducement Plan to increase the number of shares issuable under the Inducement Plan by 700,000 shares. As of December 31, 2025, there were 718,454 shares available for grant under the amended 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

The following table summarizes our stock option activity:

	Stock Options Outstanding	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value (in thousands)
Balance as of January 1, 2023	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		
Granted	—	$ —		
Exercised	(108,458)	$ 20.34		
Forfeited/Cancelled	(96,873)	$ 45.51		
Balance as of December 31, 2025	2,784,432	$ 36.53	4.6	$ 24,372
Exercisable as of December 31, 2025	2,779,739	$ 36.55	4.6	$ 24,306

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:

	Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of January 1, 2023	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
Granted	1,715,247	$ 22.65
Vested[1]	(1,237,950)	$ 25.38
Forfeited/Cancelled	(277,759)	$ 23.38
Balance as of December 31, 2025	3,395,762	$ 22.42

(1) The aggregate number of shares withheld upon vesting for employee tax obligations was 366,776, 281,275 and 254,197 for the years ended December 31, 2025, 2024 and 2023, 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 of directors 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 were subject to time-based vesting and vested in full on August 9, 2025.

The following table summarizes our PSU activity:

	Performance-Based Restricted Stock Units Outstanding	Weighted-Average Grant Date Fair Value
Balance as of January 1, 2023	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
Granted	172,631	$ 22.23
Vested[1]	(98,015)	$ 23.23
Forfeited/Cancelled	—	$ —
Balance as of December 31, 2025	350,144	$ 21.72

(1) The aggregate number of shares withheld upon vesting for employee tax obligations was 35,426 and 30,046 for the years ended December 31, 2025 and 2024, respectively.

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, 2025, 1,170,613 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 296,863 shares becoming available under the ESPP effective January 1, 2026. 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 issued 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:

- *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*. For our ESPP, we estimate expected volatility based on the historical volatility of our common stock. For stock options, we previously estimated expected volatility using the historical stock prices of a group of comparable companies, together with our own stock price on a relative basis, due to the limited period during which our common stock had been actively traded. Beginning in the third quarter of 2025, our common stock established a sufficient trading history and, therefore, we use solely the historical volatility of our own stock in determining expected volatility.
- *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,		
	2025[1]	2024	2023
Average expected term (years)	N/A	5.0	5.0
Expected stock price volatility	N/A	80.20% - 80.20%	75.57% - 76.01%
Risk-free interest rate	N/A	4.39% - 4.39%	3.57% - 3.57%
Dividend yield	N/A	—%	—%

(1) For the year ended December 31, 2025, no stock options were granted.

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

	Years Ended December 31,		
	2025	2024	2023
Average expected term (years)	1.2	1.2	1.3
Expected stock price volatility	56.55% - 85.21%	59.85% - 105.39%	72.80% - 130.95%
Risk-free interest rate	3.52% - 4.22%	3.82% - 5.14%	4.74% - 5.33%
Dividend yield	—%	—%	—%

Fair Value and Intrinsic Value

For the year ended December 31, 2025, no stock options were granted. For the years ended December 31, 2024 and 2023 the weighted-average grant date fair value of stock options was $9.23 and $15.99 per option, respectively. For the years ended December 31, 2025, 2024 and 2023 the weighted-average grant date fair value of the purchase rights issued under the ESPP was $9.71, $12.66 and $11.43 per share, respectively.

The aggregate intrinsic value of stock options exercised during the years ended December 31, 2025, 2024 and 2023 was $1.2 million, $1.7 million and $1.3 million, respectively. The aggregate intrinsic value of shares issued under the ESPP was $0.9 million, $1.0 million and $0.5 million during the years ended December 31, 2025, 2024 and 2023, respectively.

The aggregate fair value of RSUs that vested during the years ended December 31, 2025, 2024 and 2023 was $36.1 million, $27.7 million and $18.1 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,		
	2025	2024	2023
Cost of sales (exclusive of amortization of acquired intangible assets)	$ 5,666	$ 5,529	$ 4,938
Research and development	7,555	9,598	10,119
Selling, general and administrative	32,672	35,193	36,162
Total stock-based compensation expense	$ 45,893	$ 50,320	$ 51,219

Included in total stock-based compensation expense for the years ended December 31, 2025, 2024 and 2023 is $0.7 million, $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.

No tax benefits related to stock-based compensation expense were recorded in the consolidated statements of operations during the years ended December 31, 2025, 2024 and 2023 due to the valuation allowance on net deferred tax assets.

As of December 31, 2025, the total unrecognized stock-based compensation cost related to outstanding awards was $64.7 million, which is expected to be recognized over a weighted-average period of 2.4 years. The total unrecognized compensation cost will be adjusted for forfeitures in future periods as they occur.

15. Income Taxes

The components of income tax (benefit) expense are as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Current tax expense			
U.S. federal	$ (254)	$ 663	$ —
State and local	1,126	1,255	324
Total current	872	1,918	324
Deferred tax benefit			
U.S. federal	(6,081)	1,622	33
State and local	(147)	(221)	(256)
Total deferred	(6,228)	1,401	(223)
Total income tax (benefit) expense	$ (5,356)	$ 3,319	$ 101

The differences between income taxes expected at the U.S. federal statutory rate (21%) and the reported income tax benefit, following the adoption of ASU 2023-09, are summarized as follows (in thousands):

	Year Ended December 31, 2025	
	$	%
Pre-tax loss	$ (29,514)	
U.S. federal statutory income tax rate	(6,199)	21.0 %
State and local income taxes, net of federal effect	742	(2.5)%
Tax credits:		
R&D tax credit	(2,078)	7.0 %
Non-taxable and non-deductible items:		
Non-deductible meals and entertainment	2,032	(6.9)%
Stock-based compensation	2,374	(8.0)%
Other	119	(0.4)%
Change in valuation allowance	(2,401)	8.1 %
Other	55	(0.2)%
Income tax benefit	$ (5,356)	18.1 %

The differences between income taxes expected at the U.S. federal statutory rate (21%) and the reported income tax expense, prior to the adoption of ASU 2023-09, are summarized as follows (in thousands):

	Years Ended December 31,	
	2024	2023
Pre-tax income (loss)	$ 21,564	$ (57,365)
U.S. federal taxes at statutory rate	4,528	(12,046)
State income taxes	683	925
R&D tax credit	(3,381)	(2,186)
Change in valuation allowance	(4,469)	5,207
Stock-based compensation	1,528	4,323
Non-deductible officers' compensation	2,651	2,377
Permanent differences	1,712	1,474
Other	67	27
Income tax expense	$ 3,319	$ 101

Income taxes paid (net of refunds) that exceed 5% of total income taxes paid (net of refunds) by jurisdictions following the adoption of ASU 2023-09, are as follows (in thousands):

	Year Ended December 31, 2025
U.S. federal	$ 1,172
State and local	
Michigan	127
Pennsylvania	244
Virginia	(138)
Other	196
Total income taxes paid, net of refunds received	$ 1,601

Significant components of deferred tax assets and liabilities are as follows (in thousands):

	As of December 31,	
	2025	2024
Deferred tax assets:		
NOL carryforwards	$ 33,831	$ 31,782
Accrued liabilities	10,048	7,301
Capitalized R&D costs	8,925	15,485
Lease liabilities	7,050	3,774
Stock-based compensation	6,464	5,128
R&D tax credit	13,002	9,747
Total deferred tax assets	79,320	73,217
Less valuation allowance	(48,662)	(50,536)
Deferred tax assets, net	$ 30,658	$ 22,681
Deferred tax liabilities:		
Prepaid expenses	$ (213)	$ (185)
Property and equipment	(8,457)	(6,374)
Intangible assets	(18,032)	(14,986)
ROU assets	(5,654)	(2,558)
Other	(637)	(185)
Total deferred tax liabilities	(32,993)	(24,288)
Net deferred tax liability	$ (2,335)	$ (1,607)

On July 4, 2025, the One Big Beautiful Bill Act (“OBBBA”) was enacted into law. The OBBBA includes a broad range of tax reform provisions affecting businesses, including reinstatement of permanent expensing of domestic research and development costs, higher EBITDA cap on the deduction for interest expense and 100% bonus depreciation. We will benefit from the reinstatement of permanent expensing of domestic research and development costs and 100% bonus depreciation.

As of December 31, 2025, we had federal NOL carryforwards of approximately $134.8 million of which $52.9 million will begin to expire in 2032 if not utilized to offset taxable income, and $81.9 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, 2025, we had state NOL carryforwards of approximately $113.0 million, which begin to expire in 2030 if not utilized to offset state taxable income. As of December 31, 2025, we had $13.0 million of R&D tax credit carryforwards, including $1.4 million of state credits. These credits begin to expire in 2037 if not utilized to offset federal income tax liabilities.

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, 2025 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, AltheaDx and Previse. Based on changes in ownership that have occurred, $36.3 million of NOLs relating to Cernostics and AltheaDx and zero relating to Previse are expected to expire unused as a result of Section 382 limitations. With respect to Previse, we acquired $2.3 million of NOLs that can be carried forward indefinitely to offset future taxable income.

As of December 31, 2025 and 2024, we placed a valuation allowance of $48.7 million and $50.5 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, 2025 and 2024 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, 2025, 2024 and 2023 was a decrease of $1.9 million, a decrease of $4.5 million, and an increase of $5.1 million, respectively.

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, 2025 and 2024. We are generally no longer subject to tax examinations for U.S. federal income tax purposes for fiscal years prior to 2022 and fiscal years prior to 2021 for multiple state jurisdictions. However, since we have been in an NOL position since 2008 until recently, our 2008 to 2021 federal tax returns and our 2008 to 2020 state tax returns are potentially subject to examination adjustments to the extent of those NOL carryforwards.

We are currently under IRS audit for fiscal year 2023. We believe our provisions for income taxes is adequate; however, any assessment may affect our results of operations and cash flows.

No material amounts of tax-related interest or penalties were recorded during the years ended December 31, 2025, 2024 and 2023.

16. 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 ("U.S.") 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.

The measures of segment loss or profit for of our single reportable segment were as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Net revenues from external customers[1]	$ 344,229	$ 332,069	$ 219,788
Significant segment expenses:			
Personnel costs	209,816	189,883	172,248
Organizational and marketing costs	51,545	44,178	39,481
Inventory usage	21,821	19,930	15,475
Clinical studies and publication costs	8,777	9,951	11,924
Professional services	10,928	10,476	7,496
Other segment items	65,500	39,406	30,630
Segment (loss) profit	$ (24,158)	$ 18,245	$ (57,466)

(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, R&D expense and SG&A expense. Our CODM considers this information injunction with test report deliveries in assessing budgeted and actual operational performance and in allocating resources.

Organizational and Marketing Costs

Organizational and marketing costs include expense incurred for travel, transportation, meals and lodging, training and conference and venue fees and are a component of cost of sales, R&D expense and SG&A expense. Our CODM considers this information in their assessment of operating expense results and in planning and budgeting for future corporate organizational and marketing 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 R&D 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, R&D expense and SG&A 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, gain or losses on disposal of fixed assets in the routine course of business, fair value adjustment for equity securities, realized gains or losses on investment securities, foreign currency exchange for certain equity securities and loan receivable, 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 loss or profit were as follows (in thousands):

	Years Ended December 31,		
	2025	2024	2023
Interest income	$ 11,772	$ 12,916	$ 10,623
Interest expense	$ 86	$ 577	$ 11
Depreciation and amortization	$ 40,771	$ 15,997	$ 12,330
Income tax (benefit) expense	$ (5,356)	$ 3,319	$ 101
Stock-based compensation expense	$ 45,893	$ 50,320	$ 51,219
Net gains on equity securities	$ 1,466	$ 555	$ —

Total assets for our reportable segment were located in the U.S. and were $578.6 million and $531.2 million as of December 31, 2025 and 2024, respectively. Expenditures for additions to long-lived assets were $45.1 million, $29.3 million and $13.5 million for the years ended December 31, 2025, 2024 and 2023, respectively.

17. Subsequent Events

On January 26, 2026, in connection with SciBase's rights offering, we completed an amendment to our previously disclosed subscription commitment. We agreed to increase our commitment to subscribe for shares without subscription rights from 115.0 million shares to 125.0 million shares. This amendment was intended to achieve an outcome substantially similar to full participation under our subscription rights. In addition, we purchased subscription rights for another 30.5 million shares from a separate SciBase shareholder. These purchased rights, together with our shares without subscription rights, aggregated to a total share purchase of 155.5 million shares for $3.6 million.